DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop: S2-25-26
Baltimore, Maryland 21244-1850

State Demonstrations Group

June 25, 2025

Mitch Roob
Acting Director of Medicaid
Indiana Family and Social Services Administration
402 W. Washington Street, Room W461, MS25
Indianapolis, IN 46204

Dear Acting Director Roob:

The Centers for Medicare & Medicaid Services (CMS) is updating the section 1115 demonstration monitoring approach to reduce state burden, promote effective and efficient information sharing, and enhance CMS's oversight of program integrity by reducing variation in information reported to CMS.

Federal section 1115 demonstration monitoring and evaluation requirements are set forth in section 1115(d)(2)(D)-(E) of the Social Security Act (the Act), in CMS regulations in 42 CFR 431.428 and 431.420, and in individual demonstration special terms and conditions (STCs). Monitoring provides insight into progress with initial and ongoing demonstration implementation and performance, which can detect risks and vulnerabilities to inform possible course corrections and identify best practices. Monitoring is a complementary effort to evaluation. Evaluation activities assess the demonstration's success in achieving its stated goals and objectives.

Key changes of this monitoring redesign initiative include introducing a structured template for monitoring reporting, updating the frequency and timing of submission of monitoring reports, and standardizing the cadence and content of the demonstration monitoring calls.

Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Healthy Indiana Plan (HIP) (Project Number 11-W-00296/5) demonstration.

Reporting Cadence and Due Date

CMS determined that, when combined with monitoring calls, an annual monitoring reporting cadence will generally be sufficient to monitor potential risks and vulnerabilities in demonstration implementation, performance, and progress toward stipulated goals. Thus, pursuant to CMS's authority under 42 CFR 431.420(b)(1) and 42 CFR 431.428, CMS is updating the cadence for this demonstration to annual monitoring reporting (see also section

1115(d)(2)(D)-(E) of the Act). This transition to annual monitoring reporting is expected to alleviate administrative burden for both the state and CMS. In addition, CMS is extending the due date of the annual monitoring report from 90 days to 180 days after the end of each demonstration year to balance Medicaid claims completeness with the state's work to draft, review, and submit the report timely.

CMS might increase the frequency of monitoring reporting if CMS determines that doing so would be appropriate. The standard for determining the frequency of monitoring reporting will ultimately be included in each demonstration's STCs. CMS expects that this standard will permit CMS to make on-going determinations about reporting frequency under each demonstration by assessing the risk that the state might materially fail to comply with the terms of the approved demonstration during its implementation and/or the risk that the state might implement the demonstration in a manner unlikely to achieve the statutory purposes of Medicaid. *See* 42 CFR 431.420(d)(1)-(2).

The Healthy Indiana Plan (HIP) demonstration will transition to annual monitoring reporting effective June 25, 2025. The next annual monitoring report will be due on June 29, 2026 which reflects the first business day following 180 calendar days after the end of the current demonstration year. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect the new reporting cadence and due date.

Structured Monitoring Report Template

As noted in STC 12.6, "Monitoring Reports," monitoring reports "must follow the framework provided by CMS" which is "subject to change as monitoring systems are developed/evolve, and will be provided in a structured manner that supports federal tracking and analysis." Pursuant to that STC, CMS is introducing a structured monitoring report template to minimize variation in content of reports across states, which will facilitate drawing conclusions over time and across demonstrations with broadly similar section 1115 waivers or expenditure authorities. The structured reporting framework will also provide CMS and the state opportunities for more comprehensive and instructive engagement on the report's content to identify potential risks and vulnerabilities and associated mitigation efforts as well as best practices, thus strengthening the overall integrity of demonstration monitoring.

This structured template will include a set of base metrics for all demonstrations. For demonstrations with certain waiver and expenditure authorities, there are additional policy-specific metrics that will be collected through the structured reporting template.

Some of the metrics currently required for Substance Use Disorder (SUD) and Serious Mental Illness (SMI)/Serious Emotional Disturbance (SED) demonstrations will no longer be required.

CMS is also removing the requirement for a Monitoring Protocol deliverable, which has been required under certain types of section 1115 demonstration, including but not limited to the SUD, SMI/ SED, Health-Related Social Needs (HRSN), and reentry demonstrations. Removal of the Monitoring Protocol requirement simplifies and streamlines demonstration monitoring activities for states and CMS.

Demonstration Monitoring Calls

As STC 12.9 "Monitoring Calls" describes, CMS may "convene periodic conference calls with the state," and the calls are intended "to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration." Going forward, CMS envisions implementing a structured format for monitoring calls to provide consistency in content and frequency of demonstration monitoring calls across demonstrations. CMS also envisions convening quarterly monitoring calls with the state and will follow the structure and topics in the monitoring report template. We anticipate that standardizing the expectations for and content of the calls will result in more meaningful discussion and timely assessment of demonstration risks, vulnerabilities, and opportunities for intervention. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect that monitoring calls will be held no less frequently than quarterly.

CMS will continue to be available for additional calls as necessary to provide technical assistance or to discuss demonstration applications, pending actions, or requests for changes to demonstrations. CMS recognizes that frequent and regular calls are appropriate for certain demonstrations and at specific points in a demonstration's lifecycle.

In the coming weeks, CMS will reach out to schedule a transition meeting to review templates and timelines outlined above. As noted above, the pertinent Healthy Indiana Plan (HIP) section 1115 demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect these updates.

If you have any questions regarding these updates, please contact Danielle Daly, Director of the Division of Demonstration Monitoring and Evaluation, at Danielle.Daly@cms.hhs.gov.

Sincerely,

[redacted]

Karen LLanos
Acting Director

Enclosure
cc: Rhonda Gray, State Monitoring Lead, Medicaid and CHIP Operations Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, Maryland 21244-1850

State Demonstrations Group

March 21, 2023

Allison Taylor
Medicaid Director
Indiana Family and Social Services Administration
402 W. Washington Street, Room W461, MS25
Indianapolis, IN 46204

Dear Ms. Taylor:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Eligibility and Coverage, Substance Use Disorder (SUD), and Serious Mental Illness/Serious Emotional Disturbance (SMI/SED) Evaluation Designs, which are required by the Special Terms and Conditions (STCs), specifically, STC #IX.8 of Indiana's section 1115 demonstration, "Healthy Indiana Plan (HIP)" (Project No: 11-W-00296/5), effective through December 31, 2030 with the SUD and SMI/SED components effective through December 31, 2025. CMS has determined that the Eligibility and Coverage Evaluation Design, which was submitted on June 23, 2021 and revised on February 24, 2022, the SUD Evaluation Design, which was submitted on July 23, 2021 and revised on December 29, 2022, and the SMI/SED Evaluation Design, which was submitted on June 23, 2021 and revised on February 28, 2022, all meet the requirements set forth in the STCs and CMS's evaluation design guidance, and therefore, approves the state's aforenamed three Evaluation Designs.

CMS has added the approved Eligibility and Coverage, SUD, and SMI/SED Evaluation Designs to the demonstration's STCs as Attachments K, E, and H, respectively. A copy of the STCs, which includes the new attachments, is enclosed with this letter. In accordance with 42 CFR 431.424, the approved Evaluation Designs may now be posted to the state's Medicaid website within thirty days. CMS will also post the approved Evaluation Designs as standalone documents, separate from the STCs, on Medicaid.gov.

Consistent with the approved SUD and SMI/SED Evaluation Designs, please note that the SUD and SMI/SED Interim Evaluation Reports, are due to CMS one year prior to the expiration of these policy components (i.e., December 31, 2024), or at the time of the extension applications, if the state chooses to extend these policies. Additionally, consistent with the approved Eligibility and Coverage Evaluation Design, the state is expected to submit three drafts of the HIP Interim Evaluation Reports, in which the last report (representing demonstration years 1–8)

is due one year prior to the expiration of the demonstration, or at the time of the extension applications, if the state chooses to extend the HIP demonstration. Likewise, the Summative Evaluation Reports, consistent with these approved Evaluation Designs, are due to CMS within 18 months of the end of the demonstration period. In accordance with 42 CFR 431.428 and the STCs, we look forward to receiving updates on evaluation activities in the Quarterly and Annual Monitoring Reports.

We appreciate our continued partnership with Healthy Indiana Plan section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly -S

Digitally signed by Danielle Daly -S
Date: 2023.03.21 09:56:06 -04'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

cc: Mai Le-Yuen, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST

NUMBER: **No. 11-W- 00296/5**

TITLE: **Healthy Indiana Plan (HIP)**

AWARDEE: **Indiana Family and Social Services Administration (FSSA)**

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived in this list, shall apply to the demonstration populations.

The demonstration will operate under these waiver authorities beginning January 1, 2021. The waivers will continue through December 31, 2030, unless otherwise stated.

As discussed in the Centers for Medicare & Medicaid Services (CMS) approval letter, the Secretary of Health and Human Services has determined that this section 1115 demonstration, including the waivers described below, is likely to assist in promoting the objectives of title XIX of the Social Security Act.

The following waivers shall enable Indiana to implement the HIP Medicaid section 1115 demonstration. These waivers may only be implemented consistent with the approved special terms and conditions (STC).

Title XIX Waivers

1. Premiums **Section 1902(a)(14) insofar as it incorporates Section 1916 and 1916A**

To the extent necessary to enable the state to charge monthly premiums, as described in the STCs.

2. Reasonable Promptness **Section 1902(a)(8)**

To the extent necessary, as described in the STCs, to enable Indiana to start enrollment in HIP Plus on the first day of the month in which an individual makes their initial contribution to the POWER account, or, for individuals with incomes at or below 100 percent FPL who fail to make an initial POWER account payment within 60 days following the date of invoice, the first day of the month in which the 60 day payment period expires, except for individuals who are found eligible through presumptive eligibility.

3. Provision of Medical Assistance **Section 1902(a)(8) and 1902(a)(10)**

This waiver authority is conditional on the Supreme Court issuing a decision in *Azar v. Gresham*, No. 20-37 that legally authorizes this element of the demonstration and if so authorized would continue through December 31, 2025.

4. Eligibility **Section 1902(a)(10) and 1902(a)(52)**

This waiver authority is conditional on the Supreme Court issuing a decision in *Azar v. Gresham*, No. 20-37 that legally authorizes this element of the demonstration, and if so authorized would continue through December 31, 2025.

To the extent necessary to enable Indiana to prohibit reenrollment, and deny eligibility, for up to six months, for individuals with income over 100 percent of the FPL who are disenrolled for failure to make POWER Account premium contributions within sixty (60) days of the date of invoice, subject to the exceptions and qualifying events described in the STCs.

To the extent necessary to enable Indiana to prohibit reenrollment, and deny eligibility, for up to three months following the end of the 90-day reconsideration period for individuals who are disenrolled for failure to provide the necessary information for the state to complete an annual redetermination, subject to the exceptions and qualifying events described in the STCs.

5. Methods of Administration **Section 1902(a)(4) insofar as it incorporates 42 CFR 431.53**

To the extent necessary to relieve Indiana of the requirement to assure transportation to and from medical providers for HIP demonstration populations. No waiver of methods of administration is authorized for pregnant women, individuals determined to be medically frail, and section 1931 parents and caretaker relatives.

6. Comparability **Sections 1902(a)(17) and 1902(a)(10)(B)**

To the extent necessary to enable the state to vary cost sharing requirements for beneficiaries for cost sharing to which they otherwise would be subject under the state plan, such that beneficiaries who are in HIP Plus will be charged only one co-payment (for non-emergency use of the emergency department) and individuals who are in HIP Basic will be subject to copayments at Medicaid permissible levels, as described in the STCs.

To the extent necessary to enable Indiana to vary premium requirements, as described in the STCs, for different HIP Plus program beneficiaries based on income and on tobacco use, and in a manner consistent with all otherwise applicable law.

7. Retroactivity Section 1902(a)(34)

To enable the state not to provide three months of retroactive eligibility for beneficiaries receiving coverage through the HIP program as described in the STCs, except for pregnant women.

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITIES

NUMBER: **No. 11-W- 00296/5**

TITLE: **Healthy Indiana Plan (HIP)**

AWARDEE: **Indiana Family and Social Services Administration (FSSA)**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the state for the items identified below (which would not otherwise be included as matchable expenditures under section 1903 of the Act) shall, for the period beginning January 1, 2021 through December 31, 2030, unless otherwise specified, be regarded as matchable expenditures under the state's Medicaid state plan, but are further limited by the special terms and conditions (STC) for the HIP section 1115 demonstration.

As discussed in the Centers for Medicare & Medicaid Services (CMS) approval letter, the Secretary of Health and Human Services has determined that this section 1115 demonstration, including the expenditure authorities described below, is likely to assist in promoting the objectives of title XIX of the Social Security Act.

The following expenditure authorities shall enable Indiana to implement the HIP section 1115 demonstration:

1. **Managed Care Expenditures.** Expenditures under contracts with managed care entities that do not meet the requirements in section 1903(m)(2)(A) of the Act specified below. Indiana's managed care organizations (MCO) participating in the demonstration will have to meet all the requirements of section 1903(m) except the following:

    a. Section 1903(m)(2)(A)(vi) of the Act insofar as it requires compliance with requirements in section 1932(a)(4) of the Act and 42 CFR 438.56(c)(2)(i) that enrollees be permitted an initial period to disenroll without cause, except as described in the terms and conditions.

    b. Section 1903(m)(2)(A)(vi) of the Act insofar as it requires compliance with requirements in section 1932(a)(4) of the Act and 42 CFR 438.56(g) that automatic MCO reenrollment occur only if the beneficiary’s disenrollment was due to a Medicaid eligibility lapse of two months or less, as described in the terms and conditions.

2. **Residential and Inpatient Treatment for Individuals with Substance Use Disorder.** This expenditure authority will begin January 1, 2021 and continue through December 31, 2025. Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).

3. **Inpatient Treatment for Individuals with Serious Mental Illness.** This expenditure authority will begin January 1, 2021 and continue through December 31, 2025. Expenditures for Medicaid state plan services furnished to eligible individuals who are primarily receiving short-term treatment services for a serious mental illness (SMI) in facilities that meet the definition of an IMD.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W- 00296/5**

TITLE: **Healthy Indiana Plan (HIP)**

AWARDEE: **Indiana Family and Social Services Administration**

I. PREFACE

The following are the special terms and conditions (STC) for the Healthy Indiana Plan (HIP) section 1115(a) Medicaid demonstration (hereinafter "demonstration") to enable Indiana to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted a waiver of requirements under section 1902(a) of the Social Security Act (the Act). These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during the life of the demonstration. The demonstration will be statewide and is approved for a ten-year period, from January 1, 2021 through December 31, 2030, unless otherwise specified for specific HIP demonstration components in the waiver and expenditure authorities.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Populations Affected
V. Benefits
VI. HIP POWER Account
VII. HIP Cost Sharing
VIII. Redetermination & Managed Care Organization (MCO) Enrollment
IX. Substance Use Disorder (SUD)
X. Serious Mental Illness (SMI)
XI. Delivery System
XII. General Reporting Requirements
XIII. General Financial Requirements
XIV. Budget Neutrality Determination
XV. Evaluation of the Demonstration

Additional attachments have been included to provide supplementary information and guidance for specific STCs:

Attachment A: Developing the Evaluation Design
Attachment B: Preparing the Interim and Summative Evaluation Reports
Attachment C: SUD Implementation Plan
Attachment D: SUD Monitoring Protocol
Attachment E: SUD Evaluation Design

Attachment F: SMI Implementation Plan (includes Financing Plan)
Attachment G: SMI Monitoring Protocol
Attachment H: SMI Evaluation Design
Attachment I: Eligibility and Coverage Implementation Plan (reserved)
Attachment J: Eligibility and Coverage Monitoring Protocol
Attachment K: Eligibility and Coverage Evaluation Design (including any HIP policies other than SUD and SMI/SED)

II. PROGRAM DESCRIPTION AND OBJECTIVES

This section 1115(a) demonstration provides authority for the state to offer HIP, which provides health care coverage for adults and an account similar to a health savings account called a Personal Wellness and Responsibility (POWER) Account. Under this approval, Indiana has been granted the authority to change premium and copayment amounts without submitting an amendment to CMS.

Under HIP, beneficiaries who consistently make required monthly contributions to their POWER Account will maintain access to an enhanced benefit plan, known as "HIP Plus," which will include enhanced benefits such as dental, vision, and chiropractic coverage. HIP Plus is intended to encourage personal responsibility, improve healthy behaviors, and develop cost conscious consumer behaviors among all beneficiaries. Beneficiaries with income at or below 100 percent of the federal poverty level (FPL) who do not make monthly POWER Account contributions will be defaulted to a more limited benefit plan meeting alternative benefit plan requirements (known as "HIP Basic"). Individuals above 100 percent of the FPL who do not make monthly contributions would be disenrolled and, in the event that the Supreme Court issues a decision in *Azar v. Gresham* that would so authorize, subject to 6-month non-eligibility period. . The HIP Basic plan will require co-payments for all services in amounts that would be permitted in the state plan rather than the monthly POWER Account contributions required to participate in the HIP Plus plan. All beneficiaries will have the opportunity to have their POWER Account contributions reduced in subsequent years for completion of preventive services and through successfully managing their POWER Accounts. Along with POWER Account contributions, the demonstration allows for Indiana to impose a tobacco user surcharge.

Under HIP, in the event of a favorable Supreme Court decision, Indiana would have the authority to implement a non-eligibility period for a period of three months after the 90-day reconsideration period for beneficiaries failing to complete the redetermination process in a timely manner, with the exception of pregnant women and women in the 60-day post-partum period.

The HIP demonstration also includes a SUD program available to all Medicaid beneficiaries to ensure that a broad continuum of care is available to beneficiaries with SUD, which will help improve the quality, care, and health outcomes for Indiana Medicaid beneficiaries. In an amendment to this demonstration dated December 20, 2019, the state also received authority under the demonstration to receive federal financial participation (FFP) for delivering high-quality, clinically appropriate treatment to beneficiaries ages 21 through 64 diagnosed with a serious mental illness (SMI) and receiving treatment while they are short-term residents in settings that meet the definition of an Institution for Mental Diseases (IMD).

Over the demonstration period, the state seeks to achieve several demonstration goals. The state's goals will inform the state's evaluation design hypotheses, subject to CMS approval, as described in these STCs. The state's goals include, but are not limited to determining whether:

- Improve health care access, appropriate utilization, and health outcomes among HIP members;
- Discourage tobacco use among HIP members through premium surcharge and the utilization of tobacco cessation benefits;
- Promote member understanding and increase compliance with payment requirements by changing the monthly POWER Account payment requirement to a tiered structure;
- Ensure HIP program policies align with commercial policies, encourage members understanding, and promote positive member experience and minimize gaps in coverage;
- Assess the costs to implement and operate HIP and other non-cost outcomes for the demonstration; and
- Receiving FFP for Medicaid services rendered in an IMD for beneficiaries with an SMI and/or a SUD reduces utilization and length of stays in emergency departments and preventable readmissions to acute care hospitals and residential settings.

Monitoring and evaluation sections in the STCs specify that CMS has the authority to require the state to submit a corrective action plan if monitoring or evaluation data indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid. The STCs further specify that any such corrective action plan, submitted by the state, could include a temporary suspension of implementation of demonstration programs, in circumstances where data indicate substantial, sustained directional change inconsistent with state targets (such as substantial, sustained trends indicating increased difficulty accessing services, increases in disenrollment from coverage, and increased instances of unpaid medical bills). These corrective actions will aid the state in measuring and tracking the demonstration's impact on beneficiaries affected by it, and give CMS additional tools to protect applicants and beneficiaries if necessary. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act (Section 1557). Such compliance includes providing reasonable accommodations to individuals with disabilities under the ADA, Section 504, and Section 1557 with eligibility and documentation requirements, understanding program rules and notices, to ensure they understand program rules and notices, as well as meeting other program requirements

necessary to obtain and maintain benefits.

2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program expressed in federal law, regulation, and written policy, not expressly waived or identified as not applicable in the waiver and expenditure authority documents, of which these terms and conditions are part, must apply to the demonstration.

3. **Changes in Federal Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable . In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7 of this section. CMS will notify the state within thirty (30) business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**

    a. To the extent that a change in federal law, regulation, or policy requires a change in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.

    b. If mandated changes in federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under federal law, whichever is sooner.

5. **State Plan Amendments.** The state will not be required to submit title XIX or title XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan may be required except as otherwise noted in these STCs. In all such cases, the Medicaid state plan governs.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid state plan or

amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or service-based expenditures, will be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 of this section, except as provided in STC 3 of this section.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

   a. An explanation of the public process used by the state, consistent with the requirements listed in STC 12 of this section. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;

   b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;

   c. A data analysis worksheet which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detail projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment; and

   d. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. **Extension of the Demonstration**. States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 442 Code of Federal Regulations (CFR) 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit a phase out plan consistent with the requirements of STC 9 of this section.

9. **Demonstration Phase Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit its notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12 of this section, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered comments received when developing the revised transition and phase-out plan.

b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries e, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.

c. Transition and Phase-Out Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.

d. Transition and Phase-out Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, and 431.213. In addition, the state must assure all applicable appeal and hearing rights afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to termination, 42 CFR 435.916. For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

e. Exemption from Public Notice Procedures 42.CFR 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).

f. Enrollment Limitations during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the

demonstrations, enrollment of new individuals into the demonstration must be suspended The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers suspended by the state, FFP must be limited to normal closeout costs associated with termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals and administrative costs of disenrolling beneficiaries.

10. **Withdrawal of Waiver Authority.** CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the public interest or promote the objectives of Title XIX. CMS must promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn or amended, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling participants.

11. **Adequacy of Infrastructure.** The state must ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

12. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

    The state must also comply with tribal and Indian Health Program/Urban Indian Health Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved state plan, when any program changes to the demonstration, either through amendment as set out in STC 7 of this section or extension, are proposed by the state.

13. **Federal Financial Participation (FFP).** No federal matching for service expenditures for this demonstration, including administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

14. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

15. **Common Rule Exemption.** The state shall ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. The Secretary has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(b)(5).

IV. POPULATIONS AFFECTED

1. **Eligibility Groups Affected By the HIP Demonstration Component.** This demonstration affects individuals age 19 through 64 who are eligible in the new adult group under the state plan that is described in 1902(a)(10)(A)(i)(VIII) of the Act, and 42 CFR 435.119, and who receive services described in the alternative benefit plans (ABP) under the state plan, unless otherwise excluded as described in STC 2 of this section. HIP will also affect pregnant women who are eligible under 42 CFR 435.116 who have income at or below 133 percent of the FPL, parents and caretaker relatives under the state plan who are eligible under 42 CFR 435.110, and also parents and caretaker relatives who are eligible under the state plan for Transitional Medical Assistance (TMA) under Section 1925 of the Act unless otherwise excluded as described in STC 2 of this section. Other Medicaid eligible individuals are affected by the new coverage options under the SUD provisions in this demonstration.

   All affected groups derive their eligibility through the Medicaid state plan, and are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid state plan, except as expressly listed as waived or not applicable, as described in this demonstration, subject to the operational limits as described in these STCs. The state plan Medicaid eligibility standards and methodologies for these eligibility groups, including the conversion to a modified adjusted gross income standard effective January 1, 2014, remain applicable.

Medicaid State Plan Group	Population Description
Adult group under 42 CFR 435.119, including individuals who are medically frail	Individuals age 19 through 64 who are eligible in the adult group under the state plan that is described in 1902(a)(10)(A)(i)(VIII) of the Act, including individuals who meet the definition of medically frail consistent with 42 CFR Section 440.315(f).
Parents & caretaker relatives eligible under 42 CFR 435.110	Parents and other caretaker relatives, as defined in 42 CFR 435.4, with household income at or below the income standard established by the state, consistent with section 1931 of the Act
Adult Transitional Medical Assistance beneficiaries under section 1902(a)(52) and 1925 of the Act (including individuals who are medically frail)	Former Parent & Caretaker relatives eligible for a minimum of 6 and a maximum of 12 months of continued coverage under Transitional Medical Assistance.
Pregnant women, age 19 and older, eligible under 42 CFR 435.116	Pregnant women with incomes up to 133 % of FPL who are enrolled in HIP at the time they become pregnant or are determined eligible for HIP after applying for benefits.

2. **HIP Demonstration Excluded Populations.** The following individuals are excluded from the demonstration, even if otherwise within the populations described in STC 1 of this section:

   a. Individuals eligible for a Medicaid category under the state plan not listed under STC 1 of this section.
   b. Individuals eligible for Medicare at the time of enrollment. If an individual becomes eligible for Medicare after enrolling in HIP, then disenrollment from HIP would become effective starting the date of Medicare Part B eligibility and in accordance with Medicaid and Medicare rules and regulations.

3. **Effective Date of Coverage.** For individuals who participate in HIP Plus, coverage will

be effective no later than the first day of the month in which the initial POWER account contribution or fast track payment is made. For individuals with income at or below 100 percent of the FPL who do not pay POWER account contributions for access to the HIP Plus plan, coverage will be effective the first day of the month in which the 60-day payment period expires. For individuals found presumptively eligible, who are subsequently determined eligible for full eligibility, there shall be no gap in coverage between presumptive coverage and HIP Plus or HIP Basic coverage as described in STC 4 of this section. For such individuals, at state option, the effective date of HIP coverage may begin at the end of the PE period (or earlier) so long as there is no gap in coverage.

This waiver of effective date of coverage (reasonable promptness) is conditioned as described in the terms outlined in STC 4 of this section related to presumptive eligibility standards.

4. **Presumptive Eligibility.** The state includes Federally Qualified Health Centers, Rural Health Centers, Community Mental Health Centers, and Health Department sites in the presumptive eligibility program, to allow potentially eligible individuals to gain temporary coverage. All provisions of 42 CFR 435.1103 and 435.1110 are applicable to these entities in determining presumptive eligibility.

   Individuals determined presumptively eligible for HIP (Adult PE) will not have a break in coverage if they are found eligible for Medicaid through the Indiana Health Coverage Programs (IHCP) application process. Adult PE beneficiaries who do not submit a full IHCP application will have their PE benefit end on the last day of the following month after PE approval. For individuals who complete the IHCP application, Adult PE coverage will continue, at minimum, for the duration of application processing. Adult PE beneficiaries who have their IHCP application denied will be closed on the date of IHCP denial. Adult PE beneficiaries who have their IHCP application approved will move into HIP coverage the first of the month following approval of the application. Beneficiaries will have 60 days to pay any required premium payment starting from the date of HIP enrollment. PE members will receive HIP Plus or HIP Basic coverage following transition to HIP per the standard processes.

   a. At state option, Indiana can reclassify presumptively eligible individuals as eligible in the new adult group for up to 3 months prior to the effective date of coverage as outlined in STC 3 of this section. Members transitioned from Adult PE who do not make a POWER Account payment in the 60-day time frame and who have household incomes greater than 100 percent of the FPL will be terminated from HIP.

5. **Pregnant Women.** Pregnant women eligible under 42 CFR 435.116 with income under 133 percent of the FPL will be enrolled into HIP. Women who are enrolled in HIP and report a pregnancy will begin to receive state plan equivalent benefits that are equal to or more generous in all categories than the benefits provided in the HIP ABPs and all required prenatal services. Pregnant beneficiaries have no cost sharing and receive 60 days of postpartum coverage. After the completion of postpartum coverage, the beneficiaries will seamlessly transition back to the appropriate Medicaid eligibility category and will be provided an option to pay for HIP Plus benefits.

Newly eligible adults who are pregnant can continue to be claimed by the state at the enhanced match until redetermination, at which time, if the beneficiary identifies as pregnant, that beneficiary must be claimed at the applicable match for pregnant women.

6. **Transitional Medical Assistance.** Beneficiaries whose job income increases to over 133 percent of the FPL can either attain or remain in HIP Plus coverage for up to twelve months. If after the first six months of TMA coverage income remains over 133 percent of the FPL, but below 185 percent of the FPL, coverage can extend an additional six months as long as POWER Account contributions are paid. Except for the income limit and frequency of reporting, all other existing TMA rules will be used for the over 133 percent of the FPL parent/caretaker group. All other individuals that would have previously qualified as TMA with income over the section 1931 limit, but less than 133 percent of FPL will be enrolled directly in HIP and receive the applicable HIP Basic or HIP Plus ABP.

V. BENEFITS

1. **HIP Benefits.** HIP beneficiaries, other than section 1931 parents and caretaker relatives and pregnant women, will receive benefits available in one of the state's approved ABPs. These beneficiaries will have access to the HIP Plus plan containing an enhanced benefit package that includes adult chiropractic, vision, and dental as additional state plan services. Such beneficiaries with income at or below 100 percent of the FPL (other than AI/AN individuals) who do not make their required monthly POWER account contributions within the 60-day payment period, will be defaulted to the HIP Basic benefit plan. Beneficiaries who are section 1931 parents and caretaker relatives will be enrolled in HIP, but will receive all benefits as described in the state plan. Beneficiaries in the new adult group who qualify as medically frail will be enrolled in HIP, but will also receive ABP coverage equivalent to coverage in the state plan.

2. **Calendar Year Benefit Period**. Members have a benefit period that runs for the calendar year of January through December, with all program benefit limitations aligning with the benefit period. Each member will have a POWER Account established for the benefit period. The MCO selection and POWER Account will remain active for the Benefit Period, even with a gap in coverage for the member.

3. **EPSDT for individuals up to age 21**. Both HIP Basic and HIP Plus shall include all Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits that would be available under the approved state plan for individuals up to age 21, including non-emergency medical transportation.
   a.

VI. HIP POWER ACCOUNT

1. **General Description.** The POWER Account is styled like a health savings account arrangement under a consumer-directed health plan. The POWER Account will hold state and beneficiary contributions (including beneficiary contributions donated by employers or other entities). The POWER Account funds will be used to pay for the first $2,500 in claims; claims beyond the initial $2,500 will be fully covered through capitation payments

or other payments made by the state. POWER Accounts may not be used to pay for beneficiary copayments. A member will have one POWER Account established per calendar year.

2. Beneficiary and State Contributions.

a. **All HIP eligible beneficiaries** will be eligible for HIP Plus. HIP Plus requires beneficiaries to make a monthly contribution to their POWER Accounts based upon their FPL, except for populations that are otherwise excluded from cost sharing requirements.

b. **Beneficiaries with income above 100 percent of the FPL** will, lose eligibility for HIP Plus if they fail to pay their monthly contributions within the 60 day grace period. At the end of the grace period, such beneficiaries who fail to pay the monthly contribution will be terminated from coverage after at least 10 days advance notice in accordance with 42 CFR 431.206-214 and 42 CFR 435.917 and if authorized by the Supreme Court, subject to a 6-month non-eligibility period, with the exception of those who are medically frail, or who fall under a designated "qualifying events" category, as discussed in STC 11(d) of this section. If authorized by the Supreme Court, individuals who do not pay their initial contribution and never fully enroll in HIP Plus would not be subject to non-eligibility period for non-payment. If authorized by the Supreme Court, individuals subject to a non-eligibility period will not be able to reenroll until the end of the non-eligibility period; payment of unpaid debt shall not be a condition of re-enrollment at the end of the non-eligibility period, but may be owed as a debt that the MCO can collect and does not affect prospective eligibility.

c. **Beneficiaries with income at or below 100 percent of the FPL**. Beneficiaries with income at or below l00 percent of the FPL will lose HIP Plus copayment protection (and HIP Plus benefits for those in the new adult group) if they fail to pay their monthly contributions within the 60-day grace period. Effective the first day following the expiration of the grace period, these beneficiaries will be automatically enrolled in HIP Basic, with no gap in coverage. In HIP Basic, the beneficiary would then be responsible for paying co-payments in accordance of amounts specified in the state plan, but not monthly POWER account contributions. The minimum monthly contribution amount to access HIP Plus is one dollar per month. The beneficiary would have the option to resume making monthly POWER account contributions and enroll in HIP Plus during the annual redetermination process or upon receipt of rollover. The state may add additional times for movement from HIP Plus to HIP Basic at the state's discretion.

d. **Medically frail beneficiaries and section 1931 parents and caretaker relatives** would have the same cost sharing opportunity as described in subsection (b) or (c) above, to either make monthly POWER account contributions consistent with HIP Plus, or to transition to co-payments consistent with the HIP Basic plan. Medically frail beneficiaries above the 100 percent of the FPL who do not make monthly POWER account contributions would have cost sharing described in STC 11(c) of this section.

e. **State Contributions.** The state will annually contribute to the POWER account for each beneficiary an amount equal to the difference between the required beneficiary contribution and $2500. The state will make an initial $1300 POWER Account contribution promptly upon the beneficiary's full enrollment with the MCO. The MCO will be responsible for reimbursing providers up to the full $2500 amount regardless of the beneficiary's current POWER Account balance, as described in STC 4 of this section. Following the conclusion of the 12-month benefit period, the MCO and state shall reconcile the POWER Account.

3. Determination of Beneficiary Contribution Amounts.

a. The household's POWER Account contributions will be calculated based upon a tiered contribution structure established by the state and described in Table 4. POWER Account contribution amounts shall not exceed three (3) percent of household income. When added to other cost sharing incurred by the beneficiary or the beneficiary's family members, the household's out of pocket expenses shall not exceed five percent of a beneficiary's gross quarterly household income. Required beneficiary contributions will be reduced by the amounts of contributions made by third parties to the POWER Account on behalf of the beneficiary. Permissible contributions may be made by employers or other entities as indicated in STCs 9 and 10 of this section.

b. In families with two enrolled spouses, each beneficiary will have their own POWER Account. However, the total of both beneficiaries' required POWER Account contributions cannot exceed the total POWER Account contribution for the two spouses determined by the state under the tiered structure and described in Table 4.

c. The state shall notify beneficiaries of POWER Account payment requirements upon eligibility determination. The state shall determine the amount of a beneficiary's monthly contribution based on the modified adjusted gross income and will notify the beneficiary and MCO of this amount. The MCO must bill for and collect this contribution amount from beneficiaries. Monthly invoices shall include information about how to report any change in income, shall inform individuals of the consequences of nonpayment (disenrollment from all coverage, or disenrollment from HIP Plus and default into HIP Basic) and that payment of a POWER Account contribution means an individual can now only change plans for cause and how enrollment broker can help.

d. Beneficiaries enrolled in HIP Plus who are identified as tobacco users will have a tobacco user surcharge applied to their POWER Account contribution amount. This amount will be equal to a 50 percent increase in individual contribution amount. The MCO will identify tobacco users and apply the surcharge as a distinct line item separate from the regular POWER Account contribution amount in the monthly invoice. The tobacco surcharge will be waived for the first year of enrollment in order to provide the individual the opportunity to take advantage of the robust tobacco cessation benefits offered through HIP. During this 12-month period, the MCOs will be required to conduct active outreach and member education related to the tobacco cessation benefits available through HIP. If after twelve months, the member continues to be a tobacco user, a tobacco user surcharge will be applied to their POWER Account contribution

amount beginning in the first month of their renewed benefit period. If a beneficiary informs the state that he or she has stopped using tobacco, the tobacco user surcharge will be removed from the following benefit year's contribution amount. The application of the tobacco user surcharge will be appealable for a beneficiary who disagrees with the application of the surcharge.

e. Beneficiaries enrolled in HIP Plus will contribute to the POWER Account according to their income tier as described in Table 4.

Table 4. POWER Account Tier Amounts

FPL	Monthly PAC Single Individual	Monthly PAC Spouses (each)	PAC with Tobacco Surcharge (Individual)	Spouse PAC when one has tobacco surcharge	Spouse PAC when both have tobacco surcharge (each)
Up to and including 22% of the FPL	$1.00	$1.00	$1.50	$1.00 & $1.50	$1.50
Above 22% of the FPL & up to and including 50% of the FPL	$5.00	$2.50	$7.50	$2.50 & $3.75	$3.75
Above 50% of the FPL & up to and including 75% of the FPL	$10.00	$5.00	$15.00	$5.00 & $7.50	$7.50
Above 75% of the FPL & up to and including 100% of the FPL	$15.00	$7.50	$22.50	$7.50 & $11.25	$11.25
Above 100% of the FPL and up to and including 133% of the FPL	$20.00	$10.00	$30.00	$10.00 & $15.00	$15.00

f. The state allows for a ten dollar ($10.00) initial fast track POWER Account payment that makes available immediate enrollment into HIP Plus effective the first date of the month in the month in which payment is received, once an individual has been determined eligible. This option is available via both fast track invoicing from the member's managed care plan and via the application. Individuals completing the application will have an option to select fast track and make a payment directly to the plan to lock in their eligibility start date to the 1st of the month of application, provided they are determined eligible. The fast track invoice option will be available only to individuals who through an initial screening process are not found to be pregnant, below age of 19, receiving Social Security Income (SSI), or potentially disabled. The initial fast track payment must be paid within 60 calendar days from the date of invoice to allow enrollment into HIP Plus (effective the first date of the month in the month in which payment is received, once the

eligibility has been determined. For individuals initially screened eligible for HIP, the invoice shall be dated no later than five business days after the date of application.

Both the application and the fast track payment invoice must include a notice explaining that the individual has not yet been determined eligible for HIP benefits, and that the payment is optional and does not guarantee eligibility.

g. The initial fast track invoice shall notify potentially eligible members that the fast track payment is an optional payment that is fully refundable if the individual is determined not to be eligible for HIP. The initial fast track payment is the minimum amount required to obtain HIP Plus benefits, however, the member will remain responsible for the full amount of the POWER Account contribution during the first month of coverage and any such amount not covered by the fast track payment will be included on the subsequent month POWER Account invoice. If the member's POWER Account contribution is less than the fast track pre-payment, the MCO shall credit the fast track payment against the member's required POWER Account contributions. Further, the initial fast track invoice must also include a prominent notice stating in substance that the individual has the right to select another MCO only before the fast track payment is made.

h. The state shall continue the fast-track prepayment process as documented in the operational protocol.

i. Account contributions by beneficiaries will be made through payments to the MCO in which the beneficiary is enrolled. Further details of how such payments can be made to an MCO are provided in the operational protocol.

4. **Changes in POWER Account Contribution Tier Amount.** The state will annually assess the amount of the contribution tiers and reserves the right to modify the POWER Account contribution tiers within the limitations set forth in these STCs at STC VII.3.a in response to findings from this annual assessment. The state will notify CMS of upcoming POWER Account contribution changes through a monitoring report described in these STCs, as well as send a letter stating such changes. The state will notify beneficiaries at least 60 days prior to implementing a POWER Account contribution change.

5. **Grace Period/Payment Period**. Applicants and beneficiaries will have 60 days from the date of the payment invoice to make the required monthly contribution.

6. **Recalculation of Beneficiary POWER Account Contribution Amount.** At annual redetermination or anytime the state is made aware that the beneficiary's income has changed during the current coverage term, the state shall determine whether an adjustment to the beneficiary's POWER Account contribution is necessary. During the current coverage term or changes of income at redetermination, recalculated POWER Account contributions are effective the first of the month following the recalculation. Any overpayments made by the member reduce the next month(s) contribution.

7. **Medicaid Transitions.** For members transitioning to HIP from other Medicaid categories, including pregnant women in HIP exiting their postpartum period, individuals making such

a transition will be immediately enrolled in the HIP Basic plan with a 60-day opportunity to make an initial POWER Account contribution to move to HIP Plus.

8. **Employer Contributions**. Employers are permitted and encouraged to contribute to their employees' POWER accounts. An employer's contribution must be used to offset the beneficiary's required contribution only—not the state's—and thus may not be greater than the beneficiary's expected annual contribution amount.

9. **Contributions from other third parties.** Third parties are permitted to contribute to a beneficiary's POWER account contribution. There are no limits on the amounts third parties can contribute to a beneficiary's POWER account except that the contribution must be used to offset the beneficiary's required contribution only—not the state's contribution. Health care provider or provider-related entities making contributions on individuals' behalf must have criteria for providing assistance that do not distinguish between individuals based on whether or not they receive or will receive services from the contributing provider(s) or class of providers. Providers may not include the cost of such payments in the cost of care for purposes of Medicare and Medicaid cost reporting and cannot be included as part of a Medicaid shortfall or uncompensated care for any purpose.

10. **Non-Payment of Monthly POWER Account Contribution.**

    a. **Beneficiaries Eligible for HIP Plus.** If a beneficiary with income above 100 percent of the FPL does not make a required monthly contribution within the grace period the beneficiary would be disenrolled, and if authorized by the Supreme Court, subjected to a six month non-eligibility period, unless the beneficiary lost coverage due to a "qualifying event" as described below. Any debt accrued, may be owed to the health plan in which the individual was previously enrolled, but will not prevent re-entry into HIP. Before terminating the beneficiary –

    i. Per 42 CFR 457.570(b), the state shall review eligibility for all other eligibility categories under the state's Title XIX program including notifying the beneficiary the option of requesting a medically frail status review; and

    ii. The MCO would be required to provide at least two written notices advising the beneficiary of the delinquent payment, the date by which the contribution must be paid to prevent disenrollment, the option for medically frail screening and the beneficiary's appeal rights. The first notice would have to be sent to the beneficiary on or before the seventh day of the month of coverage for which the POWER account contribution was to be applied and must state that the beneficiary will be disenrolled and terminated from participation in HIP if payment is not received prior to the date specified in the notice. Notices would be required to include information about reporting any changes in income.

    b. **Beneficiaries Eligible for the HIP Basic Plan**. Beneficiaries with income at or below 100 percent of the FPL have the opportunity to participate in the HIP Plus

plan, if they make required monthly POWER account contribution. However, if such beneficiary does not pay required monthly POWER account within the grace period, they will be automatically defaulted to the HIP Basic Plan with no gap in coverage or non-eligibility period. Beneficiaries will continue to maintain a POWER account.

c. **Medically Frail and 1931 Parents and Caregivers.** Any beneficiaries who are in the new adult group who are medically frail or qualify as 1931 parents and caregivers, would be exempt from any period of non-eligibility that may be implemented.

i. Medically frail beneficiaries with income above 100 percent of the FPL are required to make monthly POWER account contributions. In the event that such a beneficiary does not make a payment within the 60-day grace period the beneficiary shall --
   1. Remain in their existing benefit package;
   2. Be required to pay copayments as required under the HIP Basic plan; and
   3. Continue to be billed for monthly POWER account contributions, however payment of contributions are not a condition of eligibility.

ii. The beneficiary's total required cost sharing may not exceed five percent of household income during any quarter. Maintenance of HIP Plus coverage requires a minimum contribution of one dollar per month. Any debt collected by the health plan shall be subject to processes documented in the POWER Account contribution and co-payment operational protocol.

iii. Medically frail beneficiaries with income at or below 100 percent of the FPL and section 1931 parents and caregivers, may pay monthly POWER account contributions in lieu of copayments. In the event that such a beneficiary does not make a payment within the 60-day payment period, the beneficiary shall --
   1. Maintain their existing benefit package; and
   2. Be required to pay copayments as required under the HIP Basic.

d. **Qualifying Events**. Any beneficiary with income above 100 percent of the FPL who has been terminated from the HIP program for failure to pay POWER account contributions after exhausting the 60-day grace period could be reinstated to HIP prior to the expiration of the six month non-eligibility period (should the non-eligibility period be authorized by the Supreme Court), if a new application is filed and the individual can provide verification of non-payment due to the following:

i. Obtained and subsequently lost private insurance coverage;

ii. Had a loss of income after disqualification due to increased income;

iii. Took up residence in another state and later returned;

iv. Is a victim of domestic violence;

v. Was residing in a county subject to a disaster declaration made in accordance with IC 10-14-3-12 at the time the member was terminated for non-payment or at any time in the 60 calendar days prior to date of member termination for non-payment; or

vi. Is medically frail.

If loss of eligibility is implemented, the state may add additional circumstances for granting exceptions, as it deems necessary. If any of the above criteria are met, the individual could return to HIP Plus prior to the expiration of the six- month non-eligibility period provided the individual resumes making POWER account contributions. The state would be required to ensure that payment of any debt plus new POWER account contributions do not exceed five percent of the family's household income on a quarterly basis.

11. **Ineligibility and POWER Account Contributions.** If a beneficiary is determined ineligible, the beneficiary will be disenrolled from HIP. At such time, the beneficiary may be owed a refund by the state for contributions made or may owe a debt to the MCO as described in the operational protocol.

VII. HIP COST-SHARING

1. **Co-payments**. Beneficiaries with income at or below 100 percent of the FPL, medically frail beneficiaries and section 1931 parents and caregivers who do not pay their monthly POWER account contributions within the 60-day grace period will be enrolled in HIP Basic and will be subject to co-payments. The state may assess the nominal copayments, as described in 42 CFR 447.52(b), 447.53(b), and 447.54(b), on any item or service listed in Table 5 up to the maximum allowable amounts for each service.

2. **New Co-**payments. In order to assess a copayment on a new item or service that is not described in Table 5, the state will submit an amendment and receive approval from CMS before assessing the copayment.

3. **Changes to Co-payments.** The maximum allowable amounts are updated annually and co-payment amounts described in Table 5 show the allowable amounts for FFY21. The state may assess a lower copayment without the need for an amendment. The state will supply general public and beneficiary notices consistent with 42 CFR 447.57(a) and (b) prior to implementing changes. The state will notify beneficiaries at least 60 days prior to implementing a co-payment change.

Table 5. Co-payments for FFY21	
HIP Basic	
Preventive Care Services (including family planning and maternity services)	$0
Outpatient Services	$4.70

Inpatient Services	$87.90
Preferred Drugs	$4.70
Non-Preferred Drugs	$9.40
HIP Basic & HIP Plus	
Non-emergent use of the ER	$8

4. **Beneficiary and State Contributions: State Assurances.** The state shall make the general assurance that it is in compliance with protections for beneficiaries related to Section III STC 2, and will:

a. Permit the MCO to attempt to collect the unpaid premiums from the beneficiary, but the MCO may not report the premium amount owed to credit reporting agencies, place a lien on a beneficiary's home, refer the case to debt collectors, file a lawsuit, or seek a court order to seize a portion of the beneficiary's earnings for enrollees at any income level. The state will not "sell" the obligation for collection by a third-party. Further, while the amount is collectible by the state, re-enrollment is not conditioned upon repayment.

b. Monitor that beneficiaries do not incur household cost sharing and premiums that, when combined, exceed five (5) percent of the aggregate household income, in accordance with 42 CFR 447.56(f), without regard to MCO enrollment of members in the household. Once a household reaches the cap, the state assures that no further copayments can be charged to beneficiaries, and the premium amount will be reduced for the remainder of the quarter.

c. Charge copayment amounts, if applicable, that do not exceed Medicaid cost sharing permitted by federal law and regulation in accordance with 42 CFR 447.52-56 and the terms of this demonstration.

d. Ensure that the state, or its designee, does not pass along the cost of any surcharge associated with processing payments to the beneficiary. Any surcharges or other fees associated with payment processing are considered an administrative expense by the state.

e. Ensure that all payments from the beneficiary, or on behalf of the beneficiary, are accurately credited toward unpaid premiums in a timely manner, and provide the beneficiary an opportunity to review and seek correction of the payment history.

f. Ensure that the state has a process to refund any POWER Account contributions paid for a month in which the beneficiary is ineligible for Medicaid services for that month.

g. Ensure that a beneficiary will not be charged a higher premium the following month due to nonpayment or underpayment of a premium in the previous month(s), except that amounts outstanding and due from the previous month/s may be reflected separately on subsequent invoices.

h. Conduct outreach and education to beneficiaries to ensure that they understand the program policies regarding good cause, premiums and associated consequences for nonpayment. Beneficiaries must be informed of how premium payments should be made; the potential

impact of a change in income on premium payments owed; the consequences of failure to report a change in income or circumstances that affect eligibility; the time period over which income is calculated (e.g., monthly income); the deadline for reporting changes in circumstances; and how to reenroll if disenrolled for non-payment of premiums.

i. Provide all applicants timely determinations of eligibility in accordance with 42 CFR 435.912.

j. Provide all applicants and beneficiaries with timely and adequate written notices of any decision affecting their eligibility, including an approval, denial, termination, or suspension of eligibility, or a denial or change in benefits and services pursuant to 42 CFR 435.917 and consistent with 42 CFR 435.905(b) and 431.206-214.

k. The state must send a notice at least 10 days in advance of the date of action (as defined at 42 CFR 431.201 pursuant to 42 CFR 431.211-214.

l. Provide all applicants and beneficiaries with fair hearing rights consistent with 42 CFR part 431, subpart E.

m. Ensure program information is available, and accessible in accordance with 42 CFR 435.901 and 435.905.

n. Provide beneficiaries written notice of requirements to qualify for reactivation of Medicaid coverage following disenrollment due to non-payment of POWER Account contributions described in Section VI STC 11.

o. Provide notice (consistent with 42 CFR 435.917 and 431.206-214) in advance of any adverse action, including information about the non-eligibility period with an explanation of what the status means, including but not limited to: the right to appeal; the right to apply for Medicaid on a basis not affected by this status; what the suspension status means with respect to the ability to access other coverage (such as coverage in a qualified health plan through the Exchange, or access to premium tax credits through the Exchange); what to do if circumstances change such that they may be eligible for coverage in another Medicaid category; as well as any implications with respect to whether they have minimum essential coverage.

p. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable accommodations related to premium payments.

q. Maintain a system that identifies, confirms, and provides reasonable accommodations related to the obligation to pay premiums to beneficiaries with disabilities protected by the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Patient Protection and Affordable Care Act.

r. Assess appropriately—including through demonstration evaluation—that there is not a disparate impact on certain beneficiaries based on various sociodemographic characteristics, including gender, sexual orientation, race or ethnicity

VIII. REDETERMINATION & MCO ENROLLMENT

1. **Redetermination.** On an annual basis, HIP enrollees have their eligibility reconfirmed through a redetermination period. Individuals are auto-renewed if the system has sufficient information to renew the individual. When there is information required to complete the HIP renewal for an individual, a request for information will be generated and sent to the individual consistent with 42 CFR 435.916. In the event a loss of eligibility is implemented following a Supreme Court decision, individuals who do not complete this request prior to the expiration of their HIP coverage will be disenrolled, and the individual will be prohibited from re-enrollment as described in STC 2 of this section.

2. **Failure to Complete a Redetermination.** Beneficiaries that fail to provide necessary information or documentation to complete the redetermination process will be disenrolled from HIP, in accordance with Medicaid regulations. Redetermination begins 45 days prior to the expiration of a beneficiary's 12-month eligibility period. Beneficiaries failing to complete the redetermination process prior to the expiration of their 12-month eligibility period will be disenrolled from the program. Beneficiaries subject to disenrollment will be granted a 90-day reconsideration period to submit their redetermination paperwork to be reenrolled in HIP without submitting a new application consistent with 42 CFR 435.916(a)(3)(iii). After the 90-day reconsideration period, individuals not exempt under STC 2(c) of this section, will be prohibited from re-enrolling in HIP for three months after the expiration of the reconsideration period, unless the individual meets a good cause exception, as described in STC 3(d) of this section.

    a. The state will not be able to terminate eligibility if the beneficiary has provided documentation that the state has not processed yet, provided the beneficiary returned the required documentation prior to the end of the eligibility period consistent with 42 CFR 435.930(b). The state must also determine the beneficiary ineligible for all other bases of Medicaid eligibility prior to disenrollment and review him/her for eligibility for other insurance affordability programs in accordance with 42 CFR 435.916(f).

    b. If implemented following a Supreme Court decision, the state would not be permitted to apply the three-month non-eligibility period if the beneficiary has provided documentation that the state has not processed yet, provided the beneficiary returned the required documentation no later than the last day of the 90-day reconsideration period.

    c. If implemented following a Supreme Court decision, any beneficiary who becomes pregnant or is determined to be medically frail during the non-eligibility period can reapply and if determined eligible, reneroll, consistent with an effective date consistent with the beneficiary's eligibility category. Beneficiaries who are pregnant, medically frail, or parents or caretakers under section 1931 of the Act would be exempt from this non-eligibility period. In addition, individuals whose 90-day reconsideration period has expired, but who experience a change in circumstances which prevented completion of the redetermination process as detailed in state code, 405 IAC 10-10-13(e) would also

be exempt from the open enrollment period and may reapply and be assessed for eligibility taking into account the individual's notification to the state of their exemption. The exemptions in that state code are as follows:

i. Obtained and subsequently lost private insurance coverage;
ii. Had a loss of income after disqualification due to increased income;
iii. Took up residence in another state and later returned;
iv. Was a victim of domestic violence;
v. Was residing in a county subject to a disaster declaration made in accordance with IC 10-14-3-12 at any time during the 60 calendar days prior to or including the date such member was terminated from the plan.

d. Beneficiaries who experienced a good cause exception that prevented the completion of the annual redetermination requirements, as described in STC 3(d) of this section, would, if a non-eligibility period is implemented, be permitted to re-enroll prior to the expiration of the three-month non-eligibility period by providing verification of the exception.

e. If a non-eligibility period is implemented, the state would not be permitted to terminate eligibility of any individual with a disability under the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act for failure to submit redetermination paperwork if the individual needed and was not provided with reasonable modifications necessary to complete the process

3. **Non-eligibility period for Failure to Complete Redetermination: State Assurances.** If a non-eligibility period is implemented following a Supreme Court decision the State would be required to do the following:
   a. Have a renewal process, including ex parte renewals and use of pre-populated forms, consistent with all applicable Medicaid requirements, for at least twelve months prior to implementation of the demonstration.

   b. Maintain or improve upon systems in place with the goal of completing to complete ex parte renewals based on available information for at least 75 percent of their beneficiaries, not including beneficiaries in a non-eligibility period or suspension at the time of the redetermination.

   c. Maintain timely processing of applications to avoid further delays in accessing benefits once the non-eligibility period is over.

   d. Include good cause exceptions to the non-eligibility period that would allow beneficiaries to re-enroll under certain conditions without waiting three months, including but not limited to the following:
      i. Obtained and subsequently lost private insurance coverage;
      ii. Had a loss of income after disqualification due to increased income;
      iii. Took up residence in another state and later returned;
      iv. Is a victim of domestic violence;

v. Was residing in a county subject to a disaster declaration made in accordance with IC 10-14-3-12 at the time the member was terminated for non-payment or at any time in the 60 calendar days prior to date of member termination for non-payment;

vi. The beneficiary is hospitalized, otherwise incapacitated, or has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and as a result was unable to provide information necessary to complete the redetermination during the entire ninety redetermination or reconsideration reporting period, or is a person with a disability who was not provided with reasonable modifications needed to complete the process, or is a person with a disability and there were no reasonable modifications that would have enabled the individual to complete the process; or

vii. A member of the beneficiary's immediate family who was living in the home with the beneficiary was institutionalized or died during the redetermination reporting period or the immediate family member has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and caretaking or other disability-related responsibilities resulted in an inability to complete redetermination.

The state may add additional circumstances for granting exceptions, as it deems necessary.

e. Provide written notice to beneficiaries of any exceptions that would allow them to re-enroll during a non-eligibility period (such as becoming pregnant or medically frail). Such notice must include an explanation of the availability of good cause exceptions, as indicated in STC3 (d) of this section.

f. Provide written notice to beneficiaries of any non-eligibility period exemptions and good cause exceptions, as described in STCs 2(c) and 3(d) of this section, which would allow them to re-enroll during a non-eligibility period. Such notice must include an explanation of the availability of good cause exceptions, as indicated in STC3(d) of this section.

g. Provide notice to beneficiaries, prior to adverse action, regarding the non-eligibility period, and explaining what this status means, including but not limited to: their right to appeal, their right to apply for Medicaid on a basis not affected by this status, what this status means with respect to their ability to access other coverage (such as coverage in a qualified health plan through the Exchange, or access to premium tax credits through the Exchange), what they should do if their circumstances change such that they may be eligible for coverage in another Medicaid category, as well as any implications with respect to whether they have minimum essential coverage.

h. Provide beneficiary education and outreach that supports compliance with redetermination requirements, such as through communications or coordination with state-sanctioned assistors, providers, MCOs, or other stakeholders.

i. Provide full appeal rights prior to disenrollment and observe all requirements for due process for beneficiaries who will be disenrolled for failing to provide the necessary

information to the state to complete their redeterminations to allow beneficiaries the opportunity to raise additional issues in a hearing, including whether the beneficiary should be subject to the non-eligibility period and/or provide additional documentation through the appeals process.

j. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable modifications that will assist them in meeting redetermination requirements

k. Provide reasonable modifications to the annual redetermination process to beneficiaries with disabilities protected by the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Patient Protection and Affordable Care Act to enable and assist them in completing the annual redetermination process.

4. **MCO Selection Period.** MCO selection is held annually from November 1 – December 15. During this period, beneficiaries can switch MCO plans. If an individual is in a non-eligibility period, should one be imposed following a Supreme Court decision, during the open enrollment period, the individual can change plans upon reenrollment into HIP. The individual will stay with this MCO for the entire following calendar year, even if they lose coverage and then return to the program within the same calendar year.

IX. SUBSTANCE USE DISORDER

1. **Opioid Use Disorder (OUD)/Substance Use Disorder (SUD) Program.** Effective upon CMS' approval of the SUD Implementation Protocol, the benefit package for all Medicaid recipients will include OUD/SUD treatment services, including services provided in residential and inpatient treatment settings that qualify as an Institution for Mental Disease (IMD), which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Medicaid recipients residing in IMDs under the terms of this demonstration for coverage of medical assistance and OUD/SUD benefits that would otherwise be matchable if the beneficiary were not residing in an IMD once CMS approves the state's Implementation Protocol. Under this demonstration, beneficiaries will have access to high quality, evidence-based OUD and other SUD treatment services ranging from acute withdrawal management to on-going chronic care for these conditions in cost-effective settings while also improving care coordination and care for comorbid physical and mental health conditions.

   The coverage of SUD residential treatment and withdrawal management will expand Indiana's current SUD benefit package available to all Indiana Medicaid recipients as outlined in Table 6. These services will be delivered through FFS and managed care delivery systems. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

Table 6: Indiana SUD Benefits Coverage with Expenditure Authority

SUD Benefit	Medicaid Authority	Expenditure Authority
Early Intervention (Screening, Brief Intervention and Referral to Treatment)	State plan (Individual services covered)	
Outpatient Services	State plan (Individual services covered)	
Intensive Outpatient Services	State plan (Individual services covered)	
Partial Hospitalization Treatment	State plan (Individual services covered)	
Residential Treatment	Section 1115 demonstration	Services provided to individuals in IMDs
Withdrawal Management	State plan	Services provided to individuals in IMDs
Opioid Treatment Program Services	State plan (contingent on anticipated SPA approval)	Services provided to individuals in IMDs
Addiction Recovery Management Services	State plan (contingent on anticipated SPA approval)	Services provided to individuals in IMDs

2. **Residential Treatment Services.** Treatment services delivered to residents of an institutional care setting, including facilities that meet the definition of an institution for mental diseases (IMD), are provided to Indiana Medicaid recipients with a SUD diagnosis when determined to be medically necessary by the MCO utilization review staff and in accordance with an individualized service plan.

   a. Residential treatment services are provided in an Indiana Division of Mental Health and Addiction (DMHA)-certified facility that has been enrolled as a Medicaid provider and assessed by DMHA as delivering care consistent with ASAM, SUD-specific program standards for residential treatment facilities.

   b. Residential treatment services can be provided in settings of any size.

   c. The implementation date for residential treatment services is February 1, 2018.

   d. Room and board costs are not considered allowable costs for residential treatment

service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

Covered services include:

a. Clinically-directed therapeutic treatment to facilitate recovery skills, relapse prevention, and emotional coping strategies.

b. Addiction pharmacotherapy and drug screening;

c. Motivational enhancement and engagement strategies;

d. Counseling and clinical monitoring;

e. Withdrawal management and related treatment designed to alleviate acute emotional, behavioral, cognitive, or biomedical distress resulting from, or occurring with, an individual's use of alcohol and other drugs;

f. Regular monitoring of the individual's medication adherence;

g. Recovery support services;

h. Counseling services involving the beneficiary's family and significant others to advance the beneficiary's treatment goals, when (1) the counseling with the family member and significant others is for the direct benefit of the beneficiary, (2) the counseling is not aimed at addressing treatment needs of the beneficiary's family or significant others, and 3) the beneficiary is present except when it is clinically appropriate for the beneficiary to be absent in order to advance the beneficiary's treatment goals; and,

i. Education on benefits of medication assisted treatment and referral to treatment as necessary.

3. **SUD Implementation Plan.** The state's SUD Implementation Plan, initially approved for the period from February 1, 2018 through December 31, 2020, remains in effect for the approval period from January 1, 2021 through December 31, 2025, and is affixed to the STCs as Attachment C. Any future modifications to the approved Implementation Plan will require CMS approval. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral.

   The approved SUD Implementation Plan describes the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of this SUD demonstration project:

   a. **Access to Critical Levels of Care for SUDs:** Service delivery for new benefits, including residential treatment, withdrawal management, opioid treatment program and

addiction recovery and management services within 12-24 months of OUD/SUD program demonstration approval;

b. **Use of Evidence-based SUD-specific Patient Placement Criteria:** Establishment of a requirement that MCOs and providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria within 12-24 months of OUD/SUD program demonstration approval;

c. **Patient Placement:** Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of OUD/SUD demonstration approval;

d. **Use of Nationally Recognized SUD-specific Program Standards for Residential Treatment:** Currently, residential treatment service providers must be certified by the Indiana Department of Mental Health and Addiction. The state will establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of OUD/SUD demonstration approval;

e. **Standards of Care:** Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of OUD/SUD demonstration approval;

f. **MAT Standards of Care:** Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of OUD/SUD demonstration approval;

g. **Sufficient Provider Capacity at Critical Levels of Care including MAT:** An assessment of the availability of providers in the key levels of care throughout the state, or in the regions of the state participating under this demonstration including those that offer MAT, within twelve months of OUD/SUD demonstration approval;

h. **Implementation of Comprehensive Strategies to Address Prescription Drug Abuse and OUD:** Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand access to naloxone;

i. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in STC 9 of this section; and

j. **Improved Care Coordination and Transitions:** Establishment of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these residential and inpatient facilities within 24 months of OUD/SUD demonstration approval.

4. **SUD Monitoring Protocol.** The state must submit a SUD Monitoring Protocol within 150 calendar days after approval of the OUD/SUD program under this demonstration. The SUD Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. The state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs as Attachment D. Progress on the performance measures identified in the Monitoring Protocol must be reported via the quarterly and annual monitoring reports. Components of the Monitoring Protocol include:

   a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 3 of this section and reporting relevant information to the state's Health IT plan described in STC 9;
   b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section XII of the demonstration; and
   c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

5. **Mid-Point Assessment.** The state must conduct an independent mid-point assessment by December 31, 2023. In the design, planning and conduction of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of managed care organizations (MCO), SUD treatment providers, beneficiaries, and other key partners.

   The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 days after December 31, 2023. This timeline will allow for the assessment report to capture approximately the first two-and-a-half years of demonstration program data, accounting for data run-out and data completeness. The state must brief CMS on the report.

   For milestones and measure targets at medium to high risk of not being achieved, the state must submit to CMS modifications to the SUD Implementation Plan and the SUD Monitoring Protocol for ameliorating these risks. Modifications to the Implementation Plan and Monitoring Protocol are subject to CMS approval. Elements of the mid-point assessment include:

   a. An examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plan and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol;

b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;

c. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets;

d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's SUD Implementation Plan or to pertinent factors that the state can influence that will support improvement; and

e. An assessment of whether the state is on track to meet the budget neutrality requirements.

6. **Deferral for Insufficient Progress Toward Milestones and Failure to Report Measurement Data.** If the state does not demonstrate sufficient progress on milestones, as specified in the SUD Implementation Plan, as determined by CMS, or fails to report data as approved in the SUD Monitoring Protocol, CMS will defer funds in the amounts specified in Section XII STC 1 for each incident of insufficient progress or failure to report in each reporting quarter.

7. **Deferral of Federal Financial Participation (FFP) from IMD claiming for Insufficient Progress Toward Milestones.** Up to $5 million in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in Table 6 and the required performance measures in the monitoring protocol agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to $5 million will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.

8. **SUD Evaluation.** The SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections XII (General Reporting Requirements) and XV (Evaluation of the Demonstration) of these STCs. The state will follow CMS guidelines to ensure the evaluation design is developed and amended to support a rigorous evaluation of the SUD component of the demonstration.

9. **SUD Health Information Technology (Health IT).** The state has provided CMS with an assurance that it has a sufficient health IT infrastructure/"ecosystem" at every appropriate level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration—or it will submit to CMS a plan to develop the infrastructure/capabilities. This "SUD Health IT Plan," or assurance, has been included as a section of the state's Implementation Plan (see STC 3 of this section). The SUD Health IT Plan does detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The Plan also is used to identify areas of SUD health IT ecosystem improvement.

   a. The SUD Health IT section of the Implementation Plan includes implementation milestones and dates for achieving them (see Attachment C).

b. The SUD Health IT Plan must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) "Health IT" Plan.

c. Components of the Health IT Plan include:

i. The SUD Health IT Plan describes the state's goals, each DY, to enhance the state's prescription drug monitoring program's (PDMP).[1]

ii. The Health IT Plan must address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[2] This must also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.

iii. The Health IT Plan will, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.

iv. The Health IT Plan will describe how the activities described in (i), (ii) and (iii) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.[3]

v. The Health IT Plan will describe the state's current and future capabilities to support providers implementing or expanding Health IT functionality in the following areas: 1) Referrals, 2) Electronic care plans and medical records, 3) Consent, 4) Interoperability, 5) Telehealth, 6) Alerting/analytics, and 7) Identity management.

[1] Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the "opioid" epidemic and facilitate a nimble and targeted response.

[2] *Ibid*.

[3] Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017;66.

vi. In developing the Health IT Plan, states should use the following resources:

i. States may use federal resources available on Health IT.Gov (https://www.healthit.gov/topic/behavioral-health) including but not limited to "Behavioral Health and Physical Health Integration" and "Section 34: Opioid Epidemic and Health IT" (https://www.healthit.gov/playbook/health-information-exchange/).
ii. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.

vii. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

X. SERIOUS MENTAL ILLNESS

1. **Serious Mental Illness (SMI) Program Benefits.** Under this demonstration, beneficiaries will have access to high quality, evidence-based behavioral health treatment services. These services will range in intensity from short-term acute care in settings that qualify as an IMD to ongoing chronic care for such conditions in cost-effective community-based settings. The state must achieve a statewide average length of stay (ALOS) of no more than 30 days in inpatient treatment settings, to be monitored pursuant to the SMI Monitoring Plan as outlined in STCs 4 of this section.

   Indiana attests that the services indicated in Table 7 as being either already covered under the Medicaid state plan authority or being authorized under the terms of this demonstration.

Table 7. SMI Benefits Coverage

Benefit	Type	Medicaid Authority	Expenditure Authority
Crisis Stabilization Services	SMI/ SED	State plan (Individual services covered)	N/A
Outpatient services	SMI/SED	State plan (Individual services covered)	N/A
Intensive outpatient treatment (IOT) services	SMI/SED	State plan (Individual services covered)	N/A

Table 7. SMI Benefits Coverage			
Benefit	**Type**	**Medicaid Authority**	**Expenditure Authority**
Inpatient (acute) services	SMI	State plan (Individual services covered)	Services provided to individuals in IMDs
Medicaid Rehabilitation Option (MRO)	SMI/SED	State plan (Individual services covered)	N/A
Adult Mental Health Habilitation	SMI	State plan (Individual services covered)	N/A
Children's Mental Health Wraparounds	SMI/SED	State plan (Individual services covered)	N/A
Behavioral & Primary Healthcare Coordination	SMI	State plan (Individual services covered)	N/A

2. SMI Implementation Plan.

a. The state's SMI Implementation Plan, initially approved by CMS on December 20, 2019 for the period from January 1, 2020 through December 31, 2020, remains in effect for the approval period from January 1, 2021 through December 31, 2025, and is affixed to the STCs as Attachment F. Any future modifications to the approved Implementation Plan will require CMS approval. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral as described in Section X STC7.

b. The approved SMI Implementation Plan describes the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:

i. **Ensuring Quality of Care in Psychiatric Hospitals and Residential Settings.**

A. Participating hospitals must be licensed or approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals prior to the state claiming FFP for services provided to beneficiaries residing in a hospital that meets the definition of an IMD. In addition, hospitals must be in compliance with the conditions of participation set forth in 42 CFR Part 482 and be either: a) certified by the state agency as being in compliance with those conditions through a state agency survey, or b) deemed status to participate in Medicare as a hospital through accreditation by a national accrediting organization whose psychiatric hospital accreditation program or acute hospital accreditation program has been approved by CMS.

B. Establishment of an oversight and auditing process that includes unannounced visits for ensuring participating psychiatric hospitals meet state licensure or certification requirements as well as a national accrediting entity's accreditation requirements;
C. Use of a utilization review entity (for example, a managed care organization or administrative service organization) to ensure beneficiaries have access to the appropriate levels and types of care and to provide oversight to ensure lengths of stay are limited to what is medically necessary and only those who have a clinical need to receive treatment in psychiatric hospitals are receiving treatment in those facilities;
D. Establishment of a process for ensuring that participating psychiatric hospitals meet federal program integrity requirements and establishment of a state process to conduct risk-based screening of all newly enrolling providers, as well as revalidating existing providers (specifically, under existing regulations, the state must screen all newly enrolling providers and reevaluate existing providers pursuant to the rules in 42 CFR Part 455 Subparts B and E, ensure treatment providers have entered into Medicaid provider agreements pursuant to 42 CFR 431.407, and establish rigorous program integrity protocols to safeguard against fraudulent billing and other compliance issues);
E. Implementation of a state requirement that participating psychiatric hospitals screen enrollees for co-morbid physical health conditions and substance use disorders (SUDs) and demonstrate the capacity to address co-morbid physical health conditions during short-term stays in inpatient treatment settings (e.g., with on-site staff, telemedicine, and/or partnerships with local physical health providers).

ii. **Improving Care Coordination and Transitions to Community-Based Care.**

A. Implementation of a process to ensure that psychiatric hospitals provide intensive pre-discharge, care coordination services to help beneficiaries transition out of those settings into appropriate community-based outpatient services, including requirements that community-based providers participate in transition efforts (e.g., by allowing initial services with a community-based provider while a beneficiary is still residing in these settings and/or by hiring peer support specialists to help beneficiaries make connections with available community-based providers, including, where applicable, plans for employment);
B. Implementation of a process to assess the housing situation of a beneficiary transitioning to the community from psychiatric hospitals and to connect beneficiaries who are homeless or who have unsuitable or unstable housing with community providers that coordinate housing services, where available;
C. Implementation of a requirement that psychiatric hospitals have protocols in place to ensure contact is made by the treatment setting with each discharged beneficiary within 72 hours of discharge and to ensure follow-up care is accessed by individuals after leaving those facilities by contacting the individuals directly and by contacting the community-based provider they were referred to;

D. Implementation of strategies to prevent or decrease the length of stay in emergency departments among beneficiaries with SMI (e.g., through the use of peers and psychiatric consultants in EDs to help with discharge and referral to treatment providers);
E. Implementation of strategies to develop and enhance interoperability and data sharing between physical, SUD, and mental health providers, with the goal of enhancing coordination so that disparate providers may better share clinical information to improve health outcomes for beneficiaries with SMI.

iii. **Increasing Access to Continuum of Care Including Crisis Stabilization Services.**

A. Establishment of a process to annually assess the availability of behavioral health services throughout the state, particularly crisis stabilization services, and updates on steps taken to increase availability;
B. Commitment to implementation of the SMI financing plan described in STC 2(e) of this section;
C. Implementation of strategies to improve the state's capacity to track the availability of inpatient and crisis stabilization beds to help connect individuals in need with that level of care as soon as possible;
D. Implementation of a requirement that providers, plans, and utilization review entities use an evidence-based, publicly available patient assessment tool, preferably endorsed by a mental health provider association (e.g., LOCUS or CASII) to determine appropriate level of care and length of stay.

iv. **Earlier Identification and Engagement in Treatment Including Through Increased Integration**

A. Implementation of strategies for identifying and engaging individuals, particularly adolescents and young adults, with SMI in treatment sooner, including through supported employment and supported education programs;
B. Increasing integration of behavioral health care in non-specialty care settings, including schools and primary care practices, to improve identification of SMI conditions sooner and improve awareness of and linkages to specialty treatment providers;
C. Establishment of specialized settings and services, including crisis stabilization services, focused on the needs of young people experiencing SMI.

3. **SMI Health IT Plan.** The Health IT plan is intended to apply only to those State Health IT functionalities impacting beneficiaries within this demonstration and providers directly funded by this demonstration. The state will provide CMS with an assurance that it has a sufficient health IT infrastructure/ "ecosystem" at every appropriate level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration. If the state is unable to provide such an assurance, it will submit to CMS a Health IT Plan, to be included as a section of the applicable Implementation Plan (see STC 2 of this section), to develop the infrastructure/capabilities of the state's health IT infrastructure.

The Health IT Plan will detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SMI/SED goals of the demonstration. The plan(s) will also be used to identify areas of health IT ecosystem improvement. The Plan must include implementation milestones and projected dates for achieving them, and must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) IT Health Plan.

The state will include in its Monitoring Plans (see STC 4 of this section) an approach to monitoring its SMI/SED Health IT Plan which will include performance metrics to be approved in advance by CMS.

The state will monitor progress, each DY, on the implementation of its SMI/SED Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Report (see STC 6 of this section).

As applicable, the state should advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SMI/SED Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.

Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally-recognized standards, barring another compelling state interest.

Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling state interest.

Components of the Health IT Plan include:

A. The Health IT Plan will, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of *SED/SMI* care delivery. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.

    i. The Health IT Plan will describe the state's current and future capabilities to support providers implementing or expanding Health IT functionality in the following areas: 1) Referrals, 2) Electronic care plans and medical records, 3) Consent, 4) Interoperability, 5) Telehealth, 6) Alerting/analytics, and 7) Identity management.

    ii. In developing the Health IT Plan, states should use the following resources:

1. States may use federal resources available on Health IT.Gov (https://www.healthit.gov/topic/behavioral-health) including but not limited to "Behavioral Health and Physical Health Integration" and *"Section 34: Opioid Epidemic and Health IT" (https://www.healthit.gov/playbook/health-information-exchange/)*.
2. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.
3. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

d. **SMI Financing Plan.** As part of the approved SMI implementation plan referred to in STC 2 of this section, the state's SMI Financing Plan is also incorporated into the STCs as part of the SMI Implementation Plan in Attachment F. Further alterations require CMS approval. Components of the financing plan includes:

i. A plan to increase the availability of non-hospital, non-residential crisis stabilization services, including but not limited to the following: services made available through crisis call centers, mobile crisis units, coordinated community response services that includes law enforcement and other first responders, and observation/assessment centers; and
ii. A plan to increase availability of ongoing community-based services such as intensive outpatient services, assertive community treatment, and services delivered in integrated care settings;
iii. A plan to ensure the on-going maintenance of effort (MOE) on funding outpatient community-based services to ensure that resources are not disproportionately drawn into increasing access to treatment in inpatient and residential settings at the expense of community-based services.

4. **SMI Monitoring Protocol.** The state must submit a Monitoring Protocol for the SMI program authorized by this demonstration within 150 calendar days after approval of the demonstration. The Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. The state must submit the revised SMI Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments. Once approved, the SMI Monitoring Protocol will be incorporated into the STCs, as Attachment G. Progress on the performance measures identified in the SMI Monitoring Protocol must be reported via the quarterly and annual monitoring reports. Components of the SMI Monitoring Protocol include:

a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 2 of this section reporting relevant information to the state's SMI financing plan described in Attachment F, and

reporting relevant information to the state's Health IT plans described in STC 3 of this section;

b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section XII of the demonstration; and
c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

5. **SMI Mid-Point Assessment.** The state must conduct an independent mid-point assessment by December 31, 2023. In the design, planning and conduct of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of MCOs, SMI providers, and beneficiaries.

   The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 days after December 31, 2023. The state must brief CMS on the report.

   For milestones and measure targets at medium to high risk of not being achieved, the state must submit to CMS modifications to the SMI Implementation Plan, the SMI Financing Plan, and the SMI Monitoring Protocol for ameliorating these risks. Modifications to the applicable Implementation, Financing, and Monitoring Protocol are subject to CMS approval.

   Elements of the mid-point assessment include:

   a. An examination of progress toward meeting each milestone and timeframe approved in the SMI, the SMI Financing Plan, and toward meeting the targets for performance measures as approved in the SMI Monitoring Protocol;
   b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;
   c. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets;
   d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's SMI or SMI Financing Plan or to pertinent factors that the state can influence that will support improvement; and
   e. An assessment of whether the state is on track to meet the budget neutrality

6. **Evaluation.** The SMI Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections XIII (General Reporting Requirements) and XVI (Evaluation of the Demonstration) of these STCs. The state will follow CMS guidelines to ensure the evaluation design is developed and amended to support a rigorous evaluation of the SMI component of the demonstration.

7. **Availability of FFP for the SMI Services under the SMI IMD expenditure authority**. FFP is only available for services provided to beneficiaries during short term stays for acute care in IMDs. The state may claim FFP for stays up to 60 days as long as it shows at its midpoint assessment that it is meeting the requirement of a 30 day or less average length of stay (ALOS). Stays in IMDs that exceed 60 days are not eligible for FFP under this demonstration. If the state cannot show that it is meeting the 30 day or less ALOS requirement within one standard deviation at the mid-point assessment, the state may only claim FFP for stays up to 45 days until such time that the state can demonstrate that it is meeting the 30 day or less ALOS requirement. The state assures that it will provide coverage for stays that exceed 60 days—or 45 days, as relevant—with other sources of funding if it is determined that a longer length of stay is medically necessary for an individual beneficiary.

8. **Unallowable Expenditures Under the SMI IMD Expenditure Authority.** In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:

    a. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

    b. Costs for services provided in a nursing facility as defined in section 1919 of the Act that qualifies as an IMD.

    c. Costs for services provided to individuals who are involuntarily residing in a psychiatric hospital or residential treatment facility by operation of criminal law.

    d. Costs for services provided to beneficiaries under age 21 residing in an IMD unless the IMD meets the requirements for the "inpatient psychiatric services for individuals under age 21" benefit under 42 CFR 440.160, 441 Subpart D, and 483 Subpart G.

XI. DELIVERY SYSTEM

1. Managed Care Requirements. The state must comply with the managed care regulations published at 42 CFR 438. Capitation rates shall be developed and certified as actuarially sound, in accordance with 42 CFR 438.4 through 438.8.

2. Public Contracts. Payments under contracts with public agencies, that are not competitively bid in a process involving multiple bidders, shall not exceed the documented costs incurred in furnishing covered services to eligible individuals (or a reasonable estimate with an adjustment factor no greater than the annual change in the consumer price index).

3. Network Requirements. The state must deliver all covered benefits, ensuring high quality care. Services must be delivered in a culturally competent manner, and the MCO network must be sufficient to provide access to covered services. In addition, the MCO must coordinate health care services for demonstration populations. The following requirements

must be included in the state's MCO contracts:

a. **Special Health Care Needs**. Beneficiaries with special health care needs must have direct access to a specialist, as appropriate for the individual's health care condition, as specified in 42 CFR 438.208(c)(4).

b. **Out of Network Requirements**. The state, through its contracts with the HIP MCOs, will require the MCOs to provide out of network benefits in the following situations:

   i. Each MCO must allow access to non-network providers, when services cannot be provided consistent with the timeliness standards required by the state.

   ii. During the transition of beneficiaries into HIP MCOs, for any provider seen by the beneficiary during the month in which enrollment is effectuated, MCOs will honor previous care authorizations for a minimum of 30 calendar days from the member's date of enrollment with the MCO, or date the member paid their contribution (whichever is later) even on a non-network basis.

4. **HIP Managed Care Organizations (MCO).** HIP beneficiaries shall be enrolled to receive service through an MCO under contract to the state, as provided under the state plan. The MCOs are subject to the federal laws and regulations in 42 CFR Part 438. The HIP beneficiary will be given an opportunity to select an MCO at the time of application. A HIP beneficiary who does not make an MCO selection at the time of application may be auto-assigned to a HIP MCO by the state. Except in cases of presumptive eligibility, auto-assignment may occur after the date in which the state determined their eligibility.

   The state may adjust the auto-assignment methodology. In addition to the criteria identified in 42 CFR 438.54, the state may consider assignment to the lowest-cost MCO, or to the MCOs that demonstrate higher quality scores or better health outcomes, or to MCOs on a rotating basis. Any change to the auto-assignment methodology must be approved by CMS before implementation.

   Beneficiaries will be advised both at the time of application, and upon receiving an initial invoice, of the auto-assignment and their right to change MCOs prior to the first POWER account contribution payment. The notice to beneficiaries shall include information on the process to change MCOs.

5. **MCO Information and Selection.** The state shall contract with an enrollment broker to assist interested applicants with their MCO selection so they can make an informed decision in compliance with 42 CFR 438.810. The enrollment broker will provide the applicant with appropriate counseling on the full spectrum of available MCO choices and will address any questions the applicant may have. Once an MCO has been selected and after the beneficiary has made either their fast track payment or first POWER account contribution, or has begun coverage in HIP Basic after non-payment, the beneficiary is required to remain in that MCO for the remainder of the current calendar year, with exceptions specified in STC 6 of this section.

6. Beneficiary's Right to Change MCOs.

a. A beneficiary will be automatically re-enrolled into the beneficiary's prior MCO, even if the beneficiary disenrolls and re-enrolls in HIP coverage during the 12-month benefit year.

b. A beneficiary may change HIP MCOs without cause if the change is requested prior to (i) the date the beneficiary pays their initial POWER account contribution or fast track POWER account prepayment, or (ii) has defaulted into HIP Basic for non- payment of fast-track prepayment or POWER Account contribution whichever comes first. Beneficiaries may seek assistance from the enrollment broker in choosing an MCO. Disenrollment without cause for the reasons identified in 42 CFR 438.56(c)(2)(ii), (iii) and (iv) will also be permitted.

c. Each November 1- December 15th, beneficiaries will have the opportunity to select their MCO for the coming benefit period. Prior to the open selection period, beneficiaries will be reminded of their ability to select a new MCO. Beneficiaries may make a selection by contacting the enrollment broker.

d. **For Cause.** A beneficiary may change MCOs for cause at any time and will include this information in all communications about POWER account contributions. "Cause" is defined in 42 CFR 438.56(d)(2). Other reasons as described in 42 CFR 438.56(d)(2)(v), includes, but is not limited to, the following:

i. Receiving poor quality care;

ii. Failure of the Insurer to provide covered services;

iii. Failure of the Insurer to comply with established standards of medical care administration;

iv. Lack of access to providers experienced in dealing with the enrollee's health care needs;

v. Significant language or cultural barriers;

vi. Corrective Action levied against the Insurer by the Family and Social Services Administration (FSSA);

vii. Limited access to a primary care clinic or other health services within reasonable proximity to a beneficiary's residence;

viii. A determination that another MCO's formulary is more consistent with a new beneficiary's existing health care needs; or

ix. Other circumstances determined by FSSA or its designee to constitute

poor quality of health care coverage

x. If a beneficiary was unable to participate in MCO selection period for a qualified reason, they may change their MCO during the first 60 days of the new benefit period or within 60 days of transfer into HIP. Qualified reason for being unable to participate in the MCO selection period include:

- Member transitioned from other Indiana health care program to HIP.
- Member was in a non-eligibility period during MCO selection, and returned to the program via a reauthorized case.
- Member was not fully eligible during MCO selection time.

xi. The beneficiary must submit his or her request for change to the enrollment broker either orally or in writing. The beneficiary shall still have access to the grievance and appeals process required under the managed care regulations.

e. If a beneficiary misses the MCO selection period due to temporary loss of eligibility, and then reenrolls in the subsequent benefit year, the beneficiary would be able to change plans when they reenroll.

f. If the state fails to make a determination by the first day of the second month following the month in which the beneficiary files the request, the request for change will be considered approved and the beneficiary will be transferred into the new MCO.

g. If a beneficiary is transferred from the MCO, the MCO, must return the remaining balance of the individual's POWER account to the state within 120 days of the last date of participation with the MCO. The state shall then provide the entire remaining POWER account balance to the new MCO with the information needed to properly track the individual's contribution.

h. The state shall ensure that all transferring individuals receive coverage from their new MCO promptly, without any interruption in care.

7. **Withhold and Incentive Payments.** Any capitation withhold arrangements or incentive payments, to MCOs under 42 CFR 438.6(b) shall only be based on quality measures or demonstrated improved health outcomes.

XII. GENERAL REPORTING REQUIREMENTS

1. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs

(hereafter singularly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the demonstration paid under section 1115(a)(2). The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The following process will be used: 1) Thirty (30) days after the deliverable was due, if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) Thirty days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).

b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.

c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.

d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

   As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations, and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

2. **Submission of Post-Approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

3. **Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:

a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
c. Submit deliverables to the appropriate system as directed by CMS.

4. **Implementation Plan.** The state must submit a draft Implementation Plan to CMS for review and comment no later than ninety (90) calendar days after the approval of the demonstration. The state must submit a revised Implementation Plan within sixty (60) calendar days after receipt of CMS's comments. The Implementation Plan must cover at least the key policies being tested under this demonstration, including non-eligibility periods, premiums or POWER Account contributions, and waivers of retroactive eligibility. Additionally, the state may be expected to provide additional details not captured in the STCs regarding implementation of the other demonstration policies, such as incentives for healthy behaviors, waiver of NEMT, and the processes involved in modifying POWER Account contributions amount and/or co-payments and any annual assessments that may be undertaken for making such changes. Once determined complete by CMS, the Implementation Plan will be incorporated into the STCs, as Attachment I. At a minimum, the Implementation Plan must include definitions and parameters of key policies, and describe the state's strategic approach to implementing the policies, including timelines for meeting milestones associated with these key policies. Other topics to be discussed in the Implementation Plan include application assistance, reporting, insurance affordability program; appeal; renewals; coordination with other state agencies; beneficiary protections; and outreach. The state will continue to operate in compliance with information included in the Implementation Plan that CMS will determine complete. Any changes to the operations of the policy components must be consulted with CMS, and may require a formal amendment to the Implementation Plan and resubmission to CMS.

5. **Monitoring Protocol.** The state must submit to CMS a draft Monitoring Protocol no later than one hundred and fifty (150) calendar days after the approval of the demonstration. The state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments. Once approved, the Monitoring Protocol will be incorporated into the STCs, as Attachment J.

   At a minimum, the Monitoring Protocol will affirm the state's commitment to conduct quarterly and annual monitoring in accordance with CMS's templates. Any proposed deviations from CMS's templates should be documented in the Monitoring Protocol. The Monitoring Protocol will describe the quantitative and qualitative elements on which the state will report through quarterly and annual monitoring reports. For quantitative metrics (e.g., performance metrics as broadly described in STC 6 below), CMS will provide the state with performance metrics, and technical specifications for data collection and analysis covering key policies being tested under this demonstration, including but not limited to, premiums and cost-sharing, incentives for healthy behaviors, and waiver of retroactive eligibility. The state is also expected to report monitoring data for TMA beneficiaries subject to premiums, including enrollment and disenrollment. The Monitoring Protocol will specify the methods of data collection and timeframes for reporting on the state's progress as part of the quarterly and annual monitoring reports. For the qualitative elements (e.g.,

operational updates as described in STC 6 below), CMS will provide the state with guidance on narrative and descriptive information which will supplement the quantitative metrics on key aspects of the demonstration policies. The quantitative and qualitative elements will comprise the state's quarterly and annual monitoring reports.

6. **Monitoring Reports.** The state must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth-quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Monitoring Report is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework to be provided by CMS, which will be organized by milestones. The framework is subject to change as monitoring systems are developed/evolve, and will be provided in a structured manner that supports federal tracking and analysis.

    a. Operational Updates – The operational updates will focus on progress towards meeting the milestones identified in CMS's framework. Additionally, per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

    b. Performance Metrics – The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's annual goals and overall targets as will be identified in the approved Monitoring Protocol, and will cover key policies under this demonstration, including but not limited to, premiums and POWER Account payments, including tobacco surcharge, and waivers of retroactive eligibility. The performance metrics will also reflect all other components of the state's demonstration. For example, these metrics will cover enrollment, disenrollment or suspension by specific demographics (and policy, as applicable), reenrollment after suspension and reentry after disenrollment, completion of incentivized health behaviors and rewards granted, unpaid medical bills at application (if available), access to care, and quality of care and health outcomes.

        Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured

population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, and grievances and appeals.

The required monitoring and performance metrics must be included in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements – Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the CMS-64.

d. Evaluation Activities and Interim Findings – Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

7. **Corrective Action Plan Related to Monitoring.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where monitoring indicates indicate substantial and sustained directional change inconsistent with state targets (such as substantial and sustained trends indicating increased difficulty accessing services, increased premium non-payment and disenrollment, unpaid medical bills, etc.). A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in Section III STC 10. CMS will withdraw an authority, as described in Section III STC 10, when metrics indicate substantial, sustained directional change, inconsistent with state targets, and the state has not implemented corrective action. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

8. **Close Out Report**. Within 120 days prior to the expiration of the demonstration, the state must submit a draft Close Out Report to CMS for comments.

   a. The draft final report must comply with the most current Guidance from CMS.

   b. The state will present to and participate in a discussion with CMS on the Close-Out report.

c. The state must take into consideration CMS' comments for incorporation into the final Close Out Report.

d. The final Close Out Report is due to CMS no later than 30 calendar days after receipt of CMS' comments.

e. A delay in submitting the draft or final version of the Close Out Report may subject the state to penalties described in STC 1 of this section.

9. **Monitoring Calls.** CMS will convene periodic conference calls with the state.

a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, and progress on evaluation activities.

b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.

c. The state and CMS will jointly develop the agenda for the calls.

10. **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state shall afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) days prior to the date of the planned public forum, the state must publish the date, time, and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

XIII. GENERAL FINANCIAL REQUIREMENTS

1. **Standard Medicaid Funding Process.** The standard Medicaid funding process must be used during the demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this Medicaid section 1115 demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state must estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the Form CMS-37 for both the Medical Assistance Payments (MAP) and State and Local Administration Costs (ADM). CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS will reconcile

expenditures reported on the Form CMS-64 quarterly with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

2. **Extent of FFP for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the budget neutrality expenditure limits described in section XIV: Budget Neutrality Determination.

   a. Administrative costs, including those associated with the administration of the demonstration.
   b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved state plan.

   c. Medical Assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

3. **Sources of Non-Federal Share.** The state must certify that the matching non-federal share of funds for the demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non- federal share of funding are subject to CMS approval.

   a. CMS may review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.

   b. Any amendments that impact the financial status of the program shall require the state to provide information to CMS regarding all sources of the non-federal share of funding.

   c. The state assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provisions, as well as the approved Medicaid state plan.

   d. Under all circumstances, health care providers must retain 100 percent of the HIP reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business (such as payments related to taxes (including health care provider-related taxes), fees, and business relationships with

governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments) are not considered returning and/or redirecting a Medicaid payment.

e. FFP will not be available for individual contributions to the POWER accounts. FFP will be available for state contributions to the POWER accounts to the extent that funds are actually transferred to MCOs (net of any such funds returned to the state or other governmental entity), and for capitation payments to MCOs.

4. **State Certification of Funding Conditions.** The state must certify that the following conditions for non-federal share of demonstration expenditures are met:

a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.

b. To the extent the state utilizes certified public expenditures (CPEs) as the funding mechanism for Title XIX (or under section 1115 authority) payments, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under Title XIX (or under section 1115 authority) for purposes of certifying public expenditures.

c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.

d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of Title XIX payments.

e. Under all circumstances, health care providers must retain 100 percent of the HIP reimbursement amounts claimed by the state as demonstration expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, and business relationships with governments that are

unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

5. **Program Integrity.** The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.

6. **Medicaid Expenditure Groups (MEG).** MEGs are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The following table provides a master list of MEGs defined for this demonstration.

Table 4: Master MEG Chart

MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
SUD	Hypo 1	X		X	See Expenditure Authority #2
SMI FFS	Hypo 2	X		X	See Expenditure Authority #3
SMI Managed Care	Hypo 3	X		X	See Expenditure Authority #3

7. **Reporting Expenditures and Member Months.** The state must report all demonstration expenditures under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00296/5). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of services associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the

state must also report member months of eligibility for specified MEGs.

a. Cost Settlements. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.

b. Reporting of HIP POWER Account Contributions. The state must report HIP plan POWER account contributions as follows:

   i. HIP MCO Contributions. HIP plan contributions must be reported on Forms CMS-64.9 Waiver and CMS-64.9P Waiver, using Line 18A.

   ii. State's Contributions to Participants' POWER Accounts. The state's contributions to participants' POWER accounts must be reported on Forms CMS-64.9 Waiver, using Line 18E. (Because individual participants' POWER account contributions are not subject to federal matching, they are not to be reported on the CMS-64.).

   iii. Recouped State Contributions to Participants' POWER Accounts. In the event that the state recoups state POWER account contributions from HIP MCOs (for example, when a participant disenrolls from HIP; see Section VI), the amounts collected must be reported as a prior period adjustment using Line 10B of the Forms CMS- 64.9P Waiver on Line 18E.

c. Pharmacy Rebates. Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.

d. Administrative Costs. The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the table below, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

e. Member Months. As part of the Quarterly and Annual Monitoring Reports described in Section XII STC 6, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita and as also months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total.

Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

f. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 3: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
SUD	FFS expenditures and managed care capitation for SUD services		SUD	Date of service	MAP	Y	02/01/2018	12/31/2025
SMI FFS	FFS expenditure for SMI services		SMI FFS	Date of service	MAP	Y	01/01/2020	12/31/2025
SMI Managed Care	Managed Care capitation for SMI services		SMI Managed Care	Date of service	MAP	Y	01/01/2020	12/31/2025

8. Demonstration Years. Demonstration Years (DY) for this demonstration are defined in the Demonstration Years table below.

Table 4: Demonstration Years

Demonstration Year 7	January 1, 2021 to December 31, 2021	12 months
Demonstration Year 8	January 1, 2022 to December 31, 2022	12 months

Demonstration Year 9	January 1, 2023 to December 31, 2023	12 months
Demonstration Year 10	January 1, 2024 to December 31, 2024	12 months
Demonstration Year 11	January 1, 2025 to December 31, 2025	12 months

9. **Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing demonstration's actual expenditures to the budget neutrality expenditure limits described in section XIV STC 7. CMS will provide technical assistance, upon request.[4]

10. **Claiming Period.** The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

41. **Future Adjustments to Budget Neutrality.** CMS reserves the right to adjust the budget neutrality expenditure limit:

    a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments, CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

    b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance,

[4] 42 CFR 431.420(a)(2) provides that states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and 431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS's current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and in states agree to use the tool as a condition of demonstration approval.

the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

XIV. BUDGET NEUTRALITY DETERMINATION

1. **Limit on Title XIX Funding.** The state shall be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

2. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions; however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

3. **Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts.

The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

4. **Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.

5. **Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be "hypothetical;" that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS's current view that states should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending by savings elsewhere in the demonstration or to refund the FFP to CMS.

6. **Hypothetical Budget Neutrality Test 1: SMI/SED and SUD Initiative.** The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

Table 6: Hypothetical Budget Neutrality Test								
MEG	**PC or Agg***	**WOW Only, WW Only, or Both**	**TREND**	**DY 7**	**DY 8**	**DY 9**	**DY 10**	**DY 11**
SUD	PC	Both	4.9%	$7,889.45	$8,276.03	$8,681.56	$9,106.95	$9,553.19
SMI FFS	PC	Both	4.6%	$5,603.27	$5,861.02	$6,130.62	$6,412.63	$6,707.61
SMI Managed Care	PC	Both	4.6%	$1,144.80	$1,197.46	$1,252.54	$1,310.16	$1,370.43

7. **Composite Federal Share. The Composite Federal Share is the ration that will be used to convert the total computable budget neutrality limit to federal share.** The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on the Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed method. Each Main or Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

8. **Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from January 1, 2021 to December 31, 2025. If at the end of the demonstration period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

9. **Mid-Course Correction.** If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Hypothetical Budget Neutrality Test(s)

Table 10: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations		
	Cumulative Target Definition	**Percentage**
DY 7	Cumulative budget neutrality limit plus:	2.0 percent

DY 7 through DY 8	Cumulative budget neutrality limit plus:	1.5 percent
DY 8 through DY 9	Cumulative budget neutrality limit plus:	1.0 percent
DY 9 through DY 10	Cumulative budget neutrality limit plus:	0.5 percent
DY 10 through DY 11	Cumulative budget neutrality limit plus:	0.0 percent

XV. EVALUATION OF THE DEMONSTRATION

1. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to: commenting on design and other federal evaluation documents; providing data and analytic files to CMS; entering into a data use agreement that explains how the data and data files will be exchanged; and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities that collect, produce, or maintain data and files for the demonstration, a requirement that they make data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in Section XII STC1.

2. **Independent Evaluator.** Upon approval of the demonstration, the state must begin arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement to conduct the demonstration evaluation in an independent manner in accord with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

3. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than 180 calendar days after the approval of the demonstration. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable.

   The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):

   a. Attachment A (Developing the Evaluation Design) of these STCs, and all applicable technical assistance on applying robust evaluation approaches, including using comparison groups and beneficiary surveys to develop a draft Evaluation Design.

b. All applicable evaluation design guidance, including guidance about substance use disorder, serious mental illness, premiums, waiver of NEMT, co-payment for non-emergent use of emergency department, waiver of retroactive eligibility, and overall demonstration sustainability.

4. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within 60 calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as attachment K to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Monitoring Reports. Hypotheses for the SUD program must include an assessment of the objectives of the SUD component of this section 1115 demonstration, to include (but is not limited to): initiation and compliance with treatment, utilization of health services (emergency department and inpatient hospital settings), and a reduction in key outcomes such as deaths due to overdose. Hypotheses for the SMI component of the demonstration must relate to (but are not limited to): utilization and length of stay in emergency departments, reductions in preventable readmissions to acute care hospitals and residential settings, availability of crisis stabilization services, and care coordination. Hypotheses for premiums and beneficiary account payments must relate to (but are not limited to) the following outcomes: beneficiary familiarity with premiums as a feature of commercial coverage, efficient use of health services (applicable to states with beneficiary accounts only), and likelihood of enrollment and enrollment continuity. Evaluation of premiums should also account for effectiveness of the tobacco surcharge policy. Hypotheses for disenrollment for non-compliance must relate to (but are not limited to) the following outcomes: beneficiary compliance with demonstration requirements, enrollment continuity, and health status (as a result of greater enrollment continuity). Hypotheses for the waiver of retroactive eligibility must relate to (but are not limited to) the following outcomes: likelihood of enrollment and enrollment continuity, enrollment when people are healthy, and health status (as a result of greater enrollment continuity). Hypotheses for copayment for non-emergent use of emergency department (ED) must relate to (but are not limited to) the following outcomes: number of ED visits per 1,000 beneficiaries for emergent as well as non-emergent conditions, number of visits per 1,000 beneficiaries to primary care, urgent care clinic, and retail clinic, and average ED waiting time. In addition, the state must investigate cost outcomes for the demonstration as a whole, including but not limited to: administrative costs of demonstration implementation and operation, Medicaid health service expenditures, and provider uncompensated costs. Finally, the state must use results of hypothesis tests and cost analyses to assess demonstration effects on Medicaid program sustainability.

5. **Evaluation Budget.** A budget for the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or

if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

6. **Interim Evaluation Report.** The state must submit Interim Evaluation Reports for the approved evaluation design for the completed years of the demonstration specified in subparagraph c, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Report should be posted to the state's website with the application for public comment.

   a. The Interim Evaluation Reports will discuss evaluation progress and present findings to date as per the approved Evaluation Design.

   b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.

   c. The state must provide a draft Interim Evaluation Report for the corresponding years, as described in 1-3 below. The state must submit a revised Interim Evaluation Report for each Interim Evaluation Report sixty (60) calendar days after receiving CMS comments on the corresponding draft Report and post the documents to the state's website.

      1) A Draft Interim Evaluation Report for demonstration years 1-3 (calendar years 2021 – 2023) will be due no later than December 31, 2024.
      2) A Draft Interim Evaluation Report for demonstration years 1-5 (calendar years 2021 – 2025) will be due no later than June 30, 2027.
      3) A Draft Interim Evaluation Report for demonstration years 1-8 (calendar years 2021 – 2028) will be due no later than December 31, 2029.

   d. If the state is seeking to renew or extend the demonstration, the last draft Interim Evaluation Report, representing demonstration years 1-8 (calendar years 2021-2028) is due when the application for renewal is submitted.

   e. The Interim Evaluation Reports must comply with Attachment B (Preparing the Evaluation Report) of these STCs.

7. **Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Evaluation Report) of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

   a. Unless otherwise agreed upon in writing by CMS, the state shall submit a revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.

b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.

8. **Corrective Action Plan Related to Evaluation.** If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of a renewal process when associated with the state's Interim Evaluation Report. A state corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with state targets (such as substantial and sustained trends indicating increased difficulty accessing services, increased premium non-payment and disenrollment, increases in provider uncompensated care costs and unpaid medical bills, etc.) A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in Section III STC 10. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

9. **State Presentations for CMS**. CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.

10. **Public Access**. The state shall post the final documents (e.g., Monitoring Reports, Close Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 calendar days of approval by CMS.

11. **Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party connected to the demonstration over which the state has control. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials or to FSSA staff acting in their official capacity and providing information to stakeholders in a formal capacity with the expressed intent of soliciting feedback and/or comment as required by regulations.

Attachment A – Developing the Evaluation Design

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions.

Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html.

Expectations for Evaluation Designs

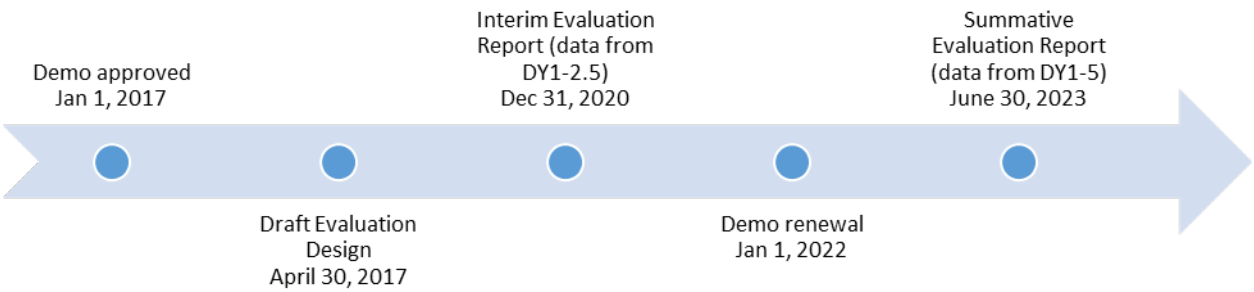
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

The format for the Evaluation Design is as follows:

A. General Background Information;
B. Evaluation Questions and Hypotheses;
C. Methodology;
D. Methodological Limitations;
E. Attachments.

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Design and Reports. The graphic below depicts an example of this timeline for a 5-year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within 30 days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of All Evaluation Designs
The Evaluation Design sets the stage for the Interim and Summative Evaluation Reports. It is important that the Evaluation Design explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology (and limitations) for the evaluation. A copy of the state's Driver Diagram (described in more detail in paragraph B2 below) should be included with an explanation of the depicted information.

A. General Background Information – In this section, the state should include basic information about the demonstration, such as:

1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

B. Evaluation Questions and Hypotheses – In this section, the state should:

1) Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.

2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended

outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf.

3) Identify the state's hypotheses about the outcomes of the demonstration:
   a. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
   b. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

1) Evaluation *Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?

2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

3) *Evaluation Period* – Describe the time periods for which data will be included.

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
   a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
   b. Qualitative analysis methods may be used, and must be described in detail.

c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

   If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
   i. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
   ii. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
   iii. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
   iv. The application of sensitivity analyses, as appropriate, should be considered.

   Other Additions – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

Table A. Example Design Table for the Evaluation of the Demonstration

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
Hypothesis 1				

Research question 1a	-Measure 1 -Measure 2 -Measure 3	-Sample e.g. All attributed Medicaid beneficiaries -Beneficiaries with diabetes diagnosis	-Medicaid FFS and encounter claims records	-Interrupted time series
Research question 1b	-Measure 1 -Measure 2 -Measure 3 -Measure 4	-sample, e.g., PPS patients who meet survey selection requirements (used services within the last 6 months)	-Patient survey	Descriptive statistics
Hypothesis 2				
Research question 2a	-Measure 1 -Measure 2	-Sample, e.g., PPS administrators	-Key informants	Qualitative analysis of interview material

D. Methodological Limitations – This section provides detailed information on the limitations of the evaluation. This could include the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize the limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review.

E. Special Methodological Considerations- CMS recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. Examples of considerations include:

1) When the state demonstration is:
    a. Long-standing, non-complex, unchanged, or
    b. Has previously been rigorously evaluated and found to be successful, or
    c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)

2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
    a. Operating smoothly without administrative changes; and
    b. No or minimal appeals and grievances; and
    c. No state issues with CMS 64 reporting or budget neutrality; and
    d. No Corrective Action Plans (CAP) for the demonstration.

F. Attachments

A. Independent Evaluator. This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. This includes "No Conflict of Interest" signed conformation statements.

B. Evaluation Budget. A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

C. Timeline and Major Milestones. Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

Attachment B: Preparing the Interim and Summative Evaluation Reports

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provide important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. With the following kind of information, states and CMS are best poised to inform and shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Attachment

Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Attachment is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

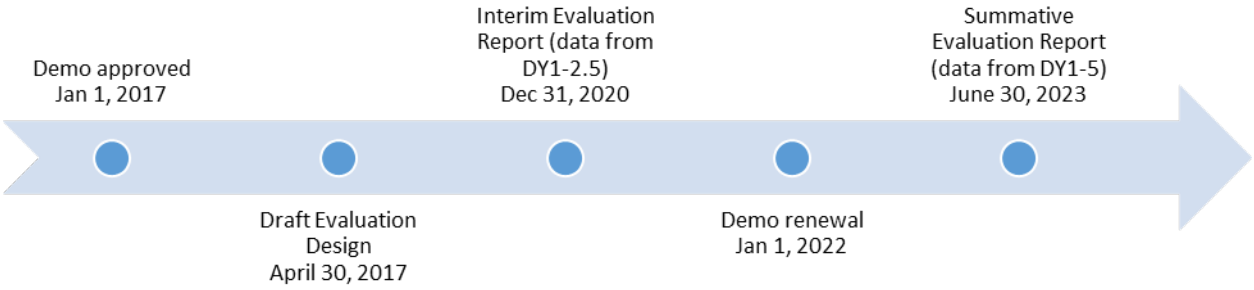
The format for the Interim and Summative Evaluation reports are as follows:

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;

H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). The graphic below depicts an example of a deliverables timeline for a 5-year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the evaluation design and reports to the state's website within 30 days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of Interim and Summative Evaluation Reports

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state's Driver Diagram (described in the Evaluation Design Attachment) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state's submission must include:

A. Executive Summary – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

B. General Background Information about the Demonstration – In this section, the state should include basic information about the demonstration, such as:

i. The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
ii. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

iii. A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
iv. For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
v. Describe the population groups impacted by the demonstration.

C. Evaluation Questions and Hypotheses – In this section, the state should:

1. Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
2. Identify the state's hypotheses about the outcomes of the demonstration;
    a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
    b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
    c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design. The evaluation Design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an interim evaluation.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. *Evaluation Design*—Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc?
2. *Target and Comparison Populations*—Describe the target and comparison populations; include inclusion and exclusion criteria.
3. *Evaluation Period*—Describe the time periods for which data will be collected

4. *Evaluation Measures*—What measures are used to evaluate the demonstration, and who are the measure stewards?
5. *Data Sources*—Explain where the data will be obtained, and efforts to validate and clean the data.
6. *Analytic methods*—Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

A. Methodological Limitations
This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

B. Results – In this section, the state presents and uses the quantitative and qualitative data to show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

C. Conclusions – In this section, the state will present the conclusions about the evaluation results.

1. In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?

2. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
   a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

D. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

E. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1. What lessons were learned as a result of the demonstration?
2. What would you recommend to other states which may be interested in implementing a similar approach?

F. Attachment

1. Evaluation Design: Provide the CMS-approved Evaluation Design

State of Indiana
1115 SUD Waiver
Implementation Plan

Indiana Family and Social Services Administration
Office of Medicaid Policy and Planning
Updated January 2018

Contents

Introduction

Indiana is experiencing the opioid epidemic that has been devastating the United States. Nearly six times as many Hoosiers died from drug overdoses in 2014 as did in 2000, and the number of heroin overdose deaths has increased by nearly 25 times between 2000 and 2014[1]. The State's Medicaid population has been particularly impacted by the crisis: nearly 100,000 individuals were treated for a diagnosis of substance use disorder in 2016[2].

As part of a response to a recommendation laid out by the Taskforce on Drug Enforcement, Treatment, and Prevention, Indiana Medicaid is building a stronger substance use disorder (SUD) treatment infrastructure, with increased benefits, stronger provider networks, and incorporation of evidenced-based SUD program standards. Indiana will utilize a section 1115 demonstration waiver to pursue the following primary goals, as outlined by the Centers for Medicare and Medicaid Services (CMS):

1. Increased rates of identification, initiation, and engagement in treatment
2. Increased adherence to and retention in treatment
3. Reductions in overdose deaths, particularly those due to opioids
4. Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriately through improved access to other continuum of care services
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate
6. Improved access to care for physical health conditions among beneficiaries

Indiana Medicaid believes it can accomplish these six goals by putting particular focus on three areas:

- Expanded SUD treatment options for as many of its members as possible
- Stronger, evidenced-based certification standards for its SUD providers, particularly its residential addiction providers
- Consistency with prior authorization criteria and determinations among its health plans

Organized by six key milestones that have been identified by CMS, the following implementation plan provides a vision for the direction Indiana Medicaid will go over the months and years ahead in combating the State's opioid epidemic.

Access to Critical Levels of Care for SUD Treatment

Indiana Medicaid provides coverage of SUD treatment services to its members. Throughout the waiver application process, Indiana Medicaid reviewed its options for individuals struggling with

[1] INDIANA STATE DEPARTMENT OF HEALTH, INDIANA:SPECIAL EMPHASIS REPORT, DRUG OVERDOSE DEATHS, 1999-2013 (2016), available at http://www.in.gov/isdh/files/2016_SER_Drug_Deaths_Indiana.pdf.

[2] Based on ICD-10 claims analysis for claims with a date a service between January 1 and December 31, 2016. Excludes tobacco use disorder.

SUD compared with the standards outlined through the American Society of Addiction Medicine (ASAM). Many services that align with an ASAM level of care are currently covered, but through the usage of the 1115 SUD waiver, State Plan Amendments, and other regulatory tools, Indiana will provide coverage for a more complete continuum of services. The following table provides an overview of each ASAM level of care with current Indiana Medicaid coverage along with proposed changes:

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage
OTP	Opioid Treatment Program	Pharmacological and non-pharmacological treatment in an office-based setting (methadone)	Currently covered for all (as of September 2017)	Continued oversight of new policy
0.5	Early Intervention	Services for individuals who are at risk of developing substance-related disorders	Currently covered for all	No change expected
1.0	Outpatient Services	Outpatient treatment (usually less than 9 hours a week), including counseling, evaluations, and interventions	Currently covered for all	No change expected
2.1	Intensive Outpatient Services	9-19 hours of structured programming per week (counseling and education about addiction-related and mental health programs)	Currently MRO-only	Will be covered for all individuals
2.5	Partial Hospitalization	20 or more hours of clinically intensive programming per week	Covered for all	No change expected
3.1	Clinically Managed Low-Intensity Residential	24-hour supportive living environment; at least 5 hours of low-intensity treatment per week	No coverage	Bundled daily rate for residential treatment
3.5	Clinically Managed High-Intensity Residential	24-hour living environment, more high-intensity treatment (level 3.7 without intensive medical and nursing component)	No coverage	Bundled daily rate for residential treatment
3.7	Medically Monitored Intensive Inpatient Services	24-hour professionally directed evaluation, observation, medical monitoring, and addiction treatment in an inpatient setting	Covered for all (based on medical necessity)	Align authorization criteria with ASAM
4.0	Medically Managed Intensive Inpatient	24-hour inpatient treatment requiring the full resources of an acute care or psychiatric hospital	Covered for all (based on medical necessity)	Align authorization criteria with ASAM
Sub-Support	Addiction Recovery Management Services	Services to help people overcome personal and environmental obstacles to recovery, assist the newly recovering person into the recovering community, and serve as a personal guide and mentor toward the achievement of goals	No coverage	Covered for all individuals
Sub-Support	Supportive Housing Services	Services for individuals who are transitioning or sustaining housing.	No coverage	Explore options for coverage

Each of the ASAM levels of care will be addressed in more detail by providing current coverage, future coverage, and a timeline for implementation over the next 12-24 months for these proposed changes.

Level of Care: OTS (Opioid Treatment Services)

Summary of Actions Needed:

- Amendment to Indiana Administrative Code (IAC) promulgating coverage of OTP services

Current State:

Through August 2017, Indiana Medicaid did not provide coverage for opioid treatment program (OTP) services, including the daily administration of methadone. The Family and Social Services Admission (FSSA), Division of Mental Health and Addiction (DMHA) currently certifies thirteen (13) OTPs, including three that are operated through a community mental health center (CMHC). Since 2008, DMHA has been prohibited from certifying new programs; however, Indiana Senate Enrolled Act 464 (2015) allows DMHA to approve up to five new programs before June 30, 2018. As a result of this legislation, DMHA is moving forward with the certification of up to five new OTPs throughout the state. In addition, DMHA is reviewing and updating the Indiana Administrative Code to clarify sections of the code and modify outdated sections.

Indiana Senate Enrolled Act 297 (2016) required that as of July 1, 2017, all OTPs operating in Indiana must either be:

- Enrolled as an Indiana Health Coverage Programs (IHCP) provider, or
- Enrolled as an ordering, prescribing, or referring provider in accordance with Section 6401 of the Patient Protection and Affordable Care Act.

As a result of this legislation, Indiana Medicaid began pursuing conversations with several OTPs about a bundled payment for all services rendered.

Future State:

Indiana Medicaid has completed making the system changes to enroll OTPs as billing providers and reimburse these programs with a daily bundled payment that includes all services as required by federal regulations and in alignment with ASAM Patient Placement Criteria. These services include the following:

- Individualized, patient-centered assessment and treatment
- Assessing, ordering, administering, reassessing, and regulating medication and dose levels appropriate to an individual
- Monitored drug testing, to be done at a minimum of eight times a year
- A range of cognitive, behavioral, and other substance use disorder-focused therapies

- Case management, including medical monitoring and coordination of on-and off-site treatment services, provided as a needed
- Psychoeducation, including HIV/AIDS education and other health education services

BT201755 was published on August 17, 2017 finalizing all of the billing guidance and enrollment information for OTP services. Services were originally announced to begin on August 2, 2017; however, due to public comment and system specifications, the effective date was delayed until September 1, 2017. Meanwhile, the State Plan Amendment (SPA) authorizing the use of the bundled payment structure was submitted to CMS on September 8, 2017. This SPA was approved on December 4, 2017.

Indiana Medicaid has made a concerted effort at working closely with DMHA to ensure that the State's Medicaid guidance is consistently aligned with the State's non-Medicaid guidance. Representatives from Indiana Medicaid continue to participate in quarterly meetings with all of the OTP providers, and the program will closely monitor the success of this new coverage and amend policy as necessary. Finally, Indiana Medicaid will promulgate its coverage of OTP services as part of a comprehensive review of its behavioral health administrative rules.

A list of action items and expected implementation timeline regarding OTP services is provided in the table below:

Action	Implementation Timeline
Pursue Indiana Administrative Code (IAC) change for coverage and reimbursement of OTPs	Will be filed by December 31, 2018

Level of Care: 0.5 (Early Intervention)

Summary of Actions Needed:

- None anticipated

Current State:

Indiana Medicaid provides coverage for several individual services around early intervention, including smoking cessation counseling and screening, brief intervention, and referral to treatment (SBIRT). These services are available to all Indiana Medicaid members without prior authorization.

Future State:

No changes are expected at this ASAM level of care.

Level of Care: 1.0 (Outpatient Services)

Summary of Actions Needed:

- Amendment to Indiana Administrative Code (IAC) aligning outpatient services with ASAM structure

Current State:

Indiana Medicaid provides coverage for two broad categories of outpatient services: office-based addiction treatment (also known as "clinic option" services) and community-based addiction treatment (also known as "Medicaid Rehabilitation Option" services).

Office-Based Treatment

All Indiana Medicaid members have coverage for office-based behavioral health services. Individuals are covered for these services for up to twenty (20) units per member, per provider, per rolling 12-month period; additional units require prior authorization based upon medical necessity. These services must be certified by and may be provided by a physician, a Health Services Provider in Psychology (HSPP), and other providers as outlined in *405 IAC 5-20-8(2)*.

Community-Based Treatment

Indiana Medicaid also has an array of services for mental health and addiction treatment known as Medicaid Rehabilitation Option (MRO). These optional services are authorized under Section 1905(a)(13)(C) of the Social Security Act and are allowed to be rendered in an individual's home or other setting within the community. Individuals are assigned an MRO package of services based upon an approved mental health or substance use diagnosis and an appropriate level of need, as determined through a DMHA-approved assessment tool called the Child and Adolescent Needs and Strengths (CANS) or Adult Needs and Strengths Assessment (ANSA). Depending upon the automated results of the CANS or ANSA, an individual with a level of need of two or higher for youth (three or higher for adults) is assigned/authorized a package/array of service that includes a specific number of units of each MRO service that's available to the member for a six-month eligibility period. Individuals who still require services at the end of six months must undergo a redetermination and be assigned/authorized a new package of services designed to meet their needs.

Services billable through MRO include the following:

- Addiction counseling (individual and group)
- Behavioral health counseling and therapy
- Behavioral health day treatment
- Case management
- Intensive outpatient treatment (IOT)
- Medication training and support
- Peer recovery services
- Skills training and development

MRO services are further distinguished by the provider staff qualifications eligible to deliver the service. Many of the services covered under MRO can be rendered by a licensed professional, a qualified behavioral health professional (an unlicensed individual who may have professional experience or education qualifications to provide services), or any other behavioral health professional (who may have an associate or bachelor's degree, or equivalent behavioral health experience). Additionally, due to a freedom of choice waiver authorized under Section 1915(b)(4) of the Social Security Act, MRO services are only reimbursable to community mental health centers.

Future State:

Indiana Medicaid currently has a robust set of services for outpatient addiction treatment. The only explicit change that will be sought, which will be discussed further in the next section, is the removal of Intensive Outpatient Treatment (IOT) from the MRO package of services. Indiana Medicaid plans to make this service available to all individuals and reimbursable to qualifying providers beyond community mental health centers.

The State is also planning to make amendments to the Indiana Administrative Code to update provider staff qualifications, including adding licensed clinical addiction counselors, and to further align its coverage standards with the ASAM Criteria.

A list of action items and expected implementation timeline regarding outpatient services is provided in the table below:

Action	Implementation Timeline
Pursue Indiana Administrative Code (IAC) amendments to Mental Health Services Rule	Will be filed by December 31, 2018

Level of Care: 2.1 (Intensive Outpatient Services)

Summary of Actions Needed:

- State Plan Amendment
- Indiana Administrative Code change
- CoreMMIS system changes
- Provider notification

Current State:

As indicated in the previous section, Indiana Medicaid has reimbursed for intensive outpatient treatment (IOT) as a service available through the MRO benefit. IOT is a treatment program that operates at least three hours per day for at least three days in a week. The service includes group therapy, interactive education groups, skills training, random drug screenings, and counseling, all of which fall in line with ASAM Level of Care 2.1 expectations for Intensive Outpatient Services. Like all other MRO services, it is only reimbursable through CMHCs.

Over the past year, providers other than CMHCs have been trying to work with our managed care entities (MCEs) on proper payment for IOT services outside of MRO. The MCEs have adopted the usage of "intensive outpatient program" (IOP) for services billed outside of MRO. In January 2017, OMPP provided clearer reimbursement instructions directly to the MCEs on IOP services that also differentiate between substance use and psychiatric treatment. The following summarizes those instructions:

For providers billing on a UB-04 claim form:

- Must bill CPT Code 90899 -*Unlisted psychiatric service or procedure* for any IOP service with one of the following revenue codes, based on the type of service rendered:
    - 905 – psychiatric
    - 906 – chemical dependency

For providers billing on a CMS-1500 claim form:

- HCPCS code S9480 (Intensive outpatient psychiatric services) would be used for psychiatric IOP
- HCPCS code H0015 (Alcohol and/or drug services; intensive outpatient) would be used for substance use IOP
    - One unit equals three hours of IOP services

Future State:

Indiana Medicaid wants to ensure that this policy is consistent for both the managed care and fee-for-service population. As a result, Indiana Medicaid will be submitting a SPA to completely remove IOT from the MRO package of services to ensure that it is reimbursable to all appropriate entities, including community mental health centers. Indiana anticipates using the same federal authority as MRO for this separate service (Section 1905(a)(13)(C) of the Social Security Act). An updated section of the Indiana Administrative Code will be devoted to coverage of IOT services.

A list of action items and expected implementation timeline regarding intensive outpatient services is provided in the table below:

Action	Implementation Timeline
Pursue Indiana Administrative Code (IAC) change to remove IOT from MRO	Will be filed by December 31, 2018
Pursue State Plan Amendment (SPA) to move IOT coverage from MRO	Will be filed by June 30, 2018
Pursue amendment to 1915(b)(4) waiver	Will be filed by June 30, 2018
Make necessary system changes to CoreMMIS	Will be completed by June 30, 2018
Develop provider communication over new benefits	Contingent upon approval of SPA (formal notification will be delivered at least 30 days prior to launch)

Level of care: 2.5 (Partial Hospitalization)

Summary of Actions Needed:

- None anticipated

Current State:

Indiana Medicaid covers partial hospitalization for all members according to medical necessity. The following program standards apply for all individuals:

- Services must be ordered and authorized by a psychiatrist
- Face-to-face evaluation and assignment of a mental health or substance use diagnosis must take place within 24 hours following admission
- Psychiatrist must actively participate in the case review and monitoring of care
- Documentation of active oversight and monitoring of progress by a physician, psychiatrist, or HSPP must appear in the patient's clinical record
- At least one psychotherapy service (group psychotherapy service) must be delivered daily
- For those under 18 years old: active psychotherapy must appear on clinical record, and one family encounter per five business days of episode of care is required
- Must include four to six hours of active treatment per day, at least four days per week
- Authorized for up to five days; must check with each health plan for other authorization criteria.

Future State:

No immediate changes are expected at this ASAM level of care. However, Indiana Medicaid's partial hospitalization criteria will undergo a complete review against the ASAM Patient Placement Criteria, and this effort may result in changes to the Indiana Administrative Code as part of the previously mentioned comprehensive review of the behavioral health administrative rule.

Level of care: 3.1 / 3.5 (Clinically Managed Low-Intensity Residential / Clinically Managed High-Intensity Residential)

Summary of Action Items:

- CoreMMIS system modifications (including finalizing coding)
- New provider specialty
- Conversation with MCEs regarding authorization criteria
- Provider notification

Current State:

Residential treatment for substance use disorders can be provided within residential addiction treatment facilities, including institutions for mental disease (IMDs). An IMD is defined as a hospital, nursing facility, or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services. Federal law prohibits federal financial participation (FFP) from going to IMDs for individuals aged 21 through 64. One of the primary goals of the 1115 SUD waiver is to waive this restriction and allow IMDs to provide treatment to all IHCP members, including inpatient and residential treatment.

Indiana Medicaid currently has no defined methodology to pay for residential treatment for substance use disorder. As a result, neither Level 3.1 (clinically managed low-intensity residential) nor Level 3.5 (clinically managed high-intensity residential) are currently reimbursable.

Future State:

Upon approval of the 1115 waiver, Indiana Medicaid will be able to reimburse for residential stays in all settings, including IMDs, for most populations (fee-for-service and managed care). Indiana will allow members to seek authorization for residential IMD stays based on a statewide average length of stay of thirty (30) days.

The State will be pursuing a bundled per diem payment based upon the approved ASAM level of care. The funding authority will be the 1115 SUD waiver. The bundled rate methodology for both Level 3.1 and 3.5 residential services will initially be based around a mix of current MRO services that is most appropriate to that particular level of care.

Consistent with the therapies offered according to ASAM Level 3.1 and Level 3.5 treatment, the following table summarizes the individual services that will be incorporated into the bundled payment rate:

Service	Unit Type	MRO Service	Cost Per Unit
Individual/Family Therapy	Hour	H0004	$108.97
Group Therapy	Hour	H0004 (Group)	$27.23
Skills Training and Development	Hour	H2014	$104.56
Medication Training and Support	Hour	H0034	$74.48
Peer Recovery Supports	Hour	H0038	$34.20
Case Management	Hour	T1016	$58.12

Drug Testing	Encounter	80101	$19.03

Through a rigorous analysis from Milliman, the following daily bundled rates will be utilized:

- Level 3.1 (clinically managed low-intensity residential)
  - Adult - $126.46 per day
  - Child - $130.37 per day
- Level 3.5 (clinically managed high-intensity residential)
  - Adult - $361.65 per day
  - Child - $439.56 per day

Only facilities that have been designated by the Division of Mental Health and Addiction (DMHA) as an ASAM Level 3.1 or Level 3.5 residential facility will be eligible to receive reimbursement from Indiana Medicaid. The development of improved certification requirements and ASAM designation for these facilities will be addressed under a later section of the implementation plan.

Indiana Medicaid will be developing a new provider specialty for residential addiction treatment facilities that have been certified by DMHA and designated at ASAM Level 3.1 or Level 3.5. The State anticipates having this new provider specialty, along with all other necessary system changes for the fee-for-service and managed care populations, complete ahead of a March 1, 2018 implementation. To allow adequate time for facilities to complete the DMHA designation process and to separately enroll as this new provider specialty, Indiana Medicaid will give currently enrolled facilities until July 1, 2018 to complete these steps; any facility seeking reimbursement for residential services after that time will be required to complete the previous two steps ahead of reimbursement.

Indiana Medicaid will also pursue conversations with our managed care entities to ensure that each health plan is basing admission decisions for residential treatment on the six dimensions of the ASAM Patient Placement Criteria. The managed care entities, as well as Indiana Medicaid's fee-for-service prior authorization vendor, will be allowed to utilize any evidence-based clinical decision system that incorporates all six specific dimensions of life care, as articulated in the ASAM Patient Placement Criteria. These six dimensions include:

- Acute intoxication and/or withdrawal potential
- Biomedical conditions and complications
- Emotional, behavioral, or cognitive conditions and complications
- Readiness to change
- Relapse, continued use, or continued problem potential
- Recovery environment

A list of action items and expected implementation timeline regarding residential treatment is provided in the table below:

Action	Implementation Timeline
Make necessary system changes to CoreMMIS to enroll residential addiction facilities and to reimburse for residential treatment	Will be completed by March 1, 2018
Develop provider communication over new benefits	Ongoing as part of roll-out; formal communication will be released with at least 30 days-notice ahead of launch

Level of care: 3.7/4.0 (Medically Monitored Intensive Inpatient / Medically Managed Intensive Inpatient)

Summary of Action Items:

- Conversation with MCEs regarding authorization criteria
- Consider change in reimbursement from DRG-based payment to per diem payment

Current State:

Due to the same federal regulatory restriction, Indiana Medicaid is prohibited from seeking federal financial participation (FFP) for treatment in IMDs for individuals aged 21 through 64 for inpatient treatment. Since July 2016, our managed care entities have had the authority to reimburse for inpatient IMD stays in lieu of services or settings covered under the State Plan. Indiana Medicaid does currently reimburse for inpatient treatment for substance use and chemical dependency treatment based upon a diagnosis-related group (DRG) payment methodology. Indiana Medicaid's managed care entities, as well as the fee-for-service prior authorization vendor, utilize evidenced-based clinical criteria for admission standards to inpatient treatment.

Future State:

Upon approval of the 1115 waiver, Indiana Medicaid will be able to reimburse for inpatient stays in IMD settings for all populations (fee-for-service and managed care). Indiana will allow members to seek authorization for inpatient IMD stays for lengths of stay of up to fifteen (15) days.

During the latter part of 2018, Indiana Medicaid will consider reimbursing substance use-related inpatient stays on a per diem basis. This would allow providers to receive payment based upon the number of days, as well as the intensity of treatment, for which an individual is seeking treatment. Indiana Medicaid will review its State Plan to determine if a SPA is necessary for this change and pursue the amendment accordingly.

The managed care entities, as well as Indiana Medicaid's fee-for-service prior authorization vendor, will be allowed to utilize any evidence-based clinical decision system for inpatient stays that incorporates all six specific dimensions of life care, as articulated in the ASAM Patient Placement Criteria.

A list of action items and expected implementation timeline regarding intensive inpatient services is provided in the table below:

Action	Implementation Timeline
Determine final action and necessary system changes to CoreMMIS to allow reimbursement for inpatient SUD stays on a per diem basis	Fall 2018
Develop provider communication over changes in reimbursement structure	Ongoing as part of roll-out; formal communication will be released with at least 30 days-notice ahead of launch

Sub Support Service – Addiction Recovery Management Services

Summary of Action Items:

- Pursue State Plan Amendment
- CoreMMIS system changes
- Pursue amendment to IAC
- Provider communication

Current State:

Indiana currently does not have coverage for addiction recovery management services. As previously described under Outpatient Services, mental health treatment is available through a Medicaid Rehabilitation Option (MRO) package of services, but these new services will be available specifically for substance use treatment.

Future State:

Indiana will be pursuing a State Plan Amendment to use the same federal authority (Section 1905 (a)(13)(C) of the Social Security Act) that currently authorizes MRO services to reimburse for Addiction Recovery Management Services. These services include the following:

- Peer Recovery Support
- Recovery-Focused Case Management

These services will be individually reimbursable services using the following tentative criteria:

	Peer Recovery Support	Recovery-Focused Case Management
Coding	H0038 (SUD modifier)	T1016 (SUD modifier)
Provider Types	• Addiction Peer Recovery Coach Other licensed professionals will be allowed to provide this service as long as they are trained as an Addiction Peer Recovery Coach.	Licensed professionals o Psychiatrist o Licensed Addiction Counselor (LAC) o Licensed Clinical Social Worker (LCSW) o Licensed Mental Health Counselor (LMHC) o Licensed Marriage and Family Therapist (LMFT) o Licensed Clinical Addiction Counselor (LCAC) Qualified Behavioral Health Provider (QBHP)
Eligibility	• All Indiana Medicaid members (except for those eligible only for family planning services, emergency services, or QMB-only/SLMB-only/QI coverage)	

	• Must meet medical necessity (have a primary or secondary diagnosis of substance use disorder)

A list of action items and expected implementation timeline regarding Addiction Recovery Management Services is provided in the table below:

Action	Implementation Timeline
Make necessary system changes to allow reimbursement for Addiction Recovery Management Services	Spring 2018
Pursue State Plan Amendment (SPA) to add coverage and reimbursement of services* *coverage of services will begin upon approval of SPA	Spring 2018
Pursue Indiana Administrative Code changes to add coverage of services	Will be filed by December 31, 2018
Develop provider communication over new benefits	Ongoing as part of roll-out; formal communication will be released with at least 30 days-notice ahead of launch

Sub Support Service – Supportive Housing Services

Summary of Action Items:

- Create collaborative workgroup
- Develop rate methodology
- CoreMMIS system changes
- Provider communication

Current State:

Indiana Medicaid currently provides no coverage for supportive housing services.

Future State:

Using the 1115 SUD waiver as a funding mechanism, Indiana will be pursuing coverage of supportive housing services. Indiana is using *CMCS Informational Bulletin: Coverage of Housing-Related Activities and Services for Individuals with Disabilities* as a template for the services that will be offered. The services will fall under two broad categories: services for individuals transitioning to housing, and services for individuals to help sustain their housing status. Indiana envisions the following activities falling under each category:

- Transitioning Services

- Identification of resources to help cover the security deposit, moving costs, environmental modifications, and other one-time expenses
- Tenant screening and housing assessment to identify individual's preferences and barriers related to successful tenancy
- Assistance with housing application or housing search process
- Assistance with arranging for and supporting details of the move
- Development of a housing support crisis plan

- Sustaining Services
  - Early identification and intervention for behaviors that may jeopardize housing
  - Education and training on the roles, rights, and responsibilities of a tenant and landlord
  - Coaching on key relationships with landlords and property managers
  - Assistance with resolving disputes with landlords
  - Assistance with housing recertification process
  - Training in being a good tenant and lease compliance

In May 2017, Indiana Medicaid participated in a day-long summit on the topic of supportive housing. The summit was hosted by one of Indiana Medicaid's MCEs and was attended by representatives from all four of the MCEs along with various stakeholders representing housing. This summit was used to lay the foundation for a larger commitment to exploring supportive housing opportunities throughout the remainder of 2017.

Indiana will utilize time throughout 2018 to get a better understanding of the terminology surrounding supportive housing. Indiana Medicaid will then invite representatives from each of the MCEs, the Indiana Housing and Community Development Authority (IHCDA), and other interested stakeholders to continue the efforts begun in May 2017 towards developing a supportive housing solution. Indiana Medicaid will provide ongoing updates to CMS as required to demonstrate progress towards a final solution.

Withdrawal Management Services (Inpatient Detoxification)

Summary of Action Items:

- Conversation with MCEs regarding authorization criteria

Current State

Indiana Medicaid currently reimburses for withdrawal management services (known as inpatient detoxification). Indiana does not address distinctions among the various withdrawal management levels of care according to the ASAM Patient Placement Criteria.

During the 2016 legislative session, the Indiana General Assembly passed Senate Enrolled Act 297, which required the Office of Medicaid Policy and Planning (OMPP) to establish inpatient detoxification admission criteria in accordance with either:

- The most current edition of the American Society of Addiction Medicine (ASAM) Patient Placement Criteria; or
- Other clinical criteria that are determined by the office and are evidenced based and peer reviewed.

Indiana Medicaid released BT201632 announcing that inpatient detoxification criteria may be based upon one of the following:

- Milliman Care Guidelines
- InterQual Criteria
- American Society of Addiction Medicine (ASAM) Patient Placement Criteria
- Anthem Clinical Utilization Management (UM) Guidelines

Future State:

Indiana will continue requiring the usage of the criteria outlined in BT201632. Similar to authorization requirements for residential and other inpatient treatment, the managed care entities, as well as Indiana Medicaid's fee-for-service prior authorization vendor, will be allowed to utilize any evidence-based clinical decision system that incorporates all six specific dimensions of life care, as articulated in the ASAM Patient Placement Criteria.

Use of Evidenced-Based SUD-Specific Patient Placement Criteria

In addition to newly covered addiction treatment services, Indiana is incorporating established standards of care for medical necessity criteria and provider qualifications. Specifically, Indiana will be incorporating the ASAM Criteria into both prior authorization requests for services as well as certification for residential providers. Indiana will accomplish this through administrative rule changes, policy manual updates, and contract amendments.

Patient Assessment

Individuals seeking substance use treatment for all ASAM levels of care, including residential and inpatient, will be required to undergo a psychosocial assessment that will be used for the completion of a plan of treatment. As part of the assessment, providers will be required to address all six dimensions of multidimensional assessment, including the following:

- Acute intoxication and/or withdrawal potential
- Biomedical conditions and complications
- Emotional, behavioral, or cognitive conditions and complications
- Readiness to change
- Relapse, continued use, or continued problem potential
- Recovery/living environment

Each of the six dimensions plays a critical role in assigning an individual to the most appropriate level of care, including residential or inpatient treatment. As part of any prior authorization

request, providers will be required to submit assessments that address all six dimensions. Indiana Medicaid will work with its managed care partners to develop a standard template that will be submitted with every authorization request for an SUD-specific service. The template will be organized according to the ASAM Patient Placement Criteria and will help guide providers towards the most appropriate level of care for a member.

As previously mentioned, Indiana Medicaid currently utilizes the CANS and ANSA assessment tools to determine an individual's placement with an MRO package of services. Indiana Medicaid will work closely with DMHA to review these tools and align them closer with the ASAM Criteria.

DMHA will pursue opportunities to provide education to Indiana's provider community around the appropriate use of the ASAM Criteria. This will include ongoing outreach to Indiana's ASAM chapter as well as the utilization of national ASAM resources.

Utilization Management

Once an eligible licensed professional has completed a psychosocial assessment for individuals needing substance use treatment, those findings must be confirmed by an independent third party that has the necessary competencies to use the ASAM Patient Placement Criteria. Services at ASAM Level 2 and above will require prior authorization through either Cooperative Managed Care Services (CMCS) – the fee-for-service prior authorization vendor – or one of our four managed care entities. All service level of care and length of stay requests will be authorized using the ASAM Patient Placement Criteria. Each vendor will be allowed to utilize any evidence-based system for clinical guidelines that incorporates the medical criteria required for an individual to meet an ASAM level of care.

Indiana will review each of its managed care partners' contracts and pursue amendments to formalize the usage of the ASAM Patient Placement Criteria as well as any other changes necessary as a result of the 1115 SUD demonstration waiver. These amendments will be used to ensure that members have access to SUD services at the most appropriate level of care, that interventions are appropriate for the diagnosis and level of care, and that providers receive an independent process for reviewing placement in residential treatment settings.

Each of Indiana Medicaid's managed care entities (MCEs) are contractually obligated to operate and maintain a utilization management program. This allows each MCE to place limits on coverage on the basis of medical necessity or utilization control criteria. The State requires the usage of a nationally recognized set of guidelines for its medical management criteria, which may include InterQual, Milliman Care Guidelines, or any other accepted set of evidence-based guidelines. When utilizing a set of guidelines for residential and inpatient addictions treatment, each MCE will be required to demonstrate incorporation of the six dimensions of multidimensional assessment, as outlined in the ASAM Patient Placement Criteria.

While each MCE is allowed to decide which nationally recognize set of guidelines to use for its medical management criteria, all MCEs are required to utilize the Indiana Health Coverage

Programs Prior Authorization Request Form. To help facilitate prior authorization requests for addiction treatment services in alignment with the ASAM Patient Placement Criteria, Indiana Medicaid will work with the MCEs to develop an additional form that will assist providers in requesting approval for the usage of the most appropriate level of care for an individual (as indicated in the previous section). Additionally, as discussed in the previous section, Indiana is expecting to update the ANSA assessment tool to be used by all SUD providers as the multidimensional assessment required by the ASAM Criteria to ensure that individuals are placed in the most appropriate level of care.

The MCEs are expected to use additional utilization review processes to ensure that services are medically necessary. Each MCE is required to have policies and procedures in place to review instances of over- and under-utilization of emergency room services and other health care services, identify aberrant provider practice patterns, ensure active participation of a utilization review committee, evaluate efficiency and appropriateness of service delivery, and identify quality of care issues. All of these processes are especially critical to the State's efforts around combatting substance use.

A list of action items and expected implementation timeline related to patient assessment and utilization management is provided in the table below:

Action	Implementation Timeline
Provider education on ASAM Criteria	Ongoing throughout 2018
Development of standard prior authorization SUD treatment form	Completed by July 1, 2018
Review contracts and pursue amendments where necessary	Filed by July 1, 2018
Review CANS/ANSA for alignment with ASAM Criteria	Completed by December 31, 2018

Use of Nationally Recognized SUD-Specific Program Standards for Residential Treatment

Indiana's current residential facility certification requirements are not designed to support residential facilities as treatment facilities. They do not adequately meet the standards placed by the ASAM Criteria. Rather than focus on treatment requirements for services rendered within a residential facility, current certification focuses on resident rights, physical building attributes and basic health/nutrition needs of residents. As a result of this insufficiency, Indiana does not have a definitive breakdown of providers by ASAM Criteria-approved level of care.

To remedy this problem, DMHA is developing new administrative rules that align residential facility certification with the higher standards of the ASAM Patient Placement Criteria. Providers who are wishing to receive reimbursement from Indiana Medicaid for residential services will need to be designated by DMHA as either an ASAM Level 3.1 or Level 3.5 facility.

The Indiana Administrative Code will be updated with specific requirements around the setting, provider type, treatment goals, and therapies required at the appropriate level of care.

Because the rulemaking process can take upwards of twelve to eighteen months for promulgation, DMHA is proposing to issue provisional ASAM designations until the new certification requirements have been promulgated. Between May and September 2017, DMHA and Indiana Medicaid visited each current residential facility to begin discussions on both the new coverage authorized through the 1115 SUD waiver as well as the new certification requirements. Ahead of each meeting, DMHA delivered a one-page memo along with a four-page questionnaire that providers were asked to complete ahead of the formal on-site visit with the provider. The completion of the questionnaire will assist DMHA in assigning a provisional ASAM Level of Care designation to the facility.

In late 2017, DMHA will be prepared to issue guidance to its currently certified residential facilities around the requirement of the ASAM designation. DMHA will begin accepting documentation and issuing provisional designations in early 2018. This designation will be instrumental during the implementation of a new Indiana Medicaid provider specialty, as discussed in the next section. Finally, DMHA will spend much of 2018 reworking its Indiana Administrative Code language for residential certification to incorporate all required aspects of the ASAM Criteria, including a requirement that residential facilities offer medication-assisted treatment (MAT) on-site or through facilitated access off-site.

A list of action items and expected implementation timeline related to standards for residential facilities is provided in the table below:

Action	Implementation Timeline
Finalize process for provisional ASAM designation	Will be completed by December 31, 2017
Insert permanent certification language in Indiana Administrative Code	Will be filed by December 31, 2018

Sufficient Provider Capacity at Critical Levels of Care

Network adequacy is a critical concern for the success of the 1115 SUD waiver. DMHA certifies all mental health and addiction providers in Indiana. For purposes of the 1115 SUD waiver, Indiana will address two current certifications:

- Addiction Treatment Services Provider (Regular) – an agency with eleven or more direct service staff
- Addiction Treatment Services Provider (Outpatient) – an agency with ten or fewer direct service staff/volunteers/contract workers

Addiction Treatment Services Provider (Regular)

The State has identified 80 facilities that are certified by DMHA as Addiction Treatment Services Providers (Regular). This group of facilities includes residential facilities, psychiatric

hospitals, acute care hospitals (and wings of acute care hospitals), and opioid treatment programs.

Due to the previously-mentioned 2015 state law change, nearly all of Indiana's opioid treatment programs (OTPs) are now enrolled with Indiana Medicaid. A new provider specialty for OTPs has been developed and went active in September 2017. Indiana will continue to pursue the remaining programs, as well as any new clinics that open in the coming months, for Medicaid enrollment.

The largest provider enrollment challenge facing Indiana Medicaid is the enrollment of residential facilities. Nearly all of the currently-enrolled facilities are community mental health centers (CMHCs) or outpatient mental health clinics with a limited number of residential beds; many facilities would not meet the standards of a psychiatric hospital or an outpatient clinic, and without reimbursement for residential stays, these facilities have had no incentive to enroll with Indiana Medicaid. In addition to pursuing updated certification standards that meet the ASAM Criteria, Indiana will also be creating a new provider specialty for residential addictions facilities. To enroll with Indiana Medicaid, these facilities will be required to be certified by DMHA as a residential sub-acute facility and will also be designated by DMHA as an ASAM Level 3.1 or 3.5 facility. By meeting the ASAM designation, these facilities will automatically meet the qualification to be certified as an Addiction Treatment Services Provider (Regular).

Addiction Treatment Services Provider (Outpatient)

The State has identified 161 organizations that are licensed as Addiction Treatment Services Provider (Outpatient). Many of these organizations are not enrolled as IHCP providers. Many are believed to be small office practices that are not overseen by a physician or HSPP, preventing Medicaid reimbursement. These addictions providers must have qualified staff and must perform at least outpatient treatment services and may provide intensive outpatient treatment services to those individuals with whom assessments indicate a need for those services. Indiana Medicaid may consider creating additional provider specialties for these office-based outpatient addictions providers.

Provider Enrollment

Indiana Medicaid enrolls its behavioral health providers using one of the following provider types and specialties:

- Type 01 (Hospital) – Specialty 011 (Psychiatric)
- Type 11 (Mental Health) – Specialty 110 (Outpatient Mental Health Clinic)
- Type 11 (Mental Health) – Specialty 111 (Community Mental Health Center)
- Type 11 (Mental Health) – Specialty 114 (Health Service Provider in Psychology)
- Type 31 (Physician) – Specialty 339 (Psychiatrist)
- Type 35 (Addiction Services) – Specialty 835 (Opioid Treatment Program)

As indicated above, many of the Addiction Treatment Services Providers (Outpatient) are considered mid-level practitioners and are not enrolled with Indiana Medicaid. Additionally,

some providers enrolled under one of these provider specialties may only provide mental health and not addiction treatment. Both pose a challenge towards understanding access to addiction services.

Indiana Medicaid will take several measures to ensure sufficient provider capacity:

- We will pursue stronger data analytics around our provider capacity. This will begin by determining, by provider specialty, how many providers are capable of providing each ASAM level of care. We will determine the correct system specifications to determine both who is capable of billing a specific level of care and who is actually billing a specific level of care. We will track this information over the course of the demonstration.
- We will also complete a full assessment of the availability of medication-assisted treatment (MAT) for Indiana Medicaid members. This will include identifying the number and locations of all Indiana Medicaid providers who have the appropriate buprenorphine training for prescribing MAT.
- We will also consider adding additional provider specialties to account for more mid-level practitioners, including licensed behavioral health professionals.

Overall Provider Strategy

Indiana's provider community is new to the principles of the ASAM Patient Placement Criteria. As a result, the State will take a multi-tiered approach to bring our providers closer in alignment with ASAM principles:

- From summer 2017 through the remainder of the year, the State will visit each residential addictions facility to begin a dialog around Medicaid reimbursement for residential treatment as well as the ASAM Patient Placement Criteria. This discussion will assist the State in assigning a provisional ASAM Level of Care designation, as previously discussed.
- By early 2018, Indiana Medicaid will have completed all necessary system modifications to ensure that residential addictions facilities are able to enroll and receive reimbursement for addictions service rendered. This will be communicated through Indiana Medicaid's provider website as well as an IHCP Provider Bulletin.
- Also by early 2018, Indiana Medicaid will have developed new training material on the 1115-approved services as well as provider enrollment for interested residential facilities. This material will be included as part of quarterly and annual IHCP provider workshops.
- By the end of the first quarter 2018, Indiana Medicaid will have developed the data analytics required to assess utilization of services by ASAM level. This analysis will be completed quarterly in anticipation of a full assessment of member access to all ASAM levels of care by the end of 2018. This will also include the availability of medication-assisted treatment.
- Throughout 2018, upon approval of new administrative certification rules, all residential facilities will be able to receive an ASAM designation. The finalized designation will be

parallel to an ongoing effort at educating providers on the use of the ASAM Patient Placement Criteria to ensure that individuals seeking treatment are placed at the most appropriate level of care.

A list of action items and expected implementation timeline related sufficient provider capacity is provided in the table below:

Action	Implementation Timeline
Create new provider specialty for residential addictions facilities	Will be completed by March 1, 2018
Data reporting by provider specialty and ASAM level of care	Will be completed by March 31, 2018
Assessment of ASAM providers and services	Will be completed by December 31, 2018

Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse

Governor's Task Force on Drug Enforcement, Treatment, and Prevention

On September 1, 2015, then-Governor Mike Pence issued Executive Order 15-09, establishing the Governor's Task Force on Drug Enforcement, Treatment, and Prevention to identify best practices and make informed recommendations for policy makers. The task force included membership from the Indiana General Assembly, the Governor's Office, the Indiana State Department of Health, the Indiana Department of Correction, the Indiana Department of Child Services, the Indiana Family and Social Services Administration, and other organizations and associations throughout Indiana. The group held multiple regional public meetings to hear from individuals affected by substance use disorders, local and state government officials, law enforcement, and other community leaders.

On December 5, 2016, the task force completed its work and issued a final report detailing all of their findings along with 17 actionable recommendations for lawmakers and state agencies to consider. The following list includes all recommendations identified by the group:

Enforcement Recommendations:

1. Support legislation to enhance penalties for persons dealing drugs convicted of serious and aggravated offenses.
2. Direct the Indiana Department of Correction to work with Starke and other northwest Indiana counties to pilot and adopt the Regional Therapeutic Communities program, which provides more treatment options for local officials in addressing addiction.
3. Direct the Indiana Criminal Justice Institute (CJI) and the Indiana Division of Mental Health & Addiction (DMHA) to identify a county criminal justice entity and implement a therapeutic substance use disorder treatment program for offenders awaiting adjudication and for those service sentences while in jail.

Treatment Recommendations:

4. Direct the Indiana Family and Social Services Administration (FSSA) to implement the Gold Card program, which removes administrative burdens by allowing qualified physicians the ability to prescribe medications without prior authorization (while still following the established criterion).
5. Direct the FSSA to pursue a Medicaid 1115 Demonstration Waiver for individuals with substance use disorders to broaden Indiana Medicaid benefit packages and provide a more comprehensive continuum of covered services and care.
6. Direct appropriate entities to promulgate and adopt with all expediency chronic pain prescribing rules for all prescribers.
7. Direct the Indiana State Department of Health (ISDH) to work with appropriate entities including those that represent physicians, nurses, dentists, physician assistants, podiatrists, and veterinarians to develop guidelines for prescribing acute pain medications. Endorse opioid and controlled substance prescribing guidelines for emergency departments as part of a larger strategy to combat prescription drug abuse in Indiana.
8. Direct the ISDH to convene a working group to send recommendations on improvements and best practices related to INSPECT – Indiana's Prescription Drug Monitoring Program - to the INSPECT Oversight Committee.
9. Direct the Indiana Professional Licensing Agency (PLA) to begin implementing a pilot program, the INSPECT Integration Initiative, to allow for the integration of INSPECT data with hospital patient records.
10. Direct the PLA to request that the INSPECT Oversight Committee explore possible measures to increase access to INSPECT for prescribers and dispensers.
11. Direct state agencies to raise awareness of Aaron's Law.
12. Direct the Indiana Department of Homeland Security (IDHS) to identify gaps in naloxone availability compared with overdose demographics.
13. Support legislation that would amend state law to require ISDH to issue a standing order for the dispensing of an overdose intervention drug, such as naloxone, and to expand the state's LifeLine Law to include immunity beyond alcohol offenses.
14. Direct the ISDH to implement a central repository naloxone distribution program for first responders should Indiana experience increased numbers of overdoses that would deplete local responders' supplies.
15. Support legislation that would modify the Governor's Commission for a Drug-Free Indiana in a way that maintains support for Local Coordinating Councils but brings together state agencies and stakeholders to address the drug abuse issues Indiana is facing today.
16. Direct the Indiana Department of Workforce Development to work closely with existing youth assistance programs and identify best practice models to replicate statewide.
17. Request the Commission for Improving the Status of Children make recommendations through its Educational Outcomes Task Force and Substance Abuse and Child Safety Task Force on the following: developing an age-appropriate substance abuse

curriculum for students, and finding ways to better connect affected youth with substance abuse services.

Gold Card Program

Indiana Medicaid implemented a Gold Card program in late 2015. This allows qualified Indiana Medicaid prescribers to be exempt from prior authorization document submission requirements for individual Indiana Medicaid members when prescribing buprenorphine and buprenorphine/naloxone. The Gold Card program currently has 16 prescribers. The following requirements currently apply to each prescriber:

- Must be an enrolled IHCP provider
- Must be licensed to practice medicine in the State of Indiana and be in good standing with the Indiana PLA and FSSA
- Must hold one of the following certifications:
    - A subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology (ABPN)
    - An addiction medicine certification from the American Board of Addiction Medicine (ABAM)
    - A certification of added qualification (CAQ) in addiction medicine from the American Osteopathic Association
- Must comply with all applicable Federal and State laws and regulations pertaining to the prescribing of controlled substances, including buprenorphine and buprenorphine/naloxone
- Must agree to comply with all current IHCP buprenorphine and buprenorphine/naloxone criteria as set forth by State and Federal law and the FSSA or its designee
- Must maintain complete medical records for individual IHCP members documenting criteria compliance
- Must commit to IHCP audits, occurring at the discretion of FSSA
- Must immediately inform FSSA, through its pharmacy benefit manager (PBM), of any change in qualification status
- Must agree that the FSSA reserves the right to withdraw the prescriber from participation in this program

Buprenorphine Prior Authorization Criteria

For non-Gold card members, Indiana Medicaid adopted specific prior authorization criteria for prescriptions of buprenorphine and buprenorphine/naloxone (also known as Suboxone). The criteria is now used by all of the MCEs' PBMs. These products may be approved for up to six months at a time, with a member receiving a 34-day supply at a time. The following authorization criteria applies for both fee-for-service and managed care members:

- Patient must be 16 years of age or older
- Physician must meet all qualifications to prescribe buprenorphine and buprenorphine/naloxone

- Patient must have a diagnosis of opiate dependence/addiction
- Physician must verify that the risks of using buprenorphine/naloxone with alcohol or benzodiazepines have been explained to the patient
- Physician must verify that there are not untreated or unstable psychiatric conditions that would interfere with buprenorphine/naloxone or buprenorphine compliance
- For pregnant members, physician must explain choice of buprenorphine/naloxone or buprenorphine over alternatives
- Physician must provide documentation of the patient's referral to or active involvement in formal counseling with a licensed behavioral health provider.

Indiana Attorney General's Prescription Drug Abuse Prevention Task Force

The Indiana Attorney General's Prescription Drug Abuse Prevention Task Force is a separate task force created in September 2012 by then-Indiana Attorney General Greg Zoeller to focus on five key components:

1. Providing education regarding the safe and appropriate prescribing and use of opioids for medical providers
2. Reducing drug diversion
3. Ensuring sustainability with the state's Prescription Drug Monitoring Program (INSPECT)
4. Increasing availability of disposal sites for unused controlled substances
5. Improving access to treatment and recovery for those suffering from addiction

The task force published a four-year report in December 2016. Many of the same objectives identified by the Governor's Task Force were acted upon by this task force. The four-year report detailed many legislative accomplishments, including the following:

- Obtained a long-term funding solution for INSPECT by moving 100% of the funds generated by the Controlled Substance Registrations back into the program
- Required licensing boards to establish opioid prescribing guidelines for chronic pain
- Required methadone clinics to check INSPECT before prescribing
- Required pharmacists to report dispensing data to INPSECT within 24 hours
- Created immunity for first responders and lay persons to administer naloxone
- Allowed for Syringe Exchange Programs to be implemented in counties at risk of HIV or Hep C outbreaks
- Appropriated $30 million to the Mental Health and Addiction Forensic Treatment Services account (administered by DMHA) for addiction services for those convicted of a felony

Prescribing Guidelines

In 2014, the Indiana Medical Licensing Board issued final rules establishing the standards and protocols for physicians in the prescribing of opioid controlled substances for pain management

treatment. These standards are outlined in 844 IAC 5-6. The rules apply for individuals who have been prescribed one of the following:

- More than sixty (60) opioid-containing pills a month for more than three (3) consecutive months
- A morphine equivalent dose of more than fifteen (15) milligrams per day for more than three (3) consecutive months
- A transdermal opioid patch for more than three (3) consecutive months
- A tramadol dose reaching a morphine equivalent of more than sixty (60) milligrams per day for more than three (3) consecutive months
- An extended release opioid medication that is not in an abuse deterrent form for which an FDA-approved abuse deterrent form is available

Additionally, in response to Indiana Senate Enrolled Act 297 (2016), DMHA created clinical practice guidelines for office-based opiate treatment. These guidelines have been distributed to OMPP, the Indiana Professional Licensing Agency, and each of the MCEs. The guidelines have been attached as an appendix to this implementation report.

The Indiana General Assembly also passed Indiana Senate Enrolled Act 226 (2017), which limited the prescription supply for opioids to only seven days for adults who are prescribed an opioid for the first time as well as for children under the age of 18.

Expanded Access to Naloxone

In 2015, the Indiana General Assembly passed Indiana Senate Enrolled Act 406 (2015), which significantly expanded the number of people who can have access to a prescription for Naloxone. Passage of the law allowed a person at risk for overdose or any individual who knows someone who may be at risk for overdosing to receive a prescription for the medication.

In 2016, this law was further amended through Indiana Senate Enrolled Act 187 (2016) that required the State Health Commissioner to issue a statewide standing order for the dispensing of naloxone. This further expanded access by allowing any individual to walk into a pharmacy for a prescription of naloxone without having to see a physician or other qualified prescriber first.

Naloxone (Narcan) is considered a preferred drug through Indiana Medicaid's pharmacy benefit. In determining ways of expanded access to naloxone further, Indiana Medicaid is exploring ways to allow emergency responders to receive reimbursement for the administration of naloxone. Indiana Medicaid does not currently enroll paramedics or emergency responders directly; rather, Indiana Medicaid enrolls transportation providers, including ambulances and common carrier providers. Indiana will consider releasing guidance allowing a physician to bill for the administration of naloxone on behalf of an emergency responder as well as consider enrolling emergency responders directly.

A list of action items and expected implementation timeline related to the expansion of naloxone for overdose reversal is included below:

Action	Implementation Timeline
Consider options for emergency responder reimbursement of naloxone	Will be completed in early 2018

Prescription Drug Monitoring Program

On August 24, 2017, Indiana Governor Eric Holcomb announced a major statewide initiative around incorporating the State's prescription drug monitoring program (knowing as INSPECT) directly into health care systems' electronic health records. Once fully integrated, practitioners will no longer be required to use multiple portals to access information around the prescribing and dispensing of controlled substances. Initial efforts at integration were made through Deaconness Midtown hospital in Evansville, Indiana; due to that system's success, the effort is being pushed across the entire state. Within three years, Indiana hopes to have all of its hospital systems fully integrated with INSPECT.

Taken as a whole, these efforts demonstrate the State's commitment to using all available resources (legislative changes, state regulations, certification, members within the community) for multiple strategies towards addressing both prescription drug use and opioid use disorder. All of these efforts should provide assurance to CMS that Indiana has a sufficient health IT infrastructure at every appropriate level to achieve the goals of this demonstration.

Improved Care Coordination and Transitions Between Levels of Care

Indiana Medicaid places contractual obligations on each of its managed care entities (MCEs) around case management and care coordination. The following list details each of those obligations:

- Each MCE must provide case management services for any member at risk for inpatient psychiatric or substance use hospitalization; for members discharged from an inpatient psychiatric or substance use hospitalization, case management services must be provided for at least 90 calendar days following the hospitalization.
- Each MCE must schedule an outpatient follow-up appointment to occur no later than seven calendar days following a psychiatric or substance use hospitalization discharge.
- Case managers are assigned to ensure that each new member already receiving behavioral health services is linked to an appropriate behavioral health provider.
- Case managers must also consult with both a member's physical and behavioral health provider(s) to facilities the sharing of clinical information
- With appropriate consent, case managers are required to notify all providers when a member is hospitalized or receives emergency treatment for behavioral health issues, including substance use within five calendar days of the admission or emergency treatment.
- Each MCE is required to have policies and procedures in place to facilitate the reciprocal exchange of health information between physical and behavioral providers treating a

member. This information sharing must include primary and secondary diagnoses, findings from assessments, medication prescribed, psychotherapy prescribed, and other relevant information.
- Each MCE is required to send a behavioral health profile to a member's primary medical provider (PMP) on a quarterly basis. Information about substance use treatment may only be released only with a member's consent, per *42 CFR Part 2* standards.

The MCEs also use advanced data analytics to help identify who may be at risk for substance use. The MCEs utilize ER claims, pharmacy claims, diagnosis codes, health needs assessments, and other tools to help predict individuals who may be high risk and high cost in a given year. Depending upon the level of risk assigned to an individual, a person may be given 1:1 care coordination.

Another idea that some of Indiana Medicaid's MCEs utilize is having points of contact housed within state's community mental health centers. These points of contact work with their members to facilitate the transition among the various levels of behavioral health services.

Indiana believes it can take additional steps to ensure a smooth transition for individuals moving between levels of care:

- While our current contracts with our MCEs require case management services for individuals transitioning from inpatient hospital stays, Indiana will pursue conversations and additional contract amendments to ensure that this obligation extends to individuals transitioning from residential treatment facilities.
- Upon release from an inpatient or residential level of treatment, Indiana believes individuals gain strength on the road to recovery through their relationships with others who have experienced the same difficulties. Indiana Medicaid is choosing to expand its coverage of peer recovery coaches as a way of helping individuals connect with professional and nonprofessional services and resources that are available in their community. This will be especially important for Traditional Medicaid members who do not have the resources available through the MCEs.

Appendix: Best Practice Guidelines for the Treatment of Opioid Use Disorders

These best practice guidelines were developed in response to Indiana Senate Enrolled Act (SEA) 297 & SEA 214 (2016). The intent of the guidelines is to provide a standard of care for the treatment of opioid use disorders (OUDs) in the State of Indiana and will be sent to the Indiana Professional Licensing Agency, the Office of Medicaid Policy and Planning, and the managed care organizations contracted with the Office for implementation. Practice standards were determined through a review of existing guidelines and research base. The Indiana guidelines are intended to quickly assist providers in locating up to date, accurate and useful information. Leslie Hulvershorn, MD, Medical Director at the Indiana Division of Mental Health and Addiction (DMHA), was the primary author. Information was then reviewed within DMHA and was circulated for review to stakeholders, such as Mental Health America of Indiana, Addiction Psychiatry faculty and fellows from the Indiana University School of Medicine, and CleanSlate Centers. This guide applies to inpatient and office-based opioid treatment (OBOT) providers and Opioid Treatment Providers (OTPs; i.e., "methadone clinics") in their use of buprenorphine and naltrexone. Sections within quoted material marked by "[text in italics]" should be interpreted as additional text provided by the authors of the Indiana guidelines, not a part of the originally published material (e.g., American Society of Addiction Medicine guidelines). These guidelines are not intended to be a substitute for formal medical training in the treatment of substance use disorders. The definition of 'physician' in these guidelines includes all DATA-waved clinicians who prescribe buprenorphine for addiction treatment legally under their license in Indiana.

Abbreviations

American Psychiatric Association = APA American Society of Addiction Medicine = ASAM Medication assisted treatment= MAT

Opioid use disorders= OUDs

Office-based opioid treatment = OBOT (e.g., DATA waived physicians)

Opioid treatment programs=OTPs (Require particular license from DEA; Offer daily supervised dosing of methadone, and other medications)

Guideline Summary:

Comprehensive treatment, including medication assisted treatment (MAT), is an effective response to opioid use disorder (OUD). The use of medications, in combination with behavioral therapies, provides a whole-patient approach to the treatment of substance use disorders. Individuals receiving MAT often demonstrate dramatic improvement in addiction-related behaviors and psychosocial functioning.

The opioid use disorder treatment protocol shall have the goal of opioid abstinence when appropriate or, if not possible, the minimal clinically necessary dose of medication. Treatment providers shall provide themselves, or through referral, comprehensive treatment options, including:

1. Opioid maintenance;
2. Opioid detox;
3. Overdose reversal;
4. Relapse prevention;
5. Long acting, nonaddictive medication assisted treatment medications.

Treatment for opioid use disorders shall be comprehensive and include:

1. Initial and periodic behavioral health assessments for each patient;
2. Informed consent from a concerning all available opioid treatment options, including each option's potential benefits and risks, before prescribing medication;
3. Appropriate use of providing overdose reversal medication, relapse prevention, counseling and ancillary services;
4. Transitioning off agonist and partial agonist therapies, when appropriate, with the goal of opioid abstinence.

Section 1. Assessment and Diagnosis of opioid use disorders for Office-based opioid treatment (OBOT) providers

Introduction:

In order to appropriately assess for opioid use disorders, as well as co-occurring mental health, other substance use disorders and physical health, best practices have been reviewed. Essential information about these best practices is as follows: .

For any provider treating opioid use disorders (OUDs), the following practices are recommended for assessment and diagnosis.

Assessment & Diagnosis Recommendations (excerpted from American Society of Addiction Medicine (ASAM) Guidelines [1]):

“(1) First clinical priority should be given to identifying and making appropriate referral for any urgent or emergent medical or psychiatric problem(s), including drug related impairment or overdose.

(2) Completion of the patient’s medical history should include screening for concomitant medical conditions including infectious diseases (hepatitis, HIV, and TB), acute trauma, and pregnancy. [If the provider does not provide this type of medical screening, the patient should be referred to a provider who does and any findings (if not readily identifiable in the medical record) should be reported to the provider treating the OUDs.]

(3) A physical examination should be completed as a component of the comprehensive assessment process. The prescriber (the clinician authorizing the use of a medication for the treatment of opioid use disorder) may conduct this physical examination him/herself, or, in accordance with the ASAM Standards, [refer to another provider to] ensure that a current physical examination is contained within the patient medical record before a patient is started on a new medication for the treatment of his/her addiction.

(4) Initial laboratory testing should include a complete blood count, liver function tests, and tests for hepatitis C and HIV. Testing for TB and sexually transmitted infections should also be considered. Hepatitis B vaccination should be offered, if appropriate.

(5) The assessment of women presents special considerations regarding their reproductive health. Women of childbearing age should be tested for pregnancy, and all women of childbearing potential and age should be queried regarding methods of contraception, given the increase in fertility that results from effective opioid use disorder treatment.

(6) Patients being evaluated for addiction involving opioid use, and/or for possible medication use in the treatment of opioid use disorder, should undergo (or have completed) an assessment of mental health status and possible psychiatric disorders (as outlined in the ASAM Standards). [Any psychiatric disorders that are identified warrant treatment, either by referral or treatment directly by the OBOT provider. Periodic mental health screens (and subsequent treatment) should be completed by the OBOT provider every 3 months, or with the emergence of psychiatric symptoms (e.g., depression, psychosis), whichever occurs first.]

(7) Opioid use is often co-occurring with other substance related disorders. An evaluation of past and current substance use and a determination of the totality of substances that surround the addiction should be conducted.

(8) The use of marijuana, stimulants, or other addictive drugs should not be a reason to suspend opioid use disorder treatment. However, evidence demonstrates that patients who are actively using substances during opioid use disorder treatment have a poorer prognosis. [The use of benzodiazepines and other sedative hypnotics is a reason to suspend agonist treatment because of safety concerns related to respiratory depression. A

thirty day benzodiazepine taper should be initiated at the onset of treatment or whenever the benzodiazepine use is discovered. On occasion, if ongoing withdrawal is clearly present and documented, a ninety day benzodiazepine taper may be warranted.]

(9) A tobacco use query and counseling on cessation of tobacco products and electronic nicotine delivery devices should be completed routinely for all patients, including those who present for evaluation and treatment of opioid use disorder.

(10) An assessment of social and environmental factors should be conducted… Addiction should be considered a bio-psycho-social-spiritual illness, for which the use of medication(s) is but only one component of overall treatment."

Diagnostic Recommendations (excerpted from ASAM Guidelines [1]):

"(1) Other clinicians may diagnose opioid use disorder, but confirmation of the diagnosis by the provider with prescribing authority and who recommends medication use must be obtained before pharmacotherapy for opioid use disorder commences.

(2) Opioid use disorder is primarily diagnosed on the basis of the history provided by the patient and a comprehensive assessment that includes a physical examination.

(3) Validated clinical scales that measure withdrawal symptoms, for example, the Objective Opiate Withdrawal Scale (OOWS), Subjective Opiate Withdrawal Scale (SOWS), and the Clinical Opiate Withdrawal Scale (COWS), may be used to assist in the evaluation of patients with opioid use disorder.

(4) Urine drug testing during the comprehensive assessment process, and frequently during treatment, is recommended. The frequency of drug testing is determined by a number of factors, including the stability of the patient, the type of treatment, and the treatment setting."

Section 2. Appropriate use of medications for the treatment of Opioid Use Disorders by OBOT Providers

Introduction:

Medications with a substantial evidence base supporting their efficacy in various stages of the treatment of opioid use disorders are reviewed in this section.

Specifically, evidence supporting detoxification, maintenance treatment, dosing recommendations and overdose reversal are reviewed. In addition, practices lacking an evidence base are also covered here.

(i) Opioid maintenance treatment options:

Buprenorphine (excerpted from ASAM Guidelines [1]): "Treatment with buprenorphine for opioid addiction consists of three phases: (1) induction, (2) stabilization, and (3) maintenance. Induction is the first stage of buprenorphine treatment and involves helping patients begin the process of switching from the opioid of abuse to buprenorphine. The goal of the induction phase is to find the minimum dose of buprenorphine at which the patient discontinues or markedly diminishes use of other opioids and experiences no withdrawal symptoms, minimal or no side effects, and no craving for the drug of abuse. The consensus panel recommends that the buprenorphine/naloxone combination be used for induction treatment (and for stabilization and maintenance) for most patients. The consensus panel further recommends that initial induction doses be administered as observed treatment; further doses may be provided via prescription thereafter... Pregnant women who are deemed to be appropriate candidates for buprenorphine treatment should be inducted and maintained on buprenorphine monotherapy. The stabilization phase has begun when a patient is experiencing no withdrawal symptoms, is experiencing minimal or no side effects, and [cravings have been significantly reduced]. Dosage adjustments may be necessary during early stabilization, and frequent contact with the patient increases the likelihood of compliance. The longest period that a patient is on buprenorphine is the maintenance phase. This period may be indefinite. During the maintenance phase, attention must be focused on the psychosocial and family issues that have been identified during the course of treatment as contributing to a patient's addiction[, rather than on buprenorphine dose escalation.]"

Minimum clinically necessary dosing (excerpted from ASAM Guidelines [1]):

> "(1) Opioid-dependent patients should wait until they are experiencing mild to moderate opioid withdrawal before taking the first dose of buprenorphine to reduce the risk of precipitated withdrawal. Generally, buprenorphine initiation should occur at least 6–12 hours after the last use of heroin or other short-acting opioids, or 24–72 hours [or more for individuals taking high doses of opioids] after their last use of long-acting opioids such as methadone.
>
> (2) Induction of buprenorphine should start with a dose of 2–4 mg, [with 8mg inductions being appropriate for a greater degree of physiologic dependence]. Dosages [are often] increased in increments of 2–4mg.
>
> (3) Clinicians should observe patients in their offices during induction.
>
> (4) Buprenorphine doses after induction and titration should be, on average, at least 8mg per day. However, if patients are continuing to use opioids, consideration should be given to increasing the dose by 4–8mg (daily doses of 12–16mg). [While the US FDA approves dosing to a limit of 24mg per day, there is little evidence for clinical benefit beyond 16mg. Dosing beyond 24 mg is not recommended.] In addition, the use of higher doses may increase the risk of diversion.

(5) Psychosocial treatment should be implemented in conjunction with the use of buprenorphine in the treatment of opioid use disorder. [Buprenorphine prescribers should be in regular contact with the psychosocial treatment team in order to be aware clinical progress. Preferably, the psychosocial and prescribing providers are co-located and on the same treatment team.]

(6) Clinicians should take steps to reduce the chance of buprenorphine diversion. Recommended strategies include frequent office visits (weekly in early treatment), drug testing, including testing for buprenorphine and [metabolites (e.g., norbuprenorphine)], and recall visits for pill counts. [In the case of diversion, the opioid treatment provider must determine that the benefit to the patient in receiving the medication outweighs the potential risk of diversion resulting from the take home medication.]

(7) Patients should be tested frequently for buprenorphine, other substances, and prescription medications. Accessing Prescription Drug Monitoring Program (PDMP) data [(INSPECT) is] useful for monitoring. [See Section V.2. below. If a patient tests positive for a controlled substance other than the buprenorphine prescribed, the clinician shall review the treatment plan and consider changes with the goal of opioid abstinence.

(8) Patients should be seen frequently at the beginning of their treatment. Weekly visits (at least) are recommended until patients are determined to be stable. There is no recommended time limit for treatment. [Provider must determine and document that the benefit of the receiving a supply of medication to treat an opioid use disorder would outweigh the potential risk of diversion.]

(9) Buprenorphine taper and discontinuation is [generally] a slow process and close monitoring is recommended… Patients should be encouraged to remain in treatment for ongoing monitoring past the point of discontinuation.

(10) When considering a switch from buprenorphine to naltrexone, 7–14 days should elapse between the last dose of buprenorphine and the start of naltrexone to ensure that the patient is not physically dependent on opioids before starting naltrexone.

(11) When considering a switch from buprenorphine to methadone, there is no required time delay because the addition of a full mu-opioid agonist to a partial agonist does not typically result in any type of adverse reaction.

(12) Patients who discontinue agonist therapy and resume opioid use should be made aware of the risks associated with an opioid overdose, and especially the increased risk of death."

(ii) Detoxification:

A. Buprenorphine detoxification (excerpted from ASAM Guidelines [1]): “Buprenorphine can be used for the medically supervised withdrawal of patients from both self-administered opioids and from opioid agonist treatment with methadone.... The goal of using buprenorphine for medically supervised withdrawal from opioids is to provide a transition from the state of physical dependence on opioids to an opioid-free state, while minimizing withdrawal symptoms. Medically supervised withdrawal with buprenorphine consists of an induction phase and a dose-reduction phase. The consensus panel recommends that patients dependent on short acting opioids (e.g., hydromorphone, oxycodone, heroin) who will be receiving medically supervised withdrawal be inducted directly onto buprenorphine/naloxone tablets. The use of buprenorphine (either as buprenorphine monotherapy or buprenorphine/naloxone combination treatment) to taper off long acting opioids should be considered only for those patients who have evidence of sustained medical and psychosocial stability, and should be undertaken in conjunction and in coordination with patients’ OTPs.”

B. Clonidine detoxification (excerpted from the APA guidelines [2]): “Clonidine is a [non-addictive] centrally acting α2-adrenergic antihypertensive medication that effectively decreases the noradrenergic hyperactivity associated with opioid withdrawal. Clonidine is not approved for opioid withdrawal in the United States but has been extensively studied and used for this indication elsewhere. Clonidine reduces withdrawal symptoms such as nausea, vomiting, diarrhea, cramps, and sweating but, unlike methadone, does little to reduce other symptoms such as muscle aches, insomnia, distress, and drug craving [3, 4]. As a non-opioid medication, clonidine has some advantages over methadone for withdrawal. For example, clonidine does not produce opioid-like tolerance or dependence or the post-methadone rebound in withdrawal symptoms [5]. In addition, patients completing a course of clonidine-assisted withdrawal can immediately be given an opioid antagonist (e.g., naltrexone) if indicated. The disadvantages of clonidine include its aforementioned inability to improve certain opioid withdrawal symptoms, associated hypotension that can be profound despite the use of low doses of this medication, and its possible sedative effects. Contraindications to the use of clonidine include acute or chronic cardiac disorders, renal or metabolic disease, and moderate to severe hypotension [6]. On the first day of clonidine-aided detoxification, a clonidine dose of 0.1 mg three times daily (totaling 0.3 mg per 24 hours) is usually sufficient to suppress signs of opioid withdrawal; inpatients can generally receive higher doses to block withdrawal symptoms because of the availability of medical staff to monitor the patient for hypotension and sedation. The dose is adjusted until withdrawal symptoms are reduced. If the patient’s blood pressure falls below 90/60 mm Hg, the next dose should be withheld, after which tapering can be resumed while the patient is monitored for signs of withdrawal. In the case of short-acting opioids such as heroin, clonidine-aided withdrawal usually takes 4–6 days. Other medications may be used along with clonidine to treat withdrawal symptoms. In general, clonidine-assisted detoxification is easier to carry out and monitor in inpatient settings. Clonidine-induced sedation is also less of a problem for inpatients.”

C. Clonidine-Naltrexone (Excerpted from APA [2]): "The combined use of clonidine and naltrexone for rapidly withdrawing patients from an opioid has been demonstrated to be safe and effective. Essentially, naltrexone-precipitated withdrawal is avoided by pretreating the patient with clonidine. This technique is most useful for opioid dependent patients who are in transition to narcotic antagonist treatment [e.g., naltrexone]. The limitations of this method include the need to monitor patients for 8 hours on the first day because of the potential severity of naltrexone-induced withdrawal and the need for careful blood pressure monitoring during the entire detoxification procedure."

D. Supplementary Medications (Excerpted from APA [2]): "Some clinicians and treatment programs have used medications targeting the symptoms of opioid withdrawal as the primary means for treating this condition. For example,…, antiemetics are prescribed to treat nausea and vomiting, NSAIDs are provided for muscle cramps, and antispasmodics [(e.g., dicyclomine)] are used to treat gastrointestinal cramping. There are limited controlled data about the use of such medications for the treatment of opioid withdrawal [8]…Diphenhydramine, hydroxyzine, and sedating antidepressants (e.g., doxepin, amitriptyline, trazodone) have been used for [insomnia and anxiety.] It should be noted that these medications have also been abused, although much less often than benzodiazepines [9]. Other medications such as NSAIDs and antispasmodics may be safely provided but appear to be less effective than mu agonist opioids for symptom relief."

(iii) Overdose Reversal (Excerpted from APA Guidelines [2]):

"The syndrome of acute opioid overdose is recognizable by respiratory depression, extreme miosis, and stupor or coma [10]. Pulmonary edema may also be observed. Naloxone is a competitive antagonist at all three types of opiate receptors (mu, kappa, and sigma) and has no intrinsic agonist activity [11]. It is clinically indicated to rapidly reverse a known or suspected opioid overdose [10, 12]…Because naloxone is rapidly absorbed by the brain and then quickly redistributed and eliminated from the body, its activity in the brain is short-lived [10, 13]. Thus, further monitoring and infusion of additional naloxone are needed to continue antagonizing the effects of severe opioid overdose, particularly if longer-acting opioids have been ingested [12, 14]. Monitoring for opioid withdrawal symptoms is also indicated because patients may experience significant distress that can last for several hours after reversal of an opioid overdose with an antagonist [9]." [Currently, in the State of Indiana, naloxone is available without a prescription from individual prescribers, as pharmacies have a written order to prescribe from the State Health Commissioner. At the time of assessment, OBOT providers should provide education about naloxone's role in overdose reversal to all patients in treatment for OUDs, as well as any involved family, caregivers or friends.

OBOT providers should recommend that patients in treatment obtain a supply of naloxone to use in case of an overdose, but provide education that not all overdoses can be rescued.]

(iv) Relapse prevention:

Relapse prevention is the use of pharmacologic and psychotherapeutic techniques that have been shown to decrease the risk of relapse in individuals in treatment for substance use disorders. See section 4 for psychotherapeutic techniques. FDA approved pharmacological treatments shown to reduce relapse in persons with OUDs include naltrexone, buprenorphine containing products and methadone.

Naltrexone (ASAM guidelines [1]):

"(1) Naltrexone is a recommended treatment for preventing relapse in opioid use disorder [and is generally well tolerated]. Oral formula naltrexone may be considered for patients in whom adherence can be supervised or enforced [e.g., individuals who are incarcerated, adolescents supervised by parents, inpatients]. Extended-release injectable naltrexone [Vivitrol TM] may be more suitable for patients who have issues with adherence, [particularly individuals living in the community, receiving outpatient treatment.]

(2) [Oral naltrexone should usually be taken daily in 50-mg doses.]

(3) Extended-release injectable naltrexone [Vivitrol TM] should be administered every 4 weeks by deep IM injection in the gluteal muscle at a set dosage of 380 mg per injection.

(4) Psychosocial treatment, [in conjunction with treatment with naltrexone, is required.] The efficacy of naltrexone use in conjunction with psychosocial treatment has been established, whereas the efficacy of extended release injectable naltrexone without psychosocial treatment ''has not'' been established.

(5) There is no recommended length of treatment with oral naltrexone or extended-release injectable naltrexone. Duration depends on clinical judgment and the patient's individual circumstances. Because there is no physical dependence associated with naltrexone, it can be stopped abruptly without withdrawal symptoms.

(6) Switching from naltrexone to methadone or buprenorphine should be planned, considered, and monitored. Switching from an antagonist such as naltrexone to a full agonist (methadone) or a partial agonist (buprenorphine) is generally less complicated than switching from a full or partial agonist to an antagonist because there is no physical dependence associated with antagonist treatment and thus no possibility of precipitated withdrawal. Patients being switched from naltrexone to buprenorphine or methadone will not have physical dependence on opioids and thus the initial doses of methadone or

buprenorphine used should be low. Patients should not be switched until a significant amount of the naltrexone is no longer in their system, about 1 day for oral naltrexone or 30 days for extended-release injectable naltrexone.

(7) Patients who discontinue antagonist therapy and resume opioid use should be made aware of the increased risks associated with an opioid overdose, and especially the increased risk of death.

(8) Naltrexone should be used with ‘‘caution’’ under the following conditions:

(a) All patients should be warned of the risk of hepatic injury and advised to seek medical attention if they experience symptoms of acute hepatitis. Hepatic injury is a concern if very high doses are used, for example, 200–300 mg per day. Use of naltrexone should be discontinued in the event of symptoms and/or signs of acute hepatitis. Cases of hepatitis and clinically significant liver dysfunction were observed in association with naltrexone exposure during the clinical development program and in the post marketing period. Transient, asymptomatic hepatic transaminase elevations were also observed in the clinical trials and post marketing period.

(b) Patients with [clinically significant] liver impairment should complete liver enzyme tests before and during treatment with naltrexone to check for additional liver impairment.

(c) Patients who experience injection site reactions should be monitored for pain, redness, or swelling. Incorrect administration may increase the risk of injection site reactions. Reactions have occurred with extended-release injectable naltrexone. To reduce injection site reactions in obese patients, a longer needle size may be used.

(d) [Patients with co-occurring psychiatric disorders should be monitored for [psychiatric] adverse events. Suicidal thoughts, attempted suicide, and depression have been reported [with naltrexone]].

(9) Significant ‘‘medication interactions’’ with naltrexone are as follows:

(a) Naltrexone should not be used with methylnaltrexone or naloxegol.

(b) Naltrexone blocks the effects of opioid analgesics because it is an opioid antagonist.

(c) Glyburide may increase serum concentration of naltrexone. Monitor for increased toxicity effects of naltrexone.”

Section 3. Switching between medications that treat OUDs

Introduction:

In order to assist providers with the process of switching between medications, detailed, current evidence is provided. Switching may be needed for the following reasons, including but not limited to: patient preference, side effects, difficulty accessing a particular medication, etc.

(Excerpted from ASAM guidelines [1]):

"(I) Switching from methadone to other opioid treatment medications may be appropriate in the following cases:

(1) Patient experiences intolerable methadone side effects.

(2) Patient has not experienced a successful course of treatment on methadone.

(3) Patient wants to change and is a candidate for the alternative treatment. Transfer of medications should be planned, considered, and monitored. Particular care should be taken in reducing methadone dosing before transfer to avoid precipitating a relapse. If the patient becomes unstable and appears at risk for relapse during the transfer of medications, reinstating methadone may be the best option.

(II) Switching from methadone to buprenorphine:

[This medication switch should be referred or closely supervised by an experienced addictionologist.] Patients on low doses of methadone (30–40mg per day or less) generally tolerate the transition to buprenorphine with minimal discomfort; whereas patients on higher doses of methadone may find that switching causes significant discomfort. Patients should be closely monitored during such a switch because there is a risk that stable methadone patients may become unstable when changing to buprenorphine...

Patients should be experiencing mild to moderate opioid withdrawal before the switch. This would typically occur at least 24 hours after the last dose of methadone, and indicates that sufficient time has elapsed for there to be minimal risk that the first dose of buprenorphine will precipitate significant withdrawal.

Moderate withdrawal would equate to a score greater than 12 on the COWS. An initial dose of 2–[8] mg of buprenorphine should be given and the patient should be observed for 1 hour. If withdrawal symptoms improve, the patient can be dispensed two additional 2–4-mg doses to be taken as needed.

(III) Switching from Methadone to Naltrexone

[This medication switch should be referred or closely supervised by an experienced addictionologist. This process often takes place in inpatient settings.] Patients switching from methadone to oral naltrexone or extended- release injectable naltrexone need to be completely withdrawn from methadone and other opioids before they can receive naltrexone. This may take up to 14 days, but can typically be achieved in 7 days. A naloxone challenge (administration of 0.4–0.8 mg naloxone and observation for precipitated withdrawal) may be useful before initiating treatment with naltrexone to document the absence of physiological dependence and to minimize the risk for precipitated withdrawal.

(IV) Switching from Buprenorphine to Naltrexone

Buprenorphine has a long half-life; 7–14 days should elapse between the last dose of buprenorphine and the start of naltrexone to ensure that the patient is not physically dependent on opioids before starting naltrexone. It may be useful to conduct a naloxone challenge before starting naltrexone to demonstrate an absence of physical dependence. Recently, investigators have begun to evaluate newer methods of rapidly transitioning patients from buprenorphine to naltrexone using repeated dosing over several days with very low doses of naltrexone along with ancillary medications. Although the results are promising, it is too early to recommend these techniques for general practice, and the doses of naltrexone used may not be readily available to most clinicians. [However, for physicians with addiction expertise, the American Academy of Addiction Psychiatry in partnership with the American Psychiatric Association, the American Society of Addiction Medicine, and the American Osteopathic Academy of Addiction Medicine provides the Columbia Rapid Naltrexone Induction Protocol at: http://pcssmat.org/wp-content/uploads/2015/02/PCSSMAT-Implementing- Antagonist-with-Case.Bisaga.CME_.pdf]

(V) Switching to Methadone

Transitioning from buprenorphine to methadone is less problematic because the addition of a full mu-opioid agonist to a partial agonist does not typically result in any type of adverse reaction. There is no time delay required in transitioning a patient from buprenorphine to treatment with methadone."

Section 4. Counseling and Ancillary services for OBOT providers

Introduction:

The combination of behavioral interventions and medications to treat substance use disorder is commonly referred to as MAT. While prescribing health care professionals can provide some or all of these interventions, some patients will require additional professionals to care for their medical, psychiatric, and addictive conditions. Best practice requires ensuring evidence-based interventions can be accessed as available, treatment should be individualized to the needs of the specific patient.

Excerpted from APA Guidelines [2]:

"When considering psychosocial treatments for treating opioid-related disorders, it is essential to note that all clinical trials of psychosocial interventions for opioid abusers have taken place in programs that also provide either opioid agonist maintenance (e.g., methadone) or treatment with opioid antagonists. Although some follow-up studies of naturalistic treatment have found equivalent efficacy for methadone maintenance and outpatient drug-free programs for heroin users [10, 15-18], early attempts at providing psychotherapy alone yielded unacceptably high attrition rates [19]."

Evidence based treatments which should be used to supplement medication assisted treatment for OUDs (excerpted from APA guidelines [2]):

"1. Cognitive-behavioral therapies

> In individuals who are receiving methadone maintenance, CBT is efficacious in reducing illicit substance use and achieving a wide range of other treatment goals. The benefits of CBT in combination with drug counseling are equivalent to those of drug counseling alone or drug counseling plus supportive-expressive psychotherapy in patients with low levels of psychiatric symptoms; however, in the presence of higher degrees of depression or other psychiatric symptoms, supportive-expressive therapy or CBT has been shown to be much more effective than drug counseling alone [19-24]. CBT may also help reduce other target symptoms or behaviors (e.g., HIV risk behaviors) in opioid-using individuals [25]. Group based relapse prevention therapy, when combined with self-help group participation, may also help recently detoxified patients reduce opioid use and criminal activities and decrease unemployment rates [26].

2. Behavioral therapies

Contingency management approaches are beneficial in reducing the use of illicit substances in opioid-dependent individuals who are maintained on methadone [27- 29]. Although other reinforcers or rewards (e.g., vouchers for movie tickets or sporting goods) may be provided to patients who demonstrate specified target behaviors (e.g., providing drug-free urine specimens, accomplishing specific treatment goals, attending treatment sessions), methadone take-home privileges are a commonly offered and effective incentive that is made contingent on reduced drug use [30-33]. Furthermore, contingency management, either alone or in conjunction with family therapies, can also be used to enhance adherence with unpopular treatments such as naltrexone and has been shown to result in diminutions in drug use among recently detoxified opioid-dependent individuals [34-40].

3. *Psychodynamic and interpersonal therapies*

The utility of adding a psychodynamic therapy to a program of methadone maintenance has been investigated. The provision of supportive-expressive therapy, a specific approach to such treatment, may be particularly helpful for patients with high levels of other psychiatric symptoms [20, 23]. However, in terms of individual IPT, the potential benefits of treatment are unclear, as it is very difficult to engage opioid-dependent patients in such approaches. Psychodynamically oriented group therapy, modified for substance-dependent patients, appears to be effective in promoting abstinence when combined with behavioral monitoring and individual supportive psychotherapy [41].

4. *Family therapies*

Family therapy has been demonstrated to enhance treatment adherence and facilitate implementation and monitoring of contingency contracts with opioid- dependent patients [42, 43]. [Family therapies are particularly beneficial for adolescents with OUDs].

5. *Self-help groups and 12-step-oriented treatments*

Self-help groups, such as Narcotics Anonymous, are beneficial for some individuals in providing peer support for continued participation in treatment, avoiding substance-using peers and high-risk environments, confronting denial, and intervening early in patterns of thinking and behavior that often lead to relapse.

Because of the emphasis on abstinence in the 12-step treatment philosophy, patients maintained on methadone or other opioid agonists may encounter disapproval for this type of pharmacotherapy at Narcotics Anonymous meetings."

Section 5. Transitioning off agonist and partial agonist therapies, with the goal, when appropriate of opioid abstinence

Introduction:

For many individuals, agonist treatments may be necessary until they have reached a point in their treatment where taper and discontinuation can be considered with their treatment providers.

Excerpted from ASAM guidelines [1]:

"There is no recommended time limit for treatment with buprenorphine. Buprenorphine taper and discontinuation is a slow process and close monitoring is recommended…Patients and clinicians should not take the decision to terminate treatment with buprenorphine lightly. Factors associated with successful termination of treatment with buprenorphine are not well described, but may include the following:

(1) Employment, engagement in mutual help programs, or involvement in other meaningful activities.

(2) Sustained abstinence from opioid and other drugs during treatment.

(3) Positive changes in the psychosocial environment.

(4) Evidence of additional psychosocial supports.

(5) Persistent engagement in treatment for ongoing monitoring past the point of medication discontinuation.

Patients who relapse after treatment has been terminated should be returned to treatment with buprenorphine."

Section 6. Training and experience requirements for providers who treat and manage individuals with OUDs

(1) Minimal Prescriber Requirements for Buprenorphine Prescribing

Excerpted from ASAM Guidelines [1]: "To practice office-based treatment of opioid addiction under the auspices of DATA 2000, physicians must first obtain a waiver from the special registration requirements established in the Narcotic Addict Treatment Act of 1974 and its enabling regulations. To obtain a DATA 2000 waiver, a physician must submit notification to SAMHSA of his or her intent to begin dispensing and/or prescribing this treatment. The Notification of Intent form must contain information on the physician's qualifying credentials

and must contain additional certifications, including that the physician (or the physician's group practice) will not treat more than 30 patients for addiction at any one time.

Notification of Intent forms can be filled out and submitted online at the SAMHSA Buprenorphine Web site at http://www.buprenorphine.samhsa.gov.

Physicians who meet the qualifications defined in DATA 2000 are issued a waiver by SAMHSA and a special identification number by DEA. To qualify for a DATA 2000 waiver, physicians must have completed at least 8 hours of approved training in the treatment of opioid addiction or have certain other qualifications as defined in the legislation (e.g., clinical research experience with the treatment medication, certification in addiction medicine) and must attest that they can provide or refer patients to the necessary, concurrent psychosocial services. The consensus panel recommends that all physicians who plan to practice opioid addiction treatment with buprenorphine attend a DATA 2000-qualifying 8-hour training program on buprenorphine. SAMHSA maintains a list of upcoming DATA 2000- qualifying buprenorphine training sessions on the SAMHSA Buprenorphine Web site. Additional information about DATA 2000 and buprenorphine also can be obtained by contacting the SAMHSA Buprenorphine Information Center by phone at 866-BUP-CSAT (866-287-2728) or via e-mail at info@buprenorphine.samhsa.gov."

(2) It is recommended that physicians obtain advanced training such as formal ASAM certification or addiction psychiatry fellowship training.

(3) Requirements for INSPECT reviews when prescribing opioids

At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing opioids for a patient shall run an INSPECT report on that patient under and document in the patient's chart whether the INSPECT report is consistent with the physician's knowledge of the patient's controlled substance use history.

Section 7. Addressing benzodiazepine use

Introduction:

Given the potential lethality of opioids and benzodiazepines, special attention needs to be given to patients taking both classes.

Excerpted from Management of Benzodiazepines in Medication-Assisted Treatment

[44]:

"Generally:

1. Individuals must be agreeable to engage in a plan to address their benzodiazepine use before beginning MAT.

2. [The evidence base does not support the use of chronic] benzodiazepines in a person presenting for MAT with methadone or buprenorphine is contraindicated. It presents an extremely high risk for adverse drug reaction involving overdose and/or death during the induction process. [A closely supervised, short-term benzodiazepine taper is indicated in this instance.]

3. CNS [central nervous system] depressant use is not an absolute contraindication for either methadone or buprenorphine, but is a reason for caution because of potential respiratory depression. Serious overdose and death may occur if MAT is administered in conjunction with benzodiazepines, sedatives, tranquilizers, anti- depressants, or alcohol.

4. Individuals who use benzodiazepines, even if used as a part of long-term therapy, should be considered at risk for adverse drug reactions including overdose and death….

6. If a person presenting for MAT will not allow a clinician to coordinate care, he or she [is not] appropriate for methadone and/or buprenorphine

Section 8. Managing Relapse

Introduction:

Relapse is an anticipated event in the process of recovery. . Nonetheless, there are practices that prescribers can adopt that are more likely to promote recovery than others. Best practices to address relapse are detailed here.

Excerpted from APA guidelines [2]:

“Because individuals with substance use disorders are often ambivalent about giving up their substance use, it can be useful to monitor their attitudes about participating in treatment and adhering to specific recommendations. These patients often deny or minimize the negative consequences attributable to their substance use; this tendency is often erroneously interpreted by clinicians and significant others as evidence of dishonesty. Even patients entering treatment with high motivation to achieve abstinence will struggle with the reemergence of craving for a substance or preoccupation with thoughts about attaining or using a substance. Moreover, social influences (e.g., substance- using family or friends), economic influences (e.g., unemployment), medical conditions (e.g., chronic pain, fatigue), and psychological influences (e.g., hopelessness, despair) may make an individual more vulnerable to a relapse episode even when he or she adheres to prescribed treatment. For these reasons, it can be helpful for clinicians and patients to anticipate the possibility that the patient may return to substance use and to agree on a corrective

plan of action should this occur. If the patient is willing, it can be helpful to involve significant others in preventing the patient's relapse and prepare significant others to manage relapses should they occur.

Supporting patients in their efforts to reduce or abstain from substance use positively reinforces their progress. Overt recognition of patient efforts and successes helps to motivate patients to remain in treatment despite setbacks. Clinicians can optimize patient engagement and retention in treatment through the use of motivational enhancement strategies [45, 46] and by encouraging patients to actively partake in self-help strategies. Monitoring programs, such as EAPs and impaired-physician programs [47-49], can sometimes help patients adhere to treatment.

Early in treatment a clinician may educate patients about cue-, stress-, and substance-induced relapse triggers [50, 51]. Patients benefit from being educated in a supportive manner about relapse risk situations, thoughts, or emotions; they must learn to recognize these as triggers for relapse and learn to manage unavoidable triggers without resorting to substance-using behaviors. Participation in AA or similar self-help group meetings can also support patients' sobriety and help them avoid relapse. Many other strategies can also help prevent relapse. Social skills training is targeted at improving individual responsibility within family relationships, work related interactions, and social relationships. During the early recovery phase, it can be helpful to encourage patients to seek new experiences and roles consistent with a substance-free existence (e.g., greater involvement in vocational, social, or religious activities) and to discourage them from instituting major life changes that might increase the risk of relapse. Facilitating treatment of co-occurring psychiatric and medical conditions that significantly interact with substance relapse is a long- term intervention for maintaining sobriety [52-54]. Therapeutic strategies to prevent relapse have been well studied and include teaching individuals to anticipate and avoid substance-related cues (e.g., assessing individual capacity to avoid relapse in the presence of substance-using peers), training individuals how to monitor their affective or cognitive states associated with increased craving and substance use, behavioral contingency contracting, training individuals in cue extinction and relaxation therapies to reduce the potency of substance-related stimuli and modulate craving intensity, and supporting patients in the development of coping skills and lifestyle changes that support sobriety [55, 56]. Behavioral techniques that enhance the availability and perceived value of social reinforcement as an alternative to substance use or reward for remaining abstinent have also been used [57]. If relapse does occur, individuals should be praised for even limited success and encouraged to continue in or resume treatment. Clinicians may help patients analyze relapses as well as periods of sobriety from a functional and behavioral standpoint and use what is learned to adjust the treatment plan to fit the individual's present needs. For chronically relapsing substance users, medication therapies may be necessary adjuncts to treatment."

Section 9. Obtaining informed consent concerning all available opioid use disorder treatment options, including risks and benefits of each option.

Introduction:

The informed consent process should ensure that each patient voluntarily chooses their treatment and that relevant facts concerning the use of the medications (including non-opioid medication treatment options) are clearly and adequately explained, such as follows :

Opioids are drugs that stimulate mu-receptors in the brain to produce a wide range of effects including pain relief, sedation, euphoria, addiction, and, with high enough doses, death. Opioids include heroin, morphine, methadone, oxycodone, hydrocodone, buprenorphine, tramadol and others. An opioid use disorder (i.e. addiction) is diagnosed when opioids are used in a compulsive, uncontrolled way producing negative physical, mental and social consequences. Treatment options for opioid addictions are compared below.

Behavioral Interventions: Behavioral interventions are recommended to accompany any addiction treatment.

Benefits and advantages

- Capable of addressing a host of contexts associated with addiction (e.g., depression or pain)
- No medication costs or side effects, except in the case of adolescents, where groups have been shown to worsen prognosis

Risks and downsides

- The long-term chance of quitting opioids is low without taking medication like those listed below.
- Group therapies involve some compromise of confidentiality and can be time consuming.

Methadone: Methadone is an opioid dispensed by a government regulated Opiate Treatment Provider (OTP).

Benefits and advantages

- Scientifically proven to reduce withdrawal, illicit opioid relapse, psychiatric, legal, medical, social and financial consequences of opioid addiction.
- Clients are monitored closely for progress.

Risks and downsides

- Requires ongoing use of opioids
- Requires daily, often early morning visits to the OTP in the first months.
- OTPs typically focus on only opioid addiction and do not treat other co-occurring addictions and mental illnesses.
- OTP/Methadone treatment is generally not covered by public/private insurance. Only 13 OTP clinics and the Veteran's Administration in Indiana--so may need to drive long distances.
- Methadone can cause serious side effects with high doses, or when mixed with alcohol, benzodiazepines, barbiturates or certain muscle relaxants; Can cause irregular heartbeat, cessation of breathing and death.
- Stopping methadone, as with any opioid, causes opioid withdrawal sickness. Accidental ingestion by children can be fatal.

Buprenorphine (Suboxone, Subutex, Zubsolv, Bunavail): Buprenorphine is an opioid prescribed by an OTP or a doctor with a special prescribing certification. It has many of the same benefits and risks as methadone. However there are several key differences listed as follows.

Benefits and advantages

- Buprenorphine treatment (outside of an OTP) typically requires fewer treatment appointments than methadone to receive medication.
- Buprenorphine treatment is more often covered by public and private insurance. Risk of lethal over dose is much less than with methadone or other opioids.
- Babies born to mothers maintained on Buprenorphine have less risk of experiencing NAS.

Risks and downsides

- May not work as well as methadone in certain patients with severe opioid addiction. Lack of highly structured treatment programming with buprenorphine does not serve some people well.

Naltrexone (Revia, Vivitrol): Naltrexone is a prescription drug that blocks the effects of opioids in the brain. Naltrexone comes as a pill that is taken one or two times a day or as a shot given by a nurse once a month. You can not take opioids for about two weeks before starting naltrexone. Naltrexone is also used to treat alcohol addiction.

Benefits and advantages

- Does not require the use of an opioid to facilitate recovery Increases adherence to psycho-social treatment.
- Significantly reduces cravings for opioids.

- Will not result in respiratory depression if taken in excess Covered by most insurance plans.
- Treats alcohol addiction too.

Risks and downsides

- Naltrexone may cause opioid withdrawal symptoms if started before someone has detoxed from opioids.
- Can cause serious liver problems, although this is more likely when taking high doses of the oral form. Opioid pain medications will not work as well when taking naltrexone. The injection can cause some discomfort, rarely could become infected. Individuals can still overdose on opioids, while taking naltrexone.
- Should not be started during pregnancy.

This information has been reviewed with the client, by the signing physician. Signature of

Client: date:

Signature of

Physician: date:

Section 10. Drug Testing

Introduction:

Testing biological samples for the presence of drugs of abuse is an essential part of the treatment of OUDs. Best practices of drug screening are detailed here.

Excerpted from APA[2]:

"Urine drug testing, or other reliable biological tests for the presence of drugs, during the initial evaluation and frequently throughout treatment, is highly recommended. Results from some studies have indicated that more intensive monitoring of substance use may increase recovery rates from a substance use disorder…There are a variety of toxicology tests available, some with greater and lesser reliability and validity. Urine testing is useful for detecting substance use over the preceding 5-day period for common substances of abuse (cocaine, opiates, cannabis, amphetamines, benzodiazepines, and PCP); however, certain opioids (buprenorphine, oxycodone, hydrocodone, and fentanyl) cannot be detected with routine methods and require special assays. [It is important to screen for the metabolites of the prescribed opioid agonist (e.g. norbuprenorphine), to ensure compliance with the treatment. Point of care testing (e.g., urine testing) is needed to make rapid clinical decisions, supplemented by "send out," confirmatory

laboratory values.] The person who is interpreting these labs should be very familiar with the methodology and the reliability.

There is little research on the optimal frequency of testing, [however, random drug testing is optimal.]….The frequency of drug testing will be determined by a number of factors, including the stability of the patient, the type of treatment, the treatment setting, and the half-life of drugs in the matrix being tested. Patients will likely require more testing early in treatment or during periods of relapse. Patients participating in office based treatment with buprenorphine may be tested at each office visit.

Opioids are detectable in the urine for 1–3 days after use. A negative urine test combined with no history of withdrawal may indicate a lack of physical dependence.

However, a negative urine test does not rule out opioid use, disorder, or physical dependence. Urine testing is also helpful to identify

(1) Use of other psychoactive substances.

(2) If a patient tests positive for an illegal drug…or a controlled substance that the patient is not taking as part of the treatment plan, then the provider needs to review the treatment plan and consider changes with the goal of opioid abstinence."

Section 11. Pregnant Women with OUDs

Introduction:

Pregnant women have unique needs and require treatment customized to their situation. Best practices for their treatment are highlighted here.

(Excerpted from ASAM guidelines [1]

"(1) The first priority in "treating" pregnant women for opioid use disorder should be to identify emergent or urgent medical conditions that require immediate referral for clinical evaluation.

(2) A medical examination and psychosocial assessment is recommended when evaluating pregnant women for opioid use disorder.

(3) Obstetricians and gynecologists should be alert to signs and symptoms of opioid use disorder. Pregnant women with opioid use disorder are more likely to seek prenatal care late in pregnancy, miss appointments, experience poor weight gain, or exhibit signs of withdrawal or intoxication.

(4) [As with all patients with OUDs,] psychosocial treatment is [strongly] recommended in the treatment of pregnant women with opioid use disorder.

(5) Counseling and testing for HIV should be provided in accordance with state law. Tests for hepatitis B and C and liver function are also suggested. Hepatitis A and B vaccination is recommended for those whose hepatitis serology is negative.

(6) Urine drug testing may be used to detect or confirm suspected opioid and other drug use with informed consent from the mother, realizing that there may be adverse legal and social consequences of her use. State laws differ on reporting substance use during pregnancy. Laws that penalize women for use and for obtaining treatment serve to prevent women from obtaining prenatal care and worsen outcomes.

(7) Pregnant women who are physically dependent on opioids should receive treatment using methadone or buprenorphine mono-product rather than withdrawal management or abstinence.

(8) Care for pregnant women with opioid use disorder should be co-managed by an obstetrician and an addiction specialist physician. Release of information forms need to be completed to ensure communication among healthcare providers.

(9) Treatment with [buprenorphine or] methadone [(within a licensed Opioid Treatment Program)] should be initiated as early as possible during pregnancy.

(10) Hospitalization during initiation of methadone and treatment with buprenorphine may be advisable due to the potential for adverse events, especially in the third trimester.

(14) Clinicians should be aware that the pharmacokinetics of [buprenorphine] are affected by pregnancy….Increased or split doses may be needed as pregnancy progresses. After child birth, doses may need to be adjusted.

(15) Buprenorphine monoproduct is a reasonable and recommended alternative to methadone for pregnant women. Whereas there is evidence of safety, there is insufficient evidence to recommend the combination buprenorphine/ naloxone formulation.

(16) If a woman becomes pregnant while she is receiving naltrexone, it is appropriate to discontinue the medication if the patient and doctor agree that the risk of relapse is low. If the patient is highly concerned about relapse and wishes to continue naltrexone, she should be informed about the risks of staying on naltrexone and provide her consent for ongoing treatment. If the patient wishes to discontinue naltrexone, but then reports relapse to opioid use, it may be appropriate to consider treatment with methadone or treatment with buprenorphine.

(17) Naloxone is not recommended for use in pregnant women with opioid use disorder except in situations of life-threatening overdose.

(18) Mothers receiving methadone and buprenorphine monoproduct for the treatment of opioid use disorders should be encouraged to breastfeed.

(19) [Naltrexone may be appropriate for a mother after delivery who is capable of detoxification and at risk of relapse.]

Methadone Versus Buprenorphine

The discussion and decision for medication should be reviewed with the patient and documented in her chart. For women who are pregnant or breastfeeding, opioid agonist treatment with methadone or buprenorphine is seen as the most appropriate treatment, taking into consideration effects on the fetus, neonatal abstinence syndrome, and impacts on perinatal care and parenting of young children. Methadone is the accepted standard of care for use during pregnancy; however, buprenorphine monoproduct is a reasonable alternative and also has some advantages over methadone. Infants born to mothers treated with buprenorphine had shorter hospital stays (10 vs. 17.5 days), had shorter treatment durations for neonatal abstinence syndrome (NAS) (4.1 vs. 9.9 days), and required a lower cumulative dose of morphine (1.1 vs. 10.4 mg) compared to infants born to mothers on treatment with methadone.

Combination Buprenorphine/Naloxone

There is some evidence suggesting that buprenorphine/ naloxone is equivalent in safety and efficacy to the monoproduct for pregnant women…At present, however, this evidence is insufficient to recommend the combination buprenorphine/naloxone formulation in this population."

References

1. Sandra Comer, P., et al., National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. 2015, American Society of Addiction Medicine. p. 1-66.

2. WORK GROUP ON SUBSTANCE USE DISORDERS, A.P.A., PRACTICE GUIDELINE for the Treatment of Patients With Substance Use Disorders. 2006.

3. Charney, D.S., et al., The clinical use of clonidine in abrupt withdrawal from methadone. Effects on blood pressure and specific signs and symptoms. Arch Gen Psychiatry, 1981. 38(11): p. 1273- 7.

4. Kleber, H.D., et al., Clonidine in outpatient detoxification from methadone maintenance. Arch Gen Psychiatry, 1985. 42(4): p. 391-4.

5. Cami, J., et al., Efficacy of clonidine and of methadone in the rapid detoxification of patients dependent on heroin. Clin Pharmacol Ther, 1985. 38(3): p. 336-41.

6. Jasinski, D.R., R.E. Johnson, and T.R. Kocher, Clonidine in morphine withdrawal. Differential effects on signs and symptoms. Arch Gen Psychiatry, 1985. 42(11): p. 1063-6.

7. Collins, E.D., et al., Anesthesia-assisted vs buprenorphine- or clonidine-assisted heroin detoxification and naltrexone induction: a randomized trial. JAMA, 2005. 294(8): p. 903-13.

8. O'Connor, P.G., et al., Ambulatory opiate detoxification and primary care: a role for the primary care physician. J Gen Intern Med, 1992. 7(5): p. 532-4.

9. Collins ED and K. H, Opioids: detoxification, in The American Psychiatric Publishing Textbook of Substance Abuse Treatment, K. Galanter M, Editor. 2004, American Psychiatric Publishing: Washington DC. p. 265-289.

10. HB, G. and A. H, Opioid analgesics, in Goodman and Gilman's The Pharmacological Basis of Therapeutics, 10th editon, in Goodman and Gilman's The Pharmacological Basis of Therapeutics, Hardman JG, Limbird LE, and G. AG, Editors. 2001, McGraw-Hill: New York. p. 51.

11. Martin, W.R., Naloxone. Ann Intern Med, 1976. 85(6): p. 765-8.

12. S, D., Opioids, in Emergency Medicine: A Comprehensive Study Guide, K.G. Tintinalli JE and S. JS, Editors. 2004, McGraw-Hill: New York. p. 1071-1074.

13. Berkowitz, R.L., B.W. Bonta, and J.E. Warshaw, The relationship between premature rupture of the membranes and the respiratory distress syndrome. Am J Obstet Gynecol, 1976. 124(7): p. 712-8.

14. Watson, W.A., et al., Opioid toxicity recurrence after an initial response to naloxone. J Toxicol Clin Toxicol, 1998. 36(1-2): p. 11-7.

15. Hubbard RL, Marsden ME, and R. JV:, Drug Abuse Treatment: A National Study of Effectiveness.

Chapel Hill, University of North Carolina Press, 1989.

16. Simpson, D.D., G.W. Joe, and S.A. Bracy, Six-year follow-up of opioid addicts after admission to treatment. Arch Gen Psychiatry, 1982. 39(11): p. 1318-23.

17. Simpson, D.D., L.J. Savage, and M.R. Lloyd, Follow-up evaluation of treatment of drug abuse during 1969 to 1972. Arch Gen Psychiatry, 1979. 36(7): p. 772-80.

18. Simpson, D.D. and S. Sells, Opioid Addiction and Treatment: A 12-Year Follow-Up. 1990.

19. Nyswander, M., The treatment of drug addiction. Med Clin North Am, 1958. 42(3): p. 815-22.

20. Woody, G.E., et al., Psychotherapy for opiate addicts. Does it help? Arch Gen Psychiatry, 1983.

40(6): p. 639-45.

21. Woody, G.E., et al., Sociopathy and psychotherapy outcome. Arch Gen Psychiatry, 1985. 42(11): p. 1081-6.

22. Woody, G.E., et al., Twelve-month follow-up of psychotherapy for opiate dependence. Am J Psychiatry, 1987. 144(5): p. 590-6.

23. Woody, G.E., et al., Psychotherapy in community methadone programs: a validation study. Am J Psychiatry, 1995. 152(9): p. 1302-8.

24. Woody, G.E., A.T. McLellan, and C.P. O'Brien, Treatment of behavioral and psychiatric problems associated with opiate dependence. NIDA Res Monogr, 1984. 46: p. 23-35.

25. O'Neill, K., et al., Evaluation of a cognitive-behavioural intervention for pregnant injecting drug users at risk of HIV infection. Addiction, 1996. 91(8): p. 1115-25.

26. McAuliffe, W.E., A randomized controlled trial of recovery training and self-help for opioid addicts in New England and Hong Kong. J Psychoactive Drugs, 1990. 22(2): p. 197-209.

27. McLellan, A.T., et al., The effects of psychosocial services in substance abuse treatment. JAMA, 1993. 269(15): p. 1953-9.

28. Silverman, K., et al., Sustained cocaine abstinence in methadone maintenance patients through voucher-based reinforcement therapy. Arch Gen Psychiatry, 1996. 53(5): p. 409-15.

29. Silverman, K., et al., Broad beneficial effects of cocaine abstinence reinforcement among methadone patients. J Consult Clin Psychol, 1998. 66(5): p. 811-24.

30. Iguchi MY, et al., Contingent reinforcement of group participation versus abstinence in methadone maintenance program. Exp Clin Psychopharmacol, 1996. 4: p. 7.

31. Stitzer, M. and G. Bigelow, Contingency management in a methadone maintenance program: availability of reinforcers. Int J Addict, 1978. 13(5): p. 737-46.

32. Stitzer, M.L., et al., Effect of methadone dose contingencies on urinalysis test results of polydrug- abusing methadone-maintenance patients. Drug Alcohol Depend, 1986. 18(4): p. 341-8.

33. Stitzer, M.L., M.Y. Iguchi, and L.J. Felch, Contingent take-home incentive: effects on drug use of methadone maintenance patients. J Consult Clin Psychol, 1992. 60(6): p. 927-34.

34. Carroll, K.M., et al., Targeting behavioral therapies to enhance naltrexone treatment of opioid dependence: efficacy of contingency management and significant other involvement. Arch Gen Psychiatry, 2001. 58(8): p. 755-61.

35. Carroll, K.M., et al., Contingency management to enhance naltrexone treatment of opioid dependence: a randomized clinical trial of reinforcement magnitude. Exp Clin Psychopharmacol, 2002. 10(1): p. 54-63.

36. Grabowski, J., et al., Effects of contingent payment on compliance with a naltrexone regimen. Am J Drug Alcohol Abuse, 1979. 6(3): p. 355-65.

37. Greenstein R, Fudala PJ, and O.B. CP, Alternative pharmacotherapies for opiate addiction, in Substance Abuse: A Comprehensive Textbook, Lowinson JH, et al., Editors. 1997, Williams and Wilkins: New York. p. 415-424.

38. Meyer, R.E., et al., A behavioral paradigm for the evaluation of narcotic antagonists. Arch Gen Psychiatry, 1976. 33(3): p. 371-7.

39. Preston, K.L., et al., Improvement in naltrexone treatment compliance with contingency management. Drug Alcohol Depend, 1999. 54(2): p. 127-35.

40. Rounsaville, B.J., Can psychotherapy rescue naltrexone treatment of opioid addiction? NIDA Res Monogr, 1995. 150: p. 37-52.

41. Khantzian EJ, Halliday KS, and M. WE, Addiction and the Vulnerable Self: Modified Dynamic Group Therapy for Substance Abusers. 1990.

42. Fals-Stewart W, O'Farrell TJ, and B. GR, Behavioral couples therapy for male methadone maintenance patients: effects on drug using behavior and relationship adjustment. Behavioral therapy, 2001. 32: p. 391-411.

43. Fals-Stewart, W. and T.J. O'Farrell, Behavioral family counseling and naltrexone for male opioid- dependent patients. J Consult Clin Psychol, 2003. 71(3): p. 432-42.

44. Management of Benzodiazepines in Medication-Assisted Treatment. 2013, Institute for Research, Evaluation and Training in Addictions with Support from Community Care Behavioral Health Organization. p. 1-26.

45. Connors, G.J., K.S. Walitzer, and K.H. Dermen, Preparing clients for alcoholism treatment: effects on treatment participation and outcomes. J Consult Clin Psychol, 2002. 70(5): p. 1161-9.

46. Miller WR and R. S, Motivational Interviewing: Preparing People for Change. 2002, New York: Guildford.

47. Chan, K.K., C. Neighbors, and G.A. Marlatt, Treating addictive behaviors in the employee assistance program: implications for brief interventions. Addict Behav, 2004. 29(9): p. 1883-7.

48. Domino, K.B., et al., Risk factors for relapse in health care professionals with substance use disorders. JAMA, 2005. 293(12): p. 1453-60.

49. Zarkin, G.A., J.W. Bray, and J. Qi, The effect of Employee Assistance Programs use on healthcare utilization. Health Serv Res, 2000. 35(1 Pt 1): p. 77-100.

50. Lowman, C., J. Allen, and R.L. Stout, Replication and extension of Marlatt's taxonomy of relapse precipitants: overview of procedures and results. The Relapse Research Group. Addiction, 1996. 91 Suppl: p. S51-71.

51. Stewart, J., Pathways to relapse: the neurobiology of drug- and stress-induced relapse to drug- taking. J Psychiatry Neurosci, 2000. 25(2): p. 125-36.

52. Substance Abuse and Mental Health Services Administration: Report to Congress on the Prevention and Treatment of Co-Occurring Substance Abuse Disorders and Mental Disorders., U.D.o.H.a.H. Services, Editor. 2002: Washinton DC.

53. Galanter, M., Network therapy for addiction: a model for office practice. Am J Psychiatry, 1993. 150(1): p. 28-36.

54. Khantzian, E.J., The primary care therapist and patient needs in substance abuse treatment. Am J Drug Alcohol Abuse, 1988. 14(2): p. 159-67.

55. Us Department of Health and Human Services: Brief Interventions and Brief Therapies for Substance Abuse: Treatment Improvement Protocol (TIP) Series, U.S.A.a.M.H.S. Administration, Editor. 1999, DHHS Publication: Rockville, Md.

56. Daley DC and M. GA, Relapse prevention: cognitive and behavioral interventions, in Substance Abuse: A Comprehensive Textbook, Lowinson JH, et al., Editors. 1992, Williams and Wilkins: Baltimore, Md. p. 533-542.

57. Miller WR and H. RK, The effectiveness of alcoholism treatment: what research reveals, in Treating Addictive Behaviors: Processes of Change. 1986: p. 53.

Attachment D: SUD Monitoring Protocol

1. Title page for the state's substance use disorder (SUD) demonstration or the SUD component of the broader demonstration

The state should complete this title page as part of its monitoring protocol. This form should be submitted as the title page for all monitoring reports. The content of this table should stay consistent over time. Definitions for certain rows are below the table.

State	Indiana
Demonstration name	Healthy Indiana Plan
Approval period for section 1115 demonstration	01/01/2021-12/31/2025
SUD demonstration start date[a]	01/01/2021
Implementation date of SUD demonstration, if different from SUD demonstration start date[b]	02/01/2018
SUD (or if broader demonstration, then SUD-related) demonstration goals and objectives	All Medicaid beneficiaries in Indiana will continue to have access to all current mental health and SUD benefits. In addition, all beneficiaries, ages 21 through 64 will have access to expanded covered services provided while residing in an Institution for Mental Diseases (IMD) for SUD short-term residential stays. The SUD program will allow beneficiaries with SUD to access benefits that include SUD residential treatment, crisis stabilization and withdrawal management services provided in IMDs, which would otherwise be excluded from federal reimbursement. Goals include: 1. Increased rates of identification, initiation, and engagement in treatment; 2. Increased adherence to and retention in treatment; 3. Reductions in overdose deaths, particularly those due to opioids; 4. Reduced utilization of emergency departments and inpatient settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services; 5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and 6. Improved access to care for physical health conditions among beneficiaries

[a] **SUD demonstration start date:** For monitoring purposes, CMS defines the start date of the demonstration as the *effective date* listed in the state's STCs at time of SUD demonstration approval. For example, if the state's STCs at the time of SUD demonstration approval note that the SUD demonstration is effective January 1, 2020 – December 31, 2025, the state should consider January 1, 2020 to be the start date of the SUD demonstration. Note that the effective date is considered to be the first day the state may begin its SUD demonstration. In many cases, the effective date is distinct from the approval date of a demonstration; that is, in certain cases, CMS may approve a section 1115 demonstration with an effective date that is in the future. For example, CMS may approve an

extension request on 12/15/2020, with an effective date of 1/1/2021 for the new demonstration period. In many cases, the effective date also differs from the date a state begins implementing its demonstration.

[b] **Implementation date of SUD demonstration:** The date the state began claiming federal financial participation for services provided to individuals in institutions for mental disease.

2. Acknowledgement of narrative reporting requirements

☒ The state has reviewed the narrative questions in the Monitoring Report Template provided by CMS and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested narrative information (with no modifications).

3. Acknowledgement of budget neutrality reporting requirements

☒ The state has reviewed the Budget Neutrality Workbook provided by the CMS demonstration team and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested budget neutrality information (with no modifications).

4. Retrospective reporting

The state is not expected to submit metrics data until after protocol approval, to ensure that data reflects the monitoring plans agreed upon by CMS and the state. Prior to monitoring protocol approval, the state should submit quarterly and annual monitoring reports with narrative updates on implementation progress and other information that may be applicable, according to the requirements in its STCs.

For a state that has monitoring protocols approved after one or more initial quarterly monitoring report submissions, it should report metrics data to CMS retrospectively for any prior quarters of the section 1115 SUD demonstration that precede the monitoring protocol approval date. A state is expected to submit retrospective metrics data—provided there is adequate time for preparation of these data— in its second monitoring report submission that contains metrics. The retrospective report for a state with a first SUD DY of less than 12 months, should include data for any baseline period quarters preceding the demonstration, as described in Part A of the state's monitoring protocols (see Appendix B of the instruction for further guidance determining baseline periods for first SUD DYs that are less than 12 months.) If a state needs additional time for preparation of these data, it should propose an alternative plan (i.e., specify the monitoring report that would capture the data) for reporting retrospectively on its section 1115 SUD demonstration.

In the monitoring report submission containing retrospective metrics data, the state should also provide a general assessment of metrics trends from the start of its demonstration through the end of the current reporting period. The state should report this information in Part B of its report submission (Section 3: Narrative information on implementation, by milestone and reporting topic). This general assessment is not intended to be a comprehensive description of every trend observed in the metrics data. Unlike other monitoring report submissions, for instance, the state is not required to describe all metric changes (+ or - greater than 2 percent). Rather, the assessment is an opportunity for a state to provide context on its retrospective metrics data and to support CMS's review and interpretation of these data. For example, consider a state that submits data showing an increase in the number of medication-assisted treatment (MAT) providers (Metric #14) over the course of the retrospective reporting period. This state may decide to highlight this trend for CMS in Part B of its report (under Milestone 4) by briefly summarizing the trend and explaining that during this period, a grant supporting training for new MAT providers throughout its state was implemented.

For further information on how to compile and submit a retrospective report, the state should review Section B of the Monitoring Report Instructions document.

☒ The state will report retrospectively for any quarters prior to monitoring protocol approval as described above, in the state's second monitoring report submission that contains metrics after protocol approval.

☐ The state proposes an alternative plan to report retrospectively for any quarters prior to monitoring protocol approval: *Insert narrative description of proposed alternative plan for retrospective reporting. The state should provide justification for its proposed alternative plan.*

Medicaid Section 1115 SUD Demonstrations Monitoring Protocol (Part A) - Planned Metrics (Version 5.0)
State: Indiana
Demonstration Name: Healthy Indiana Plan

Substance Use Disorder (SUD) Planned Metrics

Standard information on CMS-provided metrics										Baseline, annual goals, and demonstration target			Alignment with CMS-provided technical specifications manual		Phased-in metrics reporting		
#	Metric name	Metric description	Milestone or reporting topic	Metric type	Reporting frequency	Data source	Measurement period	Reporting frequency	Reporting priority	State will report (Y/N)	Baseline reporting period (MM/DD/YYYY-MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided technical specifications (Y/N)	Explanation of any deviation from the CMS-provided technical specifications manual (different data source, definition, codes, target population, etc.)	State plans to phase in reporting (Y/N)	Report in which metric will be phased in (Format: SUD-[#])	Explanation of any plans to phase in reporting over time
EXAMPLE: (Do not delete or edit this row)	*EXAMPLE: Assessed for SUD Treatment Needs Using a Standardized Screening Tool*	*EXAMPLE: Number of beneficiaries screened for SUD treatment needs using a standardized screening tool during the measurement period*	*EXAMPLE: Assessment of need and qualification for SUD treatment services*	*EXAMPLE: CMS-constructed*	*EXAMPLE: Other monthly and quarterly metric*	*EXAMPLE: Medical record review or claims*	*EXAMPLE: Month*	*EXAMPLE: Quarterly*	*EXAMPLE: Recommended*	*EXAMPLE: Y*	*EXAMPLE: 07/1/2018-06/30/2019*	*EXAMPLE: Increase*	*EXAMPLE: Increase*	*EXAMPLE: N*	*EXAMPLE: The Department will use state-defined procedure codes (list specific codes) to calculate this metric.*	*EXAMPLE: Y*	*EXAMPLE: DEQ1*	*EXAMPLE: This measure requires an update to the Adult Needs and Strengths Assessment tool that reflects an eSUH level of treatment. The work is in the testing phase with anticipated go live in mid to late 2025.*
1	Assessed for SUD Treatment Needs Using a Standardized Screening Tool	Number of beneficiaries screened for SUD treatment needs using a standardized screening tool during the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly metric	Medical record review or claims	Month	Quarterly	Recommended	Y	04/01/2021-3/31/2022	Increase	Increase	Y		Y	DY5 Q2	in process of acquisition of data from FFS and MCOs; there is currently no specific capture of assessment data in claims and encounters.
2	Medicaid Beneficiaries with Newly Initiated SUD Treatment/Diagnosis	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period but not in the three months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly metric	Claims	Month	Quarterly	Recommended	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
3	Medicaid Beneficiaries with SUD Diagnosis (monthly)	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period and/or in the 11 months before the measurement period.	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly metric	Claims	Month	Quarterly	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
4	Medicaid Beneficiaries with SUD Diagnosis (annually)	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period and/or in the 12 months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other annual metric	Claims	Year	Annually	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
5	Medicaid Beneficiaries Treated in an IMD for SUD	Number of beneficiaries with a claim for inpatient/residential treatment for SUD in an IMD during the measurement period.	Milestone 2	CMS-constructed	Other annual metric	Claims	Year	Annually	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	N	added HCPCS H2034	N		
6	Any SUD Treatment	Number of beneficiaries enrolled in the measurement period receiving any SUD treatment service, facility claim, or pharmacy claim during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Claims	Month	Quarterly	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	N	added HCPCS H2034 -DRG 770; 772-776	N		
7	Early Intervention	Number of beneficiaries who used early intervention services (such as procedure codes associated with SBIRT) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Claims	Month	Quarterly	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
8	Outpatient Services	Number of beneficiaries who used outpatient services for SUD (such as outpatient recovery or motivational enhancement therapies, step-down care, and monitoring for stable patients) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Claims	Month	Quarterly	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
9	Intensive Outpatient and Partial Hospitalization Services	Number of beneficiaries who used intensive outpatient and/or partial hospitalization services for SUD (such as specialized outpatient SUD therapy or other clinical services) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Claims	Month	Quarterly	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
10	Residential and Inpatient Services	Number of beneficiaries who use residential and/or inpatient services for SUD during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Claims	Month	Quarterly	Required	Y	01/01/2018 - 12/31/2018	Increase in residential; decrease in inpatient	Increase in residential; decrease in inpatient	N	added HCPCS H2034 -DRG 770; 772-776	N		
11	Withdrawal Management	Number of beneficiaries who use withdrawal management services (such as outpatient, inpatient, or residential) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Claims	Month	Quarterly	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
12	Medication-Assisted Treatment	Number of beneficiaries who have a claim for MAT for SUD during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Claims	Month	Quarterly	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
13	SUD Provider Availability	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period	Milestone 4	CMS-constructed	Other annual metric	Provider enrollment database; Claims	Year	Annually	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
14	SUD Provider Availability - MAT	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period and who meet the standards to provide buprenorphine or methadone as part of MAT	Milestone 4	CMS-constructed	Other annual metric	Provider enrollment database; Claims; SAMHSA datasets	Year	Annually	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
15	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET-AD) [NCQA; NQF #0004; Medicaid Adult Core Set; Adjusted HEDIS measure]	Percentage of beneficiaries age 18 and older with a new episode of alcohol or other drug (AOD) abuse or dependence who received the following: • Initiation of AOD Treatment—percentage of beneficiaries who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis • Engagement of AOD Treatment—percentage of beneficiaries who initiated treatment and who were engaged in ongoing AOD treatment within 34 days of the initiation visit The following diagnosis cohorts are reported for each rate: (1) Alcohol abuse or dependence, (2) Opioid abuse or dependence, (3) Other drug abuse or dependence, and (4) Total AOD abuse or dependence. A total of 8 separate rates are reported for this measure.	Milestone 6	Established quality measure	Annual metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
16	SUB-3: Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge [Joint Commission]	SUB-3: Patients who are identified with alcohol or drug use disorder who receive or refuse at discharge a prescription for FDA-approved medications for alcohol or drug use disorder, OR who receive or refuse a referral for addictions treatment. SUB-3a: Patients who are identified with alcohol or drug disorder who receive a prescription for FDA-approved medications for alcohol or drug use disorder OR a referral for addictions treatment.	Milestone 6	Established quality measure	Annual metric that is an established quality measure	Medical record review or claims	Year	Annually	Recommended	N								
17(1)	Follow-up after Emergency Department Visit for Alcohol or Other Drug Dependence (FUA-AD) [NCQA; NQF #3488; Medicaid Adult Core Set; Adjusted HEDIS measure][1]	Percentage of ED visits for beneficiaries age 18 and older with a principal diagnosis of AOD abuse or dependence who had a follow-up visit for AOD abuse or dependence. Two rates are reported. • Percentage of ED visits for which the beneficiary received follow-up within 30 days of the ED visit (31 total days) • Percentage of ED visits for which the beneficiary received follow-up within 7 days of the ED visit (8 total days).	Milestone 6	Established quality measure	Annual metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
17(2)	Follow-up after Emergency Department Visit for Mental Illness (FUM-AD) [NCQA; NQF #0576; Medicaid Adult Core Set; Adjusted HEDIS measure][1]	Percentage of ED visits for beneficiaries age 18 and older with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness. Two rates are reported. • Percentage of ED visits for mental illness for which the beneficiary received follow-up within 30 days of the ED visit (31 total days) • Percentage of ED visits for mental illness for which the beneficiary received follow-up within 7 days of the ED visit (8 total days).	Milestone 6	Established quality measure	Annual metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
18	Use of Opioids at High Dosage in Persons Without Cancer (UHD-AD) [PQA; NQF #2940; Medicaid Adult Core Set]	Percentage of beneficiaries age 18 and older who received prescriptions for opioids with an average daily dosage greater than or equal to 90 morphine milligram equivalents (MME) over a period of 90 days or more. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice are excluded.	Milestone 5	Established quality measure	Annual metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2018 - 12/31/2018	Decrease	Decrease	Y		N		
19	Use of Opioids from Multiple Providers in Persons without Cancer (OMP) [PQA; NQF #2950]	The percentage of individuals ≥18 years of age who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies within ≤180 days.	Milestone 5	Established quality measure	Annual metric that is an established quality measure	Claims	Year	Annually	Recommended	Y	01/01/2018 - 12/31/2018	Decrease	Decrease	Y		N		
20	Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer (OHDMP) [PQA; NQF #2951]	The percentage of individuals ≥18 years of age who received prescriptions for opioids with an average daily dosage of ≥90 morphine milligram equivalents (MME) AND who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies.	Milestone 5	Established quality measure	Annual metric that is an established quality measure	Claims	Year	Annually	Recommended	Y	01/01/2018 - 12/31/2018	Decrease	Decrease	Y		N		
21	Concurrent Use of Opioids and Benzodiazepines (COB-AD) [PQA; NQF #3389; Medicaid Adult Core Set]	Percentage of beneficiaries age 18 and older with concurrent use of prescription opioids and benzodiazepines. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice are excluded.	Milestone 5	Established quality measure	Annual metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2018 - 12/31/2018	Decrease	Decrease	Y		N		
22	Continuity of Pharmacotherapy for Opioid Use Disorder [USC; NQF #3175]	Percentage of adults 18 years of age and older with pharmacotherapy for OUD who have at least 180 days of continuous treatment	Milestone 1	Established quality measure	Annual metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2017 - 12/31/2018	Increase	Increase	Y		N		
23	Emergency Department Utilization for SUD per 1,000 Medicaid Beneficiaries	Total number of ED visits for SUD per 1,000 beneficiaries in the measurement period	Milestone 5	CMS-constructed	Other monthly and quarterly metric	Claims	Month	Quarterly	Required	Y	01/01/2018 - 12/31/2018	Decrease	Decrease	Y		N		
24	Inpatient Stays for SUD per 1,000 Medicaid Beneficiaries	Total number of inpatient stays per 1,000 beneficiaries in the measurement period	Other SUD-related metrics	CMS-constructed	Other monthly and quarterly metric	Claims	Month	Quarterly	Required	Y	01/01/2018 - 12/31/2018	Decrease	Decrease	Y		N		
25	Readmissions Among Beneficiaries with SUD	The rate of all-cause readmissions during the measurement period among beneficiaries with SUD	Milestone 6	CMS-constructed	Other annual metric	Claims	Year	Annually	Required	Y	01/01/2018 - 12/31/2018	Decrease	Decrease	Y		N		
26	Overdose Deaths (count)	Number of overdose deaths during the measurement period among Medicaid beneficiaries living in a geographic area covered by the demonstration. The state is encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid).	Other SUD-related metrics	CMS-constructed	Other annual metric	State data on cause of death	Year	Annually	Required	Y	01/01/2021 - 12/31/2021	Decrease	Decrease	Y		Y	DY5 Q1	Data acquisition and classification in progress but delays expected due to COVID
27	Overdose Deaths (rate)	Rate of overdose deaths during the measurement period among adult Medicaid beneficiaries living in a geographic area covered by the demonstration. The state is encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid).	Milestone 5	CMS-constructed	Other annual metric	State data on cause of death	Year	Annually	Required	Y	01/01/2021 - 12/31/2021	Decrease	Decrease	Y		Y	DY5 Q1	Data acquisition and classification in progress but delays expected due to COVID
28	SUD Spending	Total Medicaid SUD spending during the measurement period.	Other SUD-related metrics	CMS-constructed	Other annual metric	Claims	Year	Annually	Recommended	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
29	SUD Spending Within IMDs	Total Medicaid SUD spending on inpatient/residential treatment within IMDs during the measurement period.	Other SUD-related metrics	CMS-constructed	Other annual metric	Claims	Year	Annually	Recommended	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
30	Per Capita SUD Spending	Per capita SUD spending during the measurement period	Other SUD-related metrics	CMS-constructed	Other annual metric	Claims	Year	Annually	Recommended	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
31	Per Capita SUD Spending Within IMDs	Per capita SUD spending within IMDs during the measurement period	Other SUD-related metrics	CMS-constructed	Other annual metric	Claims	Year	Annually	Recommended	Y	01/01/2018 - 12/31/2018	Increase	Increase	N	added HCPCS H2034	N		
32	Access to Preventive/Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD [Adjusted HEDIS measure]	The percentage of Medicaid beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period.	Other SUD-related metrics	Established quality measure	Annual metric that is an established quality measure	Claims	Year	Annually	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase	Y		N		
33	Grievances Related to SUD Treatment Services	Number of grievances filed during the measurement period that are related to SUD treatment services	Other SUD-related metrics	CMS-constructed	Grievances and appeals	Administrative records	Quarter	Quarterly	Recommended	Y	01/01/2019- 12/31/2019	Neutral	Neutral	Y		N		
34	Appeals Related to SUD Treatment Services	Number of appeals filed during the measurement period that are related to SUD treatment services	Other SUD-related metrics	CMS-constructed	Grievances and appeals	Administrative records	Quarter	Quarterly	Recommended	Y	01/01/2019- 12/31/2019	Neutral	Neutral	Y		N		
35	Critical Incidents Related to SUD Treatment Services	Number of critical incidents filed during the measurement period that are related to SUD treatment services	Other SUD-related metrics	CMS-constructed	Grievances and appeals	Administrative records	Quarter	Quarterly	Recommended	N								
36	Average Length of Stay in IMDs	The average length of stay for beneficiaries discharged from IMD inpatient/residential treatment for SUD.	Milestone 2	CMS-constructed	Other annual metric	Claims; State-specific IMD database	Year	Annually	Required	Y	01/01/2018 - 12/31/2018	Decrease/consistent	No more than 30 days	N	added HCPCS H2034	N		
Q1	*Number of prescribers accessing INSPECT*	Count of prescribers accessing INSPECT on a statewide basis	Health IT	State-specific	*Other quarterly* as PDMP	Quarter	Quarterly	Required	Y	07/01/2019 - 06/30/2020	Increase	Increase			N		
Q2	*Number of patient requests made into INSPECT*	Number of patient requests made into INSPECT on a statewide basis	Health IT	State-specific	*Other quarterly* as PDMP	Quarter	Quarterly	Required	Y	01/01/2018 - 12/31/2018	Increase	Increase			N		
Q3	*Number of hospitals that have integrated INSPECT into their health care system's electronic health record*	A unique count of hospitals on a statewide basis who has an integrated solution to access INSPECT	Health IT	State-specific	*Other quarterly* as PDMP	Quarter	Quarterly	Required	Y	10/01/2019 - 09/30/2020	Increase	Increase			N		
State-Specific Metrics																	
Add rows for any additional state-specific metrics																	

[1] There are no CMS-provided metrics related to milestone 3
[2] Rates 1 and 2 reported for Metric #17(1) correspond to rates 2 and 3 for Metric #17 from Version 1.1 of the the Medicaid Section 1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics
[3] Rates 1 and 2 reported for Metric #17(2) correspond to rates 1 and 2 for Metric #17 from Version 1.1 of the the Medicaid Section 1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics

The SUD Monitoring Protocol Workbook (Part A) is also available in spreadsheet format on Medicaid.gov

EVALUATION DESIGN PLAN FOR INDIANA'S 1115 SUBSTANCE USE DISORDER DEMONSTRATION WAIVER EFFECTIVE JAN. 1, 2021 – DEC. 31, 2025

FINAL VERSION
DECEMBER 29, 2022

HEALTH MANAGEMENT ASSOCIATES

TABLE OF CONTENTS

Listing of Exhibits

Abbreviations List

Abbreviation	Meaning
AOD	Alcohol or Other Drug
ASAM	American Society for Addiction Medicine
B&A	Burns & Associates, Inc.
CMS	Centers for Medicare and Medicaid Services
CY	Calendar Year
DMHA	Division of Mental Health and Addiction
DOS	Date of Service
DR	Desk Review
DS	Descriptive Statistics
ED	Emergency Department
EDW	Enterprise Data Warehouse
FFS	Fee-For-Service
FQHC	Federally Qualified Health Center
FSSA	Indiana Family and Social Services Administration
FI	Facilitated Interviews
HIP	Healthy Indiana Plan
HMA-Burns	Burns & Associates, a Division of Health Management Associates
IDOC	Indiana Department of Corrections
IMD	Institution for Mental Disease
IPLA	Indiana Professional Licensing Agency

Abbreviation	Meaning
ISDH	Indiana State Department of Health
ITS	Single Segment Interrupted Time Series
MAT	Medication-Assisted Treatment
MCE	Managed Care Entity
MMIS	Medicaid Management Information System
NCQA	National Committee for Quality Assurance
NQF	National Quality Forum
OMPP	Office of Medicaid Policy and Planning
OR	Onsite Reviews
OUD	Opioid Use Disorder
PHE	Public Health Emergency
PDMP	Prescription Drug Monitoring Program
PQA	Pharmacy Quality Assurance
RCT	Randomized Control Trials
RHC	Rural Health Clinic
SAS	Statistical Analysis System
ST	Statistical Tests
STC	Special Terms and Conditions
SUD	Substance Use Disorder

SECTION I: GENERAL BACKGROUND INFORMATION

I.A Waiver Demonstration Information

The State of Indiana received authority in its Medicaid Section 1115 demonstration waiver to expand services for substance use disorder (SUD) effective February 1, 2018 through December 31, 2020. The waiver authority was selected as the means to ensure that a broad continuum of care is available to Indiana Medicaid beneficiaries with a SUD, including services that had previously not been available to Medicaid beneficiaries as well as services that are delivered in an Institution for Mental Disease (IMD) for which federal matching funds were not available absent the waiver authority.

The State applied for, and received, approval to extend its SUD waiver for an additional five years effective January 1, 2021[1]. This evaluation design plan covers the five-year renewal period shown below.

Name: Healthy Indiana Plan (HIP)
Project Number: 11-W-00296/5
Approval Date: October 26, 2020
Time Period Covered by Evaluation: January 1, 2021 through December 31, 2025

I.B Waiver Demonstration Goals

Indiana identified its primary goals for the SUD component of its waiver demonstration in its SUD Implementation Plan which was approved February 1, 2018. As per the SUD waiver renewal, the original SUD Implementation Plan is still in effect. Indiana chose to use the goals as outlined by the Centers for Medicare and Medicaid Services (CMS) as follows:

1. Increased rates of identification, initiation, and engagement in treatment;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically in appropriate through improved access to other continuum of care services;
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
6. Improved access to care for physical health conditions among beneficiaries.

I.C Brief Description and History of Implementation

On February 1, 2018, Indiana received approval of its SUD Implementation Plan Protocol as required by special terms and conditions (STC) X.10 of the state's section 1115 Healthy Indiana Plan (HIP) demonstration for its initial SUD waiver covering the period February 1, 2018 – December 31, 2020. This SUD Implementation Plan also remains in effect for the SUD waiver renewal period from January 1, 2021

[1] in-healthy-indiana-plan-support-20-ca-01012021.pdf (medicaid.gov) CMS Approval- Extension Request, Indiana. October 26, 2020

– December 31, 2025.[2] In its, SUD Implementation Plan Protocol, Indiana is focusing on the following areas to supports its waiver demonstration goals: [3]

- Expanded SUD treatment options for as many of its members as possible;
- Stronger, evidence-based certification standards for its SUD providers, particularly its residential addiction providers; and
- Consistency with prior authorization criteria and determinations among its health plans.

In support of these focus areas, Indiana Medicaid and CMS identified six key milestones, as described in their Protocol, which include:[4]

1. Access to critical levels of care for SUD treatment;

2. Use of evidence-based SUD-specific patient placement criteria;

3. Use of nationally recognized SUD-specific program standards to set provider qualifications for residential treatment facilities;

4. Sufficient provider capacity at critical levels of care, including medication assisted treatment for opioid use disorder (OUD);

5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD; and

6. Improved care coordination and transition between levels of care.

The Family and Social Services Administration's (FSSA's) Office of Medicaid Policy and Planning (OMPP) has responsibility for the administration and oversight of Indiana's Medicaid program under waiver and state authorities. Since the initial SUD waiver implementation began in early 2018, the OMPP has worked closely with the FSSA's Division of Mental Health and Addiction (DMHA) to implement the activities specified in the SUD Implementation Plan Protocol. In addition to the FSSA, the Indiana State Department of Health (ISDH), the Indiana Department of Corrections (IDOC), and the Indiana Professional Licensing Agency (IPLA) have all contributed to aspects of SUD waiver implementation activities.

The OMPP contracts with four managed care entities (MCEs) that are responsible for the delivery of services to most beneficiaries that are identified with SUD in Indiana's Medicaid program.

Exhibit 1 on the next page summarizes key implementation activities during the first SUD waiver period.

[2] Ibid. Special Terms and Conditions, Section X, Item 3, page 34 of 173.

[3] Ibid. Attachment C. Indiana 1115 SUD Waiver Implementation Plan, Updated January 2018, page 4.

[4] Ibid. Attachment C, pages 4 – 30.

Exhibit 1. Key Activities Implemented by Indiana in its SUD Implementation Protocol During Waiver Period 1, February 2018 – December 2020

Milestone	Implementation Activity	Implementation
Access to Critical Levels of Care for SUD Treatment	Pursued Indiana Administrative Code changes to expand coverage and reimbursement. Made systems changes to enroll and pay residential treatment facilities. Established criteria for authorizing inpatient detox.	2017 into 2018 Spring 2018 May 2018
Use of evidence-based SUD-specific patient placement criteria	Conducted provider education on ASAM criteria. Developed standard prior authorization form for SUD treatment across managed care plans. Issued draft level of care guidelines.	May 2018, Fall 2019, Spring 2020 (virtual) March 2019 January 2020
Use of nationally recognized SUD-specific program standards to set provider qualifications for residential treatment facilities	Finalized process for provisional ASAM designation for providers. Final designations became effective July 1, 2018. *As of July 1, 2021, there are now 322 ASAM 3.1 beds, 1,429 ASAM 3.3 beds, and 125 dually-licensed 3.1/3.5 beds in service.*	March 2018
Sufficient provider capacity at critical levels of care, including medication assisted treatment for OUD	Training materials to providers and Medicaid managed care plans on new waiver services. Create new provider specialty for residential treatment facilities in state's MMIS. Began partnership linking Open Beds with Indiana 211. Added midlevel practitioners to those who qualify to bill for services in and FQHC or RHC. Added licensed behavioral health professionals to eligible provider group.	January 2018 and throughout year March 2018 March 2018 October 2020 November 2020
Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD	Implemented a reimbursement system for emergency responders who use naloxone. Built short-term strategies to ensure continued access to services during the public health emergency and long-term strategies to continue after the PHE.	July 2020 March 2020 – ongoing
Improved care coordination and transition between levels of care	Extend case management delivered by managed care plans to individuals transitioning from residential treatment facilities Created/maintain a cross-Divisional SUD work group to address ongoing implementation tasks.	February 2018 Sept 2018 - ongoing

I.D Population Groups Impacted

Overdose deaths nationally increased to a new record in Calendar Year (CY) 2020 to 93,331, an increase of 29.4 percent from the CY 2019 total of 72,151.[5] In Indiana, the year-over-year increase was 33.1 percent, from 1,704 in CY 2019 to 2,268 in CY 2020. This placed Indiana 15th highest among states for overdose deaths in 2020. Indiana has also been adversely impacted by drug overdose using other measures, including the following:

- Over the five-year period from December 2015 to December 2020, Indiana has also outpaced overdose deaths nationwide with an increase of 84.1 percent compared to the U.S. average increase of 77.4 percent.[6]

- Using CY 2019 data, Indiana ranked 18th highest among states on a per 100,000 resident basis for drug overdose mortality.[7]

- In 2017, the drug overdose death rate was 29.4 deaths per 100,000 in Indiana compared to motor vehicle traffic-related deaths of 12.9 per 100,000.[8]

For the Summative Evaluation of Indiana's first SUD demonstration period, the evaluators used CMS's specifications for SUD Metric #3 (Medicaid Beneficiaries with SUD Diagnosis) to assess the trend in the Medicaid population most likely to be impacted by the demonstration. Exhibit 2, which appears on the next page, shows the trend on this measure on a quarterly basis from Q1-2016 to Q4-2020. This period is roughly the two-year period prior to the start of the initial demonstration and the three years during the SUD demonstration.

Medicaid beneficiaries with a SUD diagnosis grew consistently during the five-year period examined, from 43,063 in Q1-2016 to 114,317 as of Q4-2020. Over the course of the demonstration, the population of beneficiaries with SUD grew 23 percent (92,642 in Q1-2018 to 114,317 in Q4-2020).

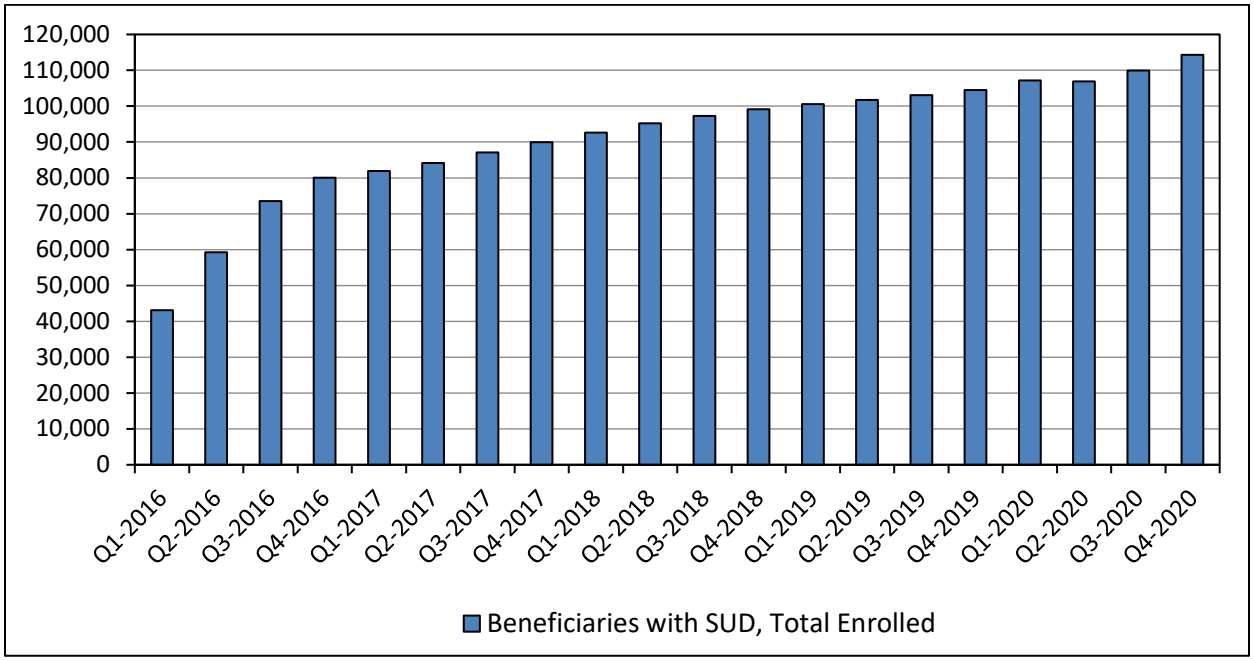
[5] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm National Vital Statistics System, information retrieved July 20, 2021

[6] Ibid.

[7] https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm Data is age-adjusted by state, information retrieved July 20, 2021

[8] 2017-SER.pdf (in.gov) Special Emphasis Report: Drug Overdose Deaths 1999-2017, retrieved July 20, 2021

Exhibit 2. Count of Indiana Medicaid Members Meeting CMS Metric #3 Criteria, CY 2016 – CY 2020



Overall, Medicaid members with a SUD diagnosis represented 6.2 percent of the total Medicaid population at the start of the demonstration in February 2018. By the end of the first SUD demonstration period in December 2020, these members represented 6.5 percent of total enrollees.

Exhibit 3 on the next page compares the percent of total enrollees with SUD against the overall Medicaid population across a number of subpopulations. As expected, non-elderly adults represent approximately half of total Medicaid enrollment, but more than 12 percent of non-elderly adults have a SUD diagnosis.

Dual eligibles, the criminally involved, and beneficiaries enrolled in the Medicaid Rehabilitation Option (MRO) benefit are also over-represented within the total population with SUD compared to their proportional enrollment in Medicaid overall (i.e., each subpopulation has a higher percentage of its members with SUD than the statewide percentage shown at the top of the exhibit).

The FSSA maps each of Indiana's 92 counties into one of eight regions shown in the exhibit. There has been modest change over the demonstration period of the percentage of the Medicaid population with SUD at the region level, but all regions did see an increase. Medicaid enrollees in the East Central, Southwest, and Southeast regions are over-represented in the percentage with SUD compared to the statewide average.

Exhibit 3. Comparison of Medicaid Members with SUD Diagnosis to Total Enrollment at the Start and End of the Initial Demonstration Period

	February 2018 start of demonstration period			December 2020 end of demonstration period		
Category	**Total Enrollment**	**Percent of Total Enrolled**	**Percent of Total Enrolled with SUD**	**Total Enrollment**	**Percent of Total Enrolled**	**Percent of Total Enrolled with SUD**
Total Demonstration Population	**1,479,615**	**100.0%**	**6.2%**	**1,768,040**	**100.0%**	**6.5%**
By Age Group						
Age Less than 18	682,021	46.1%	0.5%	744,466	42.1%	0.3%
Age 18 to 64	693,346	46.9%	12.4%	899,695	50.9%	12.0%
Age 65 and Over	104,248	7.0%	2.8%	123,879	7.0%	3.7%
By Cohort Population						
Dual Eligible	139,958	9.5%	7.0%	154,786	8.8%	7.6%
Pregnant	30,615	2.1%	5.5%	50,000	2.8%	6.4%
Criminally Involved	6,597	0.4%	7.7%	4,780	0.3%	7.2%
MRO	41,290	2.8%	16.6%	45,242	2.6%	19.0%
By FSSA Region						
Northwest	192,804	13.0%	5.0%	222,042	12.6%	5.1%
North Central	129,899	8.8%	2.9%	152,652	8.6%	2.8%
Northeast	162,746	11.0%	5.7%	197,275	11.2%	5.9%
West Central	110,129	7.4%	5.7%	130,064	7.4%	6.3%
Central	473,723	32.0%	5.6%	575,984	32.6%	5.9%
East Central	132,971	9.0%	7.2%	156,655	8.9%	8.4%
Southwest	147,762	10.0%	8.5%	177,387	10.0%	8.8%
Southeast	128,810	8.7%	10.3%	155,742	8.8%	10.4%

SECTION II: EVALUATION QUESTIONS AND HYPOTHESES

II.A Translating Demonstration Goals into Quantifiable Targets for Improvement

The Burns & Associates division of Health Management Associates (HMA-Burns)[9], the independent evaluator of Indiana's SUD demonstration waiver, examined the relationships among the State's (and CMS's) SUD demonstration goals to develop hypotheses related to Indiana's SUD waiver renewal. Given the experience of the HMA-Burns team with evaluating Indiana's first SUD waiver along with our understanding of the specific items identified and carried out in the State's SUD implementation plan since the initial waiver was approved, the approach by the HMA-Burns team for Indiana's second SUD waiver is to evaluate the pace of improvement in the access, utilization and delivery of SUD treatment services to Medicaid beneficiaries that builds on the foundation established in the first SUD waiver period.

Although Indiana's initial SUD waiver period was short in duration (35 months instead of a typical 60 months), the State undertook significant steps to expand SUD treatment coverage immediately upon waiver initiation. It should be recognized, however, that the delivery of community-based SUD treatment in Indiana's Medicaid program at a broad statewide level is still a relatively new undertaking.

II.B Defining Relationships: Waiver Policy, Short-term and Longer-term Outcomes

The HMA-Burns team constructed a logic model with the long-term outcome being a reduction in overdose deaths in Indiana. The logic model appears as Exhibit 4 on the next page. Based on key actions taken by the State either at the start of the initial SUD waiver demonstration or since the demonstration's initiation, eight short-term outcomes have been identified.

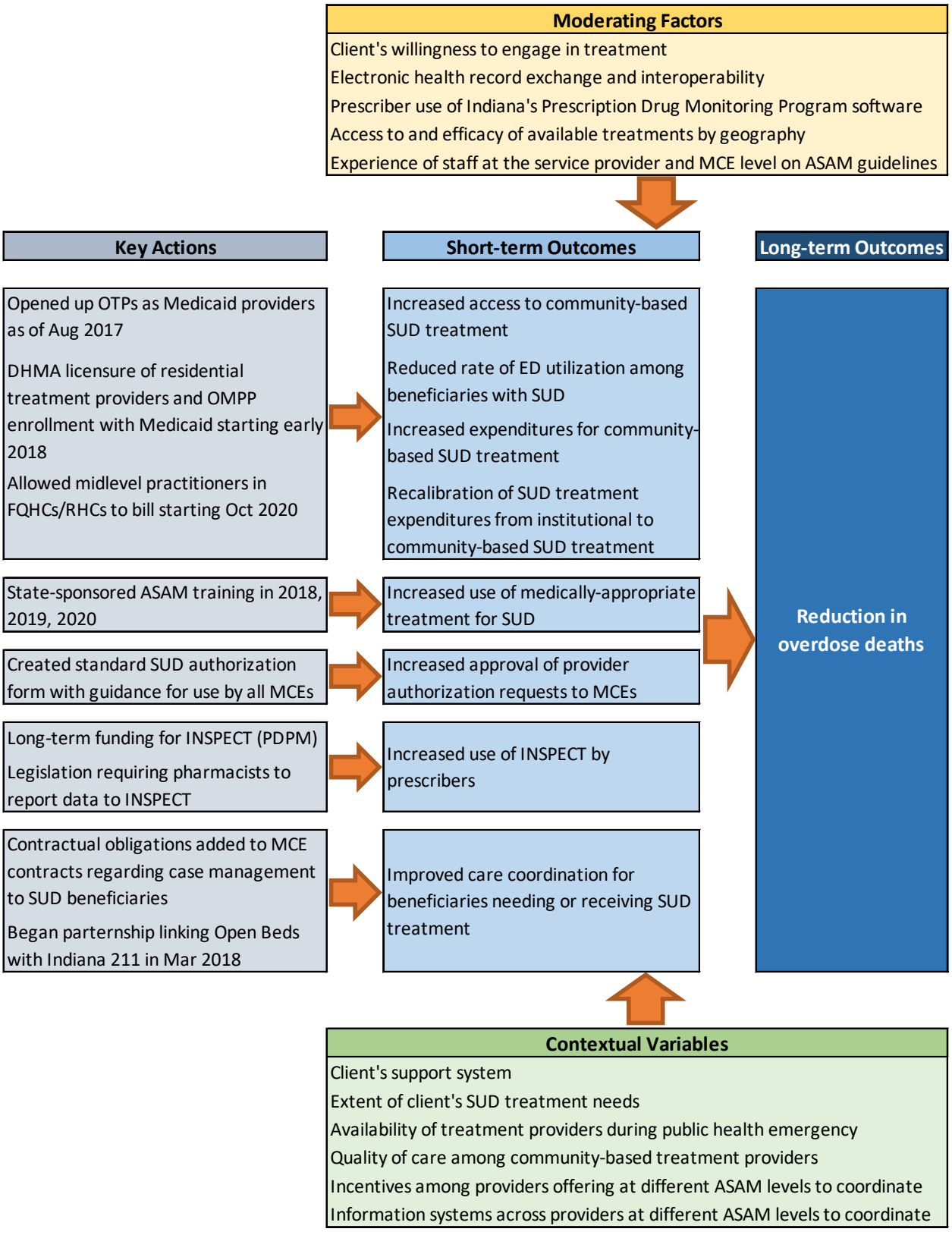
The short-term outcomes all tie to eight hypotheses and eight research questions which are introduced in Section II.C.

There is recognition that the success of short-term and long-term outcomes may be moderated by factors such as the client's willingness to engage in SUD treatment, the access to and efficacy of available treatments for SUD throughout Indiana, the experience of the staff among MCEs and service providers on ASAM guidelines, and the availability and use of technology by providers and service coordinators to effectively coordinate SUD treatment.

Contextual variables to the success of short-term and long-term outcomes include the extent of need by each client and where the client is located in the state, the client's support system to initiate or continue engagement in treatment, and incentives or disincentives for providers at different ASAM levels to coordinate the transition of care from one ASAM level to another.

[9] Burns & Associates, Inc. (B&A) was engaged by Indiana's Family and Social Services Administration to conduct the evaluation of Indiana's initial SUD waiver. B&A was acquired by Health Management Associates effective September 1, 2020. The initial B&A team that worked on the initial SUD waiver evaluation continues this work at HMA. This same team will also serve as the evaluation team of Indiana's second SUD waiver evaluation.

Exhibit 4. Logic Model for Indiana's SUD Demonstration: Reduce Overdose Deaths



II.C Hypotheses and Research Questions

Exhibit 5 identifies the hypotheses developed for Indiana's SUD waiver demonstration renewal and the research questions associated with each hypothesis. A full listing of the measures associated with each hypothesis and research question appears in Section III.G of the Methodology section. For each hypothesis, a reference is made to compare against either the initial demonstration period (February 2018 to December 2020) or prior to the initial demonstration period (prior to February 2018). When statistically significant improvement was reported in the Summative Evaluation between the initial demonstration period and the pre-demonstration period on measures tied to hypotheses, then the comparison period is the initial demonstration period. When statistically significant improvement was not reported in the Summative Evaluation, then the comparison period is the pre-demonstration period.

Exhibit 5. Hypotheses and Research Questions Developed for the Evaluation of Indiana's SUD Waiver Demonstration Renewal

Hypothesis (H)		Research Question (RQ)	
H1	The demonstration will decrease the rate of overdose deaths in Indiana since prior to the initial demonstration period.	**RQ1**	Is the rate of drug overdose deaths in Indiana impacted by the demonstration?
H2	The demonstration will increase the percentage of Medicaid beneficiaries who initiate and engage in treatment for OUD and other SUDs since the initial demonstration period.	**RQ2**	Does the demonstration increase the percentage of beneficiaries who initiate and engage in treatment for OUD and other SUDs?
H3	The demonstration will decrease the rate of emergency department visits among Medicaid beneficiaries with SUD since the initial demonstration period.	**RQ3**	Does the demonstration decrease the rate of emergency department visits among Medicaid beneficiaries with SUD?
H4	The demonstration will decrease the rate of hospital readmissions among Medicaid beneficiaries with SUD since prior to the initial demonstration period.	**RQ4**	Does the demonstration decrease the rate of hospital readmissions among Medicaid beneficiaries with SUD?
H5	The demonstration will increase the percentage of Medicaid beneficiaries who receive care for comorbid conditions since prior to the initial demonstration period.	**RQ5**	Does the demonstration increase the percentage of Medicaid beneficiaries with SUD who receive care for comorbid conditions?
H6	The demonstration will improve access to community-based services for SUD treatment since the initial demonstration period.	**RQ6**	Does the demonstration increase the level of access to community-based SUD treatment for Medicaid beneficiaries with SUD?
H7	Care coordination and transitions between ASAM levels of care will improve during the demonstration period.	**RQ7**	Does the demonstration improve transitions between ASAM levels of care?
H8	The demonstration will further rebalance Medicaid expenditures for treatment of SUD more toward community-based care since the initial demonstration period.	**RQ8**	Does the demonstration rebalance Medicaid expenditures for SUD treatment away from institutional toward community-based care?

The number of hypotheses and research questions shown in Exhibit 5 was reduced from the number included in the initial demonstration period for a variety of reasons:

1. Some hypotheses and research questions were specifically targeted towards aspect of implementation of a new program which is not relevant to the renewal demonstration period. One example is research questions related to the enrollment of residential treatment providers.

2. Some hypotheses and research questions in the initial demonstration were specifically focused on implementation tasks that were intended to occur but were never implemented. One example is the universal adoption of the Child and Adolescent Needs and Strengths (CANS) and Adult Needs and Strengths Assessment (ANSA) to place beneficiaries in ASAM levels of care.

3. Measures that were utilized to answer many research questions during the initial demonstration period will continue to be examined in the new demonstration period, but these measures are now mapped to a more general research question in this evaluation design. Specific examples pertain to care coordination and transitions of care research questions in the initial demonstration evaluation design that have been subsumed under Research Question #7 in this evaluation design.

II.D Alignment with Demonstration Goals

To ensure that the evaluation hypotheses and research questions are responsive to the CMS guidance in the approved waiver standard terms and conditions, HMA-Burns has mapped the hypotheses to the waiver demonstration goals. Each hypothesis addresses at least one demonstration goal and, in many cases, map to multiple goals. Exhibit 6 presents a visualization of this mapping.

Exhibit 6. Alignment of Hypotheses with Demonstration Goals

		Waiver Goal					
		1	2	3	4	5	6
		Increase identi-fication, initiation, engagement	Increase adherence to and retention in treatment	Reductions in overdose deaths, particularly opioids	Reduced utilization of ED and hospital settings	Fewer readmits to same or higher level of care	Improved access to care for physical health conditions
Hypothesis							
H1	Decrease the rate of overdose deaths			X			
H2	Increase the percentage of initiation and engagement in treatment	X					
H3	Decrease the rate of emergency department visits				X		
H4	Decrease the rate of hospital readmissions					X	
H5	Increase the rate of beneficiaries who receive care for comorbid						X
H6	Improve access to community-based services for SUD treatment		X				
H7	Improve care coordination and transitions between ASAM levels		X				
H8	Rebalance Medicaid expenditures toward community-based care	X					

SECTION III: METHODOLOGY

III.A Evaluation Design

The evaluation design is a mixed-methods approach, drawing from a range of data sources, measures, and analytics to best produce relevant and actionable study findings. The HMA-Burns team tailored the approach for each of the eight research questions described in Section II, Evaluation Questions and Hypotheses. The evaluation plan reflects a range of data sources, measures, and perspectives.

Indiana's Medicaid population with a SUD diagnosis is the predominant population examined in the evaluation but, at times, the entire adult Medicaid population will be used as a comparison. Within the Medicaid population with SUD, a number of study sub-populations will also be examined and tested against the overall SUD population. These are identified in Section III.B.

The five analytic methods proposed for use across the eight hypotheses and eight research questions include:

1. Chi-square (Chi),
2. Interrupted Time Series (ITS),
3. Onsite reviews (OR)
4. Desk reviews (DR) and,
5. Facilitated interviews (FI).

Exhibit 7 on the next page presents a chart displaying which method(s) are used for each hypothesis. The five methods are ordered and abbreviated as described above.

Exhibit 7. Summary of Five Analytic Methods by Hypothesis

Hypothesis (H)		Method					Data Sources
		Chi	ITS	OR	DR	FI	
H1	The demonstration will decrease the rate of overdose deaths in Indiana since prior to the initial demonstration period.	X			X		Claims data, vital statistics, PDMP stats
H2	The demonstration will increase the percentage of Medicaid beneficiaries who initiate and engage in treatment for OUD and other SUDs since the initial demonstration period.	X	X		X	X	Claims data, enrollment data
H3	The demonstration will decrease the rate of emergency department visits among Medicaid beneficiaries with SUD since the initial demonstration period.		X		X		Claims data, enrollment data
H4	The demonstration will decrease the rate of hospital readmissions among Medicaid beneficiaries with SUD since prior to the initial demonstration period.	X			X		Claims data, enrollment data
H5	The demonstration will increase the percentage of Medicaid beneficiaries who receive care for comorbid conditions since prior to the initial demonstration period.		X		X		Claims data, enrollment data
H6	The demonstration will improve access to community-based services for SUD treatment since the initial demonstration period.			X	X	X	Claims data, enrollment data, MCE data files, MCE case files
H7	Care coordination and transitions between ASAM levels of care will improve during the demonstration period.			X	X	X	Claims data, enrollment data, MCE data files, MCE case files
H8	The demonstration will further rebalance Medicaid expenditures for treatment of SUD more toward community-based care since the initial demonstration period.		X		X		Claims data, enrollment data

Chi = Chi-square; ITS = Interrupted Time Series; OR = Onsite Reviews; DR = Desk Reviews; FI = Facilitated Interviews

III.B Target Population and Comparison Groups

Target Population

The target population is any Indiana Medicaid beneficiary with a diagnosis of SUD in the study period. HMA-Burns will use the specification described in the CMS-approved Monitoring Plan for identification of beneficiaries with SUD to flag individuals as an indicator of those most likely to have exposure to the changes in the waiver.

While the key study population is the overall SUD population, a standardized set of sub-populations will be identified and examined. HMA-Burns will sub-set the SUD population, at minimum, by common demographic groups such as by age (adolescent, non-elderly adults, elderly), by delivery system (i.e., managed care or fee-for-service), and by eight geographic regions (mapping each of Indiana's 92 counties to one of the eight regions defined). In addition, there are nuances in the 1115 waiver changes which warrant identification and stratification of the data into a number of sub-populations such as the following:

- ASAM Levels: It is possible that outcomes may differ among the SUD population based on their access to services. HMA-Burns will examine the outcomes by those accessing a particular level of care for differences in health outcomes or cost in the post-waiver period compared to the pre-wavier period.

- Opioid Use Disorder (OUD): It is likely that beneficiaries with OUD, compared to those with other types of SUD, may have different health outcomes and access a different mix of services. Therefore, it is possible that the waiver impacts these populations differently. HMA-Burns will identify OUD beneficiaries (using the CMS-defined specification) to examine these individuals as a separate sub-population.

- New Member/COVID: Beneficiaries who became newly eligible for Medicaid due to the financial impact of the pandemic will be separately identified. A combination of aid category and time of enrollment will be used to identify this population.

Comparison Groups

As described in III.C below, HMA-Burns will create groups of Medicaid beneficiaries with SUD across four time periods in order to compare outcomes. In addition, a sensitivity analysis will be conducted on selected measures using enrollment duration as the control group. Refer to Section III.F for more details.

III.C Evaluation Period

Monthly Measures

For measures which are computed on a monthly basis, statistical testing using Interrupted Time Series (ITS) will be applied. HMA-Burns will consider four different time periods when conducting ITS. Each time period will contain 25 observations (months). While the initial demonstration evaluation design intended for 2015 data to be included in the pre-demonstration period, the independent evaluators did not include it as the conversion from ICD-9 to ICD-10 took place during this year. An examination of the mapping of ICD-9 to ICD-10 codes found that only 45% of the ICD-10 SUD Value Set codes had a 1:1

conversion to ICD-9. The remaining 55% of the ICD-10 codes mostly matched to multiple ICD-9 codes, with one code having no match at all.

- Time Period #1: Pre-Demonstration. This is the period just prior to the approval of Indiana's first SUD demonstration, from January 2016 through January 2018.

- Time Period #2: Demonstration 1 period. This is the first 25 months of Indiana's initial SUD demonstration, from February 2018 through March 2020. Indiana's initial SUD demonstration ended in December 2020. The first 25 months of the demonstration are included in the analysis instead of the last 25 months of the demonstration because the last nine months of Indiana's truncated 35-month demonstration period were during the onset of the public health emergency (PHE).

- Time Period #3: Demonstration 2 initial period. This is the 25-month period from December 2021 through December 2023. Time Period #3 will be compared to either Time Period #1 or Time Period #2 when ITS testing is conducted for reporting in the Interim Evaluation.

- Time Period #4: Demonstration 2 later period. This is the 25-month period from December 2023 through December 2025. Time Period #4 will be compared to either Time Period #1 or Time Period #2 when ITS testing is conducted for reporting in the Summative Evaluation.

The determination of whether Time Periods #3 and #4 are tested against either Time Period #1 or Time Period #2 are based on the results that HMA-Burns found in its Summative Evaluation of Indiana's first SUD demonstration.

- If it was found in the Summative Evaluation of the first demonstration period when ITS was run that there was not a statistically significant finding for a given measure, then HMA-Burns will run ITS on that measure using Time Period #3 (for Interim Evaluation) or Time Period #4 (for Summative Evaluation) against Time Period #1.

- If it was found in the Summative Evaluation of the first demonstration period when ITS was run that there was a statistically significant finding for a given measure, then HMA-Burns will run ITS on that measure using Time Period #3 (for Interim Evaluation) or Time Period #4 (for Summative Evaluation) against Time Period #2. Since it was already established in the first demonstration evaluation that statistically significant improvement was found, for the second demonstration evaluation HMA-Burns will assess if improvement continued and if the pace of this improvement was statistically significant compared to the findings from the first demonstration period.

Annual Measures

For measures which are computed on an annual basis, statistical testing using chi-square will be applied. HMA-Burns will consider four different time periods when conducting chi-square. While the initial demonstration evaluation design intended for calendar year 2015 data to be included in the pre-demonstration period, the independent evaluators did not include it as the conversion from ICD-9 to ICD-10 took place during this year. An examination of the mapping of ICD-9 to ICD-10 codes found that only 45% of the ICD-10 SUD Value Set codes had a 1:1 conversion to ICD-9. The remaining 55% of the ICD-10 codes mostly matched to multiple ICD-9 codes, with one code having no match at all.

- Time Period #1: Pre-Demonstration. This will include the average results for Calendar Years 2016 and 2017.

- Time Period #2: Demonstration 1 period. This will include the average results for Calendar Years 2018 and 2019.

- Time Period #3: Demonstration 2 initial period. This will include the average results for Calendar Years 2022 and 2023.

- Time Period #4: Demonstration 2 later period. This will include the average results for Calendar Years 2024 and 2025.

Similar to the approach that will be used for monthly measures, the determination of whether Time Periods #3 and #4 are tested against either Time Period #1 or Time Period #2 are based on the results that HMA-Burns found in its Summative Evaluation of Indiana's first SUD demonstration.

- If it was found in the Summative Evaluation of the first demonstration period when chi-square was run that there was not a statistically significant finding for a given measure, then HMA-Burns will run chi-square on that measure using Time Period #3 (for Interim Evaluation) or Time Period #4 (for Summative Evaluation) against Time Period #1.

- If it was found in the Summative Evaluation of the first demonstration period when chi-square was run that there was a statistically significant finding for a given measure, then HMA-Burns will run chi-square on that measure using Time Period #3 (for Interim Evaluation) or Time Period #4 (for Summative Evaluation) against Time Period #2.

III.D Evaluation Measures

The HMA-Burns team identified 32 measures in the evaluation design plan that directly relate to the outcomes described the logic model shown in Section II, the overall demonstration goals, and the research questions developed for this demonstration evaluation. The measures include those with national measure stewards, those specified by CMS, and evaluator-derived measures. Of the total 32 measures, 23 of them are currently SUD monitoring measures required by CMS for SUD waiver reporting by states. The CMS-defined metrics will be computed monthly and/or annually as deemed appropriate to each measure specification and will use the CMS technical specifications for computation.

Exhibit 8 on the next two pages summarizes the list of measures included in the evaluation design plan. Each measure is mapped to a hypothesis and research question. There is an indicator whether ITS or chi-square will be used as the basis for statistical testing on the measure. Additionally, there is an indicator if the measure will be subject to sensitivity analysis. The statistical tests using ITS or chi-square will be completed on each measure shown and reported in both the Interim and Summative Evaluations.

A comprehensive list of measures as well as a description of numerators and denominators can be found in the detailed matrices shown in Section III.G.

Exhibit 8. Summary of Measures and Steward, by Research Question

H = Hypothesis

H	Research Question (RQ) / Measures Associated with Each RQ		Measure Steward	CMS Metric	Interrupted Time Series Test	Sensitivity to ITS Tested	Chi-square Test
H1	RQ1	Is the rate of drug overdose deaths in Indiana impacted by the demonstration?					
	1	Rate of overdose deaths	HMA	#26			
	2	Use of opioids at high dosage in persons without cancer	NCQA, NQF #2940	#18			X
	3	Use of opioids from multiple providers in persons w/o cancer	PQA, NQF #2950	#19			X
	4	Concurrent use of opioids and benzodiazepines	PQA, NQF #3389	#21			X
	5	Number of prescribers accessing INSPECT	HMA	n/a			
H2	RQ2	Does the demonstration increase the percentage of beneficiaries who initiate and engage in treatment for OUD and other SUDs?					
	6	Initiation of AOD Dependence Treatment, Total Population	NCQA, NQF #0004	#15			X
	7	Initiation of AOD Dependence Treatment, Alcohol Abuse Only	NCQA, NQF #0004	#15			X
	8	Initiation of AOD Dependence Treatment, Opioid Abuse Only	NCQA, NQF #0004	#15			X
	9	Initiation of AOD Dependence Treatment, Abuse Other than Alcohol or Opioid	NCQA, NQF #0004	#15			X
	10	Engagement of AOD Dependence Treatment, Total Population	NCQA, NQF #0004	#15			X
	11	Engagement of AOD Dependence Treatment, Alcohol Abuse Only	NCQA, NQF #0004	#15			X
	12	Engagement of AOD Dependence Treatment, Opioid Abuse Only	NCQA, NQF #0004	#15			X
	13	Engagement of AOD Dependence Treatment, Abuse Other than Alcohol/Opioid	NCQA, NQF #0004	#15			X
	14	Follow-up After ED Visits for AOD Dependence, 7 days	NCQA, NQF #3488	#17			X
	15	Continuity of Pharmacotherapy for Opioid Use Disorder	USC, NQF #3175	#22			X
	16	Rate of Medicaid beneficiaries receiving outpatient services	CMS	#8	X	X	
	17	Rate of Medicaid beneficiaries receiving intensive outpatient or partial hosp	CMS	#9	X	X	
	18	Rate of Medicaid beneficiaries receiving residential or hospital treatment	CMS	#10	X	X	
	19	Rate of Medicaid beneficiaries receiving withdrawal management	CMS	#11	X	X	
	20	Rate of Medicaid beneficiaries receiving medication assisted treatment	CMS	#12	X	X	

H = Hypothesis

H	Research Question (RQ) / Measures Associated with Each RQ		Measure Steward	CMS Metric	Interrupted Time Series Test	Sensitivity to ITS Tested	Chi-square Test
H3	RQ3	Does the demonstration decrease the rate of emergency department visits among Medicaid beneficiaries with SUD?					
	21	ED utilization per 1,000 among beneficiaries with SUD	CMS	#23	X	X	
H4	RQ4	Does the demonstration decrease the rate of hospital readmissions among benefic. with SUD?					
	22	Readmissions among beneficiaries with SUD	CMS	#25			X
H5	RQ5	Does the demonstration increase the percentage of beneficiaries with SUD who receive care for comorbid conditions?					
	23	Access to Preventive Health for Adult Beneficiaries with SUD	NCQA, AAP	#32	X	X	
H6	RQ6	Does the demonstration increase the level of access to community-based SUD treatment for beneficiaries with SUD?					
	24	ASAM 3.x bed capacity for Medicaid beneficiaries	HMA	n/a			
	25	MAT prescribers in Indiana accepting Medicaid clients	HMA	n/a			
	26	Authorized residential treatment days as percent of total requested	HMA	n/a			
	27	Average distance travelled by Medicaid beneficiaries seeking residential Tx	HMA	n/a			
H7	RQ7	Does the demonstration improve transitions between ASAM levels of care?					
	28	Pct of discharges from inpatient/residential treatment for SUD which were followed by SUD treatment	RTI, NQF #3590	n/a			
	29	Pct of discharges from inpatient/residential treatment for SUD that readmit for inpt/resid within 180 days of initial discharge	HMA	n/a			
	30	Pct of beneficiaries enrolled in managed care and actively engaged in case or care management with their MCE	HMA	n/a			
H8	RQ8	Does the demonstration rebalance Medicaid expenditures for treatment of SUD away from institutional care toward community-based care?					
	31	PMPM costs, beneficiaries with SUD, all services	CMS	n/a	X	X	
	32	PMPM costs, beneficiaries with SUD, for SUD services	CMS	#25	X	X	

III.E Data Sources

As described in Section III.A, Evaluation Design, HMA-Burns will use existing secondary data sources as well as collect primary data. The evaluation design relies most heavily on the use of Indiana Medicaid administrative data, such as enrollment, claims, and encounter data. Supplemental administrative data, such as service authorization approvals and denials, will also be incorporated. Primary data will be limited and include data created by desk review and facilitated interview instruments. A brief description of these data and their strengths and weaknesses appears below.

Indiana Medicaid Administrative Data

Claims and encounters with dates of service (DOS) from January 1, 2016 and ongoing will be collected from the FSSA Enterprise Data Warehouse (EDW), facilitated by FSSA's EDW vendor, Gainwell Technologies. Managed care encounter data has the same record layout as fee-for-service claims in the EDW and includes variables such as charges and payments at the header and line level. Payment data for MCE encounters represents actual payments made to providers by the MCEs. In total, four MCEs will have encounter data in the dataset.

Because the HMA-Burns team already has built a relationship with the FSSA Data Analytics team and with Gainwell, the HMA-Burns team currently receives monthly tables from the EDW representing member enrollment and demographic information, provider enrollment and demographic information, and claims and encounter data at the detail claim line level. Data has already been received, validated, and used by HMA-Burns for the pre-waiver period. On an ongoing basis today and throughout the second demonstration period, the HMA-Burns team will continue to receive these files on a monthly basis from the EDW. The evaluation team will read in, validate, and append new data to the existing Indiana SUD evaluation database that has already been developed.

The last query of the EDW will occur at the end of December 2026 to allow for a 12-month submission lag for services rendered up until the end of the demonstration on December 31, 2025. All data delivered to HMA-Burns from the FSSA will come directly from the EDW. HMA-Burns will leverage all data validation techniques used by Gainwell before the data is submitted to the EDW. HMA-Burns will also conduct its own validations upon receipt of each monthly file from the EDW to ensure accuracy and completeness when creating our multi-year historical database.

When additional data is deemed necessary for the evaluation, HMA-Burns will outreach directly to the MCEs when they are determined to be the primary source. HMA-Burns will build data validation techniques specific to the data received from ad hoc requests made to the MCEs.

Additional data from the MCEs and the State will be collected on prior authorizations (approvals, denials, and denial reason codes) as well as data on care coordination activities. There could be some data validity or quality issues with these sources as they are not as rigorously collected as claims and encounters data. We will provide detailed specifications and reporting tools to the MCEs and the State to minimize potential for differences in reporting of the requested ad-hoc data. That being said, we will use a standard quality review and data cleaning protocol in order to validate these data upon receipt.

Indiana Vital Statistic Data

In collaboration with FSSA, vital statistics cause of death data will be transferred from the Department of Health to the evaluators for purposes of calculating overdose rates. This is currently underway for the first SUD demonstration evaluation and will continue in this second demonstration evaluation. More information on vital statistics can be found at: https://www.in.gov/health/vital-records/death-information/death-information/

Prescription Drug Monitoring Program (PDMP) Data

In accordance with state guidelines, the states PDMP (named INSPECT) collects information on queries and unique users which will be provided by the Indiana Professional Licensing Agency in collaboration from FSSA. Where possible, data available in the public domain via quarterly reports will be collected and used. Information on the Indiana's PDMP can be found at: https://www.in.gov/pla/inspect/

Facilitated Interview Data

HMA-Burns will construct facilitated interview guide instruments as a means to collect primary data for the focus studies planned in this evaluation related to service authorizations, care coordination, and transitions to care. The types of respondents that the evaluators propose to interview include the MCEs, SUD providers and SUD beneficiaries. Where focused interviews are used to collect data, HMA-Burns will use semi-structured interview protocols that are intended to be standardized within the population being interviewed. The interview protocols will vary, however, for each population interviewed due to the type of information that is intended to be collected. Although semi-structured in nature, each stakeholder will have the opportunity to convey additional information that he/she would like to convey to the evaluators in an open-ended format at the conclusion of each interview.

III.F Analytic Methods

Exhibit 7 depicted the five analytic methods to be used in the analysis. A detailed discussion of each method is described below. It should be noted that whether the statistical test that is applied is ITS or chi-square, for every measure HMA-Burns will also compile descriptive statistics to assess overall longitudinal trends. The descriptive statistics will be performed on the overall demonstration population as well as the subpopulations described in III.B.

Method 1: Chi-square

A chi-square test will be used for measures that are computed annually. Measures where chi-square testing is used will utilize two calendar year time periods, as defined in III.C. The evaluators will consider results significant at a level of probability of $p < .05$. A test statistic will be generated in the SAS© statistical program.

The chi-square test for goodness of fit would determine if the observed frequencies were different than expected; in other words, whether the difference in the pre- and post-outcomes were significantly different statistically than what would have been expected given the pre-period. The null hypothesis, therefore, is that the expected frequency distribution of all wards is the same. Rejecting the null would indicate the differences were statistically significant (i.e., exceeded difference than would be expected at a given confidence level).

The assumptions of the chi-square are:

- Simple random sample
- Sample size. Small samples subject to Type II error.
- Expected cell count. Recommended 5-10 expected counts.
- Independence. Evaluation of the appropriateness of a McNemar's test may be warranted.

Method 2: Interrupted Time Series (ITS)

Per CMS technical guidance, ITS is the preferred alternative approach to randomized control trials in the absence of an available, adequate comparison group for conducting cost-related evaluation analyses.

An ITS analysis relies on a continuous sequence of observations on a population taken at equal intervals over time in which an underlying trend is "interrupted" by an intervention. In this evaluation, the waiver is the intervention and it occurs at a known point in time. The trend in the post-waiver is compared against the expected trend in the absence of the intervention.

A reliability threshold of having a denominator of a minimum number of 100 observations at the monthly level will be used to determine if ITS analysis will ultimately be used. The current evaluation design contemplates using ITS on measures where a minimum denominator of 100 does not appear to be an issue. For all measures where ITS will be applied, descriptive statistics (e.g., mean, median, minimum, maximum, standard deviation) will be inspected for identification of anomalies and trends prior to conducting the test. Scatter plots of each measure will be created and examined to determine any seasonal trends or outliers. Moreover, each outcome will undergo bivariate comparisons; a Pearson correlation coefficient will be produced for each measure compared to the others as well as each measure in the pre- and post- periods.

Regression Analysis

Wagner et al. described the single segmented regression equation as[10]:

$$\hat{Y}_t = \beta_0 + \beta_1 * \text{time}_t + \beta_2 * \text{intervention}_t + \beta_3 * \text{time\_after\_intervention}_t + e_t$$

- Y_t is the outcome
- *time* indicates the number of months or quarters from the start of the series
- *intervention* is a dummy variable taking the values 0 in the pre-intervention segment and 1 in the post-intervention segment
- *time_after_intervention* is 0 in the pre-intervention segment and counts the quarters in the post-intervention segment at time t
- β_0 estimates the base level of the outcome at the beginning of the series
- β_1 estimates the base trend, i.e. the change in outcome in the pre-intervention segment
- β_2 estimates the change in level from the pre- to post-intervention segment
- β_3 estimates the change in trend in the post-intervention segment
- e_t estimates the error

[10] Wagner AK , Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther 2002;27:299-309.

Each outcome will be assessed through visualization for one of the following types of relationships in the pre- and post-waiver period: (a) Level change; (b) Slope change; (c) Level and slope change; (d) Slope change following a lag; (e) Temporary level change; (f) Temporary slope change leading to a level change.

Seasonality and Autocorrelation

One strength of the ITS approach is that it is less sensitive to typical confounding variables which remain fairly constant, such as population age or socio-economic status, as these changes relatively slowly over time. However, ITS may be sensitive to seasonality. To account for seasonality in the data, the same time period, measured in months or quarters, will be used in the pre- and post-waiver period. Should it be necessary, a dummy variable can be added to the model to account for the month or quarter of each observation to control for the seasonal impact.

An assumption of linear regression is that errors are independent. When errors are not independent, as is often the case for time series data, alternative methods may be warranted. To test for the independence, the evaluators will review a residual time series plot and/or autocorrelation plots of the residuals. In addition, a Durbin-Watson test will be constructed to detect the presence of autocorrelation. If the Durbin-Watson test statistic value is well below 1.0 or well above 3.0, there is an indication of serial correlation. If autocorrelation is detected, an autoregressive regression model, like the Cochrane-Orcutt model, will be used in lieu of simple linear regression.

Other assumptions of linear regression are that data are linear and that there is constant variance in the errors versus time. Heteroscedasticity will be diagnosed by examining a plot of residuals verses predicted values. If the points are not symmetrically distributed around a horizontal line, with roughly constant variance, then the data may be nonlinear and transformation of the dependent variable may be warranted. Heteroscedasticity often arises in time series models due to the effects of inflation and/or real compound growth. Some combination of logging and/or deflating may be necessary to stabilize the variance in this case.

For these reasons and in accordance with CMS technical guidance specific to models with cost-based outcomes, the evaluators will use log costs rather than untransformed costs, as costs are often not normally distributed. For example, many person-months may have zero healthcare spending and other months very large values. To address these issues, HMA-Burns will use a two-part model that includes zero costs (logit model) and non-zero costs (generalized linear model).

Controls and Stratification

As described in Section III.B, for some of the monthly measures, the ITS will be run both on the entire SUD target population as well as by a sub-population of the SUD target population that was continuously enrolled for at least 12 months within the 25-month study period examined. Results from the ITS under each scenario will be compared to determine the sensitivity of the findings using the entire SUD population.

Method #3: Onsite Reviews

In order to fill gaps and address questions for which claims-based data and other sources are insufficient, onsite reviews are proposed to gain insight on nuanced differences in approach, use and

effectiveness of different MCE and FSSA approaches to two topics—(1) care coordination and case management and (2) SUD service authorizations.

The onsite reviews will be conducted at each MCE office. Reviews will include both a standardized set of interview questions that will capture information on process and documentation as well as a review of beneficiary-level records. A sampling approach will be developed from a desk review conducted prior to the onsite review whereby a limited number of beneficiaries are selected based on a set of criteria. Internal records specific to those beneficiaries stored at each MCE will be reviewed. The criteria for sampling will be developed to reflect the representativeness of the demonstration population or sub-population served by each MCE. The same team of reviewers will be used for each MCE onsite review to strengthen inter-reliability.

Method #4: Desk Reviews

To supplement the care coordination/case management and SUD service authorization focus studies mentioned above, desk reviews will also be conducted. HMA-Burns will provide to each MCE a data reporting template where individual records—such as beneficiary records for case management or individual service authorization requests for the SUD authorization study—will be requested from each MCE for a defined time period.

Once the data is delivered to HMA-Burns by the MCEs, the evaluation team will compile and analyze the data first to ensure face validity. Later, measures will be computed to ensure consistency, accuracy, and completeness of the data across MCEs (e.g., service authorization requests for 1,000 SUD members). Statistics will be tabulated on process measures (e.g., average duration enrolled in case management, turnaround time for service authorization decisions) and compared across the MCEs. The information tabulated in the desk review will be used to develop the sample of records reviewed while at onsite at the MCE offices.

Another focus study related to transitions of care will be completed as a desk review only. HMA-Burns will use encounters submitted by the MCEs for this study. Using a defined anchor event such as an ASAM level 3 or 4 treatment stay, services utilized by each SUD client will be examined for a 12-week period prior to the anchor event (admission to residential treatment or a hospital) and for a 12-week period after discharge. Trends will be examined on changes in utilization patterns in the pre- and post-anchor event period to determine not only if appropriate transitions occurred post-discharge but also the effectiveness of the residential treatment on patient outcomes (e.g., reduction in hospital emergency department use after the anchor event). HMA-Burns will request case and care management rosters from each MCE to assess the transitions of members after the anchor event discharge date for those enrolled in case/care management with the MCE against those who are not enrolled in case/care management.

Method #5 Facilitated and/or Focus Group Interviews

HMA-Burns will construct facilitated interview guide instruments as a means to collect qualitative information from stakeholders. Intended respondents will include the MCEs, SUD providers and SUD beneficiaries. Where focused interviews are used to collect data, HMA-Burns will use semi-structured interview protocols that are intended to be standardized within the population being interviewed. The interview protocols will vary, however, for each population interviewed due to the type of information that is intended to be collected. Although semi-structured in nature, each stakeholder will have the

opportunity to convey additional information that he/she would like to convey to the evaluators in an open-ended format at the conclusion of each interview.

The approach to obtain qualitative feedback is as follows:

- *Interviews with the MCEs*. Interviews will be conducted with members of each MCE staff individually as part of the onsite reviews related to care coordination/case management and SUD service authorizations. These interviews will be with subject matter experts related to each topic. Additionally, interviews will be conducted with representatives from leadership from all MCEs in a joint setting to discuss the effectiveness of the demonstration as well as opportunities to strengthen the delivery of SUD services in Indiana's Medicaid program.

- *Interviews with providers*. Interviews will be conducted through a web-based tool for groups of providers in a small focus group as well as 1:1 with individual providers either in person or via web-based tool. HMA-Burns aims to conduct at least three focus groups with providers before submission of the Interim Evaluation and three focus groups before submission of the Summative Evaluation. The representation in each focus group will be centered on the primary service offered by the providers (e.g., MAT, intensive outpatient, or residential treatment). Additionally, HMA-Burns aims to conduct at least ten 1:1 interviews with individual providers across the ASAM continuum of services prior to the Interim Evaluation and another 10 prior to the Summative Evaluation.

- *Interviews with beneficiaries*. Interviews will be conducted either at provider locations or via a web-based tool. HMA-Burns aims to conduct at least three focus groups with members as well as a minimum of 15 1:1 interviews prior to the Interim Evaluation and the same number prior to the Summative Evaluation. For the focus groups, HMA-Burns will stratify the groups into populations with similar characteristics (e.g., pregnant women, adolescents, adult women, adult men, geographic considerations). The 1:1 interviews will ensure representation from beneficiaries who received SUD services from Medicaid providers across the ASAM continuum. As a means to incentive participation by beneficiaries, HMA-Burns will offer gift cards from Wal-Mart or Target as a gesture of thanks. The gift cards will be distributed immediately after the focus group or interview concludes.

III.G Other Additions

Beginning on the next page, Exhibit 9 provides information on each measure selected for use in the evaluation. The measures are mapped to their associated hypothesis and research question.

Exhibit 9. Summary of Evaluation Questions, Evaluation Hypotheses, Data Sources, and Analytic Approaches

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #1: ***Is the rate of drug overdose deaths in Indiana impacted by the demonstration?***					
Demonstration Goal: Reduction in overdose deaths, particularly those due to opioids.					
Evaluation Hypothesis #1: The demonstration will decrease the rate of overdose deaths in Indiana since prior to the demonstration period.					
Rate of overdose deaths, specifically overdose deaths due to any opioid	HMA-Burns, CMS SUD Monitoring Metric #27	Number of overdose deaths per month and per year	Total number of beneficiary member months (result of this formula then expressed as per 1,000 member months)	Vital statistics, claims data	Descriptive statistics (frequencies and percentages)
Use of opioids at high dosage in persons without cancer	PQA, NQF #2940, CMS SUD Monitoring Metric #18	Number of beneficiaries with opioid prescription claims where the morphine equivalent dose for 90 consecutive days or longer is greater than 120 mg	Number of beneficiaries with two or more prescription claims for opioids filled on at least two separate dates, for which the sum of the days' supply is greater than or equal to 15	Claims and enrollment data	Descriptive statistics, chi-square tests
Use of opioids from multiple providers in persons without cancer	PQA, NQF #2950, CMS SUD Monitoring Metric #19	Number of beneficiaries >=18 who received prescriptions for opioids from >=4 prescribers and >=4 pharmacies within 180 days	Number of Medicaid beneficiaries >=18 that are not excluded due to cancer diagnosis	Claims and enrollment data	Descriptive statistics, chi-square tests
Concurrent use of opioids and benzodiazepines	PQA, NQF #3389, CMS SUD Monitoring Metric #21	Number of beneficiaries with concurrent use of prescription opioids and benzodiazepines	Number of Medicaid beneficiaries >=18 with two or more prescription claims for opioids filled on two or more separate days, for which the sum of the supply is 15 or more days	Claims and enrollment data	Descriptive statistics, chi-square tests
Number of clinicians accessing the PDMP	HMA-Burns	Number of clinicians accessing the PDMP monthly	N/A	PDMP data	Descriptive statistics (frequencies and percentages)

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #2: ***Does the demonstration increase the percentage of beneficiaries who initiate and engage in treatment for OUD and other SUDs?***					
Demonstration Goal: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs.					
Evaluation Hypothesis #2: The demonstration will increase the percentage of beneficiaries who initiate and engage in treatment for OUD and other SUDs since the initial demonstration period.					
Initiation and engagement of alcohol and other drug dependence treatment	NCQA, NQF #0004, CMS SUD Monitoring Metric #15	***Initiation*** : Number of patients who began initiation of treatment within 14 days of the index episode start date.	Patients who were diagnosed with a new episode of alcohol or drug dependency during the first 10 and ½ months of the measurement year.	Claims data	***For both measures*** : Analysis will be conducted on all 4 sub-populations (total, alcohol only, opioid only, other than alcohol or opioid). Descriptive statistics, chi-square tests.
Initiation and engagement of alcohol and other drug dependence treatment	NCQA, NQF #0004, CMS SUD Monitoring Metric #15	***Engagement*** : Initiation of treatment and two or more defined SUD visits within 30 days after the date of the initiation encounter.	Patients who were diagnosed with a new episode of alcohol or drug dependency during the first 10 and ½ months of the measurement year.	Claims data	
Follow-Up After Discharge from the Emergency Department for Alcohol or Other Drug (AOD) Dependence	NCQA, CMS SUD Monitoring Metric #17(1)	1. Members who had a follow-up visit to an ED visit with a SUD indicator within 7 days of discharge within the previous rolling 12 months.	Individuals with an ED visit (with SUD indicator) within the previous rolling 12 months.	Claims data	***For both measures*** : Descriptive statistics, chi-square tests
	NCQA, Monitoring Metric #17(2)	2. Same as above for members who had a follow-up visit within 30 days.	Individuals with an ED visit (with SUD indicator) within the previous rolling 12 months.	Claims data	
Continuity of pharmacotherapy for OUD	USC, NQF #3175, CMS SUD Monitoring Metric #22	Number of participants who have at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than seven days.	Individuals who had a diagnosis of OUD and at least one claim for an OUD medication.	Claims data	Descriptive statistics, chi-square tests

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #2: ***Does the demonstration increase the percentage of beneficiaries who initiate and engage in treatment for OUD and other SUDs?***					
Rate of Medicaid beneficiaries receiving intensive outpatient tx	CMS SUD Monitoring Metric #8	Number of unique beneficiaries who received outpatient treatment during the measurement period.	Individuals identified with a SUD diagnosis using CMS Metric #3.	Claims and enrollment data	ITS, including sensitivity analysis
Rate of Medicaid beneficiaries receiving intensive outpatient tx	CMS SUD Monitoring Metric #9	Number of unique beneficiaries who received intensive outpatient or partial hospitalization during the measurement period.	Individuals identified with a SUD diagnosis using CMS Metric #3.	Claims and enrollment data	ITS, including sensitivity analysis
Rate of Medicaid beneficiaries receiving residential treatment	CMS SUD Monitoring Metric #10	Number of unique beneficiaries who have a service for residential treatment for SUD during the measurement period.	Individuals identified with a SUD diagnosis using CMS Metric #3.	Claims and enrollment data	ITS, including sensitivity analysis
Rate of Medicaid beneficiaries receiving withdrawal management	CMS SUD Monitoring Metric #11	Number of unique beneficiaries who received withdrawal management during the measurement period.	Individuals identified with a SUD diagnosis using CMS Metric #3.	Claims and enrollment data	ITS, including sensitivity analysis
Rate of Medicaid beneficiaries receiving MAT	CMS SUD Monitoring Metric #12	Number of unique beneficiaries who received MAT during the measurement period.	Individuals identified with a SUD diagnosis using CMS Metric #3.	Claims and enrollment data	ITS, including sensitivity analysis

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #3: ***Does the demonstration decrease the rate of emergency department visits among Medicaid beneficiaries with SUD?***					
Demonstration Goal: Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.					
Evaluation Hypothesis #3: The demonstration will decrease the rate of emergency department visits among Medicaid beneficiaries with SUD since the initial demonstration period.					
Emergency department visits for SUD-related diagnoses and specifically for OUD	CMS SUD Monitoring Metric #23	The number of ED visits with a SUD diagnosis present during the measurement period.	Beneficiaries enrolled in Medicaid for at least one month (30 consecutive days) during the measurement period.	Claims and enrollment data	ITS, including sensitivity analysis
Evaluation Question #4: ***Does the demonstration decrease the rate of hospital readmissions among Medicaid beneficiaries with SUD?***					
Demonstration Goal: Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappopriate.					
Evaluation Hypothesis #4: The demonstration will decrease the rate of hospital readmissions among Medicaid beneficiaries with SUD since prior to the initial demonstration period.					
Readmissions Among Beneficiaries with SUD	CMS SUD Monitoring Metric #25	At least one acute unplanned readmission for any diagnosis within 30 days of the date of discharge from the index hospital stay.	Medicaid beneficiaries age 18 and older with a SUD diagnosis and an index stay (discharges in first 11 months of measurement year).	Claims and enrollment data	Descriptive statistics, chi-square tests
Evaluation Question #5: ***Does the demonstration increase the percentage of Medicaid beneficiaries with SUD who receive care for comorbid conditions?***					
Demonstration Goal: Improved access to care for physical health conditions among beneficiaries.					
Evaluation Hypothesis #5: The demonstration will increase the percentage of Medicaid beneficiaries who receive care for comorbid conditions since prior to the initial demonstration period.					
Access to preventive/ ambulatory health services for adult Medicaid beneficiaries with SUD	NCQA, CMS SUD Monitoring Metric #32	Number of beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period.	Number of beneficiaries with a SUD diagnosis	Claims and enrollment data	ITS, including sensitivity analysis

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #6: ***Does the demonstration increase the level of access to community-based SUD treatment for Medicaid beneficiaries with SUD?***					
Demonstration Goal: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs.					
Demonstration Goal: Increased adherence to and retention in treatment.					
Demonstration Goal: Reduction in overdose deaths, particularly those due to opioids.					
Demonstration Goal: Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.					
Evaluation Hypothesis #6: The demonstration will improve access to community-based services for SUD treatment since the initial demonstration period.					
ASAM 3.x bed capacity for Medicaid beneficiaries	HMA-Burns	Total number of beds available at ASAM level 3.1 and 3.5 by providers licensed by Division of Mental Health & Addiction and registered as Medicaid providers.		FSSA-maintained report	Descriptive statistics (frequencies and percentages)
MAT prescribers in Indiana accepting Medicaid clients	HMA-Burns	Total MAT prescribers in Indiana that received payment for delivering MAT to a Medicaid beneficiary in the previous 12 months.	Total MAT prescribers in Indiana	FSSA report, claims data	Descriptive statistics (frequencies and percentages)
Authorized residential treatment days as a percentage of total requested days	HMA-Burns	Total days requested and approved by MCEs to residential treatment providers to deliver treatment to Medicaid beneficiaries.	Total days requested by residential treatment providers to deliver treatment to Medicaid beneficiaries.	MCE-submitted data	Descriptive statistics (frequencies and percentages)
Average distance travelled by Medicaid beneficiaries seeking residential treatment	HMA-Burns	Total driving miles from member's home to residential treatment provider where service is received.	Total unique member-to-provider residential treatment stays in the study period.	Claims and enrollment data	Descriptive statistics (frequencies and percentages). Results will be computed across eight regions of the state.

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #7: ***Does the demonstration improve transitions between ASAM levels of care?***					
Demonstration Goal: Increased adherence to and retention in treatment.					
Demonstration Goal: Reduction in overdose deaths, particularly those due to opioids.					
Demonstration Goal: Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.					
Evaluation Hypothesis #7: Care coordination and transitions between ASAM levels of care will improve during the demonstration period.					
Percentage of discharges from inpatient or residential treatment for SUD for Medicaid beneficiaries which were followed by a SUD treatment.	RTI, NQF #3590	Number of beneficiaries within (a) 7 and (b) 14 days who received a SUD treatment following discharge from an inpatient or residential SUD provider in a 12-month period.	Number of beneficiaries, age 18-64, with an inpatient or residential SUD stay in 12-month period.	Claims and enrollment data	Descriptive statistics (frequencies and percentages)
Percentage of discharges from inpatient or residential treatment for SUD that readmit for inpatient or residential within 180 days of initial discharge	HMA-Burns	Number of Medicaid beneficiaries an index event that readmit to inpatient hospital or residential treatment for SUD within 180 days of discharge from the index event.	Number of beneficiaries, age 18-64, with an inpatient or residential SUD stay in 12-month period.	Claims and enrollment data	Descriptive statistics (frequencies and percentages)
Rate of Medicaid beneficiaries enrolled in managed care and actively engaged in case or care management with their MCE	HMA-Burns	Number of unique beneficiaries who are actively enrolled in case or care management with their MCE. One rate will be computed for complex case management, another for care management.	Individuals identified with a SUD diagnosis using CMS Metric #3 who are enrolled with an Indiana MCE for a minimum of 90 days.	Claims and enrollment data plus MCE-submitted data	Descriptive statistics (frequencies and percentages)

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #8: ***Does the demonstration rebalance Medicaid expenditures for SUD treatment away from institutional toward community-based care?***					
Demonstration Goal: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs.					
Demonstration Goal: Increased adherence to and retention in treatment.					
Demonstration Goal: Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.					
Evaluation Hypothesis #8: The demonstration will rebalance Medicaid expenditures for treatment of SUD more toward community-based care since the initial demonstration period.					
Per beneficiary per month costs in total and by categories of service among the SUD population	CMS-specified (SMI/SED and SUD Guidance Appendix C)	Total monthly costs for SUD beneficiaries. Categories include inpatient, outpatient, pharmacy, long term care, IMDs and other.	1. Total member months for beneficiaries with an SUD diagnosis. 2. Total member months for all enrolled beneficiaries.	Claims data	ITS, including sensitivity analysis
Per capita SUD spending	CMS SUD Monitoring Metric #28	Total monthly costs for SUD beneficiaries. Categories include residential treatment, intensive outpatient, outpatient, assessment.	1. Total member months for beneficiaries with an SUD diagnosis. 2. Total member months for all enrolled beneficiaries.	Claims data	ITS, including sensitivity analysis

SECTION IV: METHODOLOGICAL LIMITATIONS

There are inherent limitations to both the study design and its specific application to the SUD waiver evaluation. That being said, the proposed design is feasible and is a rational explanatory framework for evaluating the impact of the SUD waiver on the SUD population. Moreover, to fill gaps left by the limitations of this study design, a limited number of qualitative methods are proposed to provide a more holistic and comprehensive evaluation.

Some measures and/or sub-populations may not be meaningful for reporting and insufficient statistical power to detect a difference is a concern. For any observational studies, especially if the population size exposures and the outcomes being assessed are rare, it is difficult to find statistically significant results. It is not unexpected, therefore, that many of the outcome measure sample sizes will be too small to observe statistically significant results. HMA-Burns recommends a threshold for minimum numbers of observations. For any measures below this threshold, the expectation of statistical testing would be waived.

While CMS may prefer comparator group from another state, in the last two years, the proliferation of the SUD demonstrations across the country renders few comparable states to Indiana. Moreover, this would require significantly more resources and cooperation with another state on sharing data. Therefore, HMA-Burns recommends using statistical tests comparing the pre- and post-waiver period to test hypotheses in the absence of a control group.

Another limitation is the length of time of the evaluation period. In some cases, the time period may be insufficient to observe descriptive or statically significant differences in outcomes in the SUD population. Therefore, it is expected that not all outcomes included in the study will show a demonstrable change descriptively, although we do expect some process measures to show a change during this time frame.

Moreover, with any study focused on the SUD population and potentially rare outcome measures, such as overdose rates, insufficient statistical power to detect a difference is a concern. For any observational studies, especially if the exposures and the outcomes being assessed are rare, it is difficult to find statistically significant results. It is not unexpected, therefore, that many of the outcome measure sample sizes will be too small to observe statistically significant results.

Related to the issues mentioned above, many of the outcome measures are multi-dimensional and influenced by social determinants of health. While changes under the waiver related to access to care may be one dimension of various outcomes of interest, and may contribute to improvements, it may be difficult to achieve statistically significant findings in the absence of data on other contributing dimensions, like social determinants of health such as housing, employment, and previous incarcerations.

SECTION V: SPECIAL METHODOLOGICAL CONSIDERATIONS

The proposed Evaluation Design Plan provides more than adequate rigor in the observational study design, especially when considering the range of supplemental evaluation methods proposed for inclusion. As described in Section IV, the study mitigates known limitations to the extent feasible drawing upon the range of options to fill gaps in the observational study design.

An important special consideration in Indiana is the fact this Indiana will be the first state undertaking a SUD demonstration renewal evaluation. Although other State Medicaid Agencies may have implemented more sophisticated SUD service delivery systems even prior to their own waiver demonstration approval, there may be less demonstrable changes in some measures between Indiana's second SUD demonstration and its first demonstration when compared to the State's first SUD demonstration period and pre-demonstration period.

Also, observed changes in outcome measures in the current waiver period will be difficult, if not impossible, to attribute to one specific demonstration component or activities outside the demonstration itself but occurring simultaneously (e.g., activities supported through federal grants) given the interrelationship of the components themselves. For many outcome measures, changes in the post-waiver period will be difficult, if not impossible, to attribute to coinciding related activities resulting from the combination of waiver, planning grant, and other activities occurring in the state. Therefore, it will be important to use statistical tests of significance so that findings are properly put into context.

Lastly, the evaluators recognize that the utilization patterns that will occur relatively early in this demonstration period will be severely disrupted due to public health emergency. The predictability of future utilization patterns remains uncertain as of the date of this document. The evaluators are prepared to work with CMS in the event that guidance is provided to states for all waiver evaluations as to options that CMS will offer with respect to how to account for the acute period of the pandemic. The initial plan for handling the effects of the public health emergency are addressed in Section III. Methodology.

ATTACHMENT A: INDEPENDENT EVALUATOR

Process

Burns & Associates, a division of Health Management Associates, (HMA-Burns) submitted a proposal to the Family and Social Services Administration to be to conduct the evaluation of Indiana's SUD demonstration waiver renewal. The proposal was developed based upon the criteria set forth in the waiver demonstration's Special Terms and Conditions as approved by the Centers for Medicare and Medicaid Services.

The FSSA has the authority to pursue this engagement through an existing contract with HMA that is effective from July 1, 2021 through June 30, 2025. HMA-Burns provided a proposed budget to complete all activities required for the waiver evaluation, but the current contract for this engagement ends June 30, 2025.

Vendor Qualifications

The team at HMA-Burns that will conduct this evaluation has also completed evaluation and monitoring work for Indiana's first SUD waiver demonstration. That work is ongoing, including the development of the Summative Evaluation. The HMA-Burns team joined Health Management Associates effective September 1, 2020 when HMA acquired Burns & Associates.

Burns & Associates (B&A) was founded in 2006. Its team works almost exclusively with state Medicaid agencies or related social services agencies in state government. During its 14-year history, B&A worked with 33 state agencies in 26 states. The HMA-Burns team proposed to complete this evaluation is also currently conducting the evaluation of the State of Delaware's SUD demonstration, the State of Delaware's Section 1115 Diamond State Health Plan Waiver demonstration, and the State of Colorado's Section 1115 Adult Prenatal Coverage in Child Health Plan Plus (CHP+) demonstration.

For Indiana's initial SUD demonstration, the HMA-Burns team developed the approved Evaluation Design Plan, produced the Interim Evaluation, and conducted the MidPoint Assessment. For the Delaware and Colorado waivers, the team has delivered Evaluation Design Plans and work is underway related to activities defined in these evaluation design plans.

Prior to the acquisition by HMA, the HMA-Burns team on this Indiana engagement conduced independent assessments of Indiana's 1915(b) waiver for Hoosier Care Connect and served as the External Quality Review Organization (EQRO) for Indiana from 2007 to 2020. The team wrote an External Quality Review (EQR) report each year during this period. The reports were all submitted to CMS. HMA-Burns team members also conducted independent evaluations for state agencies in Minnesota, New York, and Oklahoma.

Assuring Independence

HMA-Burns attests to having no conflicts to perform the tasks needed to serve as an independent evaluator on this engagement. HMA-Burns' Principal Investigator is prepared to deliver a signed attestation to this effect upon request.

ATTACHMENT B: EVALUATION BUDGET

The total budget for this Evaluation Design is $1,045,000. The distribution of hours and cost for each deliverable is shown in the exhibit below. All costs are built into the hourly rates for the staff conducting the work, including travel and other overhead costs.

Labor Category	Evaluation Design	Mid-Point Assessment	Interim Evaluation	Summative Evaluation	Total
Principal Investigator	120	180	280	320	**900**
Onsite Reviewers and Stakeholder Interviewers	60	220	320	430	**1,030**
Statistician	5	120	400	500	**1,025**
SAS Programmer	0	30	144	206	**380**
Data Analyst	30	80	120	180	**410**
All Labor Categories	**215**	**630**	**1,264**	**1,636**	**3,745**

Deliverable Cost	**$65,000**	**$180,000**	**$350,000**	**$450,000**	**$1,045,000**

ATTACHMENT C: TIMELINE AND MILESTONES

The HMA-Burns team was required to submit a work plan, including major tasks and milestones, to complete the scope of work requested by the State of Indiana related to its SUD demonstration waiver evaluation for activities completed through the available contracting period ending June 30, 2025. In an effort to show the complete level of effort that would be proposed to complete all deliverables, HMA-Burns is showing a work plan that covers the entire evaluation period. A summary of the work plan is shown on the next page. Tasks are further detailed out by sub-task and available upon request. Tasks are scheduled out by calendar quarter.

Major Task		CY 2021				CY 2022				CY 2023				CY 2024				CY 2025				CY 2026			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
A	**Ongoing Tasks to Support Engagement**																								
A.1	Monthly project mgmt/status mtg with FSSA																								
A.2	Read in, validate, and incorporate claims data																								
A.3	Read in, validate, and incorporate enrollment data																								
B	**Develop Evaluation Design Document**																								
B.1	Create draft Evaluation Design to submit to CMS																								
B.2	Finalize Evaluation Design based on CMS feedback																								
C	**Prepare Mid-Point Assessment**																								
C.1	Conduct focus study on member access to services																								
C.2	Conduct focus study on service auth requests																								
C.3	Conduct focus study on transitions to care																								
C.4	Conduct focus study on care coordination																								
C.5	Conduct interviews with beneficiaries																								
C.6	Conduct interviews with service providers																								
C.7	Conduct interviews with managed care entities																								
C.8	Submit draft Mid-Point Assessment to FSSA																								
C.9	Submit Mid-Point Assessment to CMS																								
D	**Prepare Interim Evaluation**																								
D.1	Compile data measures for all subpopulations																								
D.2	Perform statistical tests on results, if applicable																								
D.3	Assess FSSA status against SUD Implementation Plan																								
D.4	Submit draft Interim Evaluation to FSSA																								
D.5	Submit Interim Evaluation to CMS																								
E	**Prepare Summative Evaluation**																								
E.1	Conduct member access focus study, Round 2																								
E.2	Conduct service auth focus study, Round 2																								
E.3	Conduct transitions focus study, Round 2																								
E.4	Conduct care coordination focus study, Round 2																								
E.5	Conduct Round 2 interviews with beneficiaries																								
E.6	Conduct Round 2 interviews with service providers																								
E.7	Conduct Round 2 interviews with MCEs																								
E.8	Compile data measures for all subpopulations																								
E.9	Perform statistical tests on results, if applicable																								
E.10	Submit draft Summative Evaluation to FSSA																								
E.11	Submit Summative Evaluation to CMS																								

Attachment F: SMI Implementation Plan

Section 1115 SMI/SED Demonstration Implementation Plan

Overview: The implementation plan documents the state's approach to implementing SMI/SED demonstrations. It also helps establish what information the state will report in its quarterly and annual monitoring reports. The implementation plan does not usurp or replace standard CMS approval processes, such as advance planning documents, verification plans, or state plan amendments.
This template only covers SMI/SED demonstrations. The template has three sections. Section 1 is the uniform title page. Section 2 contains implementation questions that states should answer. The questions are organized around six SMI/SED reporting topics:

1. Milestone 1: Ensuring Quality of Care in Psychiatric Hospitals and Residential Settings
2. Milestone 2: Improving Care Coordination and Transitioning to Community-Based Care
3. Milestone 3: Increasing Access to Continuum of Care, Including Crisis Stabilization Services
4. Milestone 4: Earlier Identification and Engagement in Treatment, Including Through Increased Integration
5. Financing Plan
6. Health IT Plan

State may submit additional supporting documents in Section 3.

Implementation Plan Instructions: This implementation plan should contain information detailing state strategies for meeting the specific expectations for each of the milestones included in the State Medicaid Director Letter (SMDL) on "Opportunities to Design Innovative Service Delivery Systems for Adults with [SMI] or Children with [SED]" over the course of the demonstration. Specifically, this implementation plan should:

1. Include summaries of how the state already meets any expectation/specific activities related to each milestone and any actions needed to be completed by the state to meet all of the expectations for each milestone, including the persons or entities responsible for completing these actions; and
2. Describe the timelines and activities the state will undertake to achieve the milestones.

The tables below are intended to help states organize the information needed to demonstrate they are addressing the milestones described in the SMDL. States are encouraged to consider the evidence-based models of care and best practice activities described in the first part of the SMDL in developing their demonstrations.
The state may not claim FFP for services provided to Medicaid beneficiaries residing in IMDs, including residential treatment facilities, until CMS has approved a state's implementation plan.
Memorandum of Understanding: The state Medicaid agency should enter into a Memorandum of Understanding (MOU) or another formal agreement with its State Mental Health Authority, if one does not already exist, to delineate how these agencies will work with together to design, deliver, and monitor services for beneficiaries with SMI or SED. This MOU should be included as an attachment to this Implementation Plan.

State Response: **In accordance with Indiana's approved Medicaid State Plan, the Office of the Secretary of the Family and Social Services Administration (FSSA) is the single state agency. The Division of Mental Health and Addiction (DMHA) is within the FSSA; therefore, no MOU is applicable to this waiver request.**

State Point of Contact: Please provide the contact information for the state's point of contact for the implementation plan.

Name and Title: Amy Owens
Federal Relations Lead, Indiana Medicaid
Telephone Number: 317-233-7007
Email Address: Amy.Owens@fssa.IN.gov

1. Title page for the state's SMI/SED demonstration or SMI/SED components of the broader demonstration

The state should complete this transmittal title page as a cover page when submitting its implementation plan.

State	*Indiana*
Demonstration name	*Healthy Indiana Plan –* *Project Number 11-W-00296/5*
Approval date	*TBD – Amendment submitted* *August 30, 2019*
Approval period	*January 1, 2020 – December 31, 2020*
Implementation date	*January 1, 2020*

2. Required implementation information, by SMI/SED milestone

Answer the following questions about implementation of the state's SMI/SED demonstration. States should respond to each prompt listed in the tables. Note any actions that involve coordination or input from other organizations (government or non-government entities). Place "NA" in the summary cell if a prompt does not pertain to the state's demonstration. Answers are meant to provide details beyond the information provided in the state's special terms and conditions. Answers should be concise, but provide enough information to fully answer the question.

This template only includes SMI/SED policies.

Prompts	Summary
SMI/SED. Topic_1. Milestone 1: Ensuring Quality of Care in Psychiatric Hospitals and Residential Settings	
To ensure that beneficiaries receive high quality care in hospitals and residential settings, it is important to establish and maintain appropriate standards for these treatment settings through licensure and accreditation, monitoring and oversight processes, and program integrity requirements and processes. Individuals with SMI often have co-morbid physical health conditions and substance use disorders (SUDs) and should be screened and receive treatment for commonly co-occurring conditions particularly while residing in a treatment setting. Commonly co-occurring conditions can be very serious, including hypertension, diabetes, and substance use disorders, and can also interfere with effective treatment for their mental health condition. They should also be screened for suicidal risk. *To meet this milestone, state Medicaid programs should take the following actions to ensure good quality of care in psychiatric hospitals and residential treatment settings.*	
Ensuring Quality of Care in Psychiatric Hospitals and Residential Treatment Settings	
Assurance that participating hospitals and residential settings are licensed or otherwise authorized by the state primarily to provide mental health treatment; and that residential treatment facilities are accredited by a nationally recognized accreditation entity prior to participating in Medicaid	*Current Status:* In accordance with Indiana Administrative Code (440 IAC 1.5), all free-standing psychiatric hospitals must be licensed as a private mental health institution (PMHI)[5] by the Indiana Division of Mental Health and Addiction (DMHA). PMHI licensure must be renewed annually. Additionally, all entities must be accredited by an agency approved by DMHA, which currently include the following: • National Committee for Quality Assurance (NCQA) • CARF – The Rehabilitation Accreditation Commission • Joint Commission on Accreditation of Healthcare Organizations (JCAHO) The following general components are required for licensure: • A governing board

[5] Defined as an inpatient hospital setting, including inpatient and outpatient services provided in that setting, for the treatment and care of individuals with psychiatric disorders or chronic addictive disorders, or both, that is physically, organizationally, and programmatically independent of any hospital or health facility licensed by the Indiana State Department of Health.

Prompts	Summary
	• Medical or professional staff organization • A quality assessment and improvement program • Dietetic service • Infection control program • Medical record services • Nursing service • Physical plan, maintenance and environmental services • Intake and treatment services • Discharge planning services • Pharmacy services • A plan for special procedures An entity seeking a license as a PMHI must file an application with DMHA which includes, at minimum: • A description of the organizational structure and mission of the applicant • The location of all operational sites of the applicant • The consumer population to be served and program focus • A list of governing board members and executive staff • A copy of the applicant's procedures to ensure protection of consumer rights and confidentiality • Written evidence of an onsite review and inspection by the Indiana Department of Health and Department of Homeland Security Division of Fire and Building Safety and the correction of any deficiencies identified • Proof of accreditation including site survey recommendations from the accrediting agency and the applicant's response to such recommendations To maintain licensure, a PMHI must meet the following conditions: • Maintain accreditation from a DMHA approved accrediting agency • Maintain compliance with required health, building, fire and safety codes as prescribed by federal, state and local law • Have written policies and enforce these policies to support and protect the fundamental human, civil, constitutional and statutory rights of each consumer • Comply with requirements for providing, posting and documenting consumer statement of rights under Indiana Code 12-27 • Respond to complaints from the consumer service line in a timely manner

Prompts	Summary
	Future Status: Continued operation of current requirements.
	Summary of Actions Needed: N/A –milestone requirements already met.
Oversight process (including unannounced visits) to ensure participating hospital and residential settings meet state's licensing or certification and accreditation requirements	*Current Status:* DMHA currently conducts annual unannounced site visits of each PMHI. Site visits are conducted using a checklist which crosswalks with all licensure requirements.
	Future Status: Continued operation of current requirements.
	Summary of Actions Needed: N/A –milestone requirements already met.
Utilization review process to ensure beneficiaries have access to the appropriate levels and types of care and to provide oversight on lengths of stay	*Current Status:* In accordance with 405 IAC 5-3-13, all inpatient psychiatric, substance abuse and rehabilitation admissions require prior authorization to ensure the appropriate level of care. Medical necessity reviews are completed by Indiana's managed care organizations (MCOs) and the State's fee-for-service prior authorization (PA) entity, based on the individual's enrollment. The PA entity utilizes Milliman Care Guidelines and OMPP reviews the MCO's UM practices. As described in the Indiana Medicaid Medical Policy Manual, acute psychiatric inpatient admissions are available for enrollees with a sudden onset of a psychiatric condition manifesting itself by acute symptoms of such severity that the absence of immediate medical attention could reasonably be expected to result in one or more of the following: • Danger to the individual • Danger to others • Death of the individual Reimbursement is available for inpatient care only when the need for admission has been certified. Emergency and nonemergency admissions require telephonic precertification review. The precertification review must be followed by a written certification of need through completion of State Form 44697 – Certification of the Need for Inpatient Psychiatric Hospital Services (1261A form) along with a written plan of care. This form documents the enrollee's: • Psychiatric and medical evaluation • Functional capacity • Prognoses • Recommendations

Prompts	Summary
	• Certification by an interdisciplinary team that based upon physical, mental and social evaluations the individual requires inpatient psychiatric treatment and available alternative community resources do not meet the patient's mental health care needs All requests for PA are reviewed on a case-by-case basis. The MCO or PA entity reviews each State Form 44697 to determine whether the requested acute inpatient services meet medical necessity. Reimbursement is denied for any days the facility cannot justify a need for inpatient care. If the provider fails to complete a telephone PA precertification, reimbursement will be denied from the admission to the actual date of notification. Additionally, in accordance with 440 IAC 1.5-3-9, all PMHIs must have policies and procedures that govern the intake and assessment process to determine eligibility for services. Each admitted Medicaid enrollee must have a preliminary treatment plan formulated within 60 hours of admission on the basis of the intake assessment at admission, which must specify the services necessary to meet the consumer's needs and contain discharge or release criteria and the discharge plan. Further, progress notes must be entered daily and the consumer's treatment plan must be reviewed at least every seven days.
	Future Status: OMPP will develop a report to monitor average length of stay (ALOS) for all Medicaid programs. All reporting will follow CMS monitoring guidance. Additionally, OMPP will review timeline requirements for submission of the 1261A form.
	Summary of Actions Needed: The Quality and Outcomes section of OMPP, in coordination with the evaluation vendor and MCOs, will develop reporting specifications to implement monitoring for implementation. OMPP will make necessary updates to the provider manuals to reflect any changes by Q2 of 2020. Providers were notified of program changes via bulletin on November 26, 2019.
Compliance with program integrity requirements and state compliance assurance process	*Current Status:* In order to receive reimbursement under Medicaid, participating psychiatric hospitals must be enrolled to participate in Indiana Medicaid. Provider enrollment processes fully comply with 42 CFR Part 455 Subparts B&E. As MCOs have been reimbursing IMDs as an in lieu of service and are only permitted to contract with Indiana Medicaid screened and enrolled providers, the State is currently screening and revalidating this provider type.
	Future Status: Continued operation of current requirements.
	Summary of Actions Needed: N/A –milestone requirements already met.

Prompts	Summary
State requirement that psychiatric hospitals and residential settings screen beneficiaries for co-morbid physical health conditions, SUDs, and suicidal ideation, and facilitate access to treatment for those conditions	*Current Status:* Indiana Administrative Code (440 IAC 1.5-3-9) details a series of required policies and procedures for intake and assessment processes. This includes, but is not limited to completion of the following assessments: • Physical examination by a licensed physician, advance practice nurse or physician's assistant • Emotional, behavioral, social and legal assessment Compliance with these requirements, including screening for SUD, is reviewed during annual site reviews conducted by the DMHA.
	Future Status: Compliance will continue to be monitored via the annual unannounced site visits of hospitals as part of their recertification.
	Summary of Actions Needed: N/A –milestone requirements already met.
Other state requirements/policies to ensure good quality of care in inpatient and residential treatment settings.	*Current Status:* DMHA conducts the Mental Health Statistical Improvement Project Survey for Adults and Youth (MHSIP), an annual consumer satisfaction surveys for all individuals who have been served by DMHA contracted providers. In addition, the MCOs conduct annual consumer assessment of healthcare providers and systems (CAHPS) surveys which provide insight into the consumer experience with their healthcare providers. Findings from these surveys are utilized in quality assurance and improvement activities as needed.
	Future Status: Continued operation of current consumer satisfaction surveys.
	Summary of Actions Needed: N/A –milestone requirements already met.
SMI/SED. Topic_2. Milestone 2: Improving Care Coordination and Transitioning to Community-Based Care	
Understanding the services needed to transition to and be successful in community-based mental health care requires partnerships between hospitals, residential providers, and community-based care providers. To meet this milestone, state Medicaid programs, must focus on improving care coordination and transitions to community-based care by taking the following actions.	
Improving Care Coordination and Transitions to Community-based Care	
Actions to ensure psychiatric hospitals and residential settings carry out intensive pre-discharge planning, and include community-based providers in care transitions.	*Current Status:* Indiana Administrative Code (440 IAC 1.5-3-10) outlines minimum requirements for discharge planning. Hospitals are required to initiate discharge planning at admission that includes the following: • Facilitates the provision of follow-up care. • Transfers or refers consumers, along with necessary medical information and records, to appropriate facilities, agencies, or outpatient services for follow-up or ancillary care. Required minimum information to be transferred includes: o Medical history o Current medications o Available social, psychological and educational services o Nutritional needs o Outpatient service needs

Prompts	Summary
	○ Follow-up care needs Additionally, in accordance with the Indiana Medicaid Medical Policy Manual, all plans of care must document a post-discharge plan and a plan for coordination of inpatient services with partial discharge plans, including appropriate services in the member's community to ensure continuity of care when the patient returns to his or her family and community upon discharge. Community mental health centers (CMHCs) are required, as codified in Indiana Administrative Code (440 IAC 9-2-4), to be involved in the planning of treatment for and the discharge of consumers during the time a consumer is in inpatient care, to maintain continuity of care. Additionally, MCOs are contractually required to provide case management services for any member discharged from an inpatient psychiatric or substance abuse hospitalization for no fewer than 90 calendar days following discharge. MCO contracts also require case managers to contact members during an inpatient hospitalization, or immediately upon receiving notification of a member's inpatient behavioral health hospitalization and must schedule an outpatient follow-up appointment to occur no later than seven calendar days following the inpatient behavioral health hospitalization discharge. If a member misses an outpatient follow-up or continuing treatment, the MCO is contractually required to ensure that a behavioral health care provider or the MCO's behavioral health case manager contacts that member within three business days of notification of the missed appointment.
	Future Status: Continued operation of current requirements.
	Summary of Actions Needed: N/A –milestone requirements already met.
2.b Actions to ensure psychiatric hospitals and residential settings assess beneficiaries' housing situations and coordinate with housing services providers when needed and available.	*Current Status:* MCOs are contractually required to provide case management services for any member at risk for or discharged from an inpatient psychiatric or substance abuse hospitalization. Case managers must contact members during an inpatient hospitalization and as a component of case management, must make every effort to assist members in navigating community resources and linking members with community-based services such as Connect2Help211, food pantries, housing and housing supports, legal, employment and disaster services. Additionally, CMHCs are required, in accordance with IAC 440 IAC 9-2-10, as a component of case management, to provide advocacy and referral including helping individuals access entitlement and other services, such as Medicaid, housing, food stamps, educational services, recovery groups, and vocational services.

Prompts	Summary
	Future Status: Indiana Medicaid Provider Manual will be updated to explicitly require psychiatric hospitals have protocols in place to assess for housing insecurity as part of the social work assessment and discharge planning processes and to refer to appropriate resources. Compliance will be monitored via the annual unannounced site visits of hospitals as part of their recertification. Post-discharge follow-up will continue to be provided by MCOs and providers eligible to deliver case management services.
	Summary of Actions Needed: Provider Manual will be updated by OMPP by Q2 2020. The State issued provider communication materials detailing the requirements on November 26, 2019.
2.c State requirement to ensure psychiatric hospitals and residential settings contact beneficiaries and community-based providers through most effective means possible, e.g., email, text, or phone call within 72 hours post discharge	*Current Status:* MCOs currently undertake the primary responsibility for assuring enrollees access follow-up care post-discharge. They are contractually required to schedule an outpatient follow-up appointment to occur no later than seven calendar days following an inpatient behavioral health hospitalization discharge. If a member misses an outpatient follow-up appointment, the MCO must ensure that a behavioral health provider or the MCO's case manager contacts that member within three business days of notification of the missed appointment. Additionally, Indiana Medicaid provides coverage for bridge appointments, which are follow-up appointments after inpatient hospitalization for behavioral health issues, when no outpatient appointment is available within seven days of discharge. The goal of the bridge appointment is to provide proper discharge planning while establishing a connection between the member and the outpatient treatment provider. During the bridge appointment, the provider ensures, at minimum, the following: • The member understands the medication treatment regimen as prescribed. • The member has ongoing outpatient care. • The family understands the discharge instructions for the member. • Barriers to continuing care are addressed. • Any additional questions from the member or family are answered.
	Future Status: Indiana Medicaid Provider Manual will be updated to explicitly require psychiatric hospitals have protocols in place to ensure contact is made by the treatment setting with each discharged beneficiary within 72 hours of discharge and follow-up care is accessed. Compliance will be monitored via the annual unannounced site visits of hospitals as part of their recertification.
	Summary of Actions Needed: Provider Manual will be updated by OMPP by Q2 2020. A provider bulletin detailing these requirements was published on November 26, 2019.
2.d Strategies to prevent or decrease lengths of stay in EDs	*Current Status:* MCOs are required to identify high utilizers of ED services and ensure members are coordinated and participating in the appropriate disease management or care management services. Any member with ED utilizations at least three standard deviations from the mean are referred to care coordination.

Prompts	Summary
among beneficiaries with SMI or SED prior to admission	*Future Status:* OMPP, in collaboration with its Provider Relations contractor, will monitor provider network capacity on an annual basis and identify underserved areas for targeted provider recruitment. Additionally, DMHA plans to pilot two Crisis Stabilization Units (CSU) in the northern and southern parts of the state. The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units. FSSA's OMPP, DMHA, and Division of Disability and Rehabilitative Services (DDRS) are partnering with the Department of Child Services (DCS) and Juvenile Justice agencies to explore piloting mobile response stabilization services (MRSS). MRSS would provide community-based crisis intervention including short term follow-up and support for the youth and family to prevent reescalation, emergency department utilization and/or inpatient admission.
	Summary of Actions Needed: OMPP will annually identify geographic shortage areas and Provider Enrollment will conduct targeted outreach to non-Medicaid enrolled providers in those areas. The CSU is proposed for implementation in SFY2020. The timeline for a potential MRSS is currently under review.
2.e Other State requirements/policies to improve care coordination and connections to community-based care	*Current Status:* Please refer to previous sections.
	Future Status: N/A
	Summary of Actions Needed: N/A
SMI/SED. Topic_3. Milestone 3: Increasing Access to Continuum of Care, Including Crisis Stabilization Services	
Adults with SMI and children with SED need access to a continuum of care as these conditions are often episodic and the severity of symptoms can vary over time. Increased availability of crisis stabilization programs can help to divert Medicaid beneficiaries from unnecessary visits to EDs and admissions to inpatient facilities as well as criminal justice involvement. On-going treatment in outpatient settings can help address less acute symptoms and help beneficiaries with SMI or SED thrive in their communities. Strategies are also needed to help connect individuals who need inpatient or residential treatment with that level of care as soon as possible. To meet this milestone, state Medicaid programs should focus on improving access to a continuum of care by taking the following actions.	
Access to Continuum of Care Including Crisis Stabilization	
3.a The state's strategy to conduct annual assessments of the availability of mental health providers including psychiatrists, other practitioners, outpatient, community mental health	*Current Status:* Indiana provides a comprehensive statewide service array inclusive of: • Outpatient behavioral health services currently delivered by providers across the State, as delineated in the attached Mental Health Services Availability Assessment Template. • Medicaid rehabilitation option (MRO) delivered by the State's 24 CMHCs. All 92 counties in Indiana have at least one CMHC delivering care in the geographical area and most counties in the state, other than very rural ones, have more than one CMHC offering services within a county.

Prompts	Summary
centers, intensive outpatient/partial hospitalization, residential, inpatient, crisis stabilization services, and FQHCs offering mental health services across the state, updating the initial assessment of the availability of mental health services submitted with the state's demonstration application. The content of annual assessments should be reported in the state's annual demonstration monitoring reports. These reports should include which providers have waitlists and what are average wait times to get an appointment	• Three 1915(i) programs serving individuals with behavioral health needs. • Expanded SUD services in accordance with the State's approved SUD waiver. • Partial hospitalization programs which are time-limited medical services intended to provide a transition from inpatient psychiatric hospitalization to community-based care or, in some cases, substitute for an inpatient admission. Indiana Administrative Code and DMHA contracts require CMHCs to provide a defined continuum of care directly, or through subcontract which includes: • Individualized treatment planning to increase patient coping skills and symptom management • 24/7 crisis intervention • Case management to fulfill individual patient needs, including assertive case management • Outpatient services, including intensive outpatient services, substance abuse services, counseling and treatment • Acute stabilization, including detoxification services • Residential services • Day treatment • Family support services • Medication evaluation and monitoring • Services to prevent unnecessary and inappropriate treatment and hospitalization and the deprivation of a person's liberty Further, House Enrolled Act 1175, passed in the 2019 legislative session, will expand access to behavioral health providers for Medicaid enrollees. Under this law, licensed clinical social workers, licensed mental health counselors, licensed clinical addiction counselors and licensed marriage and family therapists will be eligible providers for the supervision of a plan of treatment for a patient's outpatient mental health or substance abuse treatment services. Prior to this legislation, midlevel behavioral health practitioners were not eligible to independently enroll in Indiana Medicaid and were required to bill under the supervision of an HSPP or psychiatrist. Additionally, effective July 1, 2019, in accordance with the CMS approval of SPA TN 18-012, Indiana Medicaid expanded crisis intervention services, intensive outpatient program services and peer recovery services to all Indiana Medicaid programs; these services were previously limited to the MRO option. This change will expand the available provider base from the Indiana's CMHCs to all Medicaid enrolled providers meeting the applicable criteria.

Prompts	Summary
	OMPP and DMHA continually assess access and availability of behavioral health services. For example, in accordance with the State's approved §1915(b)(4) waivers for MRO services and §1915(i) programs, FSSA utilizes information gathered from analysis of Indiana's MMIS, site reviews, and recipient reports and complaints to evaluate the need to expand provider agencies and/or provide training and/or corrective actions to assist provider agencies in increasing efficiencies for timely access to services. When "timely access" is identified as a provider agency issue, the State uses a request for corrective action and provides technical assistance and training in order to assist the agency in correcting the issue. If the issue is not remediated satisfactorily, further sanctions are applied, up to and including decertification of the agency as an MRO or §1915(i) provider. Further, OMPP's Provider Relations contractor identifies underserved areas by calculating the ratio of providers to members by county. Recruiting efforts are intensified in counties that are identified as not meeting HRSA provider-to-member ratio standards. Utilizing the results of this analysis, the Provider Relations team outreaches to behavioral health providers not currently Medicaid enrolled. Provider Relations employs the following strategy to reach out to potential providers: ● Analyze the provider-to-population report to prioritize the geographic areas to be targeted. ● Analyze NPI reports to determine which specialties are underrepresented in the selected geographic region. ● Collaborate with residency programs to educate graduating classes about the benefits of providing services to the Medicaid population and encourage enrollment in Medicaid when residents graduate. ● Contact providers by telephone or via on-site visit. During the contact, Provider Relations will: ○ Invite the provider to consider Medicaid enrollment. ○ Explain the benefits of Medicaid enrollment. ○ Educate the provider regarding any misconceptions about Medicaid. ○ Mitigate the provider's objections. ○ Offer to make an on-site visit to discuss enrollment and help the provider complete the online enrollment application, if applicable. ○ Ascertain the reasons the provider chooses not to enroll, if applicable. Additionally, MCOs are contractually required to meet network adequacy standards for behavioral health providers in accordance with 42 CFR §438.68. Corrective action is implemented when standards are not met.

Prompts	Summary
	Future Status: OMPP will continue to monitor provider network capacity on an annual basis. Additionally, DMHA plans to pilot two Crisis Stabilization Units (CSU) in the northern and southern parts of the state. The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units. FSSA's OMPP, DMHA, and Division of Disability and Rehabilitative Services (DDRS) are partnering with the Department of Child Services (DCS) and Juvenile Justice agencies to explore piloting mobile response stabilization services (MRSS). MRSS would provide community-based crisis intervention including short term follow-up and support for the youth and family to prevent reescalation, emergency department utilization and/or inpatient admission.
	Summary of Actions Needed: OMPP will annually identify geographic shortage areas and Provider Enrollment will conduct targeted outreach to non-Medicaid enrolled providers in those areas. The CSU is proposed for implementation in SFY2020. The timeline for MRSS is currently under review.
3.b Financing plan	*Current Status:* Please refer to Financing Plan below.
	Future Status: Please refer to Financing Plan below.
	Summary of Actions Needed: Please refer to Financing Plan below.
3.c Strategies to improve state tracking of availability of inpatient and crisis stabilization beds	*Current Status:* In March 2018, FSSA implemented a new tool to help Hoosiers seeking treatment for SUD immediately connect with available inpatient or residential treatment services. This new tool is made possible by a partnership between the State, OpenBeds, a software platform that manages health services, and Indiana 2-1-1, a non-profit organization that provides health care and other resource referrals to those in need. This service allows treatment facilities to list their vacancies in a real-time, broadly connected database and offers a comprehensive suite of information technology functionalities specific to mental health and SUD, and provides capability for: • Transparency regarding the capacity of inpatient services, including recovery housing and community services, to provide an immediate and accurate inventory of available resources • Secure and HIPAA-compliance digital communication for referrals with email and text notifications, including the ability to transmit client data, along with consent • Digital registration and authentication for health systems and organizations • Real-time analytics to track utilization and referral patterns across the region • Patient marketplace or "pull referral" functionality to expedite patient placement • Mobile platform

Prompts	Summary
	Future Status: FSSA is currently in the process of expanding use of OpenBeds beyond SUD to include tracking availability of psychiatric inpatient and crisis stabilization beds.
	Summary of Actions Needed: Expansion of OpenBeds contract in Fall 2019 to include psychiatric bed capacity.
3.d State requirement that providers use a widely recognized, publicly available patient assessment tool to determine appropriate level of care and length of stay	*Current Status:* Every individual served by a DMHA contracted provider receives a Child and Adolescent Needs and Strengths (CANS) or Adult Needs and Strengths Assessment (ANSA) to inform individualized treatment planning and level of care decision making. Individuals are reassessed every six months with adjustments to level of care and/or treatment plan being made accordingly. Further, as stated in Indiana Administrative Code 405 IAC 5-21.5, IHCP reimbursement for MRO services is available for members who meet specific diagnosis and level of need (LON) criteria under the approved DMHA assessment tool (ANSA or CANS). Additional MRO services beyond what is available for the assigned service package may be added with prior authorization (PA). MRO services are clinical behavioral health services provided to members and families of members living in the community who need aid intermittently for emotional disturbances, mental illness, and addiction. The CANS/ANSA also inform individual service needs and level of care that could include inpatient and/or residential services. In addition to use of the CANS and ANSA, determinations of medical necessity for behavioral health services are based on utilization management criteria implementation by the State's MCOs and utilization management vendor.
	Future Status: N/A
	Summary of Actions Needed: N/A
Other state requirements/policies to improve access to a full continuum of care including crisis stabilization	*Current Status:* Please refer to previous sections.
	Future Status: N/A
	Summary of Actions Needed: N/A
SMI/SED. Topic_4. Milestone 4: Earlier Identification and Engagement in Treatment, Including Through Increased Integration	
Critical strategies for improving care for individuals with SMI or SED include earlier identification of serious mental health conditions and focused efforts to engage individuals with these conditions in treatment sooner. To meet this milestone, state Medicaid programs must focus on improving mental health care by taking the following actions.	
Earlier Identification and Engagement in Treatment	
	Current Status: The Vocational Rehabilitation Services (VRS) is a program of FSSA's Division of Disability and Rehabilitative Services (DDRS). VRS are available statewide, in all regions of the state. Eligibility for

Prompts	Summary
4.a Strategies for identifying and engaging beneficiaries with or at risk of SMI or SED in treatment sooner, e.g., with supported education and employment	VRS is determined in accordance with federal requirements at 34 CFR 361.42(a). Accordingly, eligibility for VRS includes a determination that an applicant meets the following conditions: • Has a physical or mental impairment • This impairment constitutes or results in a substantial impediment to employment • VRS are required to prepare for, enter, engage in, or retain an employment outcome consistent with his or her abilities, capacities, career interests, and informed choice. Additionally, all applicants determined eligible for Social Security for Social Security Disability (SSDI) or Supplemental Security Income (SSI) are presumed eligible for VRS. Individuals receiving VRS have an Individualized Plan for Employment (IPE) based on the requirements at 34 CFR 361.45, following an assessment for determining vocational rehabilitation needs. VRS are provided in accordance with the IPE and may include: • Vocational counseling and guidance • Medical treatment to correct or modify the physical or mental impairment • Training (including vocational school, college or university, on-the-job, and other training) • Rehabilitation technology (assistive devices and services) • Placement assistance and follow-up (including supported employment) • Other planned goods and services determined to be necessary to address an identified substantial impediment to employment and to be required to enable the individual to prepare for, enter, engage in, or retain an employment outcome Supportive employment (SE) is available as a VRS. Through this service, individuals with the most severe disabilities are placed in competitive jobs with qualified job coaches/trainers to provide individualized, ongoing support services needed for each individual to retain employment. The employer is contacted monthly and the employee is visited twice monthly, either at or away from the workplace, to address any issues that may threaten the individual's ability to remain on the job. Additionally, several of Indiana's CMHCs provide supportive employment services, an evidence-based service to promote rehabilitation and return to productive employment for persons with serious mental illness. These programs use a team approach for treatment, with employment specialists responsible for carrying out all vocational services from intake through follow-along. Job placements are: community-based (i.e., not sheltered workshops, not onsite at SE or other treatment agency offices), competitive (i.e., jobs are not exclusively reserved for SE clients, but open to public), in normalized settings, and utilize multiple employers. The SE team has a small client to staff ratio. SE contacts occur in the home, at the job site, or in the community. The SE team is assertive in engaging and retaining clients in treatment, especially utilizing face-to-face community

Prompts	Summary
	visits, rather than phone or mail contacts. The SE team consults/works with family and significant others when appropriate. SE services are frequently coordinated with Vocational Rehabilitation benefits.
	Future Status: Continued operation of current programming.
	Summary of Actions Needed: N/A
4.b Plan for increasing integration of behavioral health care in non-specialty settings to improve early identification of SED/SMI and linkages to treatment	*Current Status:* In 2012, FSSA in partnership with the Indiana State Department of Health (ISDH) launched the Primary Care and Behavioral Health Integration (PCBHI) initiative, to develop a statewide strategic plan to integrate primary and behavioral health care services in Indiana. As an outgrowth of this initiative, the State was awarded the SAMHSA and National Association of State Mental Health Program Directors (NASHMHPD) Transformation Transfer Initiative (TTI) Grant which allowed the State to implement a series of initiatives aimed at increased integration. Additionally, a process was established by which Community Mental Health Centers (CMHCs), Federally Qualified Health Centers (FQHCs), Community Health Centers (CHCs) and Rural Health Clinics (RHCs) could become a state certified integrated care entity (ICE). Currently, there are 13 ICE sites operating within the State. ICE core requirements include: • Core assessments for behavioral and physical health • Integrated care plans • Interdisciplinary team meetings • Real-time physician/pharmacy consults • Leadership support • Evidence based practice and training • Electronic health records and data sharing • Quality outcome measures The State has also focused on school-based initiatives to increase behavioral health integration. For example, CMHCs across the State work in close collaboration with Indiana schools. Currently, 85% of school districts have CMHCs providing services within their schools. Additionally, DMHA released an RFP in June 2019 to contract with no more than three regionally diverse social services providers to implement an evidence-based program that partners with school corporations, charter schools, and accredited nonpublic schools to provide social work services and evidence-based prevention programs to children, parents, caregivers, teachers, and the community to prevent substance abuse, promote healthy behaviors, and maximize student success. Further, the MCOs are contractually required to plan for, develop and/or enhance relationships with school-based health centers (SBHC) with the goal of providing accessible services to school-aged enrolled members.

Prompts	Summary
	SBHCs provide on-site comprehensive preventive and primary health services including behavioral health, oral health, ancillary and enabling services. Additionally, Indiana encourages the integration of primary and behavioral health care services through the use of an alternative payment methodology (APM) for federally qualified health centers (FQHCs) which consists of: (1) an adjustment to the FQHC's prospective payment system (PPS) rate; and (2) performance incentive payments limited to an established annual amount for each participating FQHC. To qualify for an APM, the FQHC must implement a care plan that fully integrates primary care and behavioral health at the FQHC through an integration plan approved by OMPP and DMHA which includes the following components: • Incorporation of screening and evaluation processes to identify targeted patient population • Establishment of appropriate levels of behavioral health staffing • Physical integration of the provision of primary and behavioral health care together at the same FQHC location • Performance of medical and behavioral health care services by the staff at the FQHC • Full integration of medical records, billing and other data relating to primary and behavioral health care services • Ongoing monitoring of the integration plan through data collection and evaluation
	Future Status: The State will ensure the financial sustainability of a physical health and behavioral health integration model following the end of the current grant funding.
	Summary of Actions Needed: OMPP, in partnership with DMHA is pursuing options for sustainability and expansion of the State's model for primary care and behavioral health integration. DMHA is submitting an application for SAMHSA's (FY) 2020 Promoting Integration of Primary and Behavioral Health Care (Short Title: PIPBHC) grant and OMPP is exploring implementation of a health homes state plan amendment in 2021.
F4.c Establishment of specialized settings and services, including crisis stabilization, for young people experiencing SED/SMI	*Current Status:* The State's review of the crisis continuum confirmed the following crisis services are being provided in addition to the CMHC mandated 24/7 crisis services: mobile crisis teams (5), assertive community treatment (ACT) (6), 23-hour crisis stabilization units (7), short-term crisis residential (2) and peer crisis services (2).
	Future Status: DMHA plans to pilot two Crisis Stabilization Units (CSU) in the northern and southern parts of the state. The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units. FSSA's OMPP, DMHA, and Division of Disability and Rehabilitative Services (DDRS) are partnering with the Department of Child Services (DCS) and Juvenile Justice agencies to explore piloting mobile response stabilization services (MRSS). MRSS would provide community-based crisis intervention including short term

Prompts	Summary
	follow-up and support for the youth and family to prevent reescalation, emergency department utilization and/or inpatient admission.
	Summary of Actions Needed: The CSU is proposed for implementation in SFY2020. The timeline for MRSS is currently under review.
4.d Other state strategies to increase earlier identification/engagement, integration, and specialized programs for young people	*Current Status:* Please refer to previous sections.
	Future Status: N/A
	Summary of Actions Needed: N/A
SMI/SED.Topic_5. Financing Plan	
te Medicaid programs should detail plans to support improved availability of non-hospital, non-residential mental health services including crisis stabilization and on-going community-based care. The financing plan should describe state efforts to increase access to community-based mental health providers for Medicaid beneficiaries throughout the state, including through changes to reimbursement and financing policies that address gaps in access to community-based providers identified in the state's assessment of current availability of mental health services included in the state's application.	
F.a Increase availability of non-hospital, non-residential crisis stabilization services, including services made available through crisis call centers, mobile crisis units, observation/assessment centers, with a coordinated community crisis response that involves collaboration with trained law enforcement and other first responders.	*Current Status:* The State's review of the crisis continuum confirmed the following crisis services are being provided in addition to the CMHC mandated 24/7 crisis services: mobile crisis teams (5), assertive community treatment (ACT) (6), 23-hour crisis stabilization units (7), short-term crisis residential (2) and peer crisis services (2). Effective July 1, 2019, in accordance with the CMS approval of SPA TN 18-012, Indiana Medicaid expanded crisis intervention services, intensive outpatient program services and peer recovery services to all Indiana Medicaid programs; these services were previously limited to the MRO option. This change will expand the available provider base from the Indiana's CMHCs to all Medicaid enrolled providers meeting the applicable criteria.
	Future Status: The State will annually monitor access to non-residential crisis stabilization services through an agreed upon methodology. In addition, the State will encourage and support non-CMHC providers to increase access to intensive outpatient, peer support and crisis intervention services. DMHA plans to pilot two Crisis Stabilization Units (CSU) in the northern and southern parts of the state. The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units. FSSA's OMPP, DMHA, and Division of Disability and Rehabilitative Services (DDRS) are partnering with the Department of Child Services (DCS) and Juvenile Justice agencies to explore piloting mobile response

Prompts	Summary
	stabilization services (MRSS). MRSS would provide community-based crisis intervention including short term follow-up and support for the youth and family to prevent reescalation, emergency department utilization and/or inpatient admission.
	Summary of Actions Needed: The CSU is proposed for implementation in SFY2020. The timeline for MRSS is currently under review.
F.b Increase availability of on-going community-based services, e.g., outpatient, community mental health centers, partial hospitalization/day treatment, assertive community treatment, and services in integrated care settings such as the Certified Community Behavioral Health Clinic model.	*Current Status:* As described throughout this template, and as outlined in the attached "Overview of the Assessment of the Availability of Mental Health Services" template, Indiana offers a comprehensive continuum of community-based services. Effective July 1, 2019, in accordance with the CMS approval of SPA TN 18-012, Indiana Medicaid expanded crisis intervention services, intensive outpatient program services and peer recovery services to all Indiana Medicaid programs; these services were previously limited to the MRO option. This change will expand the available provider base from the Indiana's CMHCs to all Medicaid enrolled providers meeting the applicable criteria.
	Future Status: The State will annually monitor access to community-based services through an agreed upon methodology. In addition, the State will specifically monitor any changes to non-CMHC providers and the impact on access to intensive outpatient, peer support and crisis intervention services.
	Summary of Actions Needed: OMPP will annually identify geographic shortage areas and Provider Enrollment will conduct targeted outreach to non-Medicaid enrolled providers in those areas.

<table>
<tr><th>Prompts</th><th>Summary</th></tr>
<tr><td colspan="2">SMI/SED. Topic_6. Health IT Plan</td></tr>
<tr><td colspan="2">outlined in State Medicaid Director Letter (SMDL) #18-011, “[s]tates seeking approval of an SMI/SED demonstration … will be expected to submit a Health IT Plan (“HIT Plan”) that describes the state’s ability to leverage health IT, advance health information exchange(s), and ensure health IT interoperability in support of the demonstration’s goals.”[6] The HIT Plan should also describe, among other items, the:
• Role of providers in cultivating referral networks and engaging with patients, families and caregivers as early as possible in treatment; and
• Coordination of services among treatment team members, clinical supervision, medication and medication management, psychotherapy, case management, coordination with primary care, family/caregiver support and education, and supported employment and supported education.
ease complete all Statements of Assurance below—and the sections of the Health IT Planning Template that are relevant to your state’s demonstration proposal.</td></tr>
<tr><td colspan="2">Statements of Assurance</td></tr>
<tr><td>Statement 1: Please provide an assurance that the state has a sufficient health IT infrastructure/ecosystem at every appropriate level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration. If this is not yet the case, please describe how this will be achieved and over what time period</td><td>As outlined in Indiana’s State Medicaid Health Information Technology Plan (SMHP), Indiana’s HIT environment is active with multi-faceted efforts to support provider HIT capacity and foster the sharing of clinical and administrative data to improve health care and support system improvements. The State has taken an active role through its state health agencies and Medicaid program to promote HIT adoption and HIE development, building upon its private health care marketplace.

As outlined in the table below, the State is home to four well-established health information exchange networks operated by Health Information Organizations (HIOs), each functioning in different capacities for community partners.

<table>
<tr><th>Regional HIO</th><th>June 2019 Status</th></tr>
<tr><td>HealthBridge (includes greater Cincinnati tristate area)</td><td>Utilization of the Health Collaborative’s HealthBridge Suite (hb/suite):
• 58 hospitals
• 8,901 providers
• 160 million clinical results processed
• 15 million monthly messages</td></tr>
<tr><td>HealthLINC</td><td>• Delivers more than 175,000 medical results per month among hospitals, office and clinic practices and under-served clinics
• Health service directory that includes more than 350 physicians and other providers</td></tr>
</table>
</td></tr>
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[6] See SMDL #18-011, “Opportunities to Design Innovative Service Delivery Systems for Adults with a Serious Mental Illness or Children with a Serious Emotional Disturbance.” Available at https://www.medicaid.gov/federal-policy-guidance/downloads/smd18011.pdf.

<table>
<tr><th>Prompts</th><th>Summary</th></tr>
<tr><td></td><td>
<table>
<tr><td>Indiana Health Information Exchange (IHIE)</td><td>• Connection to 117 hospitals representing 38 health systems
• Over 17,055 practices
• Over 47,452 providers
• Over 14,847,271 patients
• Over 12,510,420,163 clinical data elements</td></tr>
<tr><td>Michiana Health Information Network (MHIN)</td><td>• Over 576 data sources
• 3.9 million transactions inbound per month
• 20,304 providers connected</td></tr>
</table>

However, a March 2019 assessment of Indiana's health information sharing (HIS), conducted based on capability maturity guidance from CMS and the Office of the National Coordination for Health Information Technology (ONC), revealed opportunities for increased electronic documentation and standardization among settings and providers not previously addressed through Meaningful Use, including behavioral health providers. Through this HIT Plan, the State intends to drive improvements in this area.
</td></tr>
<tr><td>Statement 2: Please confirm that your state's SUD Health IT Plan is aligned with the state's broader State Medicaid Health IT Plan and, if applicable, the state's Behavioral Health IT Plan. If this is not yet the case, please describe how this will be achieved and over what time period.</td><td>This HIT Plan is aligned with the State's broader State Medicaid Health IT Plan (SMHP). The State is in the process of completing an updated SMHP with targeted completion by the end of calendar year 2019. Through this update process, areas of prioritization will take into consideration the milestones of this waiver.</td></tr>
<tr><td>Statement 3: Please confirm that the state intends to assess the applicability of standards referenced in the Interoperability Standards Advisory (ISA)[7] and 45 CFR 170 Subpart B and, based on that assessment, intends to include them as appropriate in</td><td>Indiana will review the applicability of standards referenced in the Interoperability Standards Advisory (ISA) and 45 CFR 170 Subpart B for potential inclusion into our MCO contracts. The following standards are currently utilized by our MCOs:
• Documenting and Sharing Care Plans – The MCOs are contractually obligated to share care plans with primary medical providers (PMPs) and behavioral health providers with appropriate consent.
• The MCOs have agreements with health information exchanges, such as the Indiana Health Information Exchange (IHIE) and the Michiana Health Information Network (MHIN).</td></tr>
</table>

[7] Available at https://www.healthit.gov/isa/.

Prompts	Summary
subsequent iterations of the state's Medicaid Managed Care contracts. The ISA outlines relevant standards including but not limited to the following areas: referrals, care plans, consent, privacy and security, data transport and encryption, notification, analytics and identity management.	• Clinical Quality Measurement and Reporting – The MCEs report on the following HEDIS quality measures related to behavioral health: o Follow-up care for children prescribed ADHD medication, initiation phase o Follow-up care for children prescribed ADHD medication, maintenance phase o 30-day follow-up after hospitalization for mental illness o 7-day follow-up after hospitalization for mental illness o Use of multiple concurrent antipsychotics in children and adolescents up to age 17 o Use of first-line psychosocial care for children/adolescents on antipsychotics up to age 17 o Antidepressant medication management, acute phase o Antidepressant medication management, continuation phase o 30-day follow-up after emergency department (ED) visit for mental illness o 7-day follow-up after ED visit for mental illness
To assist states in their health IT efforts, CMS released SMDL #16-003 which outlines enhanced federal funding opportunities available to states "for state expenditures on activities to promote health information exchange (HIE) and encourage the adoption of certified Electronic Health Record (EHR) technology by certain Medicaid providers." For more on the availability of this "HITECH funding," please contact your CMS Regional Operations Group contact. [8] *Enhanced administrative match may also be available under MITA 3.0 to help states establish crisis call centers to connect beneficiaries with mental health treatment and to develop technologies to link mobile crisis units to beneficiaries coping with serious mental health conditions. States may also coordinate access to outreach, referral, and assessment services—for behavioral health care--through an established "No Wrong Door System."*[9]	
Closed Loop Referrals and e-Referrals (Section 1)	
1.1 Closed loop referrals and e-referrals from physician/mental health provider to physician/mental health provider	*Current State:* The State does not have readily accessible data on the exact number of Medicaid-enrolled behavioral health providers who have adopted certified EHRs and are utilizing them for e-referrals and/or closed loop referrals. With multiple HIEs and large health systems that have been able to exchange effectively via EHR and prescription software vendors, it is difficult to accurately assess participation. Each HIE is able to easily report on its participants but the extent to which non-participating organizations are identified and assessed individually is meticulous work. It is known that certain hospital, facility, and provider types that were not eligible for Meaningful Use (Promoting Interoperability) are not participating due to lagging technology and/or regulatory barriers, such as with CFR 42 Part 2.

[8] See SMDL #16-003, "Availability of HITECH Administrative Matching Funds to Help Professionals and Hospitals Eligible for Medicaid EHR Incentive Payments Connect to Other Medicaid Providers." Available at https://www.medicaid.gov/federal-policy-guidance/downloads/smd16003.pdf.
[9] Guidance for Administrative Claiming through the "No Wrong Door System" is available at https://www.medicaid.gov/medicaid/finance/admin-claiming/no-wrong-door/index.html.

Prompts	Summary
	The aforementioned March 2019 HIS Assessment did reveal provider tracking of referrals may be facilitated by tools within the EHR but most still struggle with closing the referral loop.
	Future State: The State will conduct a survey to identify the volume of providers utilizing closed loop referrals and e-referrals to identify the baseline of current activity and identify options for increasing provider uptake.
	Summary of Actions Needed: The provider survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
1.2 Closed loop referrals and e-referrals from institution/hospital/clinic to physician/mental health provider	*Current State:* The State does not have readily accessible data on the exact number of Medicaid-enrolled behavioral health providers who have adopted certified EHRs and are utilizing them for e-referrals and/or closed loop referrals. The aforementioned March 2019 HIS Assessment did reveal provider tracking of referrals may be facilitated by tools within the EHR but most still struggle with closing the referral loop.
	Future State: The State will conduct a survey to identify the volume of providers utilizing closed loop referrals and e-referrals to identify the baseline of current activity and identify options for increasing provider uptake.
	Summary of Actions Needed: The provider survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
1.3 Closed loop referrals and e-referrals from physician/mental health provider to community based supports	*Current State:* The State does not have readily accessible data on the exact number of Medicaid-enrolled behavioral health providers who have adopted certified EHRs and are utilizing them for e-referrals and/or closed loop referrals. The aforementioned March 2019 HIS Assessment did reveal provider tracking of referrals may be facilitated by tools within the EHR but most still struggle with closing the referral loop.
	Future State: The State will conduct a survey to identify the volume of providers utilizing closed loop referrals and e-referrals to identify the baseline of current activity and identify options for increasing provider uptake.
	Summary of Actions Needed: The provider survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
Electronic Care Plans and Medical Records (Section 2)	
2.1 The state and its providers can create and use an electronic care plan	*Current State:* The aforementioned March 2019 HIS Assessment revealed that while electronic care plans are utilized they are not standardized. HIEs receive what the provider delivers via continuity of care documents (CCD) but content and format are variable.
	Future State: The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. Additionally, FSSA will survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.
	Summary of Actions Needed: FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. The IMD survey will be conducted by FSSA. The dates for

Prompts	Summary
	completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
2.2 E-plans of care are interoperable and accessible by all relevant members of the care team, including mental health providers	*Current State:* Indiana contracts with the Indiana Health Information Exchange (IHIE) to aggregate Medicaid claims with medical and pharmacy data in its repository to create a continuity of care (CCD) record that can be shared between Medicaid providers. The aforementioned March 2019 HIS Assessment indicates some MCOs and providers are receiving admit-discharge-transfer (ADT), CCDs or other clinical data points and incorporating directly into their work flow for care coordination and quality management. Additionally, the majority of community mental health centers have certified EHRs and utilize Viewpoint, a referral portal, to communicate among entities.
	Future State: As previously described, OMPP is exploring submitting a health homes state plan amendment. A key component of this initiative will include leveraging HIT for enhanced integration and coordination. OMPP is currently in the process of developing HIT standards and requirements for participating providers. Additionally, the State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. FSSA will also survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.
	Summary of Actions Needed: OMPP is exploring submitting a health homes state plan amendment with an implementation date by 2021. FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. The IMD survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
2.3 Medical records transition from youth-oriented systems of care to the adult behavioral health system through electronic communications	*Current State:* State psychiatric hospitals utilize one EHR system which permits tracking of records as youth transition to adulthood.
	Future State: The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. Additionally, FSSA will survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.
	Summary of Actions Needed: FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. The IMD survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
2.4 Electronic care plans transition from youth-oriented systems of care to the adult behavioral health system through electronic communications	*Current State:* State psychiatric hospitals utilize one EHR system which permits tracking of care plans as youth transition to adulthood.
	Future State: The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. FSSA will also survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.

Prompts	Summary
	Summary of Actions Needed: FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. The IMD survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.

2.5 Transitions of care and other community supports are accessed and supported through electronic communications	*Current State:* In 2017, DMHA released an RFP to procure a new EHR system to be used collectively by all state psychiatric hospitals. The State's expectation is that a modern EHR will facilitate interoperability. The required HIE functionality put forth in FSSA's statement of work for this project include:
	• Admission, discharge and transfer (ADT) and census
	  o Collecting and updating patient demographic information, family contact data, alerts, insurance coverage, management of room and bed, census activities, and leave-of-absence
	  o Fully integrating the aforementioned data across the other core functions
	• Clinical documentation: Includes assessments, treatment, treatment plans, and nursing care plans, including, but not limited to, historical patient data, patient risk criteria, electronic document system capturing interdisciplinary Plans of Care and reporting, automated work lists, clinical decision support, and patient education tracking. The system must support multiple modes of data entry including, but not limited to, template notes, third-party dictation, and voice recognition. This also includes fully integrating this data across the other core functions.
	• Interfaces, data sharing and interoperability:
	  o Using common standards and implementation specifications for electronic exchange of information in accordance with MU Stage 2 guidance.
	  o Actual electronic exchange of clinical information with acute care hospitals, CMHCs, Public Health registries, LTC facilities, private practitioners, pharmacies, correctional facilities, judicial bodies, laboratories, and healthcare payers (e.g., Medicaid, Medicare, commercial insurance, Social Security Administration [SSA], private pay, etc.)
	• Case management: Functionality includes, but is not limited to, the ability for designated staff to track, manage, document, and receive alerts for case management activities.
	
	Having the State Psychiatric Hospitals interface with an HIE will give the Medicaid providers operating within the SPHs the capability to exchange health information with adjacent acute care facilities/hospitals, CMHCs, and other healthcare partners along the continuum of care. This specifically will allow Medicaid providers the capability to meet MU stage 3. More specifically the SPHs will be capable of bi-directionally exchanging summary of care records and CCDs when referring or receiving a Medicaid patient to or from another care setting. In addition, SPHs interfacing with the HIE will be capable of sending and receiving ADT notifications. These activities allow Medicaid providers within the SPHs to fulfill the objectives and enables them to report measures in accordance with MU stage 3 for HIE.

Prompts	Summary
	Future State: FSSA will survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.
	Summary of Actions Needed: The IMD survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
Consent - E-Consent (42 CFR Part 2/HIPAA) (Section 3)	
3.1 Individual consent is electronically captured and accessible to patients and all members of the care team, as applicable, to ensure seamless sharing of sensitive health care information to all relevant parties consistent with applicable law and regulations (e.g., HIPAA, 42 CFR part 2 and state laws)	*Current State:* Consent/privacy is managed in a multitude of mechanisms across the Medicaid Health Information Sharing Enterprise, many still very manual, non-standardized and not electronically transmitted. HIEs rely on the participants to manage what information is delivered to them. Substance abuse disorder laws (42 CFR Part 2) require explicit patient consent and therefore typically are only shared in a one-off manual manner. Consent, segregation of highly sensitive records, and secure transport are difficult to implement and manage and therefore infrequently done electronically. Indiana is an opt-out state for HIE. Responsibility is on provider to communicate with patients. Patient data can be shared with HIE unless the patient explicitly requests it not to be.
	Future State: To be determined based on prioritization of initiatives during the aforementioned SMHP update process.
	Summary of Actions Needed: To be determined based on prioritization of initiatives during the aforementioned SMHP update process.
Interoperability in Assessment Data (Section 4)	
4.1 Intake, assessment and screening tools are part of a structured data capture process so that this information is interoperable with the rest of the HIT ecosystem	*Current State:* Within the integrated care entities (ICE), core assessments and adjudicated Medicaid claims data are aggregated and available via the Relias ProAct Tool. This tool exclusively houses Medicaid patients and an external facing interface is provided for each ICE and applies 400+ measures to Medicaid claims and non-claims data. It provides individual patient history, as well as population demographics and associated costs of diagnoses, medications and utilization.
	Future State: The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule.
	Summary of Actions Needed: FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly.
Electronic Office Visits – Telehealth (Section 5)	
5.1 Telehealth technologies support collaborative care by facilitating broader availability of integrated mental health care and primary care	*Current State:* Indiana received $16 million from the Federal Communications Commission's (FCC's) Rural Health Care Pilot Program, and as a result, created the Indiana Telehealth Network (ITN). ITN formed an FCC Rural Health Care Steering Committee, which was made up of representatives from healthcare providers, telecommunication companies, representatives from the Indiana Office of Community & Rural Affairs, and representatives from the Indiana Rural Health Association, the lead entity for the ITN. The five-year project was divided into three phases and the work successfully concluded in 2015. The table below presents a summary of the project phases.

<table>
<tr><th>Prompts</th><th>Summary</th></tr>
<tr><td></td><td>
<table>
<tr><th>Phase 1</th><th>Phase 2</th><th>Phase 3</th></tr>
<tr><td>• Reduced bandwidth costs
• Reduced Primary Rate Interface (PRI) costs
• Doubled the speed of existing broadband connections
• 85% funding for construction of fiber to their hospitals
• Completed ability to transmit images
• Improved economic opportunities</td><td>• Expanded ability to conduct Telehealth encounters over a dedicated health care network
• Disaster Recovery
• E-Learning
• Internet Access
• Videoconferencing</td><td>• Seamless interfaces with the Indiana Health Information Organizations (HIOs)</td></tr>
</table>

As of December 2016, ITN’s healthcare participants included 153 critical access hospitals, rural hospitals, urban partner hospitals, rural health clinics, urban partner hospitals, rural health clinics, federally qualified health centers, community mental health centers and data centers.

Additionally, as part of the 21st Century Cures Act, a portion of Indiana’s awarded funding is being utilized to implement Project-ECHO-Extension for Community Healthcare Outcomes. The primary goal of ECHO is to enable rural and traditionally underserved populations to receive high-quality care, when they need it, close to home. This low-cost, high-impact intervention is achieved by leveraging technology to connect expert mentors and multiple local primary care providers in online video-conferencing TeleECHO clinics.

Future State: Continued operation of current programing.

Summary of Actions Needed: N/A</td></tr>
<tr><td>Alerting/Analytics (Section 6)</td><td></td></tr>
<tr><td rowspan="3">6.1 The state can identify patients that are at risk for discontinuing engagement in their treatment, or have stopped engagement in their treatment, and can notify their care teams in order to ensure treatment continues or resumes (Note:</td><td>Current State: Some providers may have this capability, but the current volume is unknown.</td></tr>
<tr><td>Future State: As previously described, OMPP is exploring submitting a health homes state plan amendment. A key component of this initiative will include leveraging HIT for enhanced integration and coordination. OMPP is currently in the process of developing HIT standards and requirements for participating providers.</td></tr>
<tr><td>Summary of Actions Needed: OMPP is exploring submitting a health homes state plan amendment with implementation by 2021.</td></tr>
</table>

Prompts	Summary
research shows that 50% of patients stop engaging after 6 months of treatment[10])	
6.2 Health IT is being used to advance the care coordination workflow for patients experiencing their first episode of psychosis	*Current State:* Some providers may have this capability, but the current volume is unknown.
	Future State: As previously described, OMPP is exploring submitting a health homes state plan amendment, with implementation 2021. A key component of this initiative will include leveraging HIT for enhanced integration and coordination. OMPP is currently in the process of developing HIT standards and requirements for participating providers.
	Summary of Actions Needed: OMPP is exploring submitting a health homes state plan amendment by the end of 2020 with implementation by 2021.
Identity Management (Section 7)	
7.1 As appropriate and needed, the care team has the ability to tag or link a child's electronic medical records with their respective parent/caretaker medical records	*Current State:* The State's eligibility and enrollment system can link children and parents on the same case.
	Future State: To be determined based on prioritization of initiatives during the aforementioned SMHP update process.
	Summary of Actions Needed: To be determined based on prioritization of initiatives during the aforementioned SMHP update process.
7.2 Electronic medical records capture all episodes of care, and are linked to the correct patient	*Current State:* The aforementioned March 2019 assessment of Indiana's HIS indicates patient/client identification is inconsistent between entities. Patient matching is an issue for all entities. Health systems employ entire departments to deal with multiple issues surrounding the record integrity that include duplicate records or documenting on the wrong patient record. Resolving a merged record and identifying who may have received erroneous information may take many hours of work per case. Additionally, Indiana is currently participating in the National Governor's Association "Harnessing the Power of Data to Achieve State Policy Goals: The Foundation for State Success in Improving Quality and Reducing Costs" initiative, intended to address governance, cross-sector data sharing and systems capabilities.
	Future State: The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule.
	Summary of Actions Needed: FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly.

[10] Interdepartmental Serious Mental Illness Coordinating Committee. (2017). *The Way Forward: Federal Action for a System That Works for All People Living With SMI and SED and Their Families and Caregivers*. Retrieved from https://www.samhsa.gov/sites/default/files/programs_campaigns/ismicc_2017_report_to_congress.pdf

Section 3: Relevant documents

Please provide any additional documentation or information that the state deems relevant to successful execution of the implementation plan. This information is not meant as a substitute for the information provided in response to the prompts outlined in Section 2. Instead, material submitted as attachments should support those responses.

Attachment G: SMI Monitoring Protocol

Medicaid Section 1115 Serious Mental Illness and Serious Emotional Disturbance Demonstrations Monitoring Protocol Template

Note: PRA Disclosure Statement to be added here

1. Title page for the state's serious mental illness and serious emotional disturbance (SMI/SED) demonstration or the SMI/SED component of the broader demonstration

The state should complete this title page as part of its SMI/SED monitoring protocol. This form should be submitted as the title page for all monitoring reports. The content of this table should stay consistent over time. Definitions for certain rows are below the table.

State	Indiana
Demonstration name	Healthy Indiana Plan and the Serious Mental Illness Amendment
Approval period for section 1115 demonstration	01/01/2021-12/31/2025
SMI/SED demonstration start date[a]	01/01/2021
Implementation date of SMI/SED demonstration, if different from SMI/SED demonstration start date[b]	01/01/2020
SMI/SED (or if broader demonstration, then SMI/SED - related) demonstration goals and objectives	1. Reduced utilization and length of stay in emergency departments (EDs) among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment in specialized settings; 2. Reduced preventable readmissions to acute care hospitals and residential settings; 3. Improved availability of crisis stabilization services, including services made available through call centers and mobile crisis units, intensive outpatient services, as well as services provided during acute short-term stays in residential crisis stabilization programs, psychiatric hospitals, and residential treatment settings throughout the state; 4. Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI/SED, including through increased integration of primary and behavioral health care; and 5. Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities.

[a] **SMI/SED demonstration start date:** For monitoring purposes, CMS defines the start date of the demonstration as the *effective date* listed in the state's STCs at time of SMI/SED demonstration approval. For example, if the state's STCs at the time of SMI/SED demonstration approval note that the SMI/SED demonstration is effective January 1, 2020 – December 31, 2025, the state should consider January 1, 2020 to be the start date of the SMI/SED demonstration. Note that the effective date is considered to be the first day the state may begin its SMI/SED demonstration. In many cases, the effective date is distinct from the approval date of a demonstration; that is, in certain cases, CMS may approve a section 1115 demonstration with an effective date that is in the future. For example, CMS may approve an extension request on 12/15/2020, with an effective date of 1/1/2021 for the new demonstration period. In many cases, the effective date also differs from the date a state begins implementing its demonstration.

[b] **Implementation date of SMI/SED demonstration:** The date the state began claiming federal financial participation for services provided to individuals in institutions of mental disease.

2. Acknowledgement of narrative reporting requirements

☒ The state has reviewed the narrative questions in the Monitoring Report Template provided by CMS and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested narrative information (with no modifications).

3. Annual Assessment of the Availability of Mental Health Services reporting

☒ The state will use data as of the following month and day of each calendar year to conduct its Annual Assessment of the Availability of Mental Health Services: **February 1. Data will reflect 02/01-01/31 annually.**

4. Acknowledgement of budget neutrality reporting requirements

☒ The state has reviewed the Budget Neutrality Workbook provided by the CMS demonstration team and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested budget neutrality information (with no modifications).

5. Retrospective reporting

The state is not expected to submit metrics data until after monitoring protocol approval, to ensure that data reflects the monitoring plans agreed upon by CMS and the state. Prior to monitoring protocol approval, the state should submit quarterly and annual monitoring reports with narrative updates on implementation progress and other information that may be applicable, according to the requirements in its STCs.

For a state that has monitoring protocols approved after one or more initial quarterly monitoring report submissions, it should report metrics data to CMS retrospectively for any prior quarters of the section 1115 SMI/SED demonstration that precede the monitoring protocol approval date. A state is expected to submit retrospective metrics data—provided there is adequate time for preparation of these data—in its second monitoring report submission that contains metrics. The retrospective report for a state with a first SMI/SED DY of less than 12 months should include data for any baseline period quarters preceding the demonstration, as described in Part A of the state's monitoring protocol (see Appendix B of the instructions for further guidance determining baseline periods for first SMI/SED DYs that are less than 12 months). If a state needs additional time for preparation of these data, it should propose an alternative plan (i.e., specify the monitoring report that would capture the data) for reporting retrospectively on its SMI/SED demonstration.

In the monitoring report submission containing retrospective metrics data, the state should also provide a general assessment of metrics trends from the start of its demonstration through the end of the current reporting period. The state should report this information in Part B of its report submission (Section 3. Narrative information on implementation, by milestone and reporting topic). This general assessment is not intended to be a comprehensive description of every trend observed in metrics data. Unlike other monitoring report submissions, for instance, the state is not required to describe all metrics changes (+ or - greater than 2 percent). Rather, the assessment is an opportunity for the state to provide context for its

retrospective metrics data, to support CMS's review and interpretation of these data. For example, consider a state that submits data showing an increase in the utilization of telehealth services for mental health (Metric #15) over the course of the retrospective reporting period. The state may decide to highlight this trend to CMS in Part B of its monitoring report (under Milestone 3) by briefly summarizing the trend and providing context that during this period, the state implemented a grant to improve access to mental health treatment in rural areas through the use of telemedicine.

For further information on how to compile and submit a retrospective report, the state should review Section B of the Monitoring Report Instructions document.

☒ The state will report retrospectively for any quarters prior to monitoring protocol approval as described above, in the state's second monitoring report submission that contains metrics after monitoring protocol approval.

☐ The state proposes an alternative plan to report retrospectively for any quarters prior to monitoring protocol approval: *Insert narrative description of proposed changes to retrospective reporting. The state should provide justification for its proposed alternative plan.*

Medicaid Section 1115 SMI/SED Demonstrations Monitoring Protocol (Part A) - Planned-metrics (Version 2.0)
State
Indiana
Demonstration Name
Healthy Indiana Plan- SMI

Serious Mental Illness/Serious Emotional Disturbance (SMI/SED) Planned Metrics

Standard information on CMS-provided metrics												Baseline, annual goals, and demonstration target			Alignment with CMS-provided technical specifications manual		Phased-in metrics reporting		
#	Metric name	Metric description	Milestone or reporting topic	Metric type	Reporting category	Data source	Measurement period	Reporting frequency	Reporting priority	State will report (Y/N)		Baseline Reporting Period (MM/DD/YYYY– MM/DD/YYYY)	Annual goal	Overall demonstration target	Actual data collection and reporting matches the CMS-provided technical specifications manual (Y/N)	Explanation of any deviations from the CMS-provided technical specifications manual (different data source, definition, codes, target population, etc.)	State plans to phase in reporting (Y/N)	Report in which metric will be phased in (Format SMI/SED DY#); Ex. DY1SED	Explanation of any plans to phase in reporting over time
EXAMPLE: (1) (Do not delete or edit this row)	EXAMPLE: Screening for Depression and Follow-Up Plan: Age 18 and Older (CDF-AD)	EXAMPLE: Percentage of beneficiaries age 18 and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool, AND if positive, a follow-up plan is documented on the date of the positive screen.	EXAMPLE: Milestone 4	EXAMPLE: Established quality measure	EXAMPLE: Annual metrics that are an established quality measure	EXAMPLE: Claims; Medical records	EXAMPLE: Year	EXAMPLE: Annually	EXAMPLE: Recommended	EXAMPLE: N		EXAMPLE: 01/01/2020-12/31/2020	EXAMPLE: Increase	EXAMPLE: Increase	EXAMPLE: Y	EXAMPLE: The Department will use state-defined procedure code (XXXXXX) to calculate this metric	EXAMPLE:	EXAMPLE: DY1SED	EXAMPLE: We are transitioning to a new tool to screen for depression in adults (i.e., we are transitioning from the State Anxiety-Depression Scale (SADS) to the Patient Health Questionnaire (PHQ-2 & PHQ-9)). We anticipate that this transition will be complete across sites by mid-to-late 2024 (DY3).
1	SUD Screening of Beneficiaries Admitted to Psychiatric Hospitals or Residential Treatment Settings (SUB-2)	Two rates will be reported for this measure: 1. SUB-2- Patients who screened positive for unhealthy alcohol use who received or refused a brief intervention during the hospital stay. 2. SUB-2a- Patients who received the brief intervention during the hospital stay.	Milestone 1	Established quality measure	Annual metrics that are an established quality measure	Medical record review or claims	Year	Annually	Recommended	N									
2	Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP-CH)	Percentage of children and adolescents ages 1 to 17 who had a new prescription for an antipsychotic medication and had documentation of psychosocial care as first-line treatment.	Milestone 1	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
3	All-Cause Emergency Department Utilization Rate for Medicaid Beneficiaries who may Benefit From Integrated Physical and Behavioral Health Care (PMH-20)	Number of all-cause ED visits per 1,000 beneficiary months among adult Medicaid beneficiaries age 18 and older who meet the eligibility criteria of beneficiaries with SMI.	Milestone 2	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Neutral	Decrease	Y		N		
4	30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility (IPF)	The rate of unplanned, 30-day, readmission for demonstration beneficiaries with a primary discharge diagnosis of a psychiatric disorder or dementia/Alzheimer's disease. The measurement period used to identify cases in the measure population is 12 months from January 1 through December 31.	Milestone 2	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Decrease	Decrease	Y		N		
5	Medication Reconciliation Upon Admission	Percentage of patients for whom a designated prior to admission (PTA) medication list was generated by referencing one or more external sources of PTA medications and for which all PTA medications have a documented reconciliation action by the end of Day 2 of the hospitalization.	Milestone 2	Established quality measure	Annual metrics that are an established quality measure	Electronic/paper medical records	Year	Annually	Recommended	N									
6	Medication Continuation Following Inpatient Psychiatric Discharge	This measure assesses whether psychiatric patients admitted to an inpatient psychiatric facility (IPF) for major depressive disorder (MDD), schizophrenia, or bipolar disorder filled a prescription for evidence-based medication within 2 days prior to discharge and 30 days post-discharge.	Milestone 2	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Required	Y		01/01/2019-12/31/2020	Neutral	Increase	Y		N		
7	Follow-up After Hospitalization for Mental Illness: Ages 6-17 (FUH-CH)	Percentage of discharges for children ages 6 to 17 who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are reported: • Percentage of discharges for which the child received follow-up within 30 days after discharge • Percentage of discharges for which the child received follow-up within 7 days after discharge	Milestone 2	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Neutral	Increase	Y		N		
8	Follow-up After Hospitalization for Mental Illness: Age 18 and older (FUH-AD)	Percentage of discharges for beneficiaries age 18 years and older who were hospitalized for treatment of selected mental illness diagnoses or intentional self-harm and who had a follow-up visit with a mental health practitioner. Two rates are reported: • Percentage of discharges for which the beneficiary received follow-up within 30 days after discharge • Percentage of discharges for which the beneficiary received follow-up within 7 days after discharge	Milestone 2	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Neutral	Increase	Y		N		
9	Follow-up After Emergency Department Visit for Alcohol and Other Drug Abuse (FUA-AD)	Percentage of emergency department (ED) visits for beneficiaries age 18 and older with a primary diagnosis of alcohol or other drug (AOD) abuse dependence who had a follow-up visit for AOD abuse or dependence. Two rates are reported: • Percentage of ED visits for AOD abuse or dependence for which the beneficiary received follow-up within 30 days of the ED visit • Percentage of ED visits for AOD abuse or dependence for which the beneficiary received follow-up within 7 days of the ED visit	Milestone 2	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Neutral	Increase	Y		N		
10	Follow-Up After Emergency Department Visit for Mental Illness (FUM-AD)	Percentage of emergency department (ED) visits for beneficiaries age 18 and older with a primary diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness. Two rates are reported: • Percentage of ED visits for mental illness for which the beneficiary received follow-up within 30 days of the ED visit • Percentage of ED visits for mental illness for which the beneficiary received follow-up within 7 days of the ED visit	Milestone 2	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Neutral	Increase	Y		N		
11	Suicide or Overdose Death Within 7 and 30 Days of Discharge From an Inpatient Facility or Residential Treatment for Mental Health Among Beneficiaries With SMI or SED (Users)	Number of suicide or overdose deaths among Medicaid beneficiaries with SMI or SED within 7 and 30 days of discharge from an inpatient facility or residential stay for mental health.	Milestone 2	CMS-constructed	Other annual metrics	State data on cause of death	Year	Annually	Recommended	N									
12	Suicide or Overdose Death Within 7 and 30 Days of Discharge From an Inpatient Facility or Residential Treatment for Mental Health Among Beneficiaries With SMI or SED (rate)	Rate of suicide or overdose deaths among Medicaid beneficiaries with SMI or SED within 7 and 30 days of discharge from an inpatient facility or residential stay for mental health.	Milestone 2	CMS-constructed	Other annual metrics	State data on cause of death	Year	Annually	Recommended	N									
13	Mental Health Services Utilization - Inpatient	Number of beneficiaries in the denominator population who use inpatient services related to mental health during the measurement period.	Milestone 3	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y		01/01/2020-12/31/2020	Increase	Decrease	Y		N		
14	Mental Health Services Utilization - Intensive Outpatient and Partial Hospitalization	Number of beneficiaries in the denominator population who used intensive outpatient and/or partial hospitalization services related to mental health during the measurement period.	Milestone 3	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
15	Mental Health Services Utilization - Outpatient	Number of beneficiaries in the denominator population who used outpatient services related to mental health during the measurement period.	Milestone 3	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
16	Mental Health Services Utilization - ED	Number of beneficiaries in the denominator population who use emergency department services for mental health during the measurement period.	Milestone 3	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y		01/01/2020-12/31/2020	Decrease	Decrease	Y		N		
17	Mental Health Services Utilization - Telehealth	Number of beneficiaries in the denominator population who used telehealth services related to mental health during the measurement period.	Milestone 3	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
18	Mental Health Services Utilization - Any Services	Number of beneficiaries in the denominator population who used any services related to mental health during the measurement period.	Milestone 3	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
19a	Average Length of Stay in IMDs	Average length of stay (ALOS) for beneficiaries with SMI discharged from an inpatient or residential stay in an IMD. Three rates are reported: • ALOS for all IMDs and populations • ALOS among short-term stays (less than or equal to 60 days) • ALOS among long-term stays (greater than 60 days)	Milestone 3	CMS-constructed	Other annual metrics	Claims; State-specific IMD database	Year	Annually	Required	Y		01/01/2020-12/31/2020	Neutral	All ALOS - No more than 3%		State operated facilities are reported in this measure but do not receive	N		
19b	Average Length of Stay in IMDs (IMDs receiving FFP only)	Average length of stay (ALOS) for beneficiaries with SMI discharged from an inpatient or residential stay in an IMD receiving federal financial participation (FFP). Three rates are reported: • ALOS for all IMDs and populations • ALOS among short-term stays (less than or equal to 60 days) • ALOS among long-term stays (greater than 60 days)	Milestone 3	CMS-constructed	Other annual metrics	Claims; State-specific IMD database	Year	Annually	Required	Y		01/01/2020-12/31/2020	Neutral; short term, ALOS All ALOS - No more than 3 Y				N		
20	Beneficiaries With SMI/SED Treated in an IMD for Mental Health	Number of beneficiaries in the denominator population who have a claim for inpatient or residential treatment for mental health in an IMD during the reporting year.	Milestone 3	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
21	Count of Beneficiaries With SMI/SED (monthly)	Number of beneficiaries in the denominator population during the measurement period with a diagnosis of SMI/SED in any setting.	Milestone 4	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
22	Count of Beneficiaries With SMI/SED (annually)	Number of beneficiaries in the denominator population during the measurement period and/or in the 12 months before the measurement period.	Milestone 4	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
23	Diabetes Care for Patients with Serious Mental Illness: Hemoglobin A1c (HbA1c) Poor Control (>9.0%) (HPCMH-AD)	Percentage of beneficiaries ages 18 to 75 with a serious mental illness and diabetes (type 1 and type 2) whose most recent Hemoglobin A1c (HbA1c) level during the measurement year is >9.0%.	Milestone 4	Established quality measure	Annual metrics that are an established quality measure	Claims; Medical records	Year	Annually	Required	Y		01/01/2020-12/31/2020	Decrease	Decrease	Y		N		
24	Screening for Depression and Follow-Up Plan: Age 18 and Older (CDF-AD)	Percentage of beneficiaries age 18 and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool, AND if positive, a follow-up plan is documented on the date of the positive screen.	Milestone 4	Established quality measure	Annual metrics that are an established quality measure	Claims; Medical records	Year	Annually	Recommended	N									
25	Screening for Depression and Follow-Up Plan: Ages 12–17 (CDF-CH)	Percentage of beneficiaries ages 12 to 17 screened for depression on the date of the encounter using an age appropriate standardized depression screening tool, AND if positive, a follow-up plan is documented on the date of the positive screen.	Milestone 4	Established quality measure	Annual metrics that are an established quality measure	Claims; Electronic medical records	Year	Annually	Recommended	N									
26	Access to Preventive/Ambulatory Health Services for Medicaid Beneficiaries With SMI	The percentage of Medicaid beneficiaries age 18 years or older with SMI who had an ambulatory or preventive care visit during the measurement period.	Milestone 4	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
27	Tobacco Use Screening and Follow-up for People with SMI or Alcohol or Other Drug Dependence	The percentage of patients 18 years and older with a serious mental illness or alcohol or other drug dependence who received a screening for tobacco use and follow-up for those identified as a current tobacco user. Two rates are reported: • Percentage of adults with SMI who received a screening for tobacco use and follow-up for those identified as a current tobacco user • Percentage of adults with AOD who received a screening for tobacco use and follow-up for those identified as a current tobacco user	Milestone 4	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Recommended	N									
28	Alcohol Screening and Follow-up for People with SMI	The percentage of patients 18 years and older with a serious mental illness, who were screened for unhealthy alcohol use and received brief counseling or other follow-up care if identified as an unhealthy alcohol user.	Milestone 4	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Recommended	N									
29	Metabolic Monitoring for Children and Adolescents on Antipsychotics	The percentage of children and adolescents ages 1 to 17 who had two or more antipsychotic prescriptions and had metabolic testing. Three rates are reported: •Percentage of children and adolescents on antipsychotics who received blood glucose testing •Percentage of children and adolescents on antipsychotics who received cholesterol testing •Percentage of children and adolescents on antipsychotics who received blood glucose and cholesterol testing	Milestone 4	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
30	Follow-Up Care for Adult Medicaid Beneficiaries Who are Newly Prescribed an Antipsychotic Medication	Percentage of Medicaid beneficiaries age 18 years and older with new antipsychotic prescriptions who have completed a follow-up visit with a provider with prescribing authority within four weeks (28 days) of prescription of an antipsychotic medication.	Milestone 4	Established quality measure	Annual metrics that are an established quality measure	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
31	Total Costs Associated With Mental Health Services Among Beneficiaries With SMI/SED - Not Inpatient or Residential	The sum of all Medicaid spending for mental health services not in inpatient or residential settings during the measurement period.	Other SMI/SED metrics	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
32	Total Costs Associated With Mental Health Services Among Beneficiaries With SMI/SED - Inpatient or Residential	The sum of all Medicaid costs for mental health services in inpatient or residential settings during the measurement period.	Other SMI/SED metrics	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Decrease	Decrease	Y		N		
33	Per Capita Costs Associated With Mental Health Services Among Beneficiaries With SMI/SED - Not Inpatient or Residential	Per capita costs for non-inpatient, non-residential services for mental health, among beneficiaries in the denominator population during the measurement period.	Other SMI/SED metrics	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Increase	Increase	Y		N		
34	Per Capita Costs Associated With Mental Health Services Among Beneficiaries With SMI/SED - Inpatient or Residential	Per capita costs for inpatient or residential services for mental health among beneficiaries in the denominator population during the measurement period.	Other SMI/SED metrics	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Decrease	Decrease	Y		N		
35	Grievances Related to Services for SMI/SED	Number of grievances filed during the measurement period that are related to services for SMI/SED.	Other SMI/SED metrics	CMS-constructed	Grievances and appeals	Administrative records	Quarter	Quarterly	Required	Y		01/01/2020-12/31/2020	Neutral	Neutral	Y		N		
36	Appeals Related to Services for SMI/SED	Number of appeals filed during the measurement period that are related to services for SMI/SED.	Other SMI/SED metrics	CMS-constructed	Grievances and appeals	Administrative records	Quarter	Quarterly	Required	Y		01/01/2020-12/31/2020	Neutral	Neutral	Y		N		
37	Critical Incidents Related to Services for SMI/SED	Number of critical incidents filed during the measurement period that are related to services for SMI/SED.	Other SMI/SED metrics	CMS-constructed	Grievances and appeals	Administrative records	Quarter	Quarterly	Required	Y		01/01/2020-12/31/2020	Neutral	Neutral	Y		N		
38	Total Costs Associated With Treatment for Mental Health in an IMD Among Beneficiaries With SMI/SED	Total Medicaid costs for beneficiaries in the denominator population who had claims for inpatient or residential treatment for mental health in an IMD during the reporting year.	Other SMI/SED metrics	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Decrease	Decrease	Y		N		
39	Per Capita Costs Associated With Treatment for Mental Health in an IMD Among Beneficiaries With SMI/SED	Per capita Medicaid costs for beneficiaries in the denominator population who had claims for inpatient or residential treatment for mental health in an IMD during the reporting year.	Other SMI/SED metrics	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y		01/01/2020-12/31/2020	Decrease	Decrease	Y		N		
Q1	*Jails connected to HIE*	Number of jails/criminal justice systems connected to HIE	Health IT	State-specific	Other annual metrics	Administrative records	Year	Annually	Required	Y		01/01/2021-12/31/2021	Increase	Increase			Y	DY3Q1	Delay due to acquisition of data and PHE
Q2	*Health IT to effectively treat*	Number of providers and resources managed in provider/resource directory.	Health IT	State-specific	Other annual metrics	Administrative records	Year	Annually	Required	Y		01/01/2021-12/31/2021	Increase	Increase			Y	DY3Q1	Delay due to acquisition of data and PHE
Q3	*Recovery supports and services*	Number of clinicians with list of community resources that individuals can be referred to in a	Health IT	State-specific	Other annual metrics	Administrative records	Year	Annually	Required	Y		01/01/2021-12/31/2021	Increase	Increase			Y	DY3Q1	Delay due to acquisition of data and PHE
State-specific metrics																			
Add rows for any additional state-specific metrics																			

The SMI Monitoring Protocol Workbook (Part A) is also available in spreadsheet format on Medicaid.gov

Attachment H

Indiana Family and Social Services Administration

Serious Mental Illness/Serious Emotional Disturbance 2021-2025 Waiver Evaluation Plan

Final for CMS Review

October 27, 2021

Table of Contents

A. General Background Information

The Centers for Medicare & Medicaid Services (CMS) initially approved the Indiana Family and Social Services Administration's (FSSA) §1115(a) demonstration waiver for adults with serious mental illness (SMI) on December 20, 2019 for a period of January 1, 2020 through December 31, 2020. On October 26, 2020 CMS granted approval for the waiver to remains in effect for five years, from January 1, 2021 through December 31, 2025. Through this demonstration, Indiana will be allowed to receive federal financial participation for services furnished to Medicaid beneficiaries who are primarily receiving short-term treatment services for a serious mental illness (SMI) in facilities that meet the definition of an institutions for mental diseases (IMD).

A 2015 report to the Indiana General Assembly highlighted the need for expanded crisis services, access to inpatient psychiatric beds, and improved coordination for individuals transitioning from inpatient services back into the community. Specifically, the report indicated that there is a need for increased options for individuals in psychiatric crises, with survey results suggesting that Indiana residents rely heavily on general hospital emergency rooms to handle individuals in acute crisis.[1] In 2018, the FSSA received authority from the CMS to reimburse IMDs for Medicaid-eligible individuals aged 21-64 years with substance use disorders (SUDs). In 2019, Indiana sought to expand this authority to reimburse for acute inpatient stays in IMDs for individuals diagnosed with SMI.[2]

Through the §1115(a) demonstrations and waiver authorities in the Social Security Act, states can test and evaluate innovative solutions to improve quality, accessibility, and health outcomes in a budget-neutral manner. Indiana's approved §1115 waiver Specific Terms and Conditions (STCs) to implement the SMI waiver require an evaluation of this program's ability to meet its intended goals. This Evaluation Plan will guide the federally required, independent evaluation of this program, and is organized as follows:

- Section A: General Background Information
- Section B: Evaluation Questions and Hypotheses
- Section C: Methodology
- Section D: Methodological Limitations
- Section E: Attachments
    - Attachment E.1: Summary of Independent Evaluator Approach
    - Attachment E.2: Evaluation Budget
    - Attachment E.3: Timeline and Major Milestones
- Section F: Analytic Plans by Goal

[1] DMHA distributed the Psychiatric and Addiction Crisis Survey in December 2014 and January 2015. Tailored surveys went out to respondent groups including mental health and addiction providers, hospital emergency department staff, first responders, consumer and family advocates, and probation and parole officers.

[2] Reimbursement will not be extended to IMDs for residential stays; additionally, state mental health hospitals will not be classified as IMDs eligible for reimbursement under this waiver. Facilities with more than 16 beds that are certified as Private Mental Health Institution (PMHI) by the Division of Mental Health and Addiction qualify as IMDs under this waiver.

1. Demonstration Goals

In an effort to ensure a comprehensive continuum of behavioral health services, the State will monitor the new approaches and flexibilities in Indiana's Medicaid program to reimburse for acute inpatient stays in IMDs for Medicaid enrollees with SMI. Over the demonstration period (from January 1, 2021 through December 31, 2025), the State seeks to achieve several demonstration goals (**Exhibit A.1**). These goals inform the State's evaluation of the SMI demonstration and include, but are not limited to, the following:

Exhibit A.1: Indiana §1115(a) Demonstration

Name of Demonstration:
SMI/SED Amendment Request for the Healthy Indiana Plan (HIP)

Amendment Approval Date of Demonstration:
October 26, 2020

Demonstration Period: January 1, 2021 - December 31, 2025

1. Reduced utilization and length of stay in emergency departments (EDs) among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment in specialized settings;
2. Reduced preventable readmissions to acute care hospitals and residential settings;
3. Improved availability of crisis stabilization services, including services made available through call centers and mobile crisis units, intensive outpatient services, as well as services provided during acute short-term stays in residential crisis stabilization programs, psychiatric hospitals, and residential treatment settings throughout the state;
4. Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI/SED, including through increased integration of primary and behavioral health care; and
5. Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities.

The above goals address key milestones of §1115(a) demonstrations outlined in **Exhibit A.2**.

Exhibit A.2: SMI/SED Demonstration Milestones

Milestones	
Milestone 1	Ensuring quality of care in psychiatric hospitals and residential settings
Milestone 2	Improving care coordination and transitioning to community-based care
Milestone 3	Increasing access to the continuum of care, including crisis stabilization services
Milestone 4	Earlier identification and engagement in treatment, including through increased integration

2. Description of the Demonstration and Implementation Plan

In 2018, the FSSA received authority from the CMS to reimburse for inpatient and residential stays in institutions for mental diseases (IMDs) for Medicaid eligible individuals ages 21-64 with substance use disorders (SUD). In 2019, Indiana sought to expand this authority to reimburse for acute inpatient stays in IMDs for individuals diagnosed with SMI.[3] The SMI demonstration was approved by CMS on December 20, 2019 and became effective January 1, 2020. On October 26, 2020, CMS granted approval for the waiver to remain in effect for five years (January 1, 2021 through December 31, 2025).

Under this demonstration, beneficiaries have access to high-quality, evidence-based mental health treatment services. These services range in intensity from short-term acute care in settings that qualify as an IMD to ongoing chronic care for such conditions in cost-effective community-based settings. Indiana must achieve a statewide average length of stay of no more than 30 days in inpatient treatment settings and will be continuously monitored.

Overview of Indiana's Behavioral Health System of Care

Indiana's publicly funded behavioral health (both mental health and addiction) system of care supports access to prevention, early intervention, and recovery-oriented services and supports in all 92 counties, blending federal, state and local funding streams to a provider network of agencies and individual practitioners. Indiana's FSSA and specifically its Office of Medicaid Planning and Policy (OMPP) and Division of Mental Health and Addiction (DMHA) partner to provide policy oversight and primary funding of services and supports for individuals in need of behavioral health services. OMPP includes a robust continuum of behavioral health services as a benefit to enrollees in its fee-for service and Medicaid managed care programs. DMHA leverages its block grant funding from the Substance Abuse and Mental Health Services Administration (SAMHSA) and state appropriations to complement the Medicaid service array, with a focus on serving adults with SMI, youth with SED, and individuals with SUD of any age, and who are at or below 200% of the federal poverty level (FPL). OMPP and DMHA also partner with the Department of Child Services (DCS) and the Department of Corrections (DOC) in supporting access to and oversight of behavioral services for Indiana's most vulnerable Hoosiers.

Provider Network

OMPP maintains a large network of behavioral health providers including hospitals, psychiatric residential treatment facilities (PRTF), SUD residential providers, community-based agencies, and individual practitioners. Individual practitioners are certified and/or licensed by the Indiana Professional Licensing Agency (IPLA). While IPLA is separate and independent from FSSA, both OMPP and DMHA maintain a strong collaborative relationship with the agency. DMHA is responsible for certification and licensure for SUD provider agencies, freestanding psychiatric hospitals, and community mental health centers (CMHCs). Indiana Administrative Code (IAC) outlines provider requirements that assist in assuring quality and program integrity. Addiction, residential, CMHCs, and Clubhouse providers participating within the Medicaid program must be certified/licensed by DMHA prior to provider enrollment with OMPP.

[3] Reimbursement will not be extended to IMDs for residential stays; additionally, state mental health hospitals will not be classified as IMDs eligible for reimbursement under this waiver. Facilities certified as PMHI by the DMHA with more than 16 beds qualify as IMDs under this waiver.

Community Mental Health Centers

There are currently 24 certified CMHCs in Indiana. DMHA is responsible for CMHC certification and requirements under the IAC and/or contracts which include responsibility for respective geographic service areas to ensure statewide coverage of the continuum of behavioral health services. The CMHCs are required to provide a defined continuum of care that includes:

- Individualized treatment planning;
- Access to 24 hour-a-day crisis intervention;
- Case management;
- Outpatient services, including intensive outpatient services, substance abuse services, and treatment;
- Acute stabilization services including detoxification services;
- Residential services;
- Day treatment, partial hospitalization, or psychosocial rehabilitation;
- Family support;
- Medication evaluation and monitoring; and
- Services to prevent unnecessary and inappropriate treatment and hospitalization and the deprivation of a person's liberty.

Many of these services are part of Medicaid Rehabilitation Option (MRO) state plan services, under which an assessment confirms a need for services with an eligible diagnosis and level-of-care determination using the Child and Adolescent Needs and Strengths Assessment (CANS) or Adult Needs and Strengths Assessment (ANSA).

Current Service Continuum

Prevention/Early Intervention

Prevention/early intervention occur through the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program. These services are available to Medicaid members from birth through the month of the member's 21st birthday. Members eligible for EPSDT services may be enrolled in the Healthy Indiana Plan (HIP), Hoosier Care Connect (HCC), Hoosier Healthwise (HHW), or Traditional Medicaid. A psychosocial/behavioral assessment is required at each EPDST visit. This assessment is family-centered and may include an assessment of a child's social-emotional health, caregiver depression, as well as social risk factors. The Indiana Health Coverage Programs (IHCP) also provide coverage for annual depression screening and screening and brief intervention (SBI) services. Providers are expected to use validated, standardized tests for the depression screening. These tests include, but are not limited to, the Patient Health Questionnaire (PHQ), Beck Depression Inventory, Geriatric Depression Scale, and Edinburgh Postnatal Depression Scale (EPDS). SBI identifies and intervenes with individuals who are at risk for substance abuse related problems or injuries. SBI services use established systems, such as trauma centers, emergency departments, community clinics, and school clinics, to screen patients who are at risk for substance abuse and, if necessary, provide the patients with brief interventions or referrals to appropriate treatment.

Outpatient Mental Health Services

The IHCP covers outpatient mental health services provided by a licensed medical doctor, doctor of osteopathy, psychologist endorsed as a health service provider in psychology (HSPP), psychiatric hospitals, psychiatric wings of acute care hospitals, and outpatient mental health facilities. Reimbursement is also available for services provided by mid-level practitioners when a physician or an HSPP supervises those services. The physician, psychiatrist, or HSPP is responsible for certifying the diagnosis and supervising the treatment plan.

Adult Mental Health Habilitation Services

Effective November 1, 2014, Indiana implemented the §1915(i) Adult Mental Health Habilitation (AMHH) services program. Indiana adopted AMHH services to provide community-based opportunities for the care of adults with SMI who may most benefit from keeping or learning skills to maintain a healthy safe lifestyle in the community. AMHH services are intended for individuals who meet all of the following core target group criteria: 1) enrolled in Medicaid; 2) aged 19 years or older; 3) reside in a setting which meets federal setting requirements for home and community-based services (HCBS); and 4) has an AMHH-eligible, DMHA-approved diagnosis.[4] Once approved by the State Evaluation Team, an eligible AMHH enrollee is able to receive an AMHH service package, according to an individualized care plan. All services covered under the AMHH program are applicable for an additional prior authorization (PA) option. This will allow additional units to be authorized above the initial listed limit. Additional units can be requested via the Data Assessment Registry Mental Health and Addiction (DARMHA) system. The State Evaluation Team (SET) will review all PA requests and approve or deny additional units requested. Initial eligibility in the program is for one year and can be extended if medical need remains. The following are the AMHH services:

- Adult day services
- Home- and Community-Based Habilitation and Support Services
- Respite care
- Therapy and behavioral support services
- Addiction counseling
- Supported community engagement services
- Care coordination
- Medication training and support

Inpatient/Acute Care

Prior authorization is required for all inpatient psychiatric admissions, rehabilitation, and substance abuse inpatient stays. Each Medicaid-eligible patient admitted to an acute psychiatric facility or unit must have an individually developed plan of care (POC). For members aged 22 years and older, a POC must be developed by the attending or staff physician. For members aged 21 years old and younger,

[4] Indiana recently amended its AMHH SPA, which became effective April 1, 2020. The modifications are intended to make the program more accessible for members and remove administrative burden for providers. Specific changes are as follows:

- Eligibility age was changed from 35 years and older to 19 years and older;
- The required Adult Needs and Strengths Assessment (ANSA) score was changed from 4 and above to 3 and above; and
- Each AMHH service will no longer require an individual justification. Instead, an individual service package will be assigned.

POCs must be developed by a physician and interdisciplinary team. All POCs must be developed within 14 days of the admission date, regardless of the member's age. For a patient who becomes eligible for Medicaid after admission to a facility, the POC must be prepared to cover all periods for which Medicaid coverage is claimed. The following components must be documented in each member's POC:

1. Treatment objectives and goals, including an integrated program of appropriate therapies, activities, and experiences designed to meet the objectives; and
2. A post-discharge plan and a plan for coordination of inpatient services with partial discharge plans, including appropriate services in the member's community to ensure continuity of care when the patient returns to their family and community upon discharge.

The POC is developed as a result of a diagnostic evaluation that includes an examination of the medical, psychological, social, and behavioral aspects of the member's presenting problem and previous treatment interventions. The attending or staff physician reviews the POC to ensure that appropriate services are provided and that they continue to be medically necessary. The attending or staff physician also recommends necessary adjustments in the plan, as indicated by the member's overall adjustment while an inpatient. The POC must be in writing and must be part of the member's record.

State Hospitals

Indiana's six state psychiatric hospitals provide intermediate and longer-term inpatient psychiatric stays for adults who have co-occurring mental health and addiction issues; who are deaf or hearing impaired; and who have forensic involvement; as well as youth with SED. Individuals are admitted to a state hospital only after a screening by a CMHC. CMHCs are responsible for providing case management to the individual in both the hospital and their transition to the community following discharge. The state psychiatric hospitals are accredited by the Joint Commission (JC). To maintain JC accreditation, all hospitals are required to participate in a performance measurement program. This is accomplished through participation in the National Research Institute Performance Measurement System, which provides a framework within which the state psychiatric hospitals can identify and implement consistent measures of performance and outcomes.

On March 15, 2019, Indiana opened its NeuroDiagnostic Institute (NDI) and Advanced Treatment Center located on the campus of Community East Hospital in Indianapolis. Operated in partnership with Community Health Network, NDI delivers advanced evaluation and treatment for patients with the most challenging and complex neuropsychiatric illnesses and transitions them more efficiently into the most appropriate treatment settings within the community or to a state-operated inpatient system of care. The NDI is a key component of FSSA's initiative to modernize and reengineer Indiana's network of state-operated inpatient mental health facilities, including reducing lengths of stay. The NDI also serves as a teaching hospital by partnering with local universities for medical and nursing students, as well as social work and psychology interns, which affords them hands-on experience helping NDI patients in their recovery.

Telehealth

Effective March 1, 2020 and through the duration of Indiana's coronavirus disease 2019 (COVID-19) Public Health Emergency (PHE), the OMPP was authorized via executive order to expand the variety of services, providers, and modalities rendered via telehealth. This expansion included the following

allowances: 1) voice-only modalities (e.g., telephones) could be utilized for telehealth purposes, 2) health care services that were allowed via telehealth were no longer limited to procedure codes on IHCP's Telemedicine Services Code Set, and 3) the set of providers who could use telehealth was no longer limited by licensure restrictions defined under the Indiana Professional Licensing Agency (IPLA) section of Indiana Code.

Due to these changes in policy, IHCP saw an increase in the number of claims billed when using telehealth services. In 2019, there were only 63,844 paid claims for telehealth services, versus 2,673,241 claims in 2020, an increase of over 4000%. A majority of these claims were submitted by behavioral health providers, with claims for psychotherapy services making up a significant portion of health care services provided via telehealth.

As a result of this increase in access to services using telehealth, OMPP was supportive of Indiana Senate Bill 3: "Telehealth Matters," which expanded the "telemedicine" section of code under the IPLA to include an expanded list of "practitioners" able to utilize telehealth service delivery under their scope of licensure and updated the term "telemedicine" to instead the more inclusive term of "telehealth." The bill therefore allowed OMPP to keep some of the policy expansions bestowed to the agency during the PHE in relation to telehealth. The bill was signed into law April 20th, 2021 and is effective starting at the end of executive order permissions. OMPP is currently working to adopt this new legislation into permanent telehealth policy.

State Strategies for Addressing Waiver Milestones

Current Oversight of Institutions for Mental Disease (IMDs)

In order to operate in the state of Indiana, all free-standing psychiatric hospitals must be licensed as a private mental health institution (PMHI) by DMHA. 440 IAC 1.5 currently requires PMHIs to be accredited by an accrediting body approved by the Division. This list only includes accrediting agencies also approved by CMS for deeming authority for Medicare requirements under 42 CFR 488.5 or 42 CFR 488.6. PMHI licensure must be renewed annually. DMHA conducts annual visits to ensure requirements are being met. In SFY 2019, all PMHI renewal site visits were unannounced. In SFY 2020, all site visits were conducted virtually due to the PHE. DMHA utilizes a site visit checklist that crosswalks with licensure requirements. The site visit checklist includes confirmation that individuals receive a physical within 24 hours of admission as well as an initial emotional, behavioral, social and legal assessment per IAC requirements. This includes screening for chronic health conditions and substance use disorders. Prior authorization is currently required for inpatient psychiatric care under both managed care and for fee for service enrollees, and, with the implementation of the State's SMI demonstration, includes IMD admissions as well. There are currently 29 freestanding psychiatric hospitals licensed in the state of Indiana with a capacity of 1,193 beds. Only 11 of the 29 PMHIs have 16 or fewer beds. DMHA is in the process of reviewing the IAC related to PMHIs with attention to quality assurance and monitoring for these providers based on the most recent cycle of onsite reviews and compliance with the goals and milestones under Indiana's current §1115 SMI waiver authority.

Improving Integration and Care Coordination, including Transitions to Community Based Care

Indiana has several initiatives, leveraging different authorities outside the §1115(a) waiver, to promote and expand care coordination and integrated delivery of behavioral health and primary care. These efforts focus on both youths with SED and adults with SMI and include cross-collaboration with Indiana's DMHA and State Department of Health (ISDH).

Indiana's Primary Care and Behavioral Health Integration

FSSA in partnership with ISDH launched an initiative in 2012 to develop a statewide strategic plan to integrate primary and behavioral health care services in Indiana. Indiana's Primary Care and Behavioral Health Integration (PCBHI) efforts include the formation of a statewide stakeholder group, formalized definition for integration for Indiana, and the original creation of five subcommittees that spearheaded research and collaboration in the following areas that support integrated care:

- Data/Technology
- Education/Training
- Funding/Reimbursement
- Health Homes/Care Coordination
- Policy Development

In addition, FSSA applied for and was awarded the SAMHSA and National Association of State Mental Health Program Directors (NASHMHPD) Transformation Transfer Initiative (TTI) Grant, which allowed Indiana to complete the following initiatives toward integration:

- Eight integration educational training events in 2013;
- Completion of a statewide integration survey;
- Cross-training opportunities for Community Health Workers (CHW) and Certified Recovery Specialists;
- Creation of an established process for state approved integrated care CHW certification; and
- Creation of established PCBHI Guiding Principles.

FSSA and ISDH established a process by which CMHCs, Federally Qualified Health Centers (FQHCs), Community Health Centers (CHCs), and Rural Health Clinics (RHCs) could become a state-certified, integrated care entity (ICE). ICE providers are required to provide care coordination that includes partnering with physicians, nurses, social workers, discharge planners, pharmacists, representatives in the education system, representatives of the legal system, representatives of the criminal justice system and others during any transition of care. The goals of this coordination include reducing unnecessary inpatient and emergency room use and increasing consumer and family members' ability to manage their own care and live safely in the community. Due to the Covid-19 pandemic, the State has to postpone this project. OMPP and DMHA are reevaluating the changes that need to be made within the Behavioral Health System in order to successfully transition from the ICE model to a health home program.

Behavioral and Primary Healthcare Coordination Service Program

Conceived under a separate §1915(i) state plan amendment, the Behavioral and Primary Healthcare Coordination (BPHC) program offers a service that consists of the coordination of health care services to manage the mental health/addiction and physical health care needs of eligible recipients. This includes logistical support, advocacy and education to assist individuals in navigating the health care system and activities that help recipients gain access necessary to manage their physical and behavioral health conditions.

BPHC service activities may include support in adhering to health regimens, scheduling and keeping medical appointments, obtaining and maintaining a primary medical provider and facilitating communication across providers. In addition, BPHC includes direct assistance in gaining access to services; coordination of care within and across systems; oversight of the entire case; linkage to appropriate services; needs-based assessment of the eligible recipient to identify service needs; development of an individualized integrated care plan (IICP); referral and related activities to help the recipient obtain needed services; monitoring and follow-up; and evaluation.

Child Mental Health Wraparound (CMHW) Services

The §1915(i) Child Mental Health Wraparound (CMHW) Services Program is authorized through Medicaid state plan authority. The §1915(i) CMHW Services are outlined in 405 IAC 5- 21.7. CMHW services provide youth with SED with intensive home and community-based wraparound services provided within a system of care (SOC) philosophy and consistent with wraparound principles. Services are intended to augment the youth's existing or recommended behavioral health treatment plan. The State's purpose for providing CMHW services is to serve eligible participants who have SED and enable them to benefit from receiving intensive wraparound services within their home and community with natural family/caregiver supports and provided sustainability of these services, which were originally offered under the CMS Community Alternatives to Psychiatric Residential Treatment Facilities (CA-PRTF)

demonstration. Under the demonstration, Indiana was able to provide a quicker and more seamless transition of youth from PRTF placement as well as prevent some youth from placement within a PRTF setting. The CMHW services available to the eligible participant include wraparound facilitation, habilitation, respite care, and training and support for the unpaid caregiver. In 2020, the State incorporated auto-renewals to ensure that individuals did not lose coverage during the PHE.

Increasing Access to Continuum of Care Including Crisis Stabilization Services

On March 18, 2019, CMS approved a state plan amendment that expands crisis intervention services, intensive outpatient program services, and peer recovery services to all Indiana Medicaid programs. Previously, these services were limited to the MRO program. This change expands the potential number of providers eligible to deliver these services to Indiana enrollees. This SPA became effective July 1, 2019.

This expansion of the crisis continuum specifically began in 2014. DMHA partnered with the National Alliance on Mental Illness of Indiana (NAMI Indiana), Mental Health America of Indiana (MHAI), the Indiana Hospital Association (IHA), Key Consumer, and the Indiana Council on Community Mental Health Centers (ICCMHC) to conduct a review of Indiana's mental health and substance use crisis services. The review was in response to Indiana Senate Enrolled Act No. 248 of 2014, which mandated DMHA to conduct a psychiatric crisis intervention study ("crisis study") and report the results to the legislative council by September 2015. The crisis study included a review of psychiatric and addiction crisis services available in Indiana, a survey of professionals and individuals in Indiana who have experience with the current state of Indiana's crisis response, and a review of crisis services and models implemented by other states that could improve outcomes for individuals who experience psychiatric or addiction crises.

In Indiana's application for the Serious Mental Illness (SMI) 1115 Waiver, the State indicated interest in expanding and improving the crisis services available to members across the State. These programmatic changes were supposed to be implemented by DMHA during calendar year 2020 but due to the COVID-19 pandemic were put on hold. Prior to the PHE, the State covered many of the crisis services that the SAMHSA suggests should be included in Community-Based Mobile Crisis Units. With the passing of the American Rescue Plan in March 2021, the State is looking into applying for the federal match opportunity related to Community-Based Mobile Crisis Response Services. In addition to establishing mobile response units, the State hopes to establish Crisis Stabilization Units (CSU). The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units. Currently, OMPP and DMHA are working together to develop a plan to expand crisis services as outlined in the approved SMI 2020 Evaluation Plan.

Additionally, in accordance with 440 IAC 9-2-2, all CMHCs must provide 24/7 crisis intervention services which meet the following minimum requirements:

- Operation and promotion of a toll-free or local call crisis telephone number staffed by individual(s) trained to recognize emergencies and refer calls to the appropriate clinician or program;
- When a determination is made by the crisis telephone line that a clinician needs to be involved, a trained clinician is available to reach the consumer by telephone within 15 minutes;
- When the assessment indicates a face-to-face meeting between the clinician and consumer is necessary, an accessible safe place is available within 60 minutes driving distance of any part of

the CMHC's service area, with a transportation plan for consumers without their own mode of transportation to be able to access the safe place; and
- Participation in a quality assurance/quality improvement system that includes a review of individual cases and identification and resolution of systemic issues including review by supervisory or management level staff for appropriateness of disposition for each crisis case.

Some of the State's CMHCs are providing the following additional crisis services:

- Mobile crisis teams
- Assertive community treatment (ACT)
- 23-hour crisis stabilization units
- Short-term crisis residential
- Peer crisis services

Additionally, Hoosier Care Connect managed care entities (MCEs), who serve the State's aged, blind and disabled Medicaid population are contractually required to ensure the availability of behavioral health crisis intervention services 24/7.

Earlier Identification and Engagement in Treatment

Indiana has expanded coverage for mental health screening, SUD screening, and referral under Medicaid. In 2014, OMPP expanded provider types eligible for reimbursement of screening and brief intervention for SUD to include midlevel licensed individuals under the supervision of a physician, including nurse practitioners (NP), health service providers in psychology (HSPP), licensed clinical social workers (LCSW), licensed mental health counselors (LMHC), and licensed marriage and family therapists (LMFT). In October 2016, OMPP began coverage for annual depression screening. Providers are expected to use validated standardized tests for the screening. These tests include, but are not limited to, the Patient Health Questionnaire (PHQ), Beck Depression Inventory, Geriatric Depression Scale, and Edinburgh Postnatal Depression Scale (EPDS). Coverage applies to all IHCP programs under Medicaid. The State has also focused on school-based initiatives to increase behavioral health integration. Indiana Medicaid allows enrolled school corporations reimbursement for Medicaid-covered services in an Individualized Education Program (IEP) or Individualized Family Service Plan (IFSP). Medicaid-covered IEP services include occupational, physical, speech and applied behavior analysis therapy, hearing, nursing and behavioral health evaluation and treatment services as well as IEP-required specialized transportation. In addition, CMHCs across the State work in close collaboration with Indiana schools. Currently 85% of school districts have partnerships with the CMHC in their area. Through these partnerships behavioral health staff are co-located within the schools and providing behavioral health services to youth and their families.

3. Population Groups Impacted by the Demonstration

Indiana will evaluate whether the demonstration has the intended effects on the target population. This waiver of the IMD exclusion includes all Medicaid beneficiaries aged 21-64 years, regardless of the delivery system. All enrollees will continue to receive services through their current delivery system and payment methodologies will be consistent with those approved in the Medicaid State Plan.

Demonstration Eligibility

Individuals apply for Medicaid services through the Division of Family Resources, which determines eligibility for Indiana Health Coverage Programs. If an individual is determined eligible, beneficiaries will have access to high quality, evidence-based mental health treatment services under this demonstration.

All enrollees eligible for a mandatory or optional eligibility group approved for full Medicaid coverage, and aged 21-64 years, would be eligible for acute inpatients stays in an IMD under the waiver. The eligibility groups outlined in **Exhibit A.3** below are not eligible for stays in an IMD as they receive limited Medicaid benefits only.

Exhibit A.3: Eligibility Groups Excluded from the Demonstration

Eligibility Group Name	Social Security Act & CFR Citation
Limited Services Available to Certain Aliens	42 CFR §435.139
Qualified Medicare Beneficiaries (QMB)	1902(a)(10)(E)(i) 1905(p)
Specified Low Income Medicare Beneficiaries (SLMB)	1902(a)(10)(E)(iii)
Qualified Individual (QI) Program	1902(a)(10)(E)(iv)
Qualified Disabled Working Individual (QDWI) Program	1902(a)(10)(E)(ii) 1905(s)
Family Planning	1902(a)(10)(A)(ii)(XXI)

B. Evaluation Questions and Hypotheses

The evaluation will focus on the demonstration policy goals described in **Section A**. This section provides the hypotheses and research questions (RQs) that correspond to each of the goals. Logic models, depicting the expected relationship between activities and short- and long-term outcomes, are included for each research question.

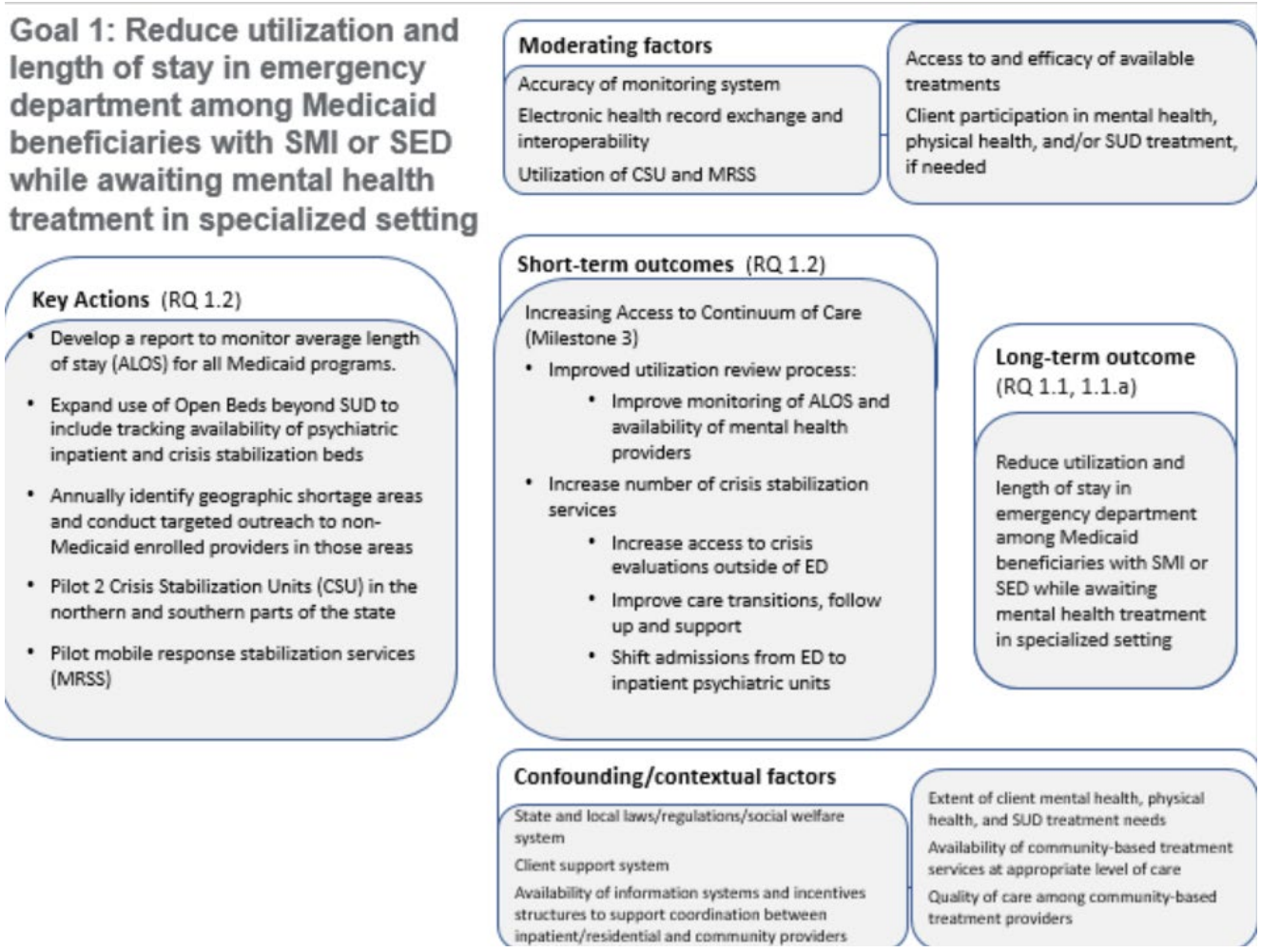
1. Goal One: Reduced utilization and length of stay in emergency departments (EDs) among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment in specialized settings

The evaluation explores the impact of expanding access to high-quality, evidence-based mental health treatment services in IMDs on utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment in specialized settings. **Exhibit B.1.a.** lists the hypothesis and research questions and **Exhibit B.1.b.** outlines the logic model corresponding to this goal.

Exhibit B.1.a.: Hypothesis and Research Questions for Goal 1

Hypotheses	Research Questions
Hypothesis 1: The SMI/SED demonstration will result in reductions in utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment.	**Primary research question 1:** Does the SMI/SED demonstration result in reductions in utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment? **Subsidiary research question 1.1:** How do the SMI/SED demonstration effects on reducing utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED vary by geographic area or beneficiary characteristics? **Subsidiary research question 1.2:** How do SMI/SED demonstration activities contribute to reductions in utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment in specialized settings?

Exhibit B.1.b.: Logic Model for Goal 1



2. Goal Two: Reduced preventable readmissions to acute care hospitals and residential settings

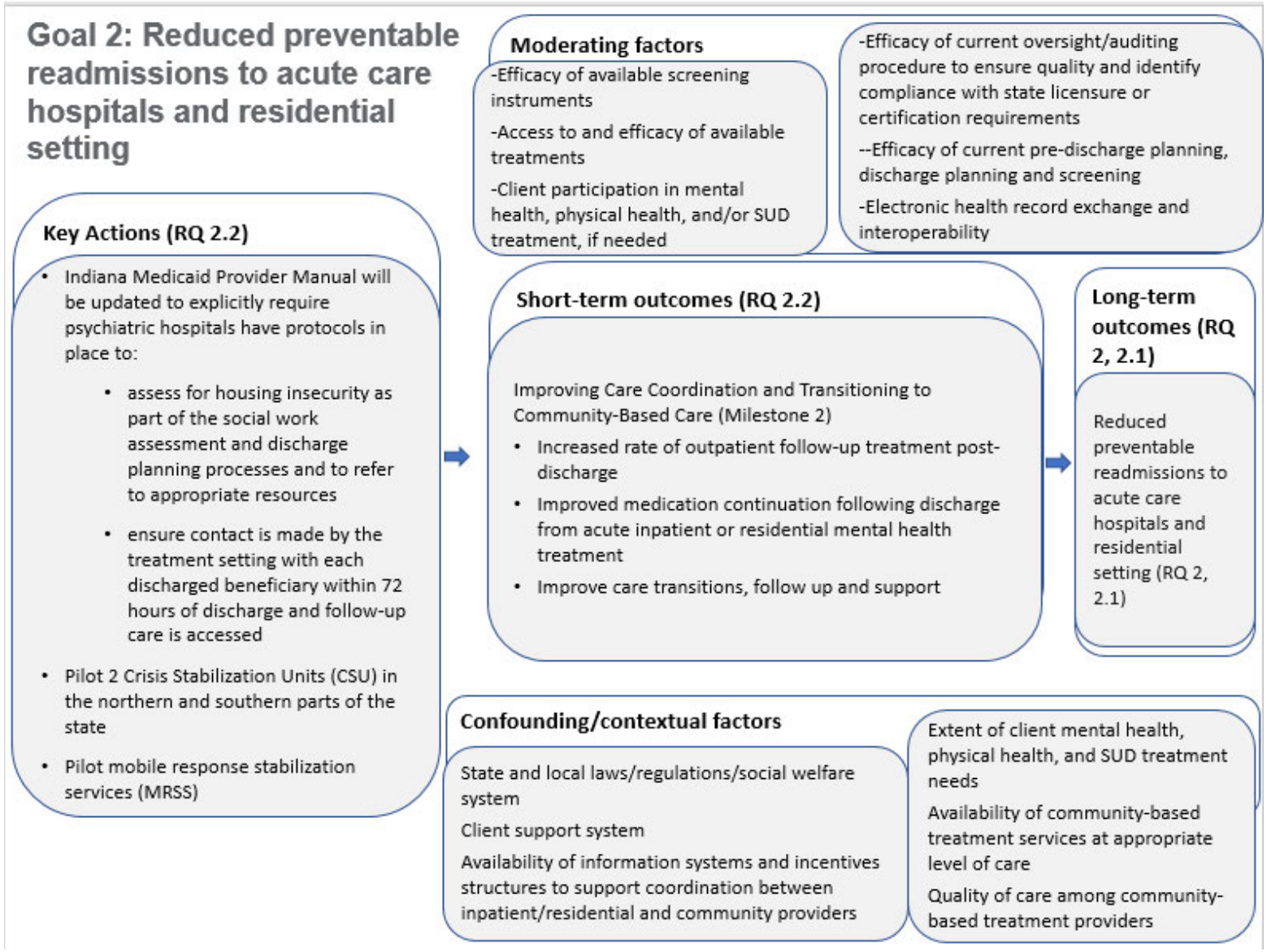
The evaluation explores the impact of expanding access to high-quality, evidence-based mental health treatment services in IMDs on reductions to preventable readmissions to acute care hospitals and residential settings. **Exhibit B.2.a.** below lists the hypothesis and research questions and **Exhibit B.2.b.** outlines the logic model corresponding to this goal.

Exhibit B.2.a.: Hypothesis and Research Questions for Goal 2[5]

Hypotheses	Research Questions
Hypothesis 2: The SMI/SED demonstration will result in reductions in preventable readmissions to acute care hospitals and residential settings.	**Primary research question 2:** Does the SMI/SED demonstration result in reductions in preventable readmissions to acute care hospitals and residential settings (including, short-term inpatient and residential admissions to both IMDs and non-IMD acute care hospitals, critical access hospitals, and residential settings)? **Subsidiary research question 2.1:** How do the SMI/SED demonstration effects on reducing preventable readmissions to acute care hospitals and residential settings vary by geographic area or beneficiary characteristics? **Subsidiary research question 2.2:** How do demonstration activities contribute to reductions in preventable readmissions to acute care hospitals and residential settings? **Subsidiary research question 2.3:** Does the SMI/SED demonstration result in increased screening and intervention for comorbid SUD and physical health conditions during acute care psychiatric hospital and residential setting stays and increased treatment for such conditions after discharge?

5 Indiana is not including Subsidiary Research Question 2.3: "Does the SMI/SED demonstration result in increased screening and intervention for comorbid SUD and physical health conditions during acute care psychiatric hospital and residential setting stays and increased treatment for such conditions after discharge?" Calculation and monitoring of such a metric will require medical reviews be performed which would require substantial resources. As this research question is not associated with primary objective of the waiver, the State determined not to monitor and calculate this metric during time of preparation of this evaluation plan.

Exhibit B.2.b.: Logic Model for Goal 2



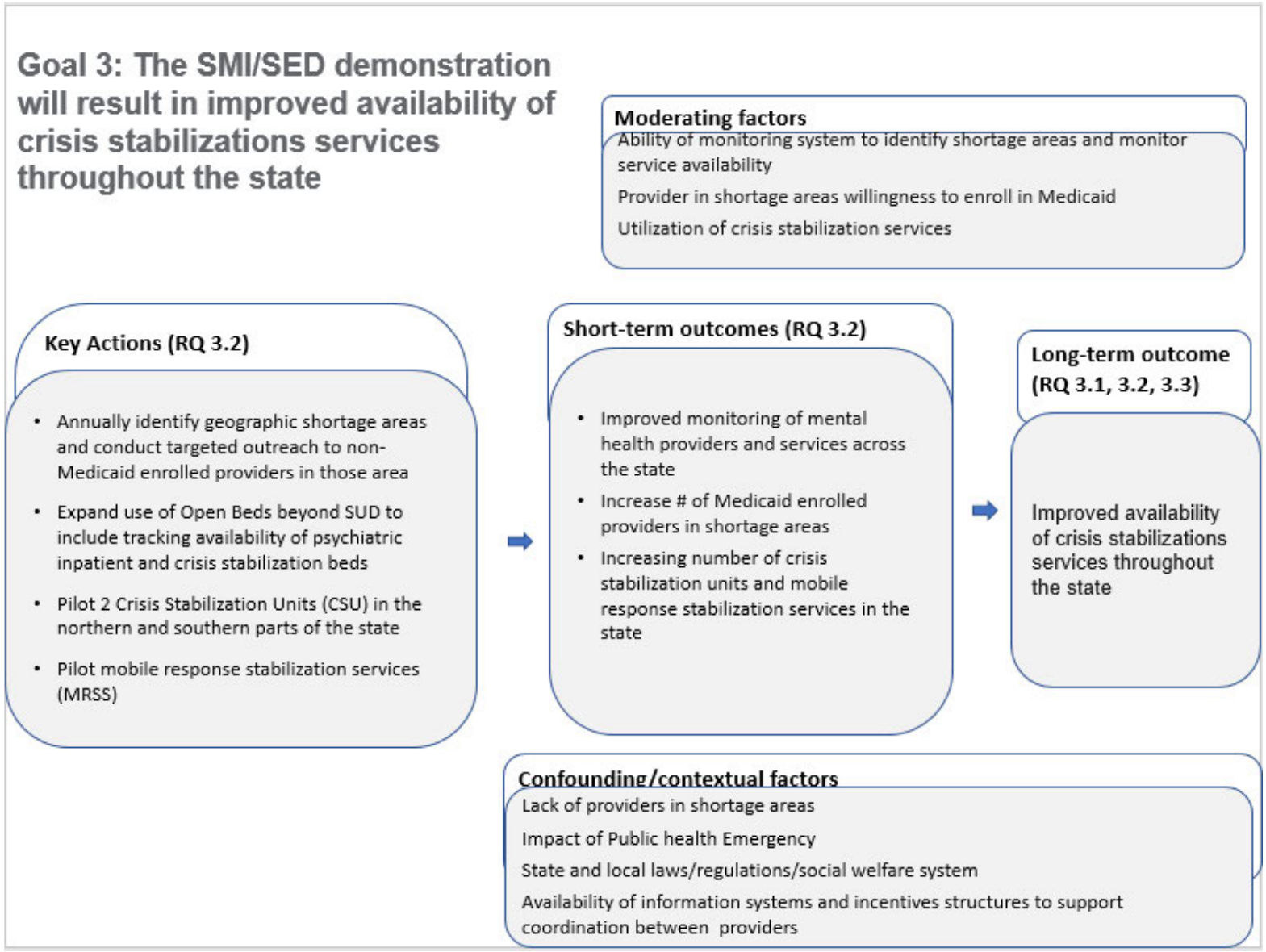
3. Goal Three: Improved availability of crisis stabilization services utilizing multiple service models to meet the unique needs across the state

Indiana will assess the availability of crisis stabilization services across the state. **Exhibit B.3.a.** below lists the hypotheses and research questions and **Exhibit B.3.b.** outlines the logic model corresponding to this goal.

Exhibit B.3.a.: Hypothesis and Research Questions for Goal 3

Hypotheses	Research Questions
Hypothesis 3: The SMI/SED demonstration will result in improved availability of crisis stabilization services throughout the state.	**Primary research question 3.1:** To what extent does the SMI/SED demonstration result in improved availability of crisis outreach and response services (including crisis call centers, mobile crisis units, crisis observation/assessment centers, and coordinated community crisis response teams) throughout the state? **Primary research question 3.2:** To what extent does the SMI/SED demonstration result in improved availability of intensive outpatient services and partial hospitalization? **Primary research question 3.3:** To what extent does the SMI/SED demonstration improve the availability of crisis stabilization services provided during acute short-term stays in each of the following: public and private psychiatric hospitals; residential treatment facilities; general hospital psychiatric units; and community-based settings (such as residential crisis stabilization programs, small inpatient units in community mental health centers, peer-run crisis respite programs, and so on)?

Exhibit B.3.b.: Logic Model for Goal 3



4. Goal Four: Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI or SED including through increased integration of primary and behavioral health care.

Indiana will assess the access to community-based services to address the chronic mental health care needs of beneficiaries with SMI or SED including through increased integration of primary and behavioral health care. **Exhibit B.4.a.** below lists the hypotheses and research questions and **Exhibit B.4.b.** outlines the logic model corresponding to this goal.

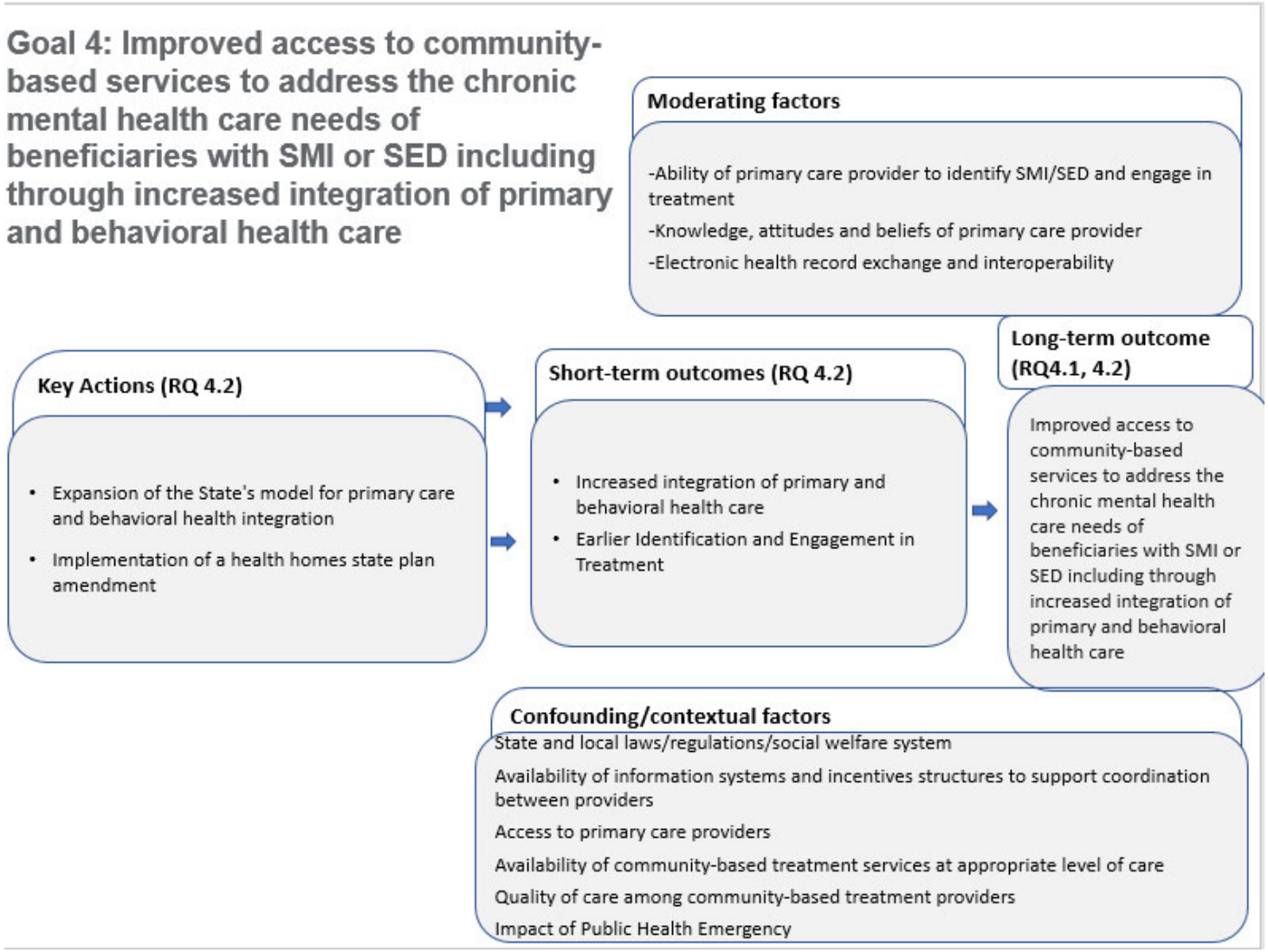
Exhibit B.4.a.: Hypothesis and Research Questions for Goal 4[6]

Hypotheses	Research Questions
Hypothesis 4: Access of beneficiaries with SMI/SED to community-based services to address their chronic mental health care needs will improve under the demonstration, including through increased integration of primary and behavioral health care.	**Primary research question 4.1:** Does the demonstration result in improved access of beneficiaries with SMI/SED to community-based services to address their chronic mental health care needs? **Subsidiary research question 4.1a:** To what extent does the demonstration result in improved availability of specific types[7] of community-based services needed to comprehensively address the chronic needs of beneficiaries with SMI/SED? **Subsidiary research question 4.1b:** To what extent does the demonstration result in improved access of SMI/SED beneficiaries to the specific types of community-based services that they need? **Primary research question 4.2:** Does the integration of primary and behavioral health care to address the chronic mental health care needs of beneficiaries with SMI/SED increase under the demonstration?

[6] Indiana is not including Subsidiary Research Question 4.1c in this Evaluation Plan: "How do the SMI/SED demonstration effects on access to community-based services vary by geographic area or beneficiary characteristics?" The provider type summaries seen in Goal 3 can address this subsidiary RQ and streamline evaluation efforts and State resources.

[7] Types of community-based services to address the chronic mental health care needs of beneficiaries with SMI/SED may include certified community behavioral health clinics, supportive housing, illness self-management, evidence-based psychotherapy, peer-support and consumer-operated services, psychosocial habilitation or rehabilitation, outreach to and engagement of those who are homeless, systematic medication management, integrated treatment for co-occurring substance use disorders and other disabilities, supported employment, education and family supports, school-based services, and trauma-informed care, among others.

Exhibit B.4.b.: Logic Model for Goal 4



5. Goal Five: Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities

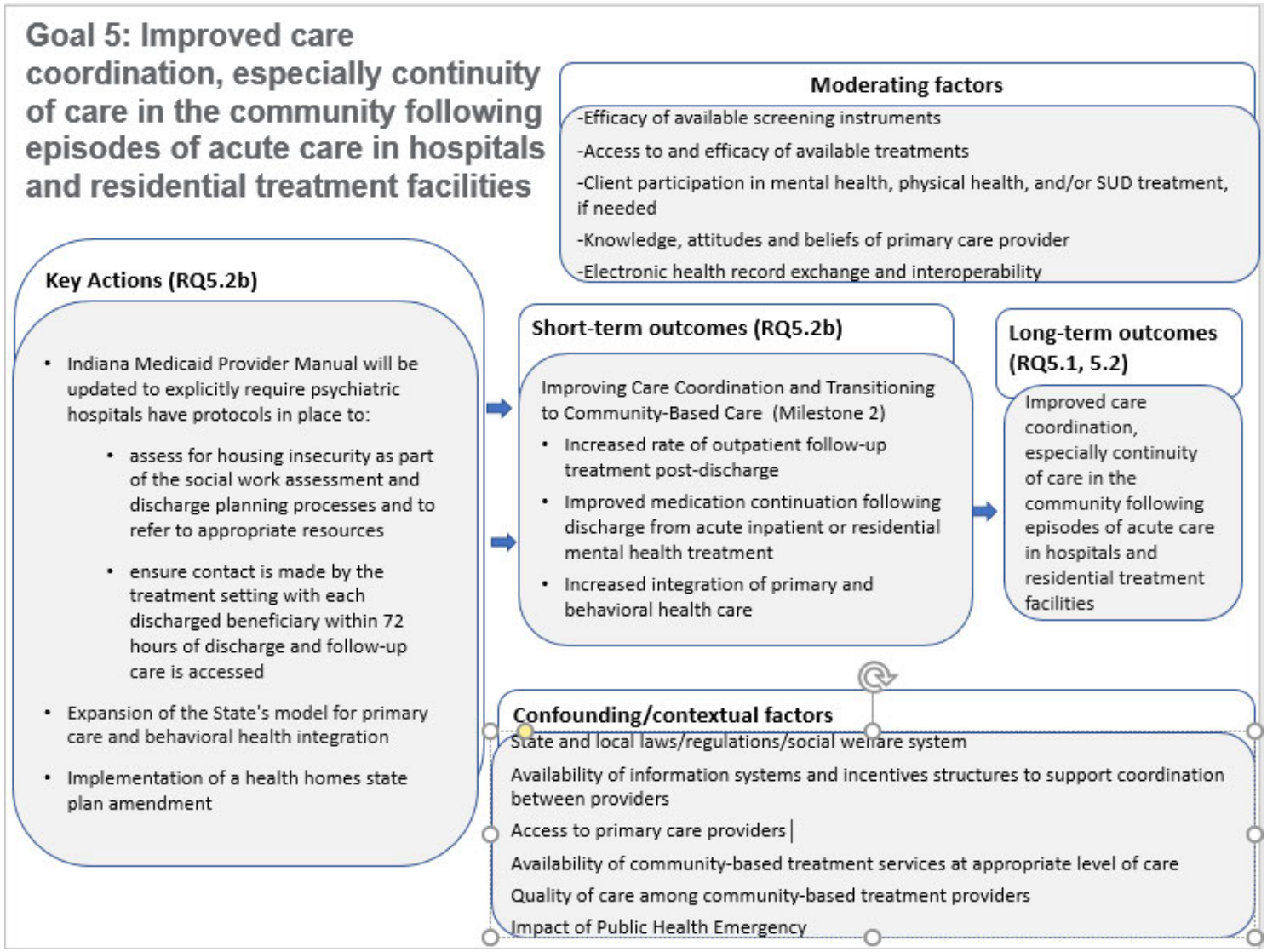
Indiana will assess care coordination for beneficiaries with SMI/SED, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities. **Exhibit B.5.a.** below lists the hypotheses and research questions and **Exhibit B.5.b.** outlines the logic model corresponding to this goal.

Exhibit B.5.a.: Hypotheses and Research Questions for Goal 5[8]

Hypotheses	Research Questions
Hypothesis 5: The SMI/SED demonstration will result in improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities.	**Primary research question 5.1:** Does the SMI/SED demonstration result in improved care coordination for beneficiaries with SMI/SED? **Primary research question 5.2:** Does the SMI/SED demonstration result in improved continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities? **Subsidiary research question 5.2b:** How do demonstration activities contribute to improved continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities?

[8] Indiana is not including Subsidiary Research Question 5.2a: "Does the SMI/SED demonstration result in improved discharge planning and outcomes regarding housing for beneficiaries transitioning out of acute psychiatric care in hospitals and residential treatment facilities?" The rationale for not addressing this question is that it is a subsidiary question (versus a primary research question), and the level of effort involved in obtaining and reviewing the facility records/facility discharge records (required for any of the CMS-recommended outcome measures) would be substantial.

Exhibit B.5.b.: Logic Model for Goal 5



C. Methodology

This section provides a summary of Indiana's evaluation design, including data sources, target populations, evaluation period, and analytic methods. This Evaluation Plan aims to provide a baseline of the demonstration through descriptive quantitative analyses and qualitative data collection and analysis to reflect all five of the program goals and to incorporate CMS' §1115(a) SMI/SED and SUD Evaluation Guidance.[9]

This Evaluation Plan covers Interim Evaluation and Summative Evaluation for SMI Demonstration (2021-2025 waiver) which will be submitted to CMS in December 2024 and June 2027 respectively. The observation period for the evaluation will be calendar years (CYs) 2018 to 2025. This period includes three years before the SMI/SED amendment took effect on January 1, 2021 through December 31, 2025.

For the Interim Evaluation, the time period is limited to fewer years (through 2023). Since we will be estimating the outcome measures based on data from the observation period, the interim evaluation will not provide conclusions about the impact of the waiver (e.g., related to health status, service use) beyond this period. The evaluation will include descriptive analyses of changes in the composition of the enrolled population, and the evaluator will consider any findings from this analysis when interpreting the results of the analyses described in the Evaluation Plan.

The evaluator will use a mixed-methods approach employing both quantitative and qualitative analyses to answer the identified research questions. Qualitative analyses will support an understanding of stakeholders' perspectives related to context, implementation, and outcomes and will identify contextual factors that help to explain outcomes. Quantitative analyses will examine changes in outcomes and estimate the impact of policy changes, as demonstration design and data permit. Quantitative and qualitative analyses will reinforce each other and contribute to understanding context, implementation, impact, and variation. Findings from evaluation activities will be summarized in key deliverables for CMS, including the Mid-Point Assessment Report, Interim Evaluation Report, and Summative Evaluation Report. Additional information on deliverables and associated timelines can be found in **Attachment E.3. Timeline and Major Milestones**.

The ongoing PHE, which began in March 2020, has continued to cause substantial changes to HIP policies, service utilization and provider availability, and will have short- and long-term impacts on Indiana's health care system. Due to the PHE, the State suspended policies regarding disenrollment of members and programmatic changes to establishing crisis services like Crisis Stabilization Units (CSU) and also expanded behavioral health telemedicine services.[10,11,12] The PHE is in effect as of this evaluation plan development and is likely to impact the evaluation of SMI/SED waiver policies. Social distancing and prioritization of health care resources are anticipated to affect utilization of a wide variety of services in 2020 and beyond, including inpatient admissions and emergency visits, demand for

[9] CMS. 1115 Demonstration State Monitoring & Evaluation Resources. Released and Accessed May 1, 2021 at https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html

[10] Indiana Medicaid allows telemedicine and telephone options for most health care and mental health interactions, FSSA News Release, March 19 2020, Accessed from https://www.in.gov/fssa/files/telemedicine_release_3_19_FINAL.pdf

[11] Senate Bill No. 3: Telehealth Matters, Accessed from http://iga.in.gov/legislative/2021/bills/senate/3#document-742b0b09

[12] These policies were suspended March 17, 2020. Based on State "Medicaid Policy Changes: re COVID-19" updated on July 28, 2020 and in discussion with State as of May 2021.

behavioral health care services, as well as mode of care changes such as increased use of telehealth. For example, mental health-related ED use in 2020 may be reduced due to concerns about acquiring the COVID-19 virus at the hospital; access to community-based services may be restricted due to temporary provider closures and/or limited hours and the use of telehealth; and initiatives to integrate physical and behavioral health and to expand crisis stabilization services may be delayed. Additionally, Medicaid enrollment is impacted due to beneficiary loss of income during the PHE, some health care providers experience financial stress due to the short-term loss of income, and there may be changes in payer mix as individuals lose employer-based coverage and Medicaid enrollment and the number of uninsured increases.

The use of data starting from 2020 to analyze the impact of the SMI/SED waiver requires careful consideration including the time frame for implementation of all waiver policies and the economic impact of COVID-19. We will consider this impact in our evaluation of the research questions, data and appropriate analytic methods during Interim and Summative Evaluation Report development.

Section F includes the analytic design tables for each goal, detailing the relevant hypotheses, research questions, data sources, outcome measures, analytic methods, and comparison group(s) (if applicable). These tables also specify the years of data to be used for individual research questions.

1. Data Sources and Collection

The evaluator will compile data from claims/encounter and enrollment data. The evaluator will also capture qualitative data via key informant interviews (i.e., State officials, MCEs, and providers). **Exhibit C.1** summarizes the data sources anticipated to be used to evaluate each goal ("X" indicates relevant sources for each goal), followed by detailed descriptions of key data sources. **Section F** provides specific information regarding how these data sources will be used in the evaluation.

Exhibit C.1: Data Sources by Goal

Type	Data Sources	Goal 1 ED Utilization and LOS	Goal 2 Preventable Readmissions	Goal 3 Crisis Stabilization	Goal 4 Community-based Services	Goal 5 Care Coordination
Indiana–Quantitative	1. Member Eligibility, Application, and Enrollment Data *Note: Enrollment data will be used to select members for key informant interviews across goals.*	X	X	-	X	X
	2. Claims / Encounter Data	X	X	-	X	X
	3. State administrative data (2018-2025) collected via the Monitoring Protocol[13]	-	X	X	X	-

[13] Other sources of State administrative data may be leveraged as available.

Type	Data Sources	Goal 1 ED Utilization and LOS	Goal 2 Preventable Readmissions	Goal 3 Crisis Stabilization	Goal 4 Community-based Services	Goal 5 Care Coordination
Indiana – Qualitative	1. Key Informant Interviews with Members	X	X	X	X	X
	2. Key Informant Interviews with State Officials	X	X	X	X	X
	3. Key Informant Interviews with MCEs	X	X	X	X	X
	4. Key Informant Interviews with Other Stakeholders (including consumer advocates)	X	X	X	X	X
	5. Key Informant Interviews with Providers	X	X	X	X	X

Note: We will build on the metric specifications developed for the 2020 Summative Evaluation (making any required refinements) for the 2021-2025 waiver. Metrics not developed for 2020 Evaluation will need to be created for the 2021-2025 waiver accounting for any changes to billing codes and service specifications.

Internal Data Source Descriptions – Quantitative

Current sources include:

- *Member Eligibility, Application, and Enrollment Data:* Member application and enrollment data provide information on the size, location, and socio-demographic makeup of SMI enrollees.
- *Claims / Encounter Data:* The claims records (encounter data) that the MCEs submit to the State provide information about the health care utilization patterns of SMI enrollees and identifies enrolled providers that are actively providing services.
- State Administrative Data: Program administrative data will include items such as the number of FQHCs that offer behavioral health services and the number of enrolled Medicaid providers of various types.

Other applicable data sources may be included as available and validated.

The data acquisition process will include identifying the data elements of interest (e.g., coverage information, beneficiary demographic characteristics, claims / encounter data including at least first two diagnosis codes) and appropriate data sources or data tables. Different data are captured in different systems and for appropriate interpretation and use of data, supporting data dictionaries from the data owners will be used. Enrollment and claims data from Enterprise Data Warehouse (EDW) will be used in conjunction to identify the SMI population. The population total will be benchmarked to State reports to ensure accurate identification of the target SMI population. Claims associated with individuals identified as having SMI and covered under the waiver will be used to develop utilization-based outcome measures (example ED visits in a year). Administrative data like summary information of number of crisis call centers, mobile centers will be studied for anomalies (e.g., very large or small numbers, benchmark to published reports).

External Data Source Descriptions – Quantitative

The State will consider using external data sources as needed – specifically for any benchmark or comparison of the evaluation measures. For example, selected adult core set quality measures can be used to benchmark the research question outcome measures. Data for these measures are publicly available on CMS website.

Internal Data Source Descriptions – Qualitative

In addition to quantitative data collection and analysis, Indiana will conduct key informant interviews to capture member, State Official, MCE, provider, and other stakeholder experience and evaluate other outcomes related to each goal. Indiana will identify potential participants based on existing contacts from the 2018-2020 HIP and the 2020 SMI/SED Summative Evaluation Report, and other member and stakeholder lists. Indiana is not planning to use any monetary incentives for recruitment, and participation will not affect member enrollment status. Indiana will use findings from the key informant interviews to answer research questions in the Mid-Point and two (Interim and Summative) Evaluation reports.[14] The evaluator will conduct three rounds of key informant interviews in the spring/summer of 2023, 2024, and 2026.

Interview topics will vary from year to year and by interviewee role, although there will be continuity in the overall topic domains. As the evaluation progresses, additional topics may surface. **Exhibit C.2** describes the targeted number of interviewees and potential topics.

For each round of key informant interviews, the evaluator will work with FSSA to develop interview protocols tailored to each role. The protocols will include semi-structured questions and potential probes and last approximately 15-60 depending on the interview type. A trained interviewer will facilitate the interviews with the support of note taker who will also provide logistical support. With participant consent, interviews will be recorded and transcribed with brief summaries written up by facilitators immediately afterwards.

14 The evaluator will also perform key informant interviews in 2021 for purposes of the 2020 Summative Evaluation Report and will leverage findings for the 2021-2025 evaluation reports.

Exhibit C.2: Summary of Indiana-Specific Qualitative Data Collection – Key Informant Interviews by Type, to be performed in 2021

Type	Potential Topics	Targeted Number of Interviewees	Approach to Selecting Participants
Member (15-minute interviews)	• Demonstration activities or their components or characteristics that stakeholders identify as most effective or hindering the effectiveness in: ○ Reducing ED visits, preventable readmissions ○ Improved availability to the range of community-based mental health services (including crisis stabilization), care coordination and continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities. ○ Reducing preventable readmissions to acute care hospitals and residential settings	25 interviews	Stratified random sample of beneficiaries
State Officials (60-minute interviews)	• Changes made to systems, processes, or policies • Demonstration activities most effective in: ○ Reducing utilization and lengths of stays in EDs ○ Reducing preventable readmissions to acute care hospitals and residential settings • Identify any obstacles as hindering the effectiveness of the demonstration in: ○ Reducing utilization and lengths of stays in EDs ○ Reducing preventable readmissions to acute care hospitals and residential settings	Two semi-structured interviews (including group interviews)	The evaluator will identify key state officials involved in the development, planning and administrative of the SMI/SED waiver.
MCEs (30–60-minute interviews)	• Demonstration activities most effective in: ○ Reducing preventable readmissions to acute care hospitals and residential settings ○ Data sharing systems, processes, or policies that staff identify as most effective for improving care coordination • Identify any obstacles as hindering the effectiveness of the demonstration in: ○ Reducing preventable readmissions to acute care hospitals and residential settings ○ Data sharing systems, processes, or policies aimed at improving care coordination	Four semi-structured interviews with representatives from the four MCEs each year	Evaluator will interview staff from each contracted MCE involved in supporting the SMI/SED waiver

Type	Potential Topics	Targeted Number of Interviewees	Approach to Selecting Participants
Providers (15–30-minute interviews – individual providers 30–60-minute interviews – provider associations	• Demonstration activities most effective in: ○ Reducing utilization and lengths of stays in EDs ○ Reducing preventable readmissions to acute care hospitals and residential settings ○ Systems, processes, or policies that staff identify as most effective for improving care coordination • Identify any obstacles as hindering the effectiveness of the demonstration in: ○ Reducing utilization and lengths of stays in EDs ○ Reducing preventable readmissions to acute care hospitals and residential settings ○ Systems, processes, or policies aimed at improving care coordination	A total of 13 provider/provider association interviews will be performed and inform all hypotheses Interviews will include provider associations and certified navigators	Evaluator will identify key provider associations serving this population (e.g., Indiana Hospital Association)
Other Stakeholders (30-60 minutes)	• Demonstration activities regarding systems, processes, or policies that staff identify as most effective for improving care coordination • Obstacles that staff identify as hindering the effectiveness of demonstration activities regarding data sharing systems, processes, or policies aimed at improving care coordination	A total of three interviews will be conducted. The interviewee will be determined based on stakeholder availability.	TBD

Data Quality and Validation

Accuracy of any data driven analyses is dependent on the quality of the underlying data used. The program evaluation will use quantitative data based primarily on state claims, enrollment and other administrative data. Qualitative analyses will be based on information collected from key informant interviews.

Prior to developing any outcome metrics based on the enrollment, claims, administrative or other identified data, the evaluator will perform data validation. Validation of data will include obtaining data dictionaries that outline the variable names and possible values for the variables included in the data. The evaluator will develop descriptive statistics (e.g., count of beneficiaries by month and sociodemographic characteristics) for trend and outlier analyses to test if the variables have the correct values and to identify potential outliers or data anomalies. In case of identified data anomalies, the evaluator will coordinate with data stakeholders to identify strategies for data resolution or as needed account for the anomalies for program impact estimation.

The proposed qualitative data collection strategy efficiently focuses on collecting information through key informant interviews that cannot be obtained through other means. The data collection process will emphasize continual improvement and we will reflect on the data collected over initial interviews to revise protocols and select participants for subsequent rounds of data collection. The evaluator will leverage best practices from experience conducting data collection for other large-scale evaluations to train team members in interviewing and note-taking techniques to ensure consistency.

2. Target and Comparison Populations

The target population for analyses encompasses all Medicaid beneficiaries covered by an IHCP program aged 21-64 years with SMI regardless of their delivery system (e.g., managed care or fee-for-service). The SMI population is identified through four diagnosis codes in the primary or secondary diagnosis position (F20.xx [Schizophrenia and sub codes up to 2 places], F25.xx [Schizoaffective Disorder and sub codes up to two places], F31.xx [Bipolar and all sub codes up to 2 places], F33.xx [Major depression Recurrent and all sub codes up to two places]). Individuals not included in this target population are outlined in **Exhibit A.3**. IHCP programs include HIP members who are low-income, non-disabled adults ages 19 to 64; other adults eligible for Medicaid in Indiana include individuals who are 65 and older, blind, or disabled and who are also not eligible for Medicare, or low-income adults who can receive home and community-based services or who are in nursing homes and other facilities.

During the development of strategies for comparative analyses, both within-state and other-state comparison groups who are similar to HIP members but not subject to the policies being evaluated were considered. Ideally, a comparison group used to evaluate the impact of program implementation is a population with similar demographics but without comparable program or policy changes.

CMS' guidance outlined several possible comparison groups[15] (like similar beneficiaries in states without SMI/SED 1115 waivers, states without SMI/SED 1115, similar non-Medicaid beneficiaries, population prior to demonstration). Some of the suggested comparison groups are not feasible or ideal for this evaluation due to specific aspects of Indiana SMI waiver, specifically:

- The State includes all Medicaid beneficiaries with SMI and thus limits the availability of appropriate within-state comparison groups.
- SMI/SED Waiver Demonstration does not involve random assignment and the State has not staged policy implementation based on beneficiary characteristics.
- Requesting claims data directly from other states will be challenging given that other states have limited resources available for such an exchange, and also often have concerns related to how their results are publicized and expressed.
- While CMS' T-MSIS contains Medicaid claims data from other states, the availability, access, and timeliness of relevant claims data for states appropriate for comparisons to Indiana for purposes of this waiver would need to be further explored. Accessing, processing, and interpreting this data will be time-consuming and potentially challenging given variances in Medicaid programs and related billing and payment requirements. T-MSIS data has not been available in a timely manner for analytic purposes until recently.
- Indiana does not have an All-Payer Claims Database (APCD) that contains claims for hospital and community-based services for non-Medicaid beneficiaries with SMI/SED diagnoses.
- Some non-claims-based data sources will not be available in a timely manner. For example, using the measures in the CMS Adult Core Set to compare Indiana to other states may not be possible to the timing of the release of measure results.

[15] https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/smi-sed-eval-guide-appendix-a.pdf.

For these reasons, depending on the research question, Indiana's Evaluation Plan uses population prior to Demonstration. The evaluator will develop quasi-experimental analyses (e.g., ITS) when adequate data are available before and after policy implementation. For such analyses, the SMI population post-policy implementation is the target while the member population prior to policy implementation is the comparison group. As necessary, the evaluator will explain in the Interim and Summative Evaluation Reports why regression discontinuity designs using factors like age, medical frailty was not used.

3. Analytic Methods

Indiana will use a use a mixed-methods approach employing both quantitative and qualitative analyses to answer the research questions in this evaluation. Qualitative analyses will support an understanding of stakeholders' perspectives related to context, implementation, and outcomes and will identify contextual factors that help to explain outcomes. Quantitative analyses will examine changes in outcomes and estimate the impact of policy changes, as demonstration design and data permit. Quantitative and qualitative analyses will reinforce each other and contribute to understanding context, implementation, impact, and variation.

Qualitative Analyses*:* Qualitative data collected through key informant interviews will be analyzed using thematic analysis, a systematic data coding and analysis process during which information is categorized with codes developed iteratively to reflect themes or patterns within the data. In general, the evaluation team will first analyze the data from each individual interview and then analyze data across all of the interviews as well as meaningful sub-groups. Indiana will use findings from the key informant interviews to answer research questions in the Mid-Point and two (Interim and Summative) Evaluation reports.

Quantitative Descriptive and Trend Analyses: Descriptive statistics (e.g., total, average, median, maximum, proportion) will be calculated to develop an understanding of characteristics of members participating in the SMI/SED waiver program (across time where necessary) as well as for observational inference on trends in outcomes of interest. The descriptive statistics will include information like the number of members, number of ED visits, proportion of beneficiaries who use certain services and so on by characteristics of interest (e.g., age, gender, race, health condition [e.g., depression, diabetes], region). To identify underlying trends, seasonal patterns and outliers, in addition to the descriptive statistics, the evaluator will also leverage data visualizations (e.g., line chart showing disenrollment rate over time, clustered bar chart showing beneficiary composition over time).

Where applicable and feasible, appropriate statistical tests (e.g., Chi-Square test for independence) will be used to test for differences between beneficiaries covered by SMI/SED waiver and comparison groups (e.g., non-SMI/SED waiver members included in the coverage) or to test for differences between subgroups of interest. These tests will use, as appropriate, regression-based adjustments to control for changes in member characteristics to estimate changes in measures of interest across time. The descriptive statistics along with related statistical analyses (test for difference or regression adjustments as appropriate) will be used to analyze impact of the waiver program.

Cross-Sectional Analyses: Where feasible, cross-sectional models will be used to assess associations and compare risk-adjusted outcomes for SMI beneficiaries to comparison beneficiaries (non-SMI/SED beneficiaries included in the coverage). The evaluator will conduct standard power calculations to ensure adequacy of sample sizes in available data for model development. A variety of parametric

models and techniques to estimate the models are available. We will use the outcome variable characteristics, for example type (e.g., categorical or continuous) and distribution (e.g., normal, skewed), to determine the model specifications (e.g., logistic, linear, log-linear). Models will include beneficiary and geographic-level covariates to control for differences between the groups of interest. The covariates will include demographic characteristics, income level, health status, regional characteristics, and other factors that are relevant and available within the data sources used. Given the lack of appropriate comparison groups (as discussed above), the evaluator does not anticipate utilizing cross-sectional analyses.

Quantitative Impact Analyses: Because the implementation of Indiana's policy changes did not involve a randomized control design, the evaluation will use quasi-experimental approaches to estimate the impact of policy changes. For some research questions, CMS guidance indicates that states should consider a difference in differences (DiD) approach. DiD is a regression technique that measures the impact of the model by comparing changes in risk-adjusted outcomes for the target population to changes in outcomes in a comparison group, between the baseline and intervention periods. Standard power calculations would be necessary to assess adequacy of sample size in available data for model development. If this approach is used, the evaluator would ensure model specifications are appropriate for the outcome variable (e.g., logit for dichotomous outcomes) of interest. Models would include beneficiary and geographic-level covariates to control for differences between the groups of interest. The covariates would include demographic characteristics, income level, health status, regional characteristics, and other variables that are relevant and available in the data sources used. The validity of the DiD approach relies on the assumption that intervention and comparison groups were on parallel trends in the baseline. As such, it would be necessary to perform tests for parallel trends in the baseline period for key outcomes using statistical testing and visual trend analysis. The evaluator does not anticipate utilizing such analytics for due to limitation of availability of appropriate comparison groups (as discussed above).

As the intervention is at the population level and multiple years of data (before and after the policy change) are available, the evaluator proposes leveraging another quasi-experimental method called ITS. The ITS analysis (or a pre/post design) assesses change in an outcome of interest (e.g., readmission rate) after the policy change compared to the expected trend if there were no policy change. To strengthen this analysis, the evaluator will consider the method (e.g., extended time series, controlled segmented regression, propensity score based weighted) appropriate for the outcome of interest and control for possible confounders. For example, a segmented regression model with indicator variables to identify pre/post implementation time-period (like below) can be used in instances where an outcome variable has a linear trend:

$$y_{it} = \beta_0 + \beta_1 T_t + \beta_2 P_t + \beta_3 P T_t + X_{it} + \varepsilon_{it}$$

where

- y_{it} = measure of interest for beneficiary 'i' at time 't'
- β_0 represents the baseline level
- $\beta_1$is the trend coefficient pre-intervention, T_t indicates time from first baseline period
- $\beta_2$is the coefficient for the change in level of outcome post intervention, P_t indicates program implementation indicator

- β_3 indicates the slope change following intervention (or program start), PT_t indicates post implementation period (2021 and later)
- X_{it} state or program beneficiary characteristics
- ε = error term for variability not captured by the model

The model specifications will be dependent on the outcome of interest as well as any other confounding factors (or presence of autocorrelation) that might need to be considered. Since the SMI demonstration began in January 2020 (first waiver), the baseline period for the model is prior to the implementation of any waiver policies (2018 – 2019). The first year of the demonstration (2020) overlapped with onset of the COVID-19 pandemic. A separate indicator variable for the 2020 time-period will likely aide capture information on changes that were caused by reasons other than the demonstration. Prior to implementing these analyses, the evaluator would evaluate pre-implementation trends and assess comparability over time. CMS guidance indicates reviewers will consider such an approach when credible comparison groups are not available. This approach will require multiple years of baseline data (e.g., 2018-2019) to enable an estimate of the baseline trend before the implementation of the waiver amendment and is best employed over longer time spans. Additionally, prior to regression model estimation, the evaluator will perform any needed checks for multicollinearity among the independent variables (e.g., beneficiary characteristics) of interest.

Subgroup Analysis: These analyses will be part of descriptive, cross-sectional, and quantitative impact analyses as listed in **Section F**. The evaluator will determine the type and number of subgroup analyses by appropriateness for the research question, and as data and sample sizes allow. ITS or DiD analysis will produce estimates of the average impact of a policy change. However, the impact may vary by beneficiary subgroups (e.g., by older and younger members, by length of enrollment, by income, by region within state). To inform the selection of characteristics that will define subgroups, information gathered through interviews as well as through the descriptive analysis will be considered. The key informant interviews will provide perspective on potential subgroups for analysis, e.g., differences in care between geographic areas, historically marginalized populations, and individuals receiving services through the Medicaid Rehabilitation Option. The evaluator will use Medicaid administrative and enrollment data to identify these populations (e.g., based on zip code of residence, reported race/ethnicity, dual eligibility, receiving Medicaid Rehabilitation Option services via fee-for-service) for analysis. We will first test whether subgroups are adequately balanced across key characteristics. If necessary, we will use matching methods to develop subgroup-specific comparison groups, to balance intervention and comparison groups in observed characteristics. The ability to look at subgroups and differentiated effects is ultimately limited by the number of beneficiaries in each group and the variability in the data. Lewin will weigh the value of testing for differences among subgroups against having adequate sample size and power to do so precisely.

Implications of the COVID-19 pandemic: Onset of COVID-19 PHE coincides with implementation of the first year of SMI waiver – resulting in complexity in parsing out the effect of the pandemic and implementation of new policies on outcomes of interest (e.g., utilization of ED visits, readmission, follow-up provider visits). The pandemic affects program enrollment, beneficiary behavior (related to varied factors like service utilization, mental health and substance use), and provider behavior and has also affected how the waiver policies were implemented. Program impact estimation will thereby need

to address these confounding effects. Some commonly adapted approaches are inclusion of time period indicators (e.g., pre-2020, first year of SMI waiver / COVID (2020), post-2020), covariates capturing COVID-19 severity in regression models, developing beneficiary-level sub-group analyses that control for individual level factors including socio-economic status and health factors. A beneficiary level analysis will typically include a regression like:

$$y_{it} = \beta_0 + \beta_1 T_t + \beta_{41} P1_t + \beta_{42} P1T_t + \beta_2 P_t + \beta_3 PT_t + X_{it} + Z_t$$

where:

- $y_{it} =$ beneficiary level measure of interest at time 't'
- β_0 represents the baseline level
- $\beta_1$is the trend coefficient pre-intervention, T_t indicates time from first baseline period
- $\beta_2$is the coefficient for the change in level of outcome post intervention, P_t indicates program implementation indicator
- β_3 indicates the slope change following intervention (or program start), PT_t indicates post implementation period
- X_{it} beneficiary characteristics at time 't'
- Z_t regional or economic factors (e.g. prevalence of COVID-19) at time 't'
- β_{41} is the coefficient for the change in level of outcome and β_{42} indicates the change in trend of the outcome after implementation of demonstration in 2020

COVID-19 has had varying impact – especially among racial and ethnic minorities, individuals with low income, and access to care.[16] The evaluator will develop sensitivity analyses by performing sub-group analyses by identified population sub-cohort (e.g., race, ethnicity, dual eligible status, geographic location) to provide valid program estimates.

16 Accessed on 02/21/2022 from:
https://www.milbank.org/wp-content/uploads/2021/06/Issue_Brief_COVID-19.pdf
https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf

D. Methodological Limitations

Exhibit D.1 describes the known limitations of the evaluation and anticipated approaches to minimizing those limitations and/or acknowledges where limitations might preclude casual inferences about the effects of demonstration policies. **Section C** contained information on limitations regarding identification of comparison groups and the potential impacts of the COVID-19 PHE on the use of data from 2020 and onwards for evaluation purposes. The Interim and Summative Evaluation Reports will describe in detail the limitations of the evaluation, which may include data and methodological challenges and other limitations identified during the evaluation process that are not described below. These reports will acknowledge approaches taken by the independent evaluator and necessary modifications made to the Evaluation Plan to address these challenges and limitations.

Exhibit D.1: Summary of Methodological Limitations and Approach to Minimizing Limitations

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Overall issues	Impact of COVID-19	The ongoing COVID-19 PHE, which began in March 2020, is anticipated to cause substantial changes to: • Service utilization • Medicaid enrollment • Provider networks	• Use and inclusion of data from CY 2020 and onwards to analyze impact of policies will require careful analyses and be dependent on multiple factors including the period for reinstatement of policies, any long-term changes to service delivery (e.g., telehealth), and COVID-19's economic impact. • Provide context for interpretation of results.
	Quality of provider contact information for key informant interviews	Reliability of provider contact information made completing provider key informant interviews challenging. For example, provider email addresses and phone numbers listed in the MCE provider list often provided only generic office email addresses.	• Obtain support from key provider associations to identify providers for key informant interview purposes. • Use interviews with key provider associations in lieu of individual providers as necessary.
	Impact of changes in population over time	Changes in the SMI case mix over time may have an impact on a variety of areas of this evaluation, including service utilization, member enrollment, and access to services.	• Provide context for interpretation of results.

E. Attachments

Attachment E.1. Summary of Independent Evaluator Approach

Due to the COVID-19 PHE issued in Indiana, and the impact of COVID-19 on the State's budget, an independent evaluator was not procured in time for the initial Evaluation Design submission. However, Indiana has selected an independent evaluator and is in the process of finalizing a contract. The State is committed to securing an independent evaluator in a timely fashion to work through iterations of this Plan with CMS. Indiana will ensure that there are no conflicts of interest to report as stated in Section XVI, Paragraph 1 of CMS's STCs for this Waiver Evaluation.

In order to ensure an independent evaluation, the evaluation process will be independent of any process involving program policy making, management, or activity implementation of the waiver demonstration. The State's responsibility towards an independent evaluation is the assurance of quality data to the evaluator, support in understanding program context of any data anomalies, and identifying the program components that are important for the evaluation.

CMS recommended inclusion of cost analysis to understand how the demonstration affected health care spending. Analyses developed by State's actuary, Milliman Inc., will be included for this portion of the evaluation.

Exhibit E.1: Organizational Conflict of Interest

Indiana Department of Administration
Healthy Indiana Plan 1115 Waiver Evaluation

Professional Services Contract #00000000000000000000051455

Organizational Conflict of Interest Disclosure

The Lewin Group, Inc. ("Lewin") is performing Professional Services Contract #00000000000000000000051455 entitled, "Serious Mental Illness ("SMI") and Serious Emotional Disturbance ("SED") Waiver Evaluation Services" ("Contract"), for the Indiana Department of Administration, Indiana Family and Social Services Administration ("FSSA").

In accordance with the Centers for Medicare and Medicaid ("CMS") Special Terms and Conditions ("STC") 11-W-00296/5 (as extended through December 31, 2030), Attachment A-Developing the Evaluation Design, Section F-Conflict of Interest, FSSA is required to assure CMS that it will obtain an Independent Evaluator which will "conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest." These types of COIs are normally referred to as Organizational Conflicts of Interest ("OCI"). Accordingly, what follows in this OCI disclosure ("Disclosure") is an explanation of why Lewin's performance as the SMIE/SED Waiver Evaluation Contractor under the Contract does not create an actual or potential OCI. This Disclosure is organized to describe; 1) Lewin's relevant corporate affiliates and, 2) Lewin's OCI analysis.

I. Lewin's Affiliate Interests

Lewin is part of UnitedHealth Group, Incorporated ("UHG"), a diversified health and well-being company dedicated to improving the health care system in the United States. UHG is organized into six businesses. Three of those businesses — UnitedHealthcare Community & State, UnitedHealthcare Medicare & Retirement and UnitedHealthcare Employer & Individual — provide network-based health care benefits and related services under the "UnitedHealthcare" brand. The other three businesses operate under the "Optum" brand and include OptumHealth, OptumRx, and OptumInsight. Amongst its services, the Optum businesses offer a large variety of services that include but are not limited to third party administration of specialty benefits, pharmacy benefit management, disease and care management, direct care delivery, consulting, health technology and innovation support to government agencies and external third party insurers and health plans as well as to UnitedHealthcare plans. Although UHG provides certain shared services across the enterprise, Optum and UnitedHealthcare operate as separate businesses with separate operational structures and separately reported financial results. For more information, please see www.unitedhealthgroup.com and www.optum.com.

In conducting a current OCI analysis, Lewin identified three (3) affiliated businesses relevant for discussion, and are as follows:

- *UnitedHealthcare Community and State ("UHC C&S"): UHC* C&S is one of the nation's largest health benefits companies dedicated to providing diversified solutions to states that care for the economically disadvantaged, the medically underserved and those without employer-funded health care coverage. C&S Managed Care Organizations ("MCOs") contract with networks of participating providers and facilities to serve more than 5 million beneficiaries covered under Medicaid (Title 19), CHIP (the Title 21, Children's Health Insurance Program), Dually Eligible (Medicaid-Medicare enrollees), Long Term Care and Children with Special Care Needs (a Title V Program) and other federal and state health care programs. UHC C&S is also a government programs Administrative Services Organization where it acts in the capacity of an administrator on a non-risk basis. C&S participates in Medicaid programs throughout the country. Presently, UHC C&S is not an MCO in the State of Indiana. However, UHC C&S is intending to bid on FSSA Request for Proposal RFP #22-68152 Risk-Based Managed Care Services for Medicaid Beneficiaries (Hoosier Healthwise and Healthy Indiana Plan Programs) (hereby referred to as the "RFP") for which proposals are due August 9, 2021.

- *MedExpress:* MedExpress, which is part of OptumHealth, includes primary and urgent care centers in multiple states that provide walk-in neighborhood care, wellness and prevention service. MedExpress currently provides services to eligible Indiana Medicaid recipients in seven (7) locations throughout the State which include Anderson, Bloomington, Indianapolis, Kokomo, Lafayette, and Muncie.

- *OptumRx:* OptumRx is one of the three largest pharmacy benefit managers and specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. OptumRx provides full-service pharmacy benefits management services, including mail order and specialty pharmacy benefits, and a synchronized pharmacy care experience that combines member engagement with health data and analytics. Its additional services include claims processing, retail network contracting, rebate contracting and management, and clinical programs, such as step therapy, formulary management and disease/drug therapy management programs. OptumRx serves customers in multiple markets and government programs, including commercial, managed care, Medicaid, Medicare, labor and trust, workers compensation and others. OptumRx is presently under contract with FSSA to provide pharmacy benefit management services for the Indiana Health Coverage Program.

II. Lewin's OCI Analysis

For the purpose of this OCI Analysis, Lewin refers to the Federal Acquisition Regulation Part 9.5 which defines three types of conflicts. Upon review, Lewin is not aware of any facts or circumstances that would create an actual or potential OCI. To the extent that an OCI may be perceived to exist, Lewin will explain how the OCI is avoided, neutralized, or mitigated. These conclusions are based on the following:

A. Biased Ground Rules

A Biased Ground Rules OCI arises where a company, as part of its performance of a government contract, sets the ground rules for a later government procurement by, for example, writing the statement of work or the specifications. The primary concern is that the company could create an unfair competitive advantage by biasing the competition in favor of itself or its affiliate. Neither Lewin nor any of its affiliates developed or assisted FSSA in the procurement of the Contract. Accordingly, no Biased Ground Rules OCI exists.

B. Impaired Objectivity

An Impaired Objectivity OCI commonly occurs when a company's work under one government contract could require the company to evaluate the work that company itself or its affiliates performed under a separate government contract. The primary concern is that the company's ability to render impartial advice to the government could be impaired, where that advice involves the use of subjective judgment, and where the advice could affect the economic interests of the company as broadly construed.

Lewin has not identified any situation while performing work as the contracted Independent Evaluator under the Contract would create an actual or potential Impaired Objectivity OCI. Where it might be perceived that the risk of a potential OCI might exist, Lewin will explain why that perceived risk would not become an actual or potential OCI.

Lewin's OCI analysis determined that primary purpose of proposed evaluation is to determine the impact of HIP with regard to eligible Indiana Medicaid recipients and their access to health care services, utilization of those services, and health outcomes. Lewin's OCI analysis concluded that Optum's MedExpress and OptumRx affiliates do not present any risk of an Impaired Objectivity OCI in the conduct of this evaluation. Lewin also established that should its UHC C&S affiliate be awarded a future role as a Managed Care Entity ("MCE") it might be perceived that Lewin would conduct the HIP evaluation in such a manner that could financially and/or contractually benefit UHC C&S. However, after conducting a thorough review of the facts surrounding the scope of Lewin's evaluation support to FSSA, it was determined that no such OCI risk would be created for the following reasons:

- *The Objective Focus of the Evaluation:* The evaluation of the HIP is to support FSSA's continuous effort to assure Indiana Medicaid recipients are receiving the best possible health care as defined by CMS' Triple Aim for better access to care, better health care outcomes, and reduced cost to beneficiaries. At no time

during the course of the evaluation will Lewin be required to evaluate the performance of any HIP MCE including its UCH C&S affiliate as an awarded MCE under the RFP.

- *Lewin's Significant Limitations to Exercise Subjective Judgment:* Lewin will execute all evaluation tasks under an FSSA/CMS-approved evaluation design in accordance with evaluation guidance set forth in CMS STC 11-W-00296/5. Data for the evaluation data is collected from FSSA-directed sources to include statewide Medicaid member surveys, focus groups, key informant interviews, and prescribed data sets from the Indiana Medicaid Management Information System ("MMIS"). Data sets required by Lewin for analysis from state MCOs are provided to Lewin directly from state staff members. Any recommended changes to the evaluation design made by Lewin must go through a review by FSSA and its stakeholders and must be approved by CMS. Combined, these FSSA/CMS mandated requirements and parameters, significantly restricts Lewin from exercising subjective judgment. Furthermore, there is no nexus between the outcomes of Lewin's evaluation of this demonstration and the financial interests of Lewin or any of its affiliates providing healthcare services to Indiana Medicaid recipients. As such, no Impaired Objectivity OCI exists.

- *Transparency:* FSSA will have complete oversight of Lewin's in-progress work and through the review of required evaluation deliverables. Additionally, FSSA has final approval of all Lewin's work with CMS being the ultimate approver.

Given these facts and circumstances as they have been presented above, Lewin's ability to perform its HIP evaluation work will not create any risk of an actual or potential Impaired Objectivity OCI should UHC C&S serve FSSA as an MCE under the RFP.

C. Unequal Access to Information

An Unequal Access to Information OCI exists where a company has access to non-public information as part of its performance of a government contract and that information may provide the company with an unfair competitive advantage in a later competition for a government contract.

In the performance of the Contract, Lewin has access to non-public and confidential information such as claims and benefit data from Indiana MCOs. If this information was inadvertently accessed by Lewin's UHC C&S affiliate it could conceivably generate an unfair competitive advantage under the current RFP and future MCE bid opportunities. However, any such OCI concerns are unfounded because Lewin understands and complies with its obligation to handle non-public and confidential information in accordance with applicable laws, regulations, and contract requirements. As a result, in the regular course if its business, Lewin has implemented measures that would prospectively prevent any Unequal Access to Information OCI from occurring and that includes the following:

- *Information and Security Firewalls:* Lewin has established effective firewalls to prevent unauthorized use or disclosure of protected information and to guard against the risk of even inadvertent disclosure of such information. These firewalls provide an information disclosure barrier between Lewin and other business units and employees of UHG, including without limitation MedExpress, OptumRx, and UHC C&S. All protected program information in electronic form will be maintained on a secure, password-protected server that is dedicated to Lewin. Electronic documents or data files containing protected information area accessible only to Lewin employees on a need to know basis.

- *Separate Staffing:* The personnel that Lewin uses for the Contract are separate and distinct from the staff used by Lewin's MedExpress, OptumRx, and C&S affiliates. There is no overlap of staffing in this regard between the very separate businesses.

- *Information Security Policies and Procedures:* Lewin has implemented numerous policies and procedures regarding the way employees are to handle and disclose confidential information. This includes, a "need-to-know" policy, which provides that individual employees have access to the minimal amount of confidential information necessary to perform his or her work on the specific project to which the employee

is assigned. Furthermore, Lewin employees are annually trained on the firewall and its policies and have a continuing obligation to report suspected violations of the policy, including any suspected violations of the information firewall. This obligation is emphasized as part of their training on the enterprise Code of Conduct. The policy identifies the company hotline and other means through which they may make such a report (anonymously, if desired). Employees are advised that violations could result in consequences such as termination of employment.

- *Contract Requirements:* In accordance with Section 12 of the Contract (Confidentiality, Security and Privacy of Personal Information), Lewin is required to abide by HIPAA Rules as such Rules apply to Business Associates.

IV. Conclusion

For all the foregoing reasons, Lewin's continued performance of the Contract does not create an actual or potential OCI nor adversely affect or impact FSSA. Lewin understands that there is a continuing obligation to provide assurance to FSSA that no OCIs arise in the course of performing the work. In the event there is a change in facts that would give rise to an actual or significant, potential OCI, Lewin will promptly disclose the circumstances to FSSA, along with a mitigation plan, and Lewin will not proceed with performing the conflicted work until a mutually acceptable mitigation plan is in place.

Attachment E.2. Evaluation Budget

The budget for the Independent Evaluation from the awarded evaluator contract is included below. Oversight and support of this contract and provision of data to the evaluator on behalf of the state are considered to be encompassed in general program administrative costs and are not reported in this document. The state will leverage its existing contract with Milliman Inc. for the required cost analysis.

Exhibit E.2: Evaluation Budget-Total Costs

Base Contract	**State Fiscal Year**	**Dates**	**Total Required Work**
	2021	7/1/20 to6/30/21	$ 44,820
	2022	7/1/21 to 6/30/22	
	2023	7/1/22 to 6/30/23	$ 158,828
	2024	7/1/23 to 6/30/24	$ 368,019
	2025	7/1/24 to 6/30/25	$ 629,620
	2026	7/1/25 to 6/30/26	$ 291,962
	2027	7/1/26 to 6/30/27	$ 623,970
	2028	7/1/27 to 6/30/28	$ 149,459
	Contract Total:		$ 2,266,679

Exhibit E.3: Evaluation Budget-Deliverables by State Fiscal Year

Deliverable	SFY 2021	SFY 2022	SFY 2023	SFY 2024	SFY 2025	SFY 2026	SFY 2027	SFY 2028
Task 1: Project Management	$ 3,645		$ 42,510	$ 40,177	$ 24,601	$ 25,368	$ 26,135	
Task 2: Develop FSSA's Evaluation Plan for the 2021-2025 waiver	$ 41,175		$ 2,866					
Task 3: Conduct Key Informant Interviews			$ 113,452	$ 117,176		$ 121,192		
Task 4: Develop Mid-Point Assessment Report				$ 210,666	$ 23,406			
Task 5: Develop Interim Evaluation Report for 2021-2025 Waiver					$ 581,612	$ 145,403		
Task 6: Develop Summative Evaluation Report for 2021-2025 Waiver							$ 597,836	$ 149,459
Total	**$ 44,820**	**$ 0**	**$ 158,828**	**$ 368,019**	**$ 629,620**	**$ 291,962**	**$ 623,970**	**$ 149,459**

Attachment E.3. Timeline and Major Milestones

This section describes the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones and deliverables, including both interim and summative evaluations.

Mid-Point Assessment

The Mid-Point Assessment is designed to summarize progress towards meeting the SMI/SED milestones and identify related risks. Consistent with Section XI.6 of the STC, the Mid-Point Assessment will contain a description of the methodologies used for examining progress and assessing risk, the limitations of the methodologies, the evaluator's determinations regarding progress towards key milestones, and any recommendations. As required by CMS, this report will include the following elements (STC Sections 5 and 6):

- An examination of progress toward meeting each milestone and timeframe approved in the SMI/SED Implementation Plan, the SMI/SED Financing Plan, and toward meeting the targets for performance measures as approved in the SMI/SED Monitoring Protocol
- A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date
- A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets
- For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the State's SMI/SED or SMI/SED Financing Plan or to pertinent factors that the State can influence that will support improvement
- An assessment of whether the State is on track to meet the budget neutrality
- An assessment if the State is meeting the STC requirement of a 30 day or less average length of stay (ALOS). If the State cannot show that it is meeting a 30 day or less ALOS requirement within one standard deviation at the Mid-Point Assessment, the State may only claim Federal financial participation (FFP) for stays up to 45 days until such time that the State can demonstrate that it is meeting a 30 day or less ALOS requirement.

The Mid-Point Assessment will also include findings from key informant interviews with stakeholders, including, but not limited to: representatives of MCEs, SMI/SED providers, members and other key partners.

The major activities associated with the development of the Mid-Point Assessment are:

- **Conduct key informant interviews** – The evaluator will use findings from key informant interviews conducted in 2021 and 2023.
- **Request and review data and key resources** – The evaluator will develop an information/data request, including FSSA monitoring reports and other program documentation. The evaluator assumes that the FSSA monitoring reports will inform the quantitative aspects of the evaluation and that primary data collection or calculation of metrics identified in the monitoring protocol will not be necessary.
- **Develop Mid-Point Assessment outline** – The evaluator will develop an outline for the Mid-

Point Assessment for review and comment by FSSA. This outline will help provide a common understanding of the content to be included within each of the sections of the assessment.

- **Develop draft and final Mid-Point Assessment Reports** – The evaluator will use FSSA's monitoring reports (based on the CMS-approved monitoring protocol), the results of the 2020 Summative Evaluation Report, and themes from key informant interviews (2021, 2023) to develop the draft Mid-Point Assessment Report.
- **Responding to CMS Feedback** – The evaluator will support FSSA in responding to feedback from CMS on the Mid-Point Assessment report.
- **CMS briefing** – The evaluator will support FSSA in briefing the Mid-Point Assessment findings to CMS. This briefing will be delivered virtually or in-person, as requested by CMS.

Interim Evaluation Report for 2021-2025 waiver

Indiana will develop the 2021-2025 Interim Evaluation Report per requirements outlined in Appendix B of the STCs, and according to the approved final evaluation plan. As such, it will include the following sections:

- Executive summary
- General background information
- Evaluation questions and hypotheses
- Methodology
- Methodological limitations
- Results
- Conclusions
- Interpretations, policy implications and interactions with other state initiatives
- Lessons learned and recommendations
- Attachment(s), including the approved evaluation design

The main activities in the development of the Interim Evaluation Report are as follows:

- **Collect quantitative data** – The evaluator will develop and submit an information/data request based on the data sources, described in Attachment F, to FSSA and will coordinate with FSSA data team members to receive and process the data.
- **Prepare collected data for analysis** – the evaluator will leverage the data dictionaries and information shared by State data team to develop data intake and processing. Additionally, data preparation will include development of basic summaries (e.g., count of beneficiaries by year and age group. The evaluator will develop multiple analytical tables (e.g., yearly count of utilization, yearly enrollment data containing beneficiary characteristics) for use across quantitative analyses.
- **Conduct quantitative analyses** – The evaluator will conduct the quantitative analyses outlined in the **Methodology Section**.
- **Collect qualitative data and conduct qualitative analysis** – The evaluator will incorporate findings from key informant interviews.

- **Develop Report outline** – The evaluator will develop an outline for the Interim report for review and comment by FSSA. This outline will help provide a common understanding of the content to be included within each of the sections of the report.
- **Develop Draft Evaluation Report** – The evaluator will use the quantitative and qualitative analyses described above to develop the draft Interim Evaluation Report for public comment. The evaluator will review public comments and adjust the draft report in consultation with FSSA, as appropriate. FSSA will submit the report to CMS by December 31, 2024.
- **Respond to CMS feedback** – Indiana review CMS feedback on the draft 2021-2025 Interim Evaluation Report, revise as appropriate and necessary and submit the final report to CMS

Develop Summative Evaluation Report for 2021-2025 waiver

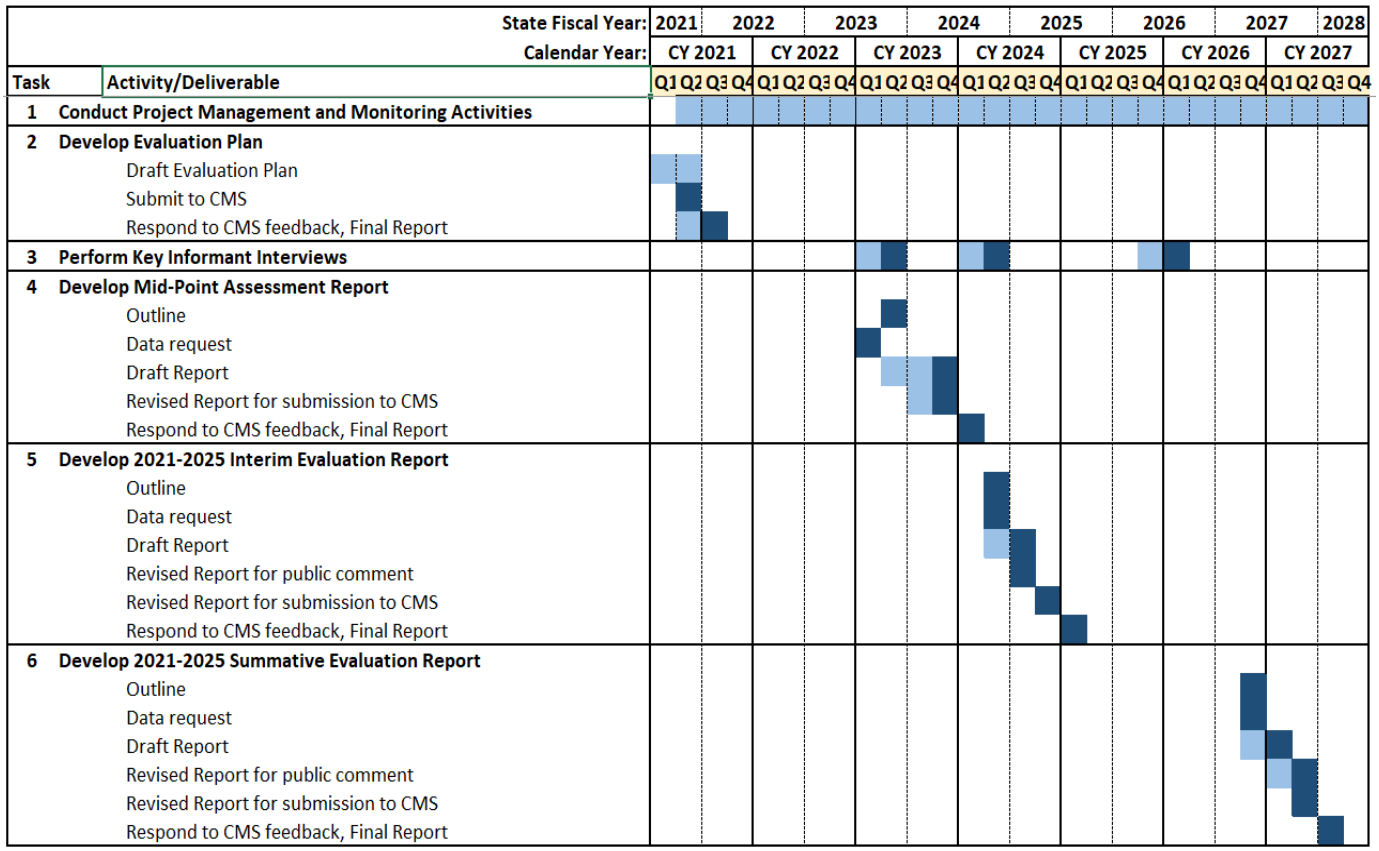
The 2021-2025 Summative Evaluation Report will be based on the requirements outlined in Appendix B of the STCs, and according to the approved Evaluation Plan. As such, it will include the following sections:

- Executive summary
- General background information
- Evaluation questions and hypotheses
- Methodology
- Methodological limitations
- Results
- Conclusions
- Interpretations, policy implications and interactions with other state initiatives
- Lessons learned and recommendations
- Attachment(s), including the approved evaluation design

This report will reflect additional key informant interviews and quantitative data analyses that reflect the full waiver time period (as described in the Methods section). The main activities in the development of the Summative Evaluation Report will be similar to those described above (development of Interim Evaluation Report) including:

- Data request (enrollment, claims / encounters, administrative)
- 2021-2025 Summative Evaluation Report outline
- Draft 2021-2025 Summative Evaluation Report for FSSA review
- Revised 2021-2025 Summative Evaluation Report for public comment
- 2021-2025 Summative Evaluation Report for CMS Review
- Final 2021-2025 Summative Evaluation Report

Exhibit E.4: Timeline and Milestones


State Fiscal Year: 2021 2022 2023 2024 2025 2026 2027 2028
Calendar Year: CY 2021 CY 2022 CY 2023 CY 2024 CY 2025 CY 2026 CY 2027
Task Activity/Deliverable
Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4
1 Conduct Project Management and Monitoring Activities
2 Develop Evaluation Plan
Draft Evaluation Plan
Submit to CMS
Respond to CMS feedback, Final Report
3 Perform Key Informant Interviews
4 Develop Mid-Point Assessment Report
Outline
Data request
Draft Report
Revised Report for submission to CMS
Respond to CMS feedback, Final Report
5 Develop 2021-2025 Interim Evaluation Report
Outline
Data request
Draft Report
Revised Report for public comment
Revised Report for submission to CMS
Respond to CMS feedback, Final Report
6 Develop 2021-2025 Summative Evaluation Report
Outline
Data request
Draft Report
Revised Report for public comment
Revised Report for submission to CMS
Respond to CMS feedback, Final Report

F. Analytic Tables

The tables include research questions, outcome measures and time specification for the interim and summative report. Assumption: all measures will be used for both Interim and Summative Evaluation Reports. To study trends over time and develop observational analyses, outcome measures will be calculated for a 12-month time-period (calendar year). All regression-based analyses (e.g., ITS) will use beneficiary level data. Depending on the research question, other time frame (e.g., quarterly, monthly) will be considered for analysis.

Goal 1: Reduced utilization and length of stay in emergency departments among Medicaid beneficiaries with SMI or SED while awaiting mental health treatment in specialized settings

Exhibit F.1: Goal 1

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.1: The SMI/SED demonstrations will result in reductions in utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment.	**Primary RQ 1.1:** Does the SMI/SED demonstration result in reductions in utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment?[17]	• Number of all-cause ED visits per 1,000 beneficiary-months among adult Medicaid beneficiaries aged 18 and older who met the eligibility criteria of beneficiaries with SMI (Denominator = total months of enrollment for beneficiaries aged 18 and older and had SMI diagnosis, Numerator = total number of all cause ED visits for beneficiaries included in Denominator) *Measure steward, endorsement (benchmark): Milestone 2 monitoring metric* *SMI/SED demonstration monitoring metric #3 All-Cause Emergency Department (ED) Utilization Rate for Medicaid Beneficiaries who may Benefit From Integrated Physical and Behavioral Health Care (PMH-20).* [18]	• Claims/encounter data (2018-2025) • Enrollment data (2018-2025)	Descriptive quantitative analysis of trends over time during the demonstration Interrupted time series analysis	n.a.

17 The research questions were drafted to align with CMS guidance (https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/smi-sed-eval-guide-appendix-a.pdf). For each research question, the State identified one outcome measure for the evaluation. For this research question, the State is assessing impact of

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.1, continued	**Subsidiary RQ 1.1:** How do the SMI/SED demonstration effects on reducing utilization and lengths of stays in EDs among Medicaid beneficiaries with SMI/SED vary by geographic area or beneficiary characteristics?	• Number of all-cause ED visits per 1,000 beneficiary-months among adult Medicaid beneficiaries aged 18 and older who met the eligibility criteria of beneficiaries with SMI (Refer to Primary RQ 1.1 for measure calculation) *Measure steward, endorsement (benchmark): Milestone 2 monitoring metric #3*	• Claims/encounter data (2018-2025) • Enrollment data (2018-2025)	Descriptive quantitative analysis of trends over time during the demonstration Interrupted time series analysis	n.a.

program based on reduced number of ED visits.

18 Based on Technical Specifications and Resource Manual, this measure is defined as the number of all-cause ED visits per 1,000 beneficiary months among adult Medicaid beneficiaries aged 18 and older who meet the eligibility criteria of beneficiaries with SMI in a year. The Technical Specifications and Resource Manual is available at: https://www.medicaid.gov/resources-for-states/innovation-accelerator-program/functional-areas/quality-measurement/physical-and-mental-health-integration-quality-measures/index.html

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.1, continued	**Subsidiary RQ 1.2:** How do SMI/SED demonstration activities contribute to reductions in utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment in specialized settings?	• Demonstration activities or their components or characteristics that stakeholders identify as most effective in reducing utilization and lengths of stays in EDs among Medicaid beneficiaries with SMI or SED • Obstacles that stakeholders identify as hindering the effectiveness of the demonstration in reducing utilization and lengths of stays in EDs	Key informant interviews with members, MCEs, State staff and ED providers	Descriptive qualitative analysis of demonstration activities most effective, and obstacles that stakeholders identify, in reducing utilization and lengths of stays in EDs	n.a.

Goal 2: Reduced preventable readmissions to acute care hospitals and residential settings

Exhibit F.2: Goal 2[19], Hypothesis 2

19 Indiana is not including Subsidiary Research Question 2.3: "Does the SMI/SED demonstration result in increased screening and intervention for comorbid SUD and physical health conditions during acute care psychiatric hospital and residential setting stays and increased treatment for such conditions after discharge?" Calculation and monitoring of such a metric will require medical reviews be performed which would require substantial resources. As this research question is not associated with primary objective of the waiver, the State determined not to monitor and calculate this metric during time of preparation of this evaluation plan.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.2: The SMI/SED demonstration will result in reductions in preventable readmissions to acute care hospitals and residential settings.	**Primary RQ 2:** Does the SMI/SED demonstration result in reductions in preventable readmissions to acute care hospitals and residential settings (including, short-term inpatient and residential admissions to both IMDs and non-IMD acute-care hospitals, critical access hospitals, and residential settings)?	Number of thirty-day, all-cause unplanned readmissions (acute care hospitals and residential settings) following psychiatric hospitalization (Study population = all beneficiaries aged 18 and older and had SMI diagnosis having psychiatric hospitalization, measure calculation = Among beneficiaries included in study population number of admission, for any reason, to acute care hospital (including Critical Access Hospitals) or residential care that occurs within 3-30 days after the discharge date from a psychiatric hospitalization) (Benchmark to State published NQF #2860 measure - *SMI/SED demonstration monitoring metrics#4. Metric #4 is30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility (IPF))20*	• Claims/encounter data (2018-2025) • Enrollment data (2018-2025) • Adult Core Set (for NQF #2860)	Descriptive quantitative analysis of trends over time during the demonstration Interrupted time series analysis	n.a.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
	Subsidiary RQ 2.1: How do the SMI/SED demonstration effects on reducing preventable readmissions to acute care hospitals and residential settings vary by geographic area or beneficiary characteristics?	Number of thirty-day, all-cause unplanned readmissions following psychiatric hospitalization (Refer to Primary RQ 2 for measure calculation) (Benchmark to State published NQF #2860 measure - *SMI/SED demonstration monitoring metrics #4. Metric #4 is 30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility (IPF)*	• Claims/encounter data (2018-2025) • Enrollment data (2018-2025) • Adult Core Set (for NQF #2860)	Descriptive quantitative analysis of trends over time during the demonstration Interrupted time series analysis	n.a.

20 This measure is based on the 30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility (IPF) in the IPFQR program. The program manual for IPFQR is available at: https://qualitynet.org/files/5df7a5ca62faad001ffd7a87?filename=FY20_IPFQR_CBM_Sp ecs.pdf.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
	Subsidiary RQ 2.2: How do demonstration activities contribute to reductions in preventable readmissions to acute-care hospitals and residential settings?	• Demonstration activities or their components or characteristics that stakeholders identify as most effective in reducing preventable readmissions to acute care hospitals and residential settings • Obstacles that stakeholders identify as hindering the effectiveness of the demonstration in reducing preventable readmissions to acute care hospitals and residential settings	Key informant interviews with members, State staff, MCEs, providers, and other stakeholders (including consumer advocates)	Qualitative analysis to identify themes associated with the effectiveness of demonstration activities for reducing preventable readmissions to acute care hospitals and residential settings	n.a.

Goal 3: The SMI/SED demonstration will result in improved availability of crisis stabilization services throughout the state

Exhibit F.6: Goal 3

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.3: The SMI/SED demonstration will result in improved availability of crisis stabilization services throughout the state.	**Primary RQ 3.1:** To what extent does the SMI/SED demonstration result in improved availability of crisis outreach and response services (including crisis call centers, mobile crisis units, crisis observation/assessment centers, and coordinated community crisis response teams) throughout the state?	• Number of crisis call centers • Number of mobile crisis units • Number of crisis observation/assessment centers • Number of coordinated community crisis response teams	State administrative data (2018-2025)[21] collected via the Quarterly Monitoring Reports submitted to CMS. These data are updated annually in the Q1 report.	Descriptive quantitative analysis of trends over time during the demonstration	Baseline assessment at the start of the demonstration
	Primary RQ 3.2: To what extent does the SMI/SED demonstration result in improved availability of intensive outpatient services and partial hospitalization?	Number of intensive outpatient and partial hospitalization providers *Note: The metric is based on State Availability Assessment. The Assessment gets submitted annually by May 30 as part of the monitoring report. The Assessment is point in time and performed on Feb 1 of that year.*	State administrative data (2018-2025) collected via the Quarterly Monitoring Reports submitted to CMS. These data are updated annually in the Q1 report.	Descriptive quantitative analysis of trends over time during the demonstration Lookback time period for trend will depend on available data	Baseline assessment at the start of the demonstration

[21] Once CMS publishes monitoring reports, they can be found here: https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/81641

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
	Primary RQ 3.2: To what extent does the SMI/SED demonstration result in improved availability of intensive outpatient services and partial hospitalization?	• Demonstration activities or their components or characteristics that stakeholders identify as most effective in improved availability of intensive outpatient services and partial hospitalization • Obstacles that stakeholders identify as hindering the effectiveness of the demonstration in improved availability of intensive outpatient services and partial hospitalization	Key informant interviews with members, State staff, MCEs, providers, and other stakeholders (including consumer advocates)	Qualitative analysis to identify themes associated with the effectiveness of demonstration activities for improved availability of intensive outpatient services and partial hospitalization	n.a.
	Primary RQ 3.3: To what extent does the SMI/SED demonstration improve the availability of crisis stabilization services provided during acute short-term stays in each of the following: public and private psychiatric hospitals; residential treatment facilities; general hospital psychiatric units; and community-based settings (such as residential crisis stabilization programs, small inpatient units in community mental health centers, peer-run crisis respite programs, and so on)?	Number of: • Intensive outpatient and partial hospitalization providers • Psychiatric hospitals • Residential mental health treatment facilities and beds • Medicaid-enrolled psychiatric units in acute care and critical access hospitals • Licensed psychiatric hospital and psychiatric unit beds • Community Mental Health Centers	State administrative data (2018-2025) collected via the Quarterly Monitoring Reports submitted to CMS. These data are updated annually in the Q1 report.	Descriptive quantitative analysis of trends over time during the demonstration Lookback time period for trend will depend on available data	Baseline assessment at the start of the demonstration

Goal 4: Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI or SED including through increased integration of primary and behavioral health care

Exhibit F.7: Goal 4[22]

[22] Indiana is not including Subsidiary Research Question 4.1c: "How do the SMI/SED demonstration effects on access to community-based services vary by geographic area or beneficiary characteristics?" in this Evaluation Plan. The outcome measures from Goal 3, the summaries of provider types, address this question. Furthermore, this Evaluation Plan is limited to one year of the demonstration and because this is a subsidiary research question.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy

H.4: Access of beneficiaries with SMI/SED to community-based services to address their chronic mental health care needs will improve under the demonstration, including through increased integration of primary and behavioral health care.	**Primary RQ 4.1:** Does the demonstration result in improved access of beneficiaries with SMI/SED to community-based services to address their chronic mental health care needs?	Proportion of beneficiaries with SMI/SED who use mental-health-related (1) outpatient, rehabilitation, and targeted case management services; (2) home and community-based services; and (3) long-term services and supports
		(Denominator = total number of beneficiaries aged 18 and older and having SMI diagnosis and meeting Medicaid coverage eligibility, Numerator = number of beneficiaries included in denominator and using specific services)
		
		Measure steward for (1): Milestone 3 monitoring metric for outpatient mental health services utilization (metric # 15) divided by Milestone 4 monitoring metric for count of beneficiaries with SMI/SED (metric #21)
		(Benchmark to State published monitoring metrics)
		SMI/SED demonstration monitoring Metric SMI/SED demonstration monitoring metric #15: Mental Health Services Utilization – Outpatient, #21: Count of Beneficiaries With SMI/SED (monthly)
			• Enrollment data (2018-2025)
			• Claims/encounter data (2018-2025)
			  • Institutional
			  • Non-institutional
			  • Pharmacy
				Descriptive quantitative analysis of trends over time during the demonstration
				
				Interrupted time series analysis
					n.a.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
	Subsidiary RQ 4.1a - To what extent does the demonstration result in improved availability of community-based services needed to comprehensively address the chronic mental health needs of beneficiaries with SMI/SED?	Number of Medicaid-enrolled: • Community mental health centers • Psychiatrists and other mental health practitioners authorized to prescribe • Mental health practitioners (other than psychiatrists) who are certified and licensed by the state to independently treat mental illness • Federally qualified health centers (FQHCs) that offer behavioral health services	State administrative data (2018-2025) collected via the Quarterly Monitoring Reports submitted to CMS. These data are updated annually in the Q1 report.	Descriptive quantitative analysis of trends over time during the demonstration Level of granularity of analysis and lookback time period for trend will depend on available data	Baseline assessment at the start of the demonstration

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
	Primary RQ 4.2: Does the integration of primary and behavioral health care to address the chronic mental health care needs of beneficiaries with SMI/SED improve under the demonstration?	• Demonstration activities or their components or characteristics that stakeholders identify as most effective in the integration of primary and behavioral health care to address the chronic mental health care needs of beneficiaries with SMI/SED • Obstacles that stakeholders identify as hindering the effectiveness of the demonstration in the integration of primary and behavioral health care to address the chronic mental health care needs of beneficiaries with SMI/SED	Key informant interviews with members, State staff, MCEs, ED providers, and other stakeholders (including consumer advocates)	Qualitative analysis to identify themes associated with the effectiveness of demonstration activities for the integration of primary and behavioral health care to address the chronic mental health care needs of beneficiaries with SMI/SED	n.a.

Goal 5: Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities

Exhibit F.9: Goal 5[23]

[23] Indiana is not including Subsidiary Research Question 5.2a: "Does the SMI/SED demonstration result in improved discharge planning and outcomes regarding housing for beneficiaries transitioning out of acute psychiatric care in hospitals and residential treatment facilities?" This is because this Evaluation Plan is limited to one year of analysis and the level of effort involved in obtaining and reviewing facility records, and facility discharge records, is substantial especially considering Indiana's budget and the impact of COVID-19.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy

H.5: The SMI/SED demonstration will result in improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities.	**Primary RQ 5.1:** Does the SMI/SED demonstration result in improved care coordination for beneficiaries with SMI/SED?	Percentage of discharges for patients aged 18 and older who had a visit to the ED with a primary diagnosis of mental health or alcohol or other drug dependence during the measurement year AND who had a follow-up visit with any provider with a corresponding primary diagnosis of mental health or alcohol or other drug dependence within 7 and 30 days of discharge
		
		(Denominator = total number discharges for beneficiaries aged 18 and older and having SMI diagnosis and a primary diagnosis of mental health or alcohol or other drug dependence, meeting Medicaid coverage eligibility and had ED visit, Numerator = number of discharges in denominator that had a follow-up visit with provider within 7 and 30 days of discharge)
		
		(*Benchmark to Milestone 2 monitoring metric, NCQA, NQF #0576 (adapted)*
		
		SMI/SED demonstration monitoring metric #8 (NQF #0576 adapted): Follow-up After Hospitalization for Mental Illness: Age 18 and older
			• Enrollment data (2018-2025)
			• Claims/encounter data (2018-2025)
			  • Institutional
			  • Non-institutional
			  • Pharmacy
			• Adult Core Set (for NQF #0576)
				Descriptive quantitative analysis of trends over time during the demonstration[24]
				
				Interrupted time series analysis
					n.a.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
	Primary RQ 5.1: Does the SMI/SED demonstration result in improved care coordination for beneficiaries with SMI/SED?	• Changes made through the demonstration to data-sharing systems, processes, or policies • Demonstration activities regarding data-sharing systems, processes, or policies that staff identify as most effective for improving care coordination • Obstacles that staff identify as hindering the effectiveness of demonstration activities regarding data sharing systems, processes, or policies aimed at improving care coordination	• Key informant interviews with members, State staff, MCEs, providers, and other stakeholders (including consumer advocates)	Qualitative analysis to identify themes associated with the effectiveness of demonstration activities to improve data sharing systems, processes, and policies to support care coordination	n.a.
	Primary RQ 5.2: Does the SMI/SED demonstration result in improved continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities?	• Demonstration activities or their components or characteristics that stakeholders identify as most effective in improving continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities • Obstacles that stakeholders identify as hindering the	Key informant interviews with members, State staff, MCEs, providers, and other stakeholders (including consumer advocates)	Qualitative analysis to identify themes associated with the effectiveness of demonstration activities for improving continuity of care in the community following episodes	n.a.

[24] This measure is part of the CMS Adult Core Set. The developed measure can be used to compare against other states using State report to CMS. Differences in results will not necessarily be due to impact of SMI waiver. The evaluation team will consider feasibility of the comparison during analysis process.)

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
	Subsidiary RQ 5.2b: How do demonstration activities contribute to improved continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities?	effectiveness of the demonstration in improving continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities		of acute care in hospitals and residential treatment facilities	n.a.

G. Impact of Demonstration on Health Care Spending

The State's actuary, Milliman, Inc. will be performing the cost analyses required as part of evaluation reports for Section 1115 demonstrations for individuals with SMI/SED or SUD. This analysis will follow the structure outlined in Appendix C of related CMS guidance.[25]

This analysis will assess how the demonstration impacts health care spending (increase, decrease or remain unchanged). Even though total costs might remain unchanged or even increase with the implementation of the demonstration as new services become available to Medicaid members, certain costs might decrease (such as emergency department visits). This is ascertained by modeling the impact of the demonstration on different types of costs.

The analysis will be conducted using costs expressed in dollars per beneficiary per month (PBPM). In Indiana, individuals with SMI diagnoses receive services through both the fee-for-service (FFS) and managed care (MC) delivery systems; therefore, this analysis will utilize the following types of claims:

- FFS claims for those receiving services on a FFS basis. This also includes FFS claims paid for members enrolled in managed care, where the services are currently or were previously carved out of the managed care capitation payments during the pre- and post-demonstration; or
- MC encounter claims (indicating the amount paid to providers as recorded by Managed Care Entities (MCEs)) as submitted to the fiscal agent and deduplicated by Milliman.

Both FFS claims and MC encounters will be summarized from the Enterprise Data Warehouse (EDW) with data provided by the fiscal agent, Gainwell, and maintained by Optum.

Administrative costs associated with SMI 1115 demonstration will also be included and will be provided to Milliman by the State.

The following three levels of cost analysis will be conducted as recommended in the CMS guidance:

1. The first level focuses on the total costs for SMI beneficiaries by adding up all the claim costs and administrative costs.
2. The second level of analysis focuses on identifying cost drivers by splitting the total costs into components based on the presence of SMI/SED diagnosis and the setting for the SMI services (IMD or other).
3. The third level of analysis strives to identify cost drivers for the SMI population by stratifying the total costs into the component for different type of care (based on T-MSIS mapping). Outpatient services are further stratified into ED services and non-ED services as ED services represent an area of potential saving given better service access to those with SMI diagnosis.

The state will utilize the interrupted time series analysis (ITS) approach. The preferred difference-in-difference analysis (DiD) has not been selected, due to the absence of a valid comparison group.

The cost analysis will be performed using the steps described below.

[25] https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/smi-sed-sud-cost-appendix-c.pdf

STEP 1 – BENEFICIARY POOL IDENTIFICATION

Starting two years prior to the demonstration (January 1, 2018), we will identify beneficiary-months (member IDs and the month and year) for all SMI/SED treatment events. SMI/SED treatment events will be identified by the diagnosis or provider type/provider specialty combination on the claim or encounter.

- Any diagnosis on the claim that meets the following SMI criteria
  - F20.xx (Schizophrenia and sub codes up to 2 places)
  - F25.xx (Schizoaffective Disorder and sub codes up to two places)
  - F31.xx (Bipolar and all sub codes up to 2 places)
  - F33.xx (Major depression Recurrent and all sub codes up to two places)

- The following provider type/provider specialty combination on the claim

Provider Type	Provider Specialty
01-Hospital	011-Psych Facility (IMDs)
11-Behavioral Health Provider	110-Outpatient Mental Health Clinic 111-CMHC 114-Health Service Provider in Psych (HSPP) 115-Adult Mental Health & Habilitation Provider 613-MRO Clubhouse 616-Licensed Psychologist 617-Licensed Independent Practice School Psychologist 618-Licensed Clinical Social Worker 619-Licensed Marriage & Family Therapist 620-Licensed Mental Health Counselor 621-Licensed Clinical Addiction Counselor

The analytic file will include an observation (beneficiary-month) for each month of service containing an SMI/SED treatment event for the beneficiary as well as up to 11 beneficiary-months following each identified event, as long as the beneficiary remains enrolled in Medicaid. If there are no subsequent claims with SMI/SED treatment events, the beneficiary may be dropped from the exposure after the initial 12 months of observation. However, if another SMI/SED treatment event occurs before the observation period is over, the observation period will be extended for up to another 11 months after the subsequent event, or through the last month of Medicaid eligibility, whichever comes first.

STEP 2 – DEMOGRAPHIC INFORMATION

For each beneficiary-month we will collect the following demographic information:

- Age
- Gender
- Race
- Dual status
- County
- Condition (stratified by the four diagnosis categories)

STEP 3 – CREATE THE ANALYTIC FILE

For each beneficiary-month identified in the Step 1 above, we will collect all the beneficiary's Medicaid costs incurred during the month, and stratify the costs based on the 10 categories specified in Table C.1 of the CMS guidance:

1. Total costs
2. Total federal costs
3. SMI IMD costs
4. Other SMI costs
5. Non-SMI costs
6. Outpatient costs, non-ED
7. Outpatient costs, ED
8. Inpatient costs
9. Pharmacy costs
10. Long-term care costs

IMD costs will be identified using billing provider IDs for facilities identified by the state as an IMD provider (consistent with IDs being used for the quarterly monitoring of the 1115 demonstration). Stratification by category of service will be performed consistent with T-MSIS mapping.

STEP 4 – REGRESSION INDICATORS

We will use indicator variables to mark time periods prior to the beginning of the demonstration (2018 and 2019), the first year of the demonstration (2020), and demonstration time periods after the implementation period (2021 and later). Since the implementation corresponds to the onset of the COVID-19 pandemic, separately collecting information for 2020 may help to account for changes that were caused by reasons other than the demonstration.

We will add the following indicators:

Impl – 0 for the period through December 2019, prior to implementing the SMI/SED 1115 waiver, 1 starting in January 2020

Demo – 0 through the first year of the SMI/SED demo (December 2020), 1 starting with the current demonstration as of January 2021

Indiana is not planning on using a comparison group, so there is no need for the treatment group indicator.

STEP 5 – DATA VALIDATION

To verify that month-to-month variation is within expected bounds, we will calculate average costs for each of the 10 service categories and summarize mean costs for each calendar quarter and service category in the format of Table C.2 (without a comparison group) from the CMS guidance. Means will be graphed for visual inspection of trends, and to check for data errors.

We plan to summarize monthly data by quarters as this is the count variable utilized in the regression in the next step. However, we will do testing and graphing on a monthly basis.

STEP 6 – REGRESSION ANALYSIS

As indicated above, we will utilize ITS to understand the impact of the demonstration on health spending as it is well suited for the interventions being evaluated here26. This time series will be run separately for each of the 10 types of costs listed in Step 3 as specified in the CMS guidance on page C.9.

We will implement ITS using the following regression model:

$Cost_{it} = \beta_0 + \beta_1 * time_t + \beta_2 * impl_t + \beta_3 * time_t * impl_t + \beta_4 * demo_t + \beta_5 * time_t * demo_t + B_i * Controls_{it} + \varepsilon_{it}$

Where:

- Cost– expenditures being evaluated (quarterly expenditures for each beneficiary)
- i – individual beneficiary
- t – indexes time (quarter as indicated in Step 5)
- impl – binary indicator for implementation of the SMI/SED 1115 as of January 2020, as described in Step 4
- demo – binary indicator for a year after implementation period (starting January 2021) as described in Step 4
- Controls – covariates (demographic characteristics defined in Step 2)
- β_0 – estimates the baseline level of the cost at time 0
- β_1 – estimates the change in the costs during the baseline period (baseline trend)
- β_2 – estimates the change in the costs immediately after the implementation of the SMI/SED demonstration as of January 2020
- β_3 – estimates the change in the trend after the implementation of the SMI/SED demonstration as of January 2020
- β_4 – estimates the change in the costs immediately after the initial year of the demonstration, starting January 2021
- β_5 – estimates the change in the trend after the initial year of the demonstration, starting January 2021
- ε – error terms that represents random variability not explained by the model

We are interested in the PBPM cost trends demonstrated by the ITS. If the average marginal effect of the interaction terms ($\beta_3 * time_t * impl_t$ and $\beta_5 * time_t * demo_{t)}$ is a positive dollar amount, then the costs in the post-demonstration and post-implementation periods are higher than the costs in the pre-demonstration period. However, if the interaction terms are negative, then post-demonstration and post-implementation costs are lower than pre-demonstration costs. We will also assess whether the effect is statistically significant from zero.

Challenges and limitations

Seasonality

Errors for quarters separated by multiples of 12 months can be examined to detect seasonal correlation. If seasonality is detected, a term could be introduced in the regression model to reduce the potentially confounding effect of seasonality.

Additional autocorrelation of error terms

Linear regression assumes that errors are independent. If errors are found to not be independent, steps would need to be taken to correct for that. A plot of residuals will be inspected, and the Durbin-Watson

26 James Lopez Bernal, Steven Cummins, Antonio Gasparrini; Interrupted time series regression for the evaluation of public health interventions: a tutorial, International Journal of Epidemiology, Volume 46, Issue 1, 1 February 2017, Pages 348–355, https://doi.org/10.1093/ije/dyw098

statistic will be examined for serial autocorrelation of the error terms. Durbin-Watson reported statistic is between 0 and 4, where 2 indicates no correlation, with values under 1 or over 3 indicating a positive or negative correlation, respectively. If autocorrelation of the error terms is detected, an autoregressive regression model, such as Cochrane-Orcutt model or auto-regressive integrated moving average (ARIMA) model will be used instead of the linear regression.

Heteroscedasticity check

Linear regression assumes that the variance in the error terms over time is constant. Heteroscedasticity occurs when the variance for all observations in the data is not the same. To test for the heteroscedasticity, we will examine the plot of error terms against predicted cost values. If the points are not symmetrically distributed around a horizontal line, then the data may be nonlinear, and transformation of the dependent variable will need to take place. This will be accomplished by logging/or deflating.

Heterogeneity check

Heterogeneity in a dataset occurs when there is a high variability in the underlying data characteristics. For the cost analysis, we will examine the difference between the FFS claims and encounter data for MC enrolled members to understand if there is variability in reimbursement levels or treatment patterns. The existence of this variability can increase the noise and possibly understate the impact of the demonstration. In order to understand the impact of heterogeneity of the underlying claims, the cost analysis could be performed separately for those receiving services through FFS or MC delivery systems to understand if these populations were impacted differently by the demonstration.

Multicollinearity check

Multicollinearity in the regression model occurs when the independent variables of the model are highly correlated. This correlation in the independent variables will cause the model results to be unstable and have significant fluctuations making it harder to interpret the results of the cost analysis. This can also cause overfitting of the model. There are bivariate correlation checks that can be performed, such as looking for correlation between Age and Dual Status or Age and condition. Another method that can be applied is Variance Inflation Factor (VIF) for each independent variable. If the value of VIF is higher than 10, then a high correlation exists with other independent variables. If multicollinearity is identified between the independent variables, we would perform cost analysis using one demographic variable at a time.

Impact of the COVID-19 pandemic

Pandemic onset corresponded closely with the implementation of the SMI 1115 waiver demonstration as of January 2020. Given the close timing, the impact of COVID-19 on service utilization and outcomes could be conflated with the impact of the demonstration. As described in Step 4 above, the addition of the implementation period indicator may help us separate the effect of the pandemic on the cost of the members, since the impact of the pandemic on service utilization and treatment was heaviest during CY 2020, while the impact of the demonstration is expected to be more sustained. We will examine the data after December 2020 and, if necessary, add another indicator or extend the period for the initial implementation indicator, in order the isolate the cost impact created by the pandemic and not the demonstration itself.

STEP 7 – REPORTING RESULTS OF THE COST ANALYSIS

The results for the marginal effects and standard errors will be reported utilizing a format similar to that illustrated in Table C.4 of the CMS guidance. CMS has offered to provide future assistance on best presentation of the results.

Attachment I: Eligibility and Coverage Implementation Plan

Attachment J: Eligibility and Coverage Monitoring Protocol

What follows are the planned metrics tabs and the reporting schedule tab from the E&C Monitoring Protocol Workbook (Part A). The full workbook is available in spreadsheet format on Medicaid.gov.

Medicaid Section 1115 Eligibility and Coverage Demonstrations Monitoring Protocol (Part A) - Planned metrics (AD) (Version 2.0)
State: Indiana
Demonstration Name: Healthy Indiana Plan

Eligibility and Coverage Demonstration Planned Metrics (AD)

Standard information on CMS-provided metrics										Baseline, annual goals, and demonstration target			Alignment with CMS-provided technical specifications manual		Phased-in metrics reporting		
#	Metric name	Metric description	Reporting topic[a]	Data source	Calculation lag	Measurement period	Reporting frequency	Reporting priority	State will report (Y/N)	Baseline reporting period (MM/DD/YYYY-MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided technical specifications manual (Y/N)	Explanation of any deviations from the CMS-provided technical specifications manual (different data sources or state-specific definitions, policies, codes, target populations, etc.)	State plans to phase in reporting (Y/N)	Report in when metric will be phased in (Format EandC DY and Q: Ex. DY1Q3)	Explanation of any plans to phase in reporting over time
EXAMPLE: AD_33 **(Do not delete or edit this row)**	*EXAMPLE: Preventive care and office visit utilization*	*EXAMPLE: Total utilization of preventive care and office visits per 1,000 demonstration beneficiary months during the measurement period*	*EXAMPLE: 1.1.7 Access to care*	*EXAMPLE: Claims and encounters and other administrative records*	*EXAMPLE: 90 days*	*EXAMPLE: Quarter*	*EXAMPLE: Quarterly*	*EXAMPLE: Recommended*	*EXAMPLE: Y*	*EXAMPLE: 10/01/2019 - 01/01/2020*	*EXAMPLE: Increase*	*EXAMPLE: Increase*	*EXAMPLE: Y*	*EXAMPLE:*	*EXAMPLE: N*	*EXAMPLE: DY1Q4*	*EXAMPLE:*
AD_1	Total enrollment in the demonstration	The unduplicated number of beneficiaries enrolled in the demonstration at any time during the measurement period. This indicator is a count of total program enrollment. It includes those newly enrolled during the measurement period and those whose enrollment continues from a prior period. This indicator is not a point-in-time count. It captures beneficiaries who were enrolled for at least one day during the measurement period.	1.1.1 Enrollment	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		N		
AD_2	Beneficiaries in suspension status for noncompliance	The number of demonstration beneficiaries in suspension status for noncompliance with demonstration policies as of the last day of the measurement period	1.1.1 Enrollment	Administrative records	30 days	Month	Quarterly	Required if state has a suspension policy	N					IN does not have a suspension policy			
AD_3	Beneficiaries in a non-eligibility period who are prevented from re-enrolling for a defined period of time	The number of prior demonstration beneficiaries who are in a non-eligibility period, meaning they are prevented from re-enrolling for some defined period of time, because they were disenrolled for noncompliance with demonstration policies. The count should include those prevented from re-enrolling until their redetermination date	1.1.1 Enrollment	Administrative records	30 days	Month	Quarterly	Required if state has a non-eligibility period policy	N					Because of the removal of lock out periods, this number will always be reported as a zero.			
AD_4	New enrollees	Number of beneficiaries in the demonstration who began a new enrollment spell during the measurement period, have not had Medicaid coverage within the prior 3 months and are not using a state-specific pathway for re-enrollment after being disenrolled for noncompliance	1.1.1 Enrollment	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		N		
AD_5	Re-enrollments or re-instatements using defined pathways after disenrollment or suspension of benefits for noncompliance with demonstration policies	Number of beneficiaries in the demonstration who began a new enrollment spell (or had benefits re-instated) in the current measurement period by using a state-defined pathway for re-enrollment (or re-instatement of benefits), i.e., meeting certain requirements, after being disenrolled (or having benefits suspended) for noncompliance with premium requirements, or other demonstration-specific requirements	1.1.1 Enrollment	Administrative records	30 days	Month	Quarterly	Required for states with a defined re-enrollment or re-instatement pathway	N					IN does not have a defined re-enrollment or re-instatement policy			
AD_6	Re-enrollments or re-instatements for beneficiaries not using defined pathways after disenrollment or suspension of benefits for noncompliance	Number of beneficiaries in the demonstration who began a new enrollment spell (or had benefits re-instated) in the current measurement period, have had Medicaid coverage within the prior 3 months and are not using a state-specific pathway for re-enrollment after being disenrolled for noncompliance (or re-instatement of benefits after being suspended for noncompliance)	1.1.1 Enrollment	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		N		
AD_7	Beneficiaries determined ineligible for Medicaid, any reason, other than at renewal	Total number of beneficiaries in the demonstration determined ineligible for Medicaid and disenrolled during the measurement period (separate reasons reported in other indicators), other than at renewal	1.1.2 Mid-year loss of demonstration eligibility	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Consistent	Consistent	N	Indiana included beneficiaries that lost eligibility at the end of their presumptive eligibility period in this metric.	N		
AD_8	Beneficiaries no longer eligible for Medicaid, failure to provide timely change in circumstance information	Number of beneficiaries enrolled in the demonstration and who lost eligibility for Medicaid during the measurement period due to failure to provide timely change in circumstance information	1.1.2 Mid-year loss of demonstration eligibility	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	N	Indiana does not disenroll members mid-month (unless deceased). Step 2 was slightly modified to capture these data to: Step 2. Retain those determined ineligible for Medicaid as of the first day of the following month of the measurement period. To calculate this metric, IN used the following failure to verify codes: EL0371, EL0372, EL0385, EL0448, EL0450, EL0451.	N		
AD_9	Beneficiaries determined ineligible for Medicaid after state processes a change in circumstance reported by a beneficiary	Number of beneficiaries who were enrolled in the demonstration and lost eligibility for Medicaid during the measurement period because they are determined ineligible after the state processes a change in circumstance	1.1.2 Mid-year loss of demonstration eligibility	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Consistent	Consistent	N	Indiana does not disenroll members mid-month (unless deceased). Step 2 was slightly modified to capture these data to: Step 2. Retain those determined ineligible for Medicaid as of the first day of the following month of the measurement period.	N		
AD_10	Beneficiaries no longer eligible for the demonstration due to transfer to another Medicaid eligibility group	Number of beneficiaries who were enrolled in the demonstration and transferred from the demonstration to a Medicaid eligibility group not included in the demonstration during the measurement period	1.1.2 Mid-year loss of demonstration eligibility	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		N		
AD_11	Beneficiaries no longer eligible for the demonstration due to transfer to CHIP	Number of beneficiaries who were enrolled in the demonstration and transferred from the demonstration to CHIP during the measurement period	1.1.2 Mid-year loss of demonstration eligibility	Administrative records	30 days	Month	Quarterly	Recommended	N								
AD_12	Enrollment duration, 0-3 months	Number of demonstration beneficiaries who lost eligibility for Medicaid during the measurement period and whose enrollment spell had lasted 3 or fewer months at the time of disenrollment	1.1.3 Enrollment duration at time of disenrollment	Administrative records	30 days	Month	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
AD_13	Enrollment duration, 4-6 months	Number of demonstration beneficiaries who lose eligibility for Medicaid during the measurement period whose enrollment spell had lasted between 4 and 6 months at the time of disenrollment	1.1.3 Enrollment duration at time of disenrollment	Administrative records	30 days	Month	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
AD_14	Enrollment duration 7-12 months	Number of demonstration beneficiaries who lost eligibility for Medicaid during the measurement period whose enrollment spell had lasted 7 or more months (up to 12 months) at the time of disenrollment	1.1.3 Enrollment duration at time of disenrollment	Administrative records	30 days	Month	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
AD_15	Beneficiaries due for renewal	Total number of beneficiaries enrolled in the demonstration who were due for renewal during the measurement period	1.1.4 Renewal	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		N		
AD_16	Beneficiaries determined ineligible for the demonstration at renewal, disenrolled from Medicaid	Number of beneficiaries enrolled in the demonstration and due for renewal during the measurement period who complete the renewal process and are determined ineligible for Medicaid	1.1.4 Renewal	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		N		
AD_17	Beneficiaries determined ineligible for the demonstration at renewal, transfer to another Medicaid eligibility category	Number of beneficiaries enrolled in the demonstration and due for renewal during the measurement period who complete the renewal process and move from the demonstration to a Medicaid eligibility group not included in the demonstration	1.1.4 Renewal	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		N		
AD_18	Beneficiaries determined ineligible for the demonstration at renewal, transferred to CHIP	Number of beneficiaries enrolled in the demonstration and due for renewal during the measurement period who complete the renewal process, but move from the demonstration to CHIP	1.1.4 Renewal	Administrative records	30 days	Month	Quarterly	Required	N					This metric does not apply to Indiana's HIP demonstration. Members who are determined ineligible for HIP at renewal, could not be transferred to CHIP due to age restrictions.			
AD_19	Beneficiaries who did not complete renewal, disenrolled from Medicaid	Number of beneficiaries enrolled in the demonstration and due for renewal during the measurement period who are disenrolled from Medicaid for failure to complete the renewal process	1.1.4 Renewal	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
AD_20	Beneficiaries who had pending/uncompleted renewals and were still enrolled	Number of beneficiaries enrolled in the demonstration and due for renewal during the measurement period for whom the state had not completed renewal determination by the end of the measurement period and were still enrolled	1.1.4 Renewal	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
AD_21	Beneficiaries who retained eligibility for the demonstration after completing renewal forms	Number of beneficiaries enrolled in the demonstration and due for renewal during the measurement period who remained enrolled in the demonstration after responding to renewal notices	1.1.4 Renewal	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y		N		
AD_22	Beneficiaries who renewed ex parte	Number of beneficiaries enrolled in the demonstration and due for renewal during the measurement period who remained enrolled as determined by third-party data sources or available information, rather than beneficiary response to renewal notices	1.1.4 Renewal	Administrative records	30 days	Month	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		N		
AD_23	Beneficiaries who reached 5% limit	Number of beneficiaries enrolled in the demonstration who reached the 5% of income limit on cost sharing and premiums during the month	1.1.5 Cost sharing limit	Administrative records	30 days	Month	Quarterly	Required for states with cost-sharing or premiums	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		Y	DY8Q3	Indiana has built this metric and will reincorporate it into normal reporting after data collection was paused due to the PHE halting all cost-sharing.
AD_24	Appeals, eligibility	Number of appeals filed by beneficiaries enrolled in the demonstration during the measurement period regarding Medicaid eligibility	1.1.6 Appeals and grievances	Administrative records	None	Quarter	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Decrease	Decrease	N	The State identifies eligibility-related appeals related to eligibility denials and closures on a quarterly basis and reports it as AD_24.	N		
AD_25	Appeals, denial of benefits	Number of appeals filed by beneficiaries enrolled in the demonstration during the measurement period regarding denial of benefits	1.1.6 Appeals and grievances	Administrative records	None	Quarter	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Decrease	Decrease	N	Each MCE captures benefit authorization denials and appeals related to denial of benefit authorization in their own way but submit data to the State on a standardized reporting template. There is a line item on each template to specifically capture appeals related to denial of benefits. Each MCE submits this report on a quarterly basis. Indiana then summarizes the line items related to denial of benefit appeals and reports it as AD_25. The report in the MCE Reporting Manual used to capture these data is Report #0202: Member Grievances and Appeals.	N		
AD_26	Grievances, care quality	Number of grievances filed by beneficiaries enrolled in the demonstration during the measurement period regarding the quality of care or services provided	1.1.6 Appeals and grievances	Administrative records	None	Quarter	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Decrease	Decrease	N	Each MCE captures grievances in their own way but submit data to the State on a standardized reporting template. There is a line item on the template to specifically capture grievances regarding the quality of care, MCEs or provider, or other matters not subject to appeal. Each MCE submits this report on a quarterly basis. Indiana then summarizes the line items related to each metric and report as AD_26, AD_27, or AD_28, respectively. The report in the MCE Reporting Manual used to capture these data is Report #0202: Member Grievances and Appeals. The State has defined grievances for the MCEs as: An expression of dissatisfaction about any matter other than an "action." Therefore, a grievance does not include any of the following matters: The denial or limited authorization of a requested service, including the type or level of service The reduction, suspension or termination of a previously authorized service The denial, in whole or in part, of payment for a service The failure to provide services in a timely manner The failure to act within the required timeframe The failure to allow a resident of a rural area, with access to only one MCE, to obtain services outside the network Any other matters that pertain to the delivery of health care, such as dissatisfaction with the quality of care or services received, provider or provider staff conduct (such as rudeness) or the failure to respect an enrollee's rights should be counted as a grievance regardless of the timeframe for resolution. If the matter requires that the MCE review the situation and supply a decision, the grievance should include appeal rights if the subsequent decision is an adverse determination.	N		
AD_27	Grievances, provider or managed care entities	Number of grievances filed by beneficiaries enrolled in the demonstration during the measurement period regarding a provider or managed care entity. Managed care entities include Managed Care Organizations (MCO), Prepaid Inpatient Health Plans (PIHP), and Prepaid Ambulatory Health Plans (PAHP)	1.1.6 Appeals and grievances	Administrative records	None	Quarter	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Decrease	Decrease	N	See AD_26	N		
AD_28	Grievances, other	Number of grievances filed by beneficiaries enrolled in the demonstration during the measurement period regarding other matters that are not subject to appeal	1.1.6 Appeals and grievances	Administrative records	None	Quarter	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Decrease	Decrease	N	In Indiana, under IC 27-13-10-7 and 27-13-10-8, all grievances are subject to appeal, therefore there are no grievances that are not subject to appeal.	N		
AD_29	Primary care provider availability	Number of primary care providers enrolled to deliver Medicaid services at the end of the measurement period	1.1.7 Access to care	Provider enrollment databases	90 days	Quarter	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y	The following provider specialties were considered primary care providers for this metric: Family practitioners, general practitioners, obstetricians/gynecologists, general internists, general pediatricians, physician assistants, pediatric nurse practioner, obstetric nurse practitioner, family nurse practitioner, certified nurse midwives, and other nurse pracitions such as clinical nurse specialist.	N		
AD_30	Primary care provider active participation	Number of primary care providers enrolled to deliver Medicaid services with service claims for 3 or more demonstration beneficiaries during the measurement period	1.1.7 Access to care	Provider enrollment databases and claims and encounters	90 days	Quarter	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y	See AD_29	N		

#	Metric name	Metric description	Reporting topic[a]	Data source	Calculation lag	Measurement period	Reporting frequency	Reporting priority	State will report (Y/N)	Baseline reporting period (MM/DD/YYYY-MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided technical specifications manual (Y/N)	Explanation of any deviations from the CMS-provided technical specifications manual (different data sources or state-specific definitions, policies, codes, target populations, etc.)	State plans to phase in reporting (Y/N)	Report in when metric will be phased in (Format EandC DY and Q: Ex. DY1Q3)	Explanation of any plans to phase in reporting over time
AD_31	Specialist provider availability	Number of specialists enrolled to deliver Medicaid services at the end of the measurement period	1.1.7 Access to care	Provider enrollment databases	90 days	Quarter	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y	The following provider specialties were considered specialty providers:Certified Registered Nurse Anesthetist (CRNA) Optometrist Allergist Anesthesiologist Cardiologist Cardiovascular Surgeon Dermatologist Emergency Medicine Practitioner Gastroenterologist General Surgeon Geriatric Practitioner Hand Surgeon Internist Neonatologist Nephrologist Neurological Surgeon Neurologist Nuclear Medicine Practitioner Oncologist Ophthalmologist Orthopedic Surgeon Otologist, Laryngologist, Rhinologist Pathologist Pediatric Surgeon Pediatrician Physical Medicine and Rehabilitation Practitioner Plastic Surgeon Proctologist	N		
AD_32	Specialist provider active participation	Number of specialists enrolled to deliver Medicaid services with service claims for 3 or more demonstration beneficiaries during the measurement period	1.1.7 Access to care	Provider enrollment databases and claims and encounters	90 days	Quarter	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y	See AD_31	N		
AD_33	Preventive care and office visit utilization	Total utilization of preventive care and office visits per 1,000 demonstration beneficiary months during the measurement period	1.1.7 Access to care	Claims and encounters and other administrative records	90 days	Quarter	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Increase	Increase	Y		N		
AD_34	Prescription drug use	Total utilization of 30-day prescription fills per 1,000 demonstration beneficiary months in the measurement period	1.1.7 Access to care	Claims and encounters; other administrative records	90 days	Quarter	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Increase	Increase	Y		N		
AD_35	Emergency department utilization, total	Total number of emergency department (ED) visits per 1,000 demonstration beneficiary months during the measurement period	1.1.7 Access to care	Claims and encounters; other administrative records	90 days	Quarter	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
AD_36	Emergency department utilization, non-emergency	Total number of ED visits for non-emergency conditions per 1,000 demonstration beneficiary months during the measurement period. If the state differentiates emergent/non-emergent visit copayments, then non-emergency visits should be identified for monitoring purposes using the same criteria used to assess the differential copayment. If the state does not differentiate emergent/non-emergent copayments, then non-emergency visits should be defined as all visits not categorized as emergent using the method below.	1.1.7 Access to care	Claims and encounters; other administrative records	90 days	Quarter	Quarterly	Recommended. Required for states with copayments for non-emergency use.	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
AD_37	Inpatient admissions	Total number of inpatient admissions per 1,000 demonstration beneficiary months during the measurement period	1.1.7 Access to care	Claims and encounters; other administrative records	90 days	Quarter	Quarterly	Recommended	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
AD_38A	Medical Assistance with Smoking and Tobacco Use Cessation (MSC-AD) [NCQA; NQF #0027; Medicaid Adult Core Set; Adjusted HEDIS measure]	This metric consists of the following components; each assesses different facets of providing medical assistance with smoking and tobacco use cessation: • Advising smokers and tobacco users to quit • Discussing cessation medications • Discussing cessation strategies	1.1.8 Quality of care and health outcomes	Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Plan survey, Adult Version	90 days	Calendar year	Annually	Required (AD_38A or AD_38B. States do not have to report both.)	N								
AD_38B	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (rate 1) [PCPI Foundation; NQF #0028]	This metric consists of the following components: 1. Percentage of beneficiaries aged 18 years and older who were screened for tobacco use one or more times within 24 months 2. Percentage of beneficiaries aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention 3. Percentage of beneficiaries aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation intervention if identified as a tobacco user	1.1.8 Quality of care and health outcomes	Claims and encounters	90 days	Calendar year	Annually	Required (AD_38A or AD_38B. States do not have to report both.)	Y	01/01/2021-12/31/2022	Increase	Increase	Y		N		
AD_39-1	Follow-Up After Emergency Department Visit for Alcohol and Other Drug Abuse or Dependence (FUA-AD) [NCQA; NQF # 2605; Medicaid adult Core Set; Adjusted HEDIS measure]	Percentage of ED visits for beneficiaries age 18 and older who have a principal diagnosis of alcohol or other drug (AOD) abuse or dependence, and who had a follow-up visit with a corresponding principal diagnosis for AOD. Two rates are reported: 1. Percentage of ED visits for AOD abuse or dependence for which the beneficiary received follow-up within 30 days of the ED visit (31 total days). 2. Percentage of ED visits for AOD abuse or dependence for which the beneficiary received follow-up within 7 days of the ED visit (8 total days).	1.1.8 Quality of care and health outcomes	Claims and encounters	90 days	Calendar year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y		N		
AD_39-2	Follow-Up After Emergency Department Visit for Mental Illness (FUM-AD) [NCQA; NQF # 2605; Medicaid adult Core Set; Adjusted HEDIS measure]	Percentage of ED visits for beneficiaries age 18 and older who have a principal diagnosis of mental illness or intentional self-harm, and who had a follow-up visit with a corresponding principal diagnosis for mental illness. Two rates are reported: 1. Percentage of ED visits for mental illness or intentional self-harm for which the beneficiary received follow-up within 30 days of the ED visit (31 total days). 2. Percentage of ED visits for mental illness or intentional self-harm for which the beneficiary received follow-up within 7 days of the ED visit (8 total days).	1.1.8 Quality of care and health outcomes	Claims and encounters	90 days	Calendar year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y		N		
AD_40	Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (IET-AD) [NCQA; NQF #0004; Medicaid Adult Core Set; Adjusted HEDIS measure]	Percentage of beneficiaries age 18 and older with a new episode of AOD abuse or dependence who received the following: 1. Initiation of AOD Treatment. Percentage of beneficiaries who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication assisted treatment (MAT) within 14 days of the diagnosis 2. Engagement of AOD Treatment. Percentage of beneficiaries who initiate treatment and who had two or more additional AOD services or MAT within 34 days of the initiation visit The following diagnosis cohorts are reported for each rate: (1) Alcohol abuse or dependence, (2) Opioid abuse or dependence, (3) Other drug abuse or dependence, and (4) Total AOD abuse or dependence. A total of 8 separate rates are reported for this measure.	1.1.8 Quality of care and health outcomes	Claims and encounters or EHR	90 days	Calendar year	Annually	Required	Y	01/01/2021-12/31/2021	Increase	Increase	Y		N		
AD_41	PQI 01: Diabetes Short-Term Complications Admission Rate (PQI01-AD) [AHRQ; NQF #0272; Medicaid Adult Core Set]	Number of inpatient hospital admissions for diabetes short-term complications (ketoacidosis, hyperosmolarity, or coma) per 100,000 beneficiary months for beneficiaries age 18 and older	1.1.8 Quality of care and health outcomes	Claims and encounters	90 days	Calendar year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
AD_42	PQI 05: Chronic Obstructive Pulmonary Disease (COPD) or Asthma in Older Adults Admission Rate (PQI05-AD) [AHRQ; NQF #0275; Medicaid Adult Core Set]	Number of inpatient hospital admissions for chronic obstructive pulmonary disease (COPD) or asthma per 100,000 beneficiary months for beneficiaries age 40 and older	1.1.8 Quality of care and health outcomes	Claims and encounters	90 days	Calendar year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
AD_43	PQI 08: Heart Failure Admission Rate (PQI08-AD) [AHRQ; NQF #0277; Medicaid Adult Core Set]	Number of inpatient hospital admissions for heart failure per 100,000 beneficiary months for beneficiaries age 18 and older	1.1.8 Quality of care and health outcomes	Claims and encounters	90 days	Calendar year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
AD_44	PQI 15: Asthma in Younger Adults Admission Rate (PQI15-AD) [AHRQ; NQF #0283; Medicaid Adult Core Set]	Number of inpatient hospital admissions for asthma per 100,000 beneficiary months for beneficiaries aged 18 to 39	1.1.8 Quality of care and health outcomes	Claims and encounters	90 days	Calendar year	Annually	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		N		
AD_45	Administrative cost of demonstration operation	Cost of contracts or contract amendments and staff time equivalents required to administer demonstration policies, including premium collection, health behavior incentives, premium assistance, and/or retroactive eligibility waivers	1.1.9 Administrative cost	Administrative records	None	Demonstration year	Annually	Recommended	N								
State-specific metrics																	
Add rows for any state-specific metrics																	

[a] The reporting topics correspond to the prompts for the any demonstration (AD) reporting topic in Section 4 of the monitoring report template.

Medicaid Section 1115 Eligibility and Coverage Demonstrations Monitoring Protocol (Part A) - Planned metrics (HB) (Version 2.0)

State: Indiana

Demonstration Name: Healthy Indiana Plan

Eligibility and Coverage Demonstration Planned Metrics (HB)

Standard information on CMS-provided metrics										Baseline, annual goals, and demonstration target			Alignment with CMS-provided technical specifications manual		Phased-in metrics reporting		
#	Metric name	Metric description	Reporting topic*	Data source	Calculation by	Measurement period	Reporting frequency	Reporting priority	State will report (Y/N)	Baseline reporting period (MM/DD/YYYY - MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided technical specifications manual (Y/N)	Explanation of any deviations from the CMS-provided technical specifications manual (different data sources or state-specific definitions, policies, codes, target populations, etc.)	State plans to phase in reporting (Y/N)	Report in which metric will be phased in (Format HB DY and Q; Ex. DY1CQ3)	Explanation of any plans to phase in reporting over time
EXAMPLE: HB_7 ***(Do not delete or edit this row)***	*EXAMPLE: Beneficiaries granted a reward in the form of additional covered benefits for completion of incentivized health behaviors*	*EXAMPLE: Number of beneficiaries enrolled in the demonstration who were flagged for or granted a reward that takes the form of an additional covered benefit or service, by benefit or service type, during the measurement period*	*EXAMPLE: HB Mod. 1: Health behavior incentives*	*EXAMPLE: Administrative records*	*EXAMPLE: 90 days*	*EXAMPLE: Quarter*	*EXAMPLE: Quarterly*	*EXAMPLE: Required*	*EXAMPLE: Y*	*EXAMPLE: 10/01/2019 - 01/01/2020*	*EXAMPLE: Increase*	*EXAMPLE: Increase*	*EXAMPLE: Y*		*EXAMPLE: N*	*EXAMPLE: DY1CQ4*	*EXAMPLE: Will be covered beginning in DY2*
HB_1	Total enrollment among beneficiaries subject to health behavior incentives	Number of beneficiaries subject to health behavior incentive policies who were enrolled in the demonstration at any time during the measurement period	HB Mod. 1: Health behavior incentives	Administrative records	90 days	Quarter	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	The only healthy behavior incentive associated with the waiver is the HIP rollover. Target population for this metric is all HIP enrollees (all enrollees can earn rollover).	N		
HB_2	Beneficiaries using incentivized services that can be documented through claims, by service	Total number of beneficiaries enrolled in the demonstration at any point during the measurement period who utilized financially incentivized services that can be documented through claims since the beginning of their enrollment spell	HB Mod. 1: Health behavior incentives	Administrative records, claims and encounters	90 days	Quarter	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	The only healthy behavior incentive associated with the waiver is the HIP rollover. Target population for this metric is all HIP enrollees who receive preventive care (preventive care is the requirement for rollover discount or state matched rollover).	Y	DY8Q3	IN needs to implement measures specific to CMSs specifications and give MCE partners time to test and implement. We will have the MCEs retrospectively report the metric starting with the baseline reporting period of 01/01/2021 - 12/31/2021.
HB_3	Completion of incentivized health behavior(s) not documented through claims analysis (i.e. health risk assessments), by health behavior	Number of beneficiaries enrolled in the demonstration at any point during the measurement period who have completed each incentivized health behavior not documented through claims analysis (i.e. health risk assessments) since the beginning of their enrollment spell	HB Mod. 1: Health behavior incentives	Administrative records	90 days	Quarter	Quarterly	Required	N					IN documents inventivized healthy behaviors through claims only			
HB_4	Completion of all incentivized health behaviors (both claims-based and other), if there are multiple	Number of beneficiaries enrolled in the demonstration at any point during the measurement period who have completed all incentivized health behaviors (including incentivized services documented through claims and other health behaviors not documented through claims) since the beginning of their enrollment spell	HB Mod. 1: Health behavior incentives	Administrative records, claims and encounters	90 days	Quarter	Quarterly	Required	N					IN documents inventivized healthy behaviors through claims only			
HB_5	Beneficiaries granted a premium reduction for completion of incentivized health behaviors	Number of beneficiaries enrolled in the demonstration who were flagged for or granted a reward related to premium obligations during the measurement period, regardless of whether the premium reduction occurs durine the measurement period or in the future	HB Mod. 1: Health behavior incentives	Administrative records	90 days	Quarter	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	The only healthy behavior incentive associated with the wavier is the HIP rollover. Target population for this metric is all HIP enrollees who received rollover in the measurement period.	Y	DY8Q3	IN needs to implement measures specific to CMSs specifications and give MCE partners time to test and implement. We will have the MCEs retrospectively report the metric starting with the baseline renortine period of 01/01/2021 - 12/31/2021.
HB_6	Beneficiaries granted a financial reward other than a premium reduction for completion of incentivized health behaviors	Number of beneficiaries enrolled in the demonstration who were flagged for or granted a reward other than a premium reduction during the measurement period, regardless of when the reward is realized	HB Mod. 1: Health behavior incentives	Administrative records	90 days	Quarter	Quarterly	Required	N					IN does not have any policies that specifically reward members in the form of financial reward for completion of preventive care.			
HB_7	Beneficiaries granted a reward in the form of additional covered benefits for completion of incentivized health behaviors	Number of beneficiaries enrolled in the demonstration who were flagged for or granted a reward that takes the form of an additional covered benefit or service, by benefit or service type, during the measurement period	HB Mod. 1: Health behavior incentives	Administrative records	90 days	Quarter	Quarterly	Required	N					IN does not have any policies that specifically reward members in the form of additional covered benefits or services for completion of preventive care.			
State-specific metrics																	
Add rows for any state-specific metrics																	

* The rerportine tonic corresponds to the health behavior incentives (HBI) rerortine tonic in Section 3 of the monitorine rerort tamnlate.

Eligibility and Coverage Demonstration Planned Metrics (PR)

Standard information on CMS-provided metrics										Baseline, annual goals, and demonstration target			Alignment with CMS-provided technical specifications manual		Phased-in metrics reporting		
#	Metric name	Metric description	Reporting topic*	Data source	Calculation lag	Measurement period	Reporting frequency	Reporting priority	State will report (Y/N)	Baseline reporting period (MM/DD/YYYY - MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided technical specifications manual (Y/N)	Explanation of any deviations from the CMS-provided technical specifications manual (different data sources or state-specific definitions, policies, codes, target populations, etc.)	State plans to phase in reporting (Y/N)	Report in which metric will be phased in (Format PR DY and Q; Ex. DY1Q3)	Explanation of any plans to phase in reporting over time
PR_1	Beneficiaries subject to premium policy (or account contribution) during the month, not exempt	The number of beneficiaries enrolled in the demonstration whose income and eligibility group were subject to the premium policy (or account contribution policy), regardless of whether they paid or did not pay during the measurement period	PR.Mod_1: Eligibility and payment amounts	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Consistent	Consistent	N	There are multiple data systems being used to capture PR1 and PR3-6. These data are captured from IN's eligibility system. This metric will probably not equal the sum of metrics PR3-6.	N		
PR_2	Beneficiaries who were exempt from premiums for that month	Among beneficiaries enrolled in the demonstration who were subject to the premium (or account contribution) policy on the basis of income or eligibility group, the count of those exempt from owing premiums or other monthly payments, and therefore not required to make payments. For example, demonstration policies may exempt beneficiaries who would otherwise be subject to premiums as incentives for health behaviors or other activities.	PR.Mod_1: Eligibility and payment amounts	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		N		
PR_3	Beneficiaries who paid a premium during the month	Among beneficiaries enrolled in the demonstration whose income and eligibility group were subject to the premium (or account contribution) policy, number of beneficiaries who paid this month	PR.Mod_1: Eligibility and payment amounts	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Increase	Increase	N	There are multiple data systems being used to capture PR_1 and PR_3-6. These data are captured from the claims system. The State will report beneficiaries that maintained HIP plus coverage by making the required monthly POWER account contribution within the 60-day payment period. This could include beneficiaries who are both above 100% FPL and have an eligibility status that prevents them from losing coverage for failure to pay (e.g. medically frail) as long as those beneficiaries: 1) are required to make POWER account contributions to maintain enrollment or HIP Plus benefits, and 2) make a POWER account contribution within the 60-day payment period.	Y	DY8Q1	IN will create and add a report to the MCE Reporting Manual to capture metric PR_3. We will have the MCEs retrospectively report through CY2021.
PR_5	Beneficiaries in short-term arrears (grace period)	Among beneficiaries enrolled in the demonstration whose income and eligibility group were subject to the premium (or account contribution) policy, the number of those who did not pay in the measurement period. but have not yet exceeded their grace period	PR.Mod_5: Operationalize strategies for noncompliance	Administrative records	30 days	Month	Quarterly	Required if state has a grace period	Y	01/01/2021-12/31/2021	Decrease	Decrease	N	There are multiple data systems being used to capture PR1 and PR3-6. These data are captured by the MCEs.	Y	DY8Q1	These data are capture by the MCEs. IN will submit to CMS a retrospective report to capture these data once available from the MCEs.
PR_6	Beneficiaries in long-term arrears	Among beneficiaries enrolled in the demonstration whose income and eligibility group were subject to the premium (or account contribution) policy, number of beneficiaries who did not pay this month, and who remain enrolled even though they have exceeded the grace period	PR.Mod_5: Operationalize strategies for noncompliance	Administrative records	30 days	Month	Quarterly	Required if state has a grace period and allows continued enrollment for any income and eligibility groups otherwise subject to premiums once the grace period has been exceeded	Y	01/01/2021-12/31/2021	Decrease	Decrease	N	These members will be a subset of PR_1, but cannot determine if they were also captured in PR_5.	Y	DY8Q1	IN will create and add a report to the MCE Reporting Manual to capture metric PR_6. We will have the MCEs retrospectively report through CY2021.
PR_7	Beneficiaries with collectible debt	Among beneficiaries enrolled in the demonstration whose income and eligibility group were subject to the premium policy (or account contribution policy), number of beneficiaries who had collectible debt.	PR.Mod_5: Operationalize strategies for noncompliance	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Decrease	Decrease	Y		Y	DY8Q1	These data are capture by the MCEs. IN will submit to CMS a retrospective report to capture these data once available from the MCEs.
PR_15	Beneficiaries disenrolled from the demonstration for failure to pay and therefore disenrolled from Medicaid	Number of demonstration beneficiaries disenrolled from Medicaid as of the last day of the measurement period for failure to pay premiums	PR.Mod_5: Operationalize strategies for noncompliance	Administrative records	30 days	Month	Quarterly	Required only for states with premiums or monthly payment with a policy of termination for failure to pay	Y	01/01/2021-12/31/2021	Decrease	Decrease	N	IN will not use AD_7 to identify numbers in Step 1. AD_7 is captured by the MCEs. IN will identify disenrollments from HIP due to a failure to pay reason code. If a member moves from one HIP sal category to another, then this is not considered a disenrollment.	N		
PR_21	Third-party premium payment	Number of beneficiaries enrolled in the demonstration who had any portion of their premium or other monthly ravements mail be a third marty	PR.Mod_1: Eligibility and ravment amounts	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2021-12/31/2021	Consistent	Consistent	Y		Y	DY8Q1	These data are captured by the MCEs. IN will submit to CMS a retrospective report to capture these data once available from the MCEs.
	Beneficiaries who have a tobacco user surcharge applied to their POWER account contribution	Number of beneficiaries enrolled in the demonstration and subject to premium policies who have a tobacco user surcharge applied to their POWER account contribution		Administrative records	90 days	Calendar Year	Annually	Required	Y				N	IN will use the following steps to calculate this metric: Step 1. Identify beneficiaries enrolled in the demonstration whose income and eligibility group were subject to the premium policy (or account contribution policy)) (Metric PR_1). Step 2. Retain beneficiaries (deduplicated) who are identified as tobacco users in the first year of enrollment and due for renewal during the measurement period. Step 3. Retain beneficiaries who have a tobacco user surcharge applied to their POWER account contribution beginning in the first month of their renewal benefit period. Step 4. Exclude beneficiaries who inform the state that he or she has stopped using tobacco or who successfully appeal the application of the surcharge. Step 5. Count unique beneficiaries (deduplicated) who meet the criteria in Steps 1, 2, 3 and 4.	Y		
IN_PR_1			*PR.Mod_1: Eligibility and payment amounts*							01/01/2024-12/31/2024	Decrease	Decrease				DY11Q2	Since the tobacco surcharge will not be implemented until CY2024, these data will not be available until the DY11Q2 report.

* The reporting topics correspond to the premiums or account payments (PR) reporting topics in Section 3 of the monitoring report template.

Medicaid Section 1115 Eligibility and Coverage Demonstrations Monitoring Protocol (Part A) - Planned metrics (RW) (Version 2.0)
State: Indiana
Demonstration Name: Healthy Indiana Plan

Eligibility and Coverage Demonstration Planned Metrics (RW)

Standard information on CMS-provided metrics										Baseline, annual goals, and demonstration target			Alignment with CMS-provided technical specifications manual		Phased-in metrics reporting		
#	Metric name	Metric description	Reporting topic*	Data source	Calculation lag	Measurement period	Reporting frequency	Reporting rebuttal	State will report (Y/N)	Baseline reporting period (MM/DD/YYYY - MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided technical specifications manual (Y/N)	Explanation of any deviations from the CMS-provided technical specifications manual (different data sources or state-specific definitions, policies, codes, latest specifications, etc.)	State plans to phase in reporting (Y/N)	Report in which metric will be phased in (Format RW DY and Q, i.e., DY1Q3)	Explanation of any plans to phase in reporting over time
EXAMPLE: RW_1 ***(Do not delete or edit this row)***	*EXAMPLE: Beneficiaries who indicated that they had unpaid medical bills at the time of application*	*EXAMPLE: The number of demonstration beneficiaries in income and eligibility groups that were subject to the waiver of retroactive eligibility policy, who began a new enrollment period in the reporting month, and who indicated at the time of application for Medicaid that they had unpaid medical bills from the past three months or other time period specified in the state's Medicaid application question*	*EXAMPLE: RW Mod. 1: Retroactive eligibility and demonstration requirements*	*EXAMPLE: Administrative records*	*EXAMPLE: 30 days*	*EXAMPLE: Month*	*EXAMPLE: Quarterly*	*EXAMPLE: Required*	*EXAMPLE: Y*	*EXAMPLE: 01/01/2020 - 01/31/2020*	*EXAMPLE: Consistent*	*EXAMPLE: Consistent*	*EXAMPLE: Y*		*EXAMPLE: N*	*EXAMPLE: DY3Q4*	
RW_1	Beneficiaries who indicated that they had unpaid medical bills at the time of application	The number of demonstration beneficiaries in income and eligibility groups that were subject to the waiver of retroactive eligibility policy, who began a new enrollment period in the reporting month, and who indicated at the time of application for Medicaid that they had unpaid medical bills from the past three months or other time period specified in the state's Medicaid application question	RW Mod. 1: Retroactive eligibility and demonstration requirements	Administrative records	30 days	Month	Quarterly	Required	Y	01/01/2025-12/31/2023	Consistent	Decrease	Y		Y	DY9Q1	IN will need to update application questions to capture the measure. Our vendor that manages our application is unable to make this change in a timely manner due to financial and contractual restraints. Full implementation of the application question and data collection for this metric is expected to take about 9 months.
RW_2	Beneficiaries who had a coverage gap at renewal	The number of demonstration beneficiaries in income and eligibility groups that were subject to the waiver of retroactive eligibility policy who re-enrolled in the demonstration within 90 days after a previous enrollment spell in the demonstration ended because the beneficiary did not comply with renewal processes on time	RW Mod. 1: Retroactive eligibility and demonstration requirements	Administrative records	90 days	Quarter	Quarterly	Required	Y	01/01/2025-12/31/2021	Decrease	Decrease	Y		N		
RW_3	Beneficiaries who had a coverage gap at renewal and had claims denied	The number of demonstration beneficiaries in income and eligibility groups that were subject to the waiver of retroactive eligibility policy who re-enrolled in the demonstration within 90 days after a previous enrollment spell in the demonstration ended, and for whom claims were submitted for services rendered during the period of disenrollment that were denied by the state	RW Mod. 1: Retroactive eligibility and demonstration requirements	Administrative records	90 days	Quarter	Quarterly	Required	Y	01/01/2025-12/31/2023	Decrease	Decrease	Y		Y	DY8Q3	These data are captured by the MCEs. IN is currently working with the MCEs to code and collect this data.
State-specific metrics																	
Add rows for any state-specific metrics																	

* The reporting topic corresponds to the retroactive eligibility waivers (RW) reporting topic in Section 3 of the monitoring report template.

Medicaid Section 1115 Eligibility and Coverage Demonstrations Monitoring Protocol (Part A) - Reporting Schedule

State	Indiana
Demonstration Name	Healthy Indiana Plan

Instructions:

(1) In the reporting periods input table (Table 1), use the prompt in column A to enter the requested information in the corresponding row of column B. All report names and reporting periods should use the format DY#Q# or CY# and all dates should use the format MM/DD/YYYY with no spaces in the cell. The information entered in these cells will auto-populate the eligibility and coverage demonstration reporting schedule in Table 2. All cells in the input table must be completed in entirety for the standard reporting schedule to be accurately auto-populated.

(2) Review the state's reporting schedule in the eligibility and coverage demonstration reporting schedule table (Table 2). For each of the reporting categories listed in columns E and F, select Y or N in the "Deviation from standard reporting schedule (Y/N)" column to indicate whether the state plans to report according to the standard reporting schedule. If a state's planned reporting does not match the standard reporting schedule for any quarter and/or reporting category, the state should describe these deviations in the "Explanation for deviations" column and use the "Proposed deviations from standard reporting schedule" column to indicate the measurement periods with which it wishes to overwrite the standard schedule. All other columns are locked for editing and should not be altered by the state.

Table 1. Reporting Periods Input Table

	Demonstration reporting periods/dates			
	AD	PR	HB	RW
Dates of first reporting quarter:				
Reporting period	DY7Q1	DY7Q1	DY7Q1	DY7Q1
Start date	1/1/2021	1/1/2021	1/1/2021	1/1/2021
End date	3/31/2021	3/31/2021	3/31/2021	3/31/2021
Broader section 1115 demonstration reporting period corresponding with the first EandC reporting quarter, if applicable. If there is no broader demonstration, fill in the first eligibility and coverage policy reporting period. (Format DY Q; Ex. DY1Q3)	DY7Q1	DY7Q1	DY7Q1	DY7Q1
First report due date (per STCs') (MM/DD/YYYY)	5/30/2021	5/30/2021	5/30/2021	5/30/2021
First report where the state plans to report calendar year (CY) metrics with a 90 day lag				
Reporting period associated with report (Format DY Q;	CY2021			
Start date	DY8Q3			
End date	7/1/2022			
Dates of last reporting quarter:	9/30/2022			
Start date	10/1/2030	10/1/2030	10/1/2030	10/1/2030
End date	12/31/2030	12/31/2030	12/31/2030	12/31/2030

Table 2. Eligibility and Coverage Demonstration Reporting Schedule

Dates of reporting quarter (MM/DD/YYYY - MM/DD/YYYY)		Report due (per STCs)	Broader section 1115 DY (if applicable, otherwise the first eligibility and coverage policy reporting period)	Reporting category		For each reporting category, measurement period for which information is captured in monitoring report per standard reporting schedule (Format DYQ; Ex. DY1Q3)[b, c]				Deviation from standard reporting schedule	Explanation for deviations	Proposed deviations from standard reporting schedule (Format DYQ; Ex. DY1Q3)			
Start date	End date	(MM/DD/YYYY)	(Format DY Q; Ex. DY1Q3)	Calculation lag	Measurement period	AD	PR	HB	RW	(Y/N)		AD	PR	HB	RW
1/1/2021	3/31/2021	5/30/2021	DY7Q1	None	Narrative information	DY7Q1	DY7Q1	DY7Q1	DY7Q1	N					
				30 days	Month	DY7Q1	DY7Q1		DY7Q1	N					
				None	Quarter	DY7Q1				N					
				90 days	Quarter					N					
				90 days	Calendar year					N					
				None	Demonstration year					N					
4/1/2021	6/30/2021	8/29/2021	DY7Q2	None	Narrative information	DY7Q2	DY7Q2	DY7Q2	DY7Q2	N					
				30 days	Month	DY7Q2	DY7Q2		DY7Q2	N					
				None	Quarter	DY7Q2				N					
				90 days	Quarter	DY7Q1		DY7Q1	DY7Q1	N					
				90 days	Calendar year					N					
				None	Demonstration year					N					
7/1/2021	9/30/2021	11/29/2021	DY7Q3	None	Narrative information	DY7Q3	DY7Q3	DY7Q3	DY7Q3	N					
				30 days	Month	DY7Q3	DY7Q3		DY7Q3	N					
				None	Quarter	DY7Q3				N					
				90 days	Quarter	DY7Q2		DY7Q2	DY7Q2	N					
				90 days	Calendar year					N					
				None	Demonstration year					N					
10/1/2021	12/31/2021	3/31/2022	DY7Q4	None	Narrative information	DY7Q4	DY7Q4	DY7Q4	DY7Q4	N					
				30 days	Month	DY7Q4	DY7Q4		DY7Q4	N					
				None	Quarter	DY7Q4				N					
				90 days	Quarter	DY7Q3		DY7Q3	DY7Q3	N					
				90 days	Calendar year					N					
				None	Demonstration year	DY7				N					
1/1/2022	3/31/2022	5/30/2022	DY8Q1	None	Narrative information	DY8Q1	DY8Q1	DY8Q1	DY8Q1	N					
				30 days	Month	DY8Q1	DY8Q1		DY8Q1	N					
				None	Quarter	DY8Q1				N					
				90 days	Quarter	DY7Q4		DY7Q4	DY7Q4	N					
				90 days	Calendar year					N					
				None	Demonstration year					N					
4/1/2022	6/30/2022	8/29/2022	DY8Q2	None	Narrative information	DY8Q2	DY8Q2	DY8Q2	DY8Q2	N					
				30 days	Month	DY8Q2	DY8Q2		DY8Q2	N					
				None	Quarter	DY8Q2				N					
				90 days	Quarter	DY8Q1		DY8Q1	DY8Q1	N					
				90 days	Calendar year					N					
				None	Demonstration year					N					
7/1/2022	9/30/2022	11/29/2022	DY8Q3	None	Narrative information	DY8Q3	DY8Q3	DY8Q3	DY8Q3	N					
				30 days	Month	DY8Q3	DY8Q3		DY8Q3	N					
				None	Quarter	DY8Q3				N					
				90 days	Quarter	DY8Q2		DY8Q2	DY8Q2	N					
				90 days	Calendar year	CY2021				N					
				None	Demonstration year					N					
10/1/2022	12/31/2022	3/31/2023	DY8Q4	None	Narrative information	DY8Q4	DY8Q4	DY8Q4	DY8Q4	N					
				30 days	Month	DY8Q4	DY8Q4		DY8Q4	N					
				None	Quarter	DY8Q4				N					
				90 days	Quarter	DY8Q3		DY8Q3	DY8Q3	N					

				90 days	Calendar year					N						
				None	Demonstration year	DY8				N						
1/1/2023	3/31/2023	5/30/2023	DY9Q1	None	Narrative information	DY9Q1	DY9Q1	DY9Q1	DY9Q1	N						
				30 days	Month	DY9Q1	DY9Q1		DY9Q1	N						
				None	Quarter	DY9Q1				N						
				90 days	Quarter	DY8Q4		DY8Q4	DY8Q4	N						
				90 days	Calendar year					N						
				None	Demonstration year					N						
4/1/2023	6/30/2023	8/29/2023	DY9Q2	None	Narrative information	DY9Q2	DY9Q2	DY9Q2	DY9Q2	N						
				30 days	Month	DY9Q2	DY9Q2		DY9Q2	N						
				None	Quarter	DY9Q2				N						
				90 days	Quarter	DY9Q1		DY9Q1	DY9Q1	N						
				90 days	Calendar year					N						
				None	Demonstration year					N						
7/1/2023	9/30/2023	11/29/2023	DY9Q3	None	Narrative information	DY9Q3	DY9Q3	DY9Q3	DY9Q3	N						
				30 days	Month	DY9Q3	DY9Q3		DY9Q3	N						
				None	Quarter	DY9Q3				N						
				90 days	Quarter	DY9Q2		DY9Q2	DY9Q2	N						
				90 days	Calendar year	CY2022				N						
				None	Demonstration year					N						
10/1/2023	12/31/2023	3/30/2024	DY9Q4	None	Narrative information	DY9Q4	DY9Q4	DY9Q4	DY9Q4	N						
				30 days	Month	DY9Q4	DY9Q4		DY9Q4	N						
				None	Quarter	DY9Q4				N						
				90 days	Quarter	DY9Q3		DY9Q3	DY9Q3	N						
				90 days	Calendar year					N						
				None	Demonstration year	DY9				N						
1/1/2024	3/31/2024	5/30/2024	DY10Q1	None	Narrative information	DY10Q1	DY10Q1	DY10Q1	DY10Q1	N						
				30 days	Month	DY10Q1	DY10Q1		DY10Q1	N						
				None	Quarter	DY10Q1				N						
				90 days	Quarter	DY9Q4		DY9Q4	DY9Q4	N						
				90 days	Calendar year					N						
				None	Demonstration year					N						
4/1/2024	6/30/2024	8/29/2024	DY10Q2	None	Narrative information	DY10Q2	DY10Q2	DY10Q2	DY10Q2	N						
				30 days	Month	DY10Q2	DY10Q2		DY10Q2	N						
				None	Quarter	DY10Q2				N						
				90 days	Quarter	DY10Q1		DY10Q1	DY10Q1	N						
				90 days	Calendar year					N						
				None	Demonstration year					N						
7/1/2024	9/30/2024	11/29/2024	DY10Q3	None	Narrative information	DY10Q3	DY10Q3	DY10Q3	DY10Q3	N						
				30 days	Month	DY10Q3	DY10Q3		DY10Q3	N						
				None	Quarter	DY10Q3				N						
				90 days	Quarter	DY10Q2		DY10Q2	DY10Q2	N						
				90 days	Calendar year	CY2023				N						
				None	Demonstration year					N						
10/1/2024	12/31/2024	3/31/2025	DY10Q4	None	Narrative information	DY10Q4	DY10Q4	DY10Q4	DY10Q4	N						
				30 days	Month	DY10Q4	DY10Q4		DY10Q4	N						
				None	Quarter	DY10Q4				N						
				90 days	Quarter	DY10Q3		DY10Q3	DY10Q3	N						
				90 days	Calendar year					N						
				None	Demonstration year	DY10				N						
1/1/2025	3/31/2025	5/30/2025	DY11Q1	None	Narrative information	DY11Q1	DY11Q1	DY11Q1	DY11Q1	N						
				30 days	Month	DY11Q1	DY11Q1		DY11Q1	N						
				None	Quarter	DY11Q1				N						
				90 days	Quarter	DY10Q4		DY10Q4	DY10Q4	N						
				90 days	Calendar year					N						
				None	Demonstration year					N						
4/1/2025	6/30/2025	8/29/2025	DY11Q2	None	Narrative information	DY11Q2	DY11Q2	DY11Q2	DY11Q2	N						
				30 days	Month	DY11Q2	DY11Q2		DY11Q2	N						
				None	Quarter	DY11Q2				N						
				90 days	Quarter	DY11Q1		DY11Q1	DY11Q1	N						
				90 days	Calendar year		CY2024			Y	IN_PR_1 is an annual metric; IN will begin reporting in DY11Q2		CY2024			
				None	Demonstration year					N						
7/1/2025	9/30/2025	11/29/2025	DY11Q3	None	Narrative information	DY11Q3	DY11Q3	DY11Q3	DY11Q3	N						
				30 days	Month	DY11Q3	DY11Q3		DY11Q3	N						
				None	Quarter	DY11Q3				N						
				90 days	Quarter	DY11Q2		DY11Q2	DY11Q2	N						
				90 days	Calendar year	CY2024				N						
				None	Demonstration year					N						
10/1/2025	12/31/2025	3/31/2026	DY11Q4	None	Narrative information	DY11Q4	DY11Q4	DY11Q4	DY11Q4	N						
				30 days	Month	DY11Q4	DY11Q4		DY11Q4	N						
				None	Quarter	DY11Q4				N						
				90 days	Quarter	DY11Q3		DY11Q3	DY11Q3	N						
				90 days	Calendar year					N						
				None	Demonstration year	DY11				N						
1/1/2026	3/31/2026	5/30/2026		None	Narrative information	DY12Q1	DY12Q1	DY12Q1	DY12Q1	N						
				30 days	Month	DY12Q1	DY12Q1		DY12Q1	N						
				None	Quarter	DY12Q1				N						
				90 days	Quarter	DY11Q4		DY11Q4	DY11Q4	N						
				90 days	Calendar year					N						
				None	Demonstration year					N						
4/1/2026	6/30/2026	8/29/2026		None	Narrative information	DY12Q2	DY12Q2	DY12Q2	DY12Q2	N						
				30 days	Month	DY12Q2	DY12Q2		DY12Q2	N						
				None	Quarter	DY12Q2				N						
				90 days	Quarter	DY12Q1		DY12Q1	DY12Q1	N						
				90 days	Calendar year		CY2025			Y	IN_PR_1 is an annual metric		CY2025			
				None	Demonstration year					N						
7/1/2026	9/30/2026	11/29/2026		None	Narrative information	DY12Q3	DY12Q3	DY12Q3	DY12Q3	N						
				30 days	Month	DY12Q3	DY12Q3		DY12Q3	N						
				None	Quarter	DY12Q3				N						
				90 days	Quarter	DY12Q2		DY12Q2	DY12Q2	N						
				90 days	Calendar year	CY2025				N						
				None	Demonstration year					N						
10/1/2026	12/31/2026	3/1/2027		None	Narrative information	DY12Q4	DY12Q4	DY12Q4	DY12Q4	N						
				30 days	Month	DY12Q4	DY12Q4		DY12Q4	N						
				None	Quarter	DY12Q4				N						
				90 days	Quarter	DY12Q3		DY12Q3	DY12Q3	N						
				90 days	Calendar year					N						
				None	Demonstration year	DY12				N						
1/1/2027	3/31/2027	5/30/2027		None	Narrative information	DY13Q1	DY13Q1	DY13Q1	DY13Q1	N						
				30 days	Month	DY13Q1	DY13Q1		DY13Q1	N						
				None	Quarter	DY13Q1				N						
				90 days	Quarter	DY12Q4		DY12Q4	DY12Q4	N						
				90 days	Calendar year					N						
				None	Demonstration year					N						
4/1/2027	6/30/2027	8/29/2027		None	Narrative information	DY13Q2	DY13Q2	DY13Q2	DY13Q2	N						
				30 days	Month	DY13Q2	DY13Q2		DY13Q2	N						
				None	Quarter	DY13Q2				N						
				90 days	Quarter	DY13Q1		DY13Q1	DY13Q1	N						
				90 days	Calendar year		CY2026			Y	IN_PR_1 is an annual metric		CY2026			
				None	Demonstration year					N						
7/1/2027	9/30/2027	11/29/2027		None	Narrative information	DY13Q3	DY13Q3	DY13Q3	DY13Q3	N						
				30 days	Month	DY13Q3	DY13Q3		DY13Q3	N						
				None	Quarter	DY13Q3				N						
				90 days	Quarter	DY13Q2		DY13Q2	DY13Q2	N						
				90 days	Calendar year	CY2026				N						
				None	Demonstration year					N						
10/1/2027	12/31/2027	2/29/2028		None	Narrative information	DY13Q4	DY13Q4	DY13Q4	DY13Q4	N						

				30 days	Month	DY13Q4	DY13Q4		DY13Q4	N						
				None	Quarter	DY13Q4				N						
				90 days	Quarter	DY13Q3		DY13Q3	DY13Q3	N						
				90 days	Calendar year					N						
				None	Demonstration year	DY13				N						
1/1/2028	3/31/2028	5/30/2028		None	Narrative information	DY14Q1	DY14Q1	DY14Q1	DY14Q1	N						
				30 days	Month	DY14Q1	DY14Q1		DY14Q1	N						
				None	Quarter	DY14Q1				N						
				90 days	Quarter	DY13Q4		DY13Q4	DY13Q4	N						
				90 days	Calendar year					N						
				None	Demonstration year					N						
4/1/2028	6/30/2028	8/29/2028		None	Narrative information	DY14Q2	DY14Q2	DY14Q2	DY14Q2	N						
				30 days	Month	DY14Q2	DY14Q2		DY14Q2	N						
				None	Quarter	DY14Q2				N						
				90 days	Quarter	DY14Q1		DY14Q1	DY14Q1	N						
				90 days	Calendar year		CY2027			Y	IN_PR_1 is an annual metric		CY2027			
				None	Demonstration year					N						
7/1/2028	9/30/2028	11/29/2028		None	Narrative information	DY14Q3	DY14Q3	DY14Q3	DY14Q3	N						
				30 days	Month	DY14Q3	DY14Q3		DY14Q3	N						
				None	Quarter	DY14Q3				N						
				90 days	Quarter	DY14Q2		DY14Q2	DY14Q2	N						
				90 days	Calendar year	CY2027				N						
				None	Demonstration year					N						
10/1/2028	12/31/2028	3/1/2029		None	Narrative information	DY14Q4	DY14Q4	DY14Q4	DY14Q4	N						
				30 days	Month	DY14Q4	DY14Q4		DY14Q4	N						
				None	Quarter	DY14Q4				N						
				90 days	Quarter	DY14Q3		DY14Q3	DY14Q3	N						
				90 days	Calendar year					N						
				None	Demonstration year	DY14				N						
1/1/2029	3/31/2029	5/30/2029		None	Narrative information	DY15Q1	DY15Q1	DY15Q1	DY15Q1	N						
				30 days	Month	DY15Q1	DY15Q1		DY15Q1	N						
				None	Quarter	DY15Q1				N						
				90 days	Quarter	DY14Q4		DY14Q4	DY14Q4	N						
				90 days	Calendar year					N						
				None	Demonstration year					N						
4/1/2029	6/30/2029	8/29/2029		None	Narrative information	DY15Q2	DY15Q2	DY15Q2	DY15Q2	N						
				30 days	Month	DY15Q2	DY15Q2		DY15Q2	N						
				None	Quarter	DY15Q2				N						
				90 days	Quarter	DY15Q1		DY15Q1	DY15Q1	N						
				90 days	Calendar year		CY2028			Y	IN_PR_1 is an annual metric		CY2028			
				None	Demonstration year					N						
7/1/2029	9/30/2029	11/29/2029		None	Narrative information	DY15Q3	DY15Q3	DY15Q3	DY15Q3	N						
				30 days	Month	DY15Q3	DY15Q3		DY15Q3	N						
				None	Quarter	DY15Q3				N						
				90 days	Quarter	DY15Q2		DY15Q2	DY15Q2	N						
				90 days	Calendar year	CY2028				N						
				None	Demonstration year					N						
10/1/2029	12/31/2029	3/1/2030		None	Narrative information	DY15Q4	DY15Q4	DY15Q4	DY15Q4	N						
				30 days	Month	DY15Q4	DY15Q4		DY15Q4	N						
				None	Quarter	DY15Q4				N						
				90 days	Quarter	DY15Q3		DY15Q3	DY15Q3	N						
				90 days	Calendar year					N						
				None	Demonstration year	DY15				N						
1/1/2030	3/31/2030	5/30/2030		None	Narrative information	DY16Q1	DY16Q1	DY16Q1	DY16Q1	N						
				30 days	Month	DY16Q1	DY16Q1		DY16Q1	N						
				None	Quarter	DY16Q1				N						
				90 days	Quarter	DY15Q4		DY15Q4	DY15Q4	N						
				90 days	Calendar year					N						
				None	Demonstration year					N						
4/1/2030	6/30/2030	8/29/2030		None	Narrative information	DY16Q2	DY16Q2	DY16Q2	DY16Q2	N						
				30 days	Month	DY16Q2	DY16Q2		DY16Q2	N						
				None	Quarter	DY16Q2				N						
				90 days	Quarter	DY16Q1		DY16Q1	DY16Q1	N						
				90 days	Calendar year		CY2029			Y	IN_PR_1 is an annual metric		CY2029			
				None	Demonstration year					N						
7/1/2030	9/30/2030	11/29/2030		None	Narrative information	DY16Q3	DY16Q3	DY16Q3	DY16Q3	N						
				30 days	Month	DY16Q3	DY16Q3		DY16Q3	N						
				None	Quarter	DY16Q3				N						
				90 days	Quarter	DY16Q2		DY16Q2	DY16Q2	N						
				90 days	Calendar year	CY2029				N						
				None	Demonstration year					N						
10/1/2030	12/31/2030	3/1/2031		None	Narrative information	DY16Q4	DY16Q4	DY16Q4	DY16Q4	N						
				30 days	Month	DY16Q4	DY16Q4		DY16Q4	N						
				None	Quarter	DY16Q4				N						
				90 days	Quarter	DY16Q3		DY16Q3	DY16Q3	N						
				90 days	Calendar year					N						
				None	Demonstration year	DY16				N						
Add rows for all additional demonstration reporting quarters																

Notes:

[a] **Eligibility and coverage demonstration start date:** For monitoring purposes, CMS defines the start date of the demonstration as the *effective date* listed in the state's STCs at the time of eligibility and coverage demonstration approval. For example, if the state's STCs at the time of eligibility and coverage demonstration approval note that the

[b] The auto-generated reporting schedule in Table 2 outlines the data the state is expected to reported for each demonstration year and quarter. However, states are not expected to begin reporting any metrics data until after protocol approval. The state should see Section B of the Monitoring Report Instructions for more information on retrospective

[c] The auto-generated reporting schedule in Table 2 ends after 5 years. The state should fill in the appropriate information for the subsequent years in its demonstration, using the prior years' schedule as a guideline.

1. Title page for the state's eligibility and coverage demonstrations or eligibility and coverage policy components of the broader demonstration

The state should complete this title page as part of its eligibility and coverage monitoring protocol.

This section collects information on the approval features of the state's section 1115 demonstration overall, followed by information for each eligibility and coverage policy. This form should be submitted as the title page for all eligibility and coverage monitoring reports. The content of this table should stay consistent over time. Definitions for certain rows are provided below the table.

For non-eligibility periods, the state should use the policy-specific rows to enter implementation dates for each applicable non-eligibility period. If the state has non-eligibility periods for community engagement or premiums, it should only include a non-eligibility period implementation date for these policies if it differs from the implementation date for community engagement or premiums. The state should include implementation dates for all other non-eligibility periods individually if the dates differ by policy. If the state has a non-eligibility period for a policy that is not listed in the table, the state should use the "other policy" row to specify the implementation date of that policy. In this row, the state should also replace "[enter here]" with the name of the policy to which the non-eligibility period implementation date applies.

Overall section 1115 demonstration	
State	Indiana
Demonstration name	Healthy Indiana Plan
Approval period for section 1115 demonstration	01/01/2021-12/31/2030
Premiums or account payments	
Premiums or account payments start date[a]	01/01/2021
Implementation date if different from premiums or account payments start date[b]	*This waiver authority is suspended due to COVID-19 and will resume after the end of the Public Health Emergency.*
Healthy behavior incentives	
Healthy behavior incentives start date	01/01/2021
Implementation date, if different from healthy behavior incentives start date	
Community engagement	
Community engagement start date	*CMS has withdrawn this waiver authority.*
Implementation date, if different from community engagement start date	

Retroactive eligibility waiver	
Retroactive eligibility waiver start date	01/01/2021
Implementation date, if different from retroactive eligibility waiver start date	
Non-eligibility periods	
Non-eligibility periods start date	01/01/2021
Implementation date for community engagement non-eligibility periods, if different from non-eligibility periods start date	*This waiver authority is suspended and conditional on the court issuing a decision in Azar v. Gresham.*
Implementation date for premiums and account payments non-eligibility periods, if different from non-eligibility periods start date	*This waiver authority is suspended and conditional on the court issuing a decision in Azar v. Gresham.*
Implementation date for non-eligibility periods for failure to complete annual eligibility renewal process, if different from non-eligibility periods start date	*This waiver authority is suspended and conditional on the court issuing a decision in Azar v. Gresham.*
Implementation date for non-eligibility periods for failure to report change in income or other change in circumstance, if different from non-eligibility periods start date	*This waiver authority is suspended and conditional on the court issuing a decision in Azar v. Gresham.*
Implementation date for other non-eligibility periods, if different from non-eligibility periods start date. Policy: *[enter here]*	

[a] **Eligibility and coverage demonstration start date:** For monitoring purposes, CMS defines the start date of the demonstration as the *effective date* listed in the state's STCs at time of eligibility and coverage demonstration approval. For example, if the state's STCs at the time of eligibility and coverage demonstration approval note that the demonstration is effective January 1, 2020 – December 31, 2025, the state should consider January 1, 2020 to be the start date of the demonstration. Note that that the effective date is considered to be the first day the state may begin its eligibility and coverage demonstration. In many cases, the effective date is distinct from the approval date of a demonstration; that is, in certain cases, CMS may approve a section 1115 demonstration with an effective date that is in the future. For example, CMS may approve an extension request on December 15, 2020, with an effective date of January 1, 2021 for the new demonstration period. In many cases, the effective date also differs from the date a state begins implementing its demonstration.

[b] **Implementation date of policy:** The date of implementation for each eligibility and coverage policy in the state's demonstration.

2. Acknowledgement of narrative reporting requirements

☒ The state has reviewed the narrative questions in Sections 3, 4, and 5 of the Monitoring Report Template provided by the CMS demonstration team and understands the expectations for quarterly and annual monitoring reports. The state will report the requested narrative information in quarterly and annual monitoring reports (no modifications).

3. Acknowledgement of budget neutrality reporting requirements

☒ The state has reviewed the Budget Neutrality Workbook provided by the CMS demonstration team and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested budget neutrality information (no modifications).

4. Retrospective reporting

The state is not expected to submit metrics data until after protocol approval, to ensure that data reflects the monitoring plans agreed upon by CMS and the state. Prior to protocol approval, the state should submit quarterly and annual monitoring reports with narrative updates on implementation progress and other information that may be applicable, according to the requirements in its STCs.

If a state's monitoring protocol is approved after one or more of its initial quarterly monitoring report submissions, it should report data to CMS retrospectively, for any prior quarters of the section 1115 eligibility and coverage demonstration that precede the monitoring protocol approval date. The state is expected to submit retrospective metrics data—provided there is adequate time for preparation of these data—in its second monitoring report submission that contains metrics.

The retrospective report for a state with a first eligibility and coverage demonstration year of less than 12 months, should include data for any baseline period quarters preceding the demonstration, as described in Part A of the state's monitoring protocol. (See Appendix B of the instructions for further guidance determining baseline periods for first eligibility and coverage demonstration years that are less than 12 months.) If a state needs additional time for preparation of these data, it should propose an alternative plan (i.e., specify the monitoring report that would capture the data) for reporting retrospectively on its section 1115 eligibility and coverage demonstration.

In the monitoring report submission containing retrospective metrics data, the state should also provide a general assessment of metrics trends from the start of its demonstration through the end of the current reporting period. The state should report this information in Part B of its monitoring report submission (Table 3: Narrative information on implementation, by eligibility and coverage policy). This general assessment is not intended to be a comprehensive description of every trend observed in metrics data. Unlike other monitoring report submissions, for instance, the state is not required to describe all metrics changes (+ or -) greater than 2 percent

for retrospective reporting periods. Rather, the assessment is an opportunity for the state to provide context on its retrospective metrics data and to support CMS's review and interpretation of these data. For example, consider a state that submits data showing a decrease in beneficiaries who did not complete renewal and were disenrolled from Medicaid (metric AD_19) over the course of the retrospective reporting period. The state could highlight this change and specify that during this period the state conducted additional outreach to beneficiaries about the renewal process. For further information on how to compile and submit a retrospective report, the state should review Section B of the Monitoring Report Instructions document.

☒ The state will report retrospectively for any quarters prior to monitoring protocol approval as described above, in the state's second monitoring report submission that contains metrics after protocol approval.

☐ The state proposes an alternative plan to report retrospectively for any quarters prior to monitoring protocol approval: *Insert narrative description of proposed alternative plan for retrospective reporting. The state should provide justification for its proposed alternative plan.*

Healthy Indiana Plan Evaluation Plan

Final

HEALTH CARE AND HUMAN SERVICES POLICY, RESEARCH, AND ANALYTICS—WITH REAL-WORLD PERSPECTIVE.

Prepared for: **Indiana Family and Social Services Administration**

Submitted by: **The Lewin Group, Inc.**

February 24, 2022

Healthy Indiana Plan
Evaluation Plan

Final

Prepared for: Indiana Family and Social Services Administration

Submitted by: The Lewin Group, Inc.

February 24, 2022

Note: This Evaluation Plan includes adjustments to reflect the impact of the COVID-19 PHE on HIP policies. The comprehensive approach for evaluating the entire demonstration approval period and all applicable demonstration components will be based on this Evaluation Plan. Since this Evaluation Plan is for the new demonstration period, the goals have been renumbered. If comparing results from previous reports, carefully compare the goal language rather than the goal number. This revised version addresses comments received from CMS on October 19, 2021 and February 1, 2022.

Table of Contents

A. General Background Information

The Centers for Medicare & Medicaid Services (CMS) renewed the Indiana Family and Social Services Administration's (FSSA) Healthy Indiana Plan (HIP) Section 1115(a) demonstration waiver for ten years from January 1, 2021, through December 31, 2030. First passed by the Indiana General Assembly in 2007 and implemented in 2008, HIP represents the nation's first consumer-driven health plan for Medicaid beneficiaries. In 2015, it became an alternative to traditional Medicaid expansion under the Patient Protection and Affordable Care Act.

Through the Section 1115(a) demonstrations and waiver authorities in the Social Security Act, states can test and evaluate innovative solutions to improve quality, accessibility, and health outcomes in a budget-neutral manner. Indiana's approved 1115 waiver Special Terms and Conditions (STCs) to implement HIP requires an evaluation of this program's ability to meet its intended goals. This Evaluation Plan will guide the federally-required independent evaluation of this program, organized as follows:

- Section A: General Background Information
- Section B: Evaluation Questions and Hypotheses
- Section C: Methodology
- Section D: Methodological Limitations
- Section E: Attachments
    - Attachment E.1: Summary of Independent Evaluator Approach
    - Attachment E.2: Evaluation Budget
    - Attachment E.3: Timeline and Major Milestones
    - Attachment E.4: Variable Descriptions for Federal Survey Data to be Used in this Evaluation
- Section F: Analytic Plans by Goal
- Section G: Goal Six – Workforce Bridge Account Evaluation Questions, Hypotheses, and Analytic Tables

In addition to the demonstration's STCs, this Evaluation Plan reflects, as feasible and appropriate, CMS feedback received on the 2018-2020 Evaluation Plan in February 2019; the CMS evaluation guidance released in March 2019;[1] CMS feedback received on the 2018-2020 Evaluation Plan in June 2019; CMS Evaluation Plan feedback received in March 2020; CMS feedback received in October 2021; CMS feedback on the 2021-2030 Evaluation Plan received in January 2022; and additional feedback received during calls with CMS and the State. Concerning CMS' evaluation guidance, this plan addresses that content and the appendix on sustainability. Due to state-specific requirements outlined in the STCs, this plan addresses the appendices on non-eligibility periods, premiums or account payments, and retroactivity as feasible and appropriate in the demonstration context. Once reactivated, this plan includes analyzing several policies (e.g., Personal Wellness and Responsibility (POWER) Account payment, tobacco surcharge) placed on hold due to the COVID-19 public health emergency (PHE). The extension of the HIP demonstration waiver includes structured monitoring with three interim and one summative evaluation over the demonstration period. Given the 10-year span of the waiver and the potential future programmatic changes (e.g., six-month non-eligibility period for non-payment of POWER Account contribution), this evaluation plan focuses on analysis for the first Interim Evaluation

[1] CMS. 1115 Demonstration State Monitoring & Evaluation Resources. Released and Accessed March 13, 2019 at https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html

Report scheduled for submission to CMS in June 2024. The baseline and intervention periods for all hypotheses and research questions included in this evaluation plan span from 2015 to 2022 (relevant to the first Interim Evaluation Report). The State anticipates building on this plan to address any future programmatic changes. The analyses plan will be reviewed and updated, as required, for future evaluations (interims and summative) to incorporate any program changes and other specifications including intervention time period and analytic methods.

1. Demonstration Goals

Building on the successes and lessons learned from the original HIP implemented in 2008, HIP 2.0 implemented in 2015, and the 2018 HIP waiver renewal, the State used the 2021-2030 HIP waiver renewal to test new approaches and flexibilities in Indiana's Medicaid program to provide incentives for members to take personal responsibility for their health. Over the current demonstration period (January 2021 through December 2030), the State seeks to achieve several demonstration goals (**Exhibit A.1**). These goals inform the State's evaluation of the HIP program and include, but are not limited to, the following:

Exhibit A.1: Indiana 1115(a) Demonstration

Name of Demonstration:
Healthy Indiana Plan

Approval Date of Demonstration:
October 26, 2020

Demonstration Renewal Period: January 1, 2021 - December 31, 2030

1. Improve health care access, appropriate utilization, and health outcomes among HIP members.
2. Discourage tobacco use among HIP members through a premium surcharge and the utilization of tobacco cessation benefits.
3. Promote member understanding and increase compliance with payment requirements by changing the monthly POWER Account payment requirement to a tiered structure.
4. Ensure HIP program policies align with commercial policies, encourage member understanding, promote positive member experience and minimize gaps in coverage.
5. Assess the costs to implement and operate HIP and other non-cost outcomes for the demonstration.
6. Support continuity of coverage and address the coverage cliff between HIP and commercial coverage.[2]

The above goals address key objectives of Section 1115(a) demonstrations, including improving access to high-quality services that produce positive health outcomes for individuals; strengthening beneficiary engagement in their personal health care plan, including incentive structures that promote responsible decision-making; and enhancing alignment between Medicaid policies and commercial health insurance products to facilitate the smoother beneficiary transition.[3]

[2] The WBA program is included in the Section 1115(a) demonstration waiver entitled "End Stage Renal Disease (ESRD)" as of January 2021. Indiana is currently working with CMS to move the WBA program into the HIP waiver with similar evaluation report timeframes and requirements. Refer to Section G for additional information on Goal 6: WBA will support HIP members transitioning to commercial with continuity of coverage, reduce benefit cliff, and churn.

[3] CMS. About Section 1115 Demonstration Waivers. Accessed March 29, 2018 at https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html

2. Description of the Demonstration and Implementation Plan

First passed by the Indiana General Assembly in 2007, HIP provides Medicaid health insurance coverage for qualified low-income, non-disabled adults ages 19 to 64. HIP offers its members a high deductible health plan paired with a POWER Account, which operates similarly to a health savings account.

The current HIP 1115 waiver renewal, approved October 26, 2020 and effective from January 1, 2021 through December 31, 2030, continues most components of HIP approved in 2018 (**Exhibit A.2**). That version added some new provisions to HIP 2.0 (approved in 2015). Changes for HIP, summarized from the State's amended 2018 waiver approval, include:[4,5]

- Adding a tobacco use surcharge by increasing users' POWER Account Contributions by 50% beginning in their second year of continuous enrollment;
- Changing POWER Account Contributions (PAC) to a tiered structure instead of a flat 2% of income (six-month non-eligibility for enrollment due to non-payment of PAC included in 2018-2020 waiver has been suspended indefinitely effective January 1, 2021);
- Adding a new HIP Plus chiropractic benefit;
- Facilitating enrollment in HIP Maternity (MA) coverage for pregnant women;
- Enhancing the managed care entity (MCE) member incentive program by increasing available healthy incentives to a maximum of $200 per initiative;
- Reestablishing an open enrollment period;
- Waiving the "institution for mental disease" payment exclusion for short-term substance use disorder (SUD) treatment services for all Medicaid adults ages 21 to 64 (Note: this provision will be the subject of a separate evaluation); and
- Discontinuing the graduated copayments for non-emergency use of the emergency department (ED) and the HIP Link premium assistance program for those with employer-sponsored insurance.

Exhibit A.2: Program History
2007: HIP passed in the Indiana General Assembly.
2008: With CMS approval, HIP began enrolling working-age, uninsured adults in coverage.
2011: State legislature passed Senate Enrolled Act 461 that called on HIP to be the program used for the eventual expansion of Medicaid through the Patient Protection and Affordable Care Act.
2014: State requested permission from CMS to expand its existing demonstration waiver via HIP 2.0.
2015: CMS approved HIP 2.0, which included Indiana's Medicaid expansion, through a three-year waiver renewal expiring January 2018.
2017: State requested permission from CMS to expand its existing demonstration waiver via HIP.
2018: CMS approved HIP through a three-year waiver renewal expiring December 2020.
2021: CMS approved HIP through a ten-year waiver renewal expiring December 2030.

In addition to the changes outlined above, several policies were modified or put on hold in March 2020 in response to the COVID-19 PHE. These included policies related to member eligibility, cost-sharing,

[4] Indiana Family and Social Services Administration. (2018). HIP Waiver Application. Retrieved from https://www.in.gov/fssa/hip/files/IN-HIP-1115-Approval-Package_2-1-2018.pdf

[5] 2021-2030 STC technical changes summary in State acceptance of CMS approval. Retrieved from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/in-healthy-indiana-plan-support-20-state-accept-ltr-hip-ext-11242020.pdf

tobacco surcharge, and prescription filling processes, among others. The details of these policy changes and their implications for the evaluation are noted throughout this document as appropriate. The State announced that any reinstatement of policies would occur after the COVID-19 PHE is lifted. Any reinstatement processes will be gradual to ensure members, MCEs, providers, and other stakeholders are aware.

Healthy Indiana Plan

In 2015, HIP's target population changed to all non-disabled, low-income adults between 19 and 64 years old with a household income at or below 138% of the FPL. HIP covers the adult group, low-income parents and caretakers, Transitional Medical Assistance (TMA), and pregnant women. HIP offers distinct benefit packages to its eligible members: HIP Plus, HIP Basic, HIP State Plan Plus, HIP State Plan Basic, HIP Maternity, and HIP Plus Copay. The State uses a managed care delivery system for HIP. Four MCEs, contracted under HIP at the time of this Evaluation Plan, provide health care coverage to HIP members. The following section outlines the intended policies; however, several policies noted below are currently on hold due to the COVID-19 PHE. Details of these policy changes are described throughout this section as applicable.

HIP Benefit Plans

Indiana's current section 1115(a) demonstration provides authority for the State to continue offering HIP with different benefit plans—HIP Plus and HIP Basic:

- **HIP Plus:** HIP members with income at or below 138% of the federal poverty level (FPL) who make required POWER Account Contributions maintain access to HIP Plus, an enhanced benefit plan, which includes additional health care benefits such as coverage for dental, vision, and chiropractic services.[6] HIP Plus members pay a monthly POWER Account Contribution based on income tiers but do not pay copayments for health care services.
- **HIP Basic:** HIP members with income at or below 100% of the FPL who do not make monthly POWER Account Contributions for HIP Plus coverage enroll in HIP Basic. This benefit plan provides more limited coverage than HIP Plus (i.e., not covering vision or dental services) and includes copayments for doctor visits, hospital stays, non-emergency ED visits, and prescriptions.[7] These payments are consistent with traditional Medicaid copayments and can range from $4 to $8 per doctor visit or prescription filled and can be as high as $75 per hospital stay. Pregnant members have no cost-sharing, and there is a 5% of income quarterly cost-sharing limit for all members. HIP Basic members can enroll in HIP Plus during their annual redetermination if they choose to begin paying their POWER Account Contribution.

[6] On June 10, 2015, the State submitted an approved copy of the Alternative Benefit Package (ABP) for HIP Plus as a State Plan Amendment to the Centers for Medicare and Medicaid Services. These benefits for the ABP were aligned using Essential Health Benefits. Indiana Family and Social Services Administration. (2014). Alternative Benefit Plan: Healthy Indiana Plan (HIP) 2.0 Plus. Retrieved from https://www.in.gov/fssa/hip/files/DraftPlusABP.pdf

[7] On June 10, 2015, the State submitted an approved copy of the Alternative Benefit Package (ABP) for HIP Basic as a State Plan Amendment to the Centers for Medicare and Medicaid Services. These benefits for the ABP were aligned using Essential Health Benefits. Indiana Family and Social Services Administration. (2014). Alternative Benefit Plan: Healthy Indiana Plan (HIP) 2.0 Basic. Retrieved from https://www.in.gov/fssa/hip/files/DraftBasicABP.pdf

- **HIP State Plan Plus:** Members have the same cost-sharing requirements as HIP Plus and do not pay copayments for services. State Plan Plus members, similarly to regular HIP Plus members, make POWER Account Contributions. Enrollment in this plan provides certain members[8] with access to the Medicaid State Plan benefits in place of the approved Alternative Benefit Plan.
- **HIP State Plan Basic:** Members have the same cost-sharing requirements and copayments for services as HIP Basic. Enrollment in this plan provides certain members[9] with access to the Medicaid State Plan benefits in place of the approved Alternative Benefit Plan.
- **HIP Maternity:** HIP members who become pregnant while enrolled in a HIP plan transition to HIP Maternity (MA). HIP Maternity covers HIP members throughout their pregnancy and 60 days postpartum. HIP Maternity enrollees do not have cost-sharing requirements and have access to the Medicaid State Plan benefits.
- **HIP Plus Copay:** HIP members above 100% of the FPL identified as medically frail[10] by the State or an MCE and have not met their HIP Plus POWER Account Contribution obligations. These members have copayments assigned to them, consistent with the HIP Basic Plan, and have access to HIP Plus benefits.

All HIP members pay $8 for a non-emergency ED visit. Members can switch between benefit plans as policies allow. Adults who meet all HIP's eligibility requirements but who are not U.S. citizens and not lawful permanent residents in the U.S. for at least five years or are not qualified aliens are entitled to "emergency services only" under HIP. The evaluator did not include this enrollment category in this evaluation due to the limited nature of covered services. Also, one other important policy change for the Evaluation Plan in response to the COVID-19 PHE is a pause on switches which result in a benefit downgrade between State Plan to regular (HIP Basic, HIP Plus) benefits; and HIP Plus to HIP Basic. The opposite switches not resulting in a downgrade (HIP Basic to HIP Plus or HIP regular to State Plan) were allowed. Monthly contributions were waived for HIP Plus members during the COVID-19 PHE. Members having HIP Basic (enrolled prior to the COVID-19 PHE) were eligible to change to HIP Plus.[11] New HIP members were and continue to be automatically enrolled in HIP Plus during the COVID-19 PHE. In addition, members were also not required to pay the $8 copay for a non-emergency ED visit since cost sharing was paused in response to the COVID-19 PHE.

Eligibility Determination Process

Individuals apply for HIP services through the Division of Family Resources, which determines eligibility for Indiana Health Coverage Programs. Members can also complete a presumptive eligibility application with qualified providers to receive temporary health coverage.

[8] Medically frail, TMA participants, Section 1931 low-income (< 19% of the FPL) parents and caretakers, and low-income (< 19% of the FPL) 19 – 20 year olds.

[9] Medically frail, TMA participants, Section 1931 low-income (< 19% of the FPL) parents and caretakers, and low-income (< 19% of the FPL) 19 – 20 year olds.

[10] Medically frail refers to a federally required designation of members who have disabling mental disorders, including serious mental illness; chronic substance use disorders; serious or complex medical conditions; physical, intellectual or developmental disabilities that significantly impair the ability to perform one or more activities of daily living; or a disability determination based on Social Security Administration criteria. These members have a medically frail flag of Y in the monthly enrollment data.

[11] Based on information available during preparation of the Evaluation Plan.

To start coverage, HIP members must wait 60 days or make an initial Fast Track payment to their POWER Account. Individuals with income greater than 100% FPL must make a payment within 60 days to obtain coverage. New HIP members in the waiting period who have not made a Fast Track payment are determined conditionally eligible by the Division of Family Resources. However, conditionally eligible members do not receive full eligibility and cannot enroll as members until one of the following occurs within the 60-day payment period:

- Enrollee makes a payment of their first POWER Account Contribution for HIP Plus
- Enrollee makes a Fast Track $10 prepayment for HIP Plus
- Enrollee at or below 100% of the FPL does not make a first payment before the 60-day payment period expires and, therefore, enrolls in HIP Basic

Members have the opportunity to select an MCE on their application. However, if an individual determined to be conditionally eligible for HIP by the Division of Family Resources does not select an MCE, the State auto-assigns the member to an MCE. Member eligibility is effective the first day of the month; coverage end dates occur on the last day of a month unless a member dies.

During the COVID-19 PHE, the State adjusted eligibility policies to ensure uninterrupted access to coverage. Self-attestation of income was accepted for income verification at the time of application.[12] Additionally, the State announced that no members would have their health coverage terminated throughout the COVID-19 PHE unless it was voluntarily withdrawn or there was a relocation outside of Indiana. The information on presumptive eligibility and Fast Track outlined below represents the policy structure in use before the COVID-19 PHE changes went into effect. Throughout the COVID-19 PHE, completion of a full application for the Indiana Health Coverage Programs (including HIP) to continue benefits beyond the end of the month following the start of PE. The State also announced that member coverage started when eligibility was determined and initial payment to begin coverage was not required. Fast Track payments were also ceased.

Presumptive Eligibility

With HIP 2.0, the State introduced a Fast Track prepayment option for POWER Account Contributions and enhancements to the presumptive eligibility (PE) process. The PE process allows qualified providers to determine eligibility for certain groups to receive temporary health coverage under the Indiana Health Coverage Programs, which includes HIP. As of April 1, 2015, the State expanded qualified PE providers to include Federally Qualified Health Centers (FQHCs), Rural Health Centers (RHCs), Community Mental Health Centers, and local County Health Departments. Qualified providers work with individuals to complete a PE application. Using an online system and member self-reported responses, qualified providers receive real-time PE determinations for individuals seeking health care services. An individual can receive PE coverage only once during a 12-month rolling period and only once per pregnancy.[13]

Individuals determined presumptively eligible can receive temporary coverage and services immediately until the end of the following month. Members must complete the full application by the last day of the next month to maintain PE coverage. Before January 1, 2019, members determined presumptively eligible received coverage under the managed care delivery system. State applicants determined

[12] Medicaid and CHIP Disaster Relief MAGI-Based Verification Plan Addendum. Retrieved from https://www.medicaid.gov/medicaid/eligibility/downloads/in-disaster-addendum.pdf

[13] Indiana Health Coverage Programs. (2019). Presumptive Eligibility Provider Reference Model. Retrieved from https://www.in.gov/medicaid/files/presumptive%20eligibility.pdf

presumptively eligible for the adult category (PE Adult) before 2019 enrolled with a MCE and received coverage similar to HIP Basic with copayment obligations. As of January 1, 2019, applicants determined presumptively eligible receive coverage under a fee-for-service delivery system.[14]

Starting in 2018, PE members determined to be conditionally eligible for HIP move directly to HIP Basic with an opportunity to pay for HIP Plus. The State refers to this population as "Potential Plus." This extension allows members to avoid a gap in coverage as long as they meet the required application and payment deadlines. Applicants have 60 days to pay any required POWER Account Contribution to be eligible for HIP Plus.[15]

Fast Track

The Fast Track option expedites HIP enrollment by allowing applicants to make a prepayment of $10 towards their POWER Account Contribution. Using Fast Track, applicants can pay a POWER Account Contribution at the time of application or any time before the State's eligibility determination. Once the State determines an applicant eligible for Medicaid, the individual's Medicaid eligibility dates back to the first day of the month in which the member made the Fast Track payment. Individuals approved for HIP with income less than 100% of the FPL who do not make a POWER Account Contribution within the 60 days enroll in HIP Basic. Individuals with income over 100% of the FPL who do not make a POWER Account payment or Fast Track pre-payment in the required 60-day period do not receive coverage and must reapply.[16]

POWER Accounts

To help members prepare for participation in the commercial marketplace, the State offers all HIP members a POWER Account, similar to a health savings account. POWER Accounts provide incentives for members to stay healthy, be value and cost-conscious, and use services in a cost-efficient manner. HIP Plus, HIP Basic, or HIP State Plan members use their POWER Accounts to pay for covered services up to their $2,500 deductible. MCEs establish and administer each member's POWER Account and pay the claims for all covered services when a member exhausts their POWER Account.

POWER Account Contributions

While all members have a POWER Account, HIP Plus members have a POWER Account Contribution. The State funds POWER Accounts up to a ceiling of $2,500 per year, contributing an amount annually for each member that is equal to the difference between the required member contribution and the $2,500 ceiling. For HIP Plus members, this monthly amount represents a combination of member, employer or not-for-profit, and State contributions. Members may also apply earned MCE incentives offered by their plan. The State fully funds the POWER Accounts for HIP Basic members and covers the member's $2,500 annual deductible.

MCEs bill for and collect HIP Plus POWER Account Contributions and send monthly statements to members. HIP Basic members also receive monthly account statements to assist them in managing the POWER Account and copayments and to increase awareness of the cost of the health care services received.

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[14] Ibid.

[15] Ibid.

[16] Indiana Family & Social Services Administration. (2019). MCE Reporting Manual HIP 2.0, Office of Medicaid Policy and Planning Version 4.0.

Determination of POWER Account Contribution Amounts

Effective with CMS' waiver approval in 2018, the State changed the determination of member POWER Account Contribution amounts from 2% of income to a tiered structure based on income level (**Exhibit A.3**). The previous monthly POWER Account Contribution amounts ranged from a maximum amount of $4.28 for members with incomes less than 22% of the FPL to a maximum amount of $27.17 for those at 100% of the FPL or higher. Fluctuations in a member's income required recalculating the member's 2% of income and changing the monthly amount due. This change could happen as frequently as every month for members with monthly income fluctuations. This ongoing variability of the POWER Account Contribution amounts created confusion among members regarding the amount owed and increased the overall administrative burden for the State and MCEs related to POWER Account Contributions.

The tiered monthly contribution amounts range from $1.00 for members with income less than 22% of the FPL to $20.00 for those at 100% of the FPL or higher. The State anticipates that this simplified tiered structure will increase member understanding, increase member compliance with payments, and minimize gaps in coverage.

The State calculates the household's POWER Account Contribution based on a tiered contribution structure for individuals. For two HIP-eligible married adults, the State divides the monthly contribution, and each member pays half of the calculated amount on a monthly basis. Married members with household incomes less than 22% both pay a $1.00 POWER Account Contribution. Other income tiers split the amount; for example, two married adults with a household income of 51% to 75% FPL each pay $5.00. Beginning in January 2019, members may pay a 50% tobacco use surcharge in addition to the POWER Account tier amounts. With the 2021 approval, the member contributions will be capped at 3% of household income, and the state will have the flexibility to change member contribution amounts up to the cap.

Exhibit A.3: Comparison of HIP Plus Previous and Current POWER Account Contribution Amounts for Single Members (2015 and 2018)

FPL	HIP 2.0 POWER Account Contribution (Previous)[a]		HIP POWER Account Contribution (Current)[b]		
	2015 Monthly Income, Single Individual	Maximum Monthly POWER Account Contribution, Single Individual	2018 Monthly Income, Single Individual	Monthly POWER Account Contribution, Single Individual	Tobacco Use Surcharge
<22%	**Less than $214**	$4.28	**Less than $222**	$1.00	$1.50
23-50%	**$214.01 to $487**	$9.74	**$222.01 to $505**	$5.00	$7.50
51-75%	**$487.01 to $730**	$14.60	**$505.01 to $758**	$10.00	$15.00
76-100%	**$730.01 to $973**	$19.46	**$758.01 to $1,011**	$15.00	$22.50
101-138%	**$973.01 to $1,358**	$27.17	**$1,011.01 to $1,396**[17]	$20.00	$30.00

[a] FSSA. HIP 2.0 Introduction, Plan options, Cost sharing, and Benefits. Accessed May 6, 2019 at https://www.in.gov/idoi/files/HIP_2_0_Training_-_Introduction_Plans_Cost-Sharing_Benefits_-_1_21_15.pdf

[b] FSSA. POWER Accounts. Accessed May 6, 2019 at https://www.in.gov/fssa/hip/2590.htm
Note: For HIP 2.0, the monthly income amounts shown here reflect 2015 FPL and the monthly POWER Account Contribution amounts represent a percentage of income. For current HIP, the POWER Account Contribution amounts reflect the tiered contribution structure as displayed in Table 4 of the STC. During the COVID-19 PHE, all new members were automatically enrolled into HIP Plus irrespective of income, and members were not required to make POWER Account Contributions.

[17] Retrieved from https://www.in.gov/fssa/hip/helpful-tools/federal-poverty-level-income-chart/

Loss of Coverage Due to Non-Payment of POWER Account Contributions

HIP Plus members with incomes from 101% to 138% of the FPL that did not make monthly POWER Account Contribution payments were disenrolled from HIP. For the 2018 – 2020 waiver, members disenrolled due to non-payment were not allowed to re-enroll for six months (also referred to as the six-month lockout or non-eligibility period). In January 2021, the State suspended the six-month non-eligibility criterion pending resolution of the stay in the federal lawsuit and in compliance with the newly approved waiver terms and conditions.[18] In addition, the State exempts members determined medically frail from non-payment penalties regardless of income; these members do not lose benefits due to non-payment of POWER Account Contributions. The enrollment lockout period also does not apply to members residing in a domestic violence shelter or in a state-declared disaster area. Members subject to a lockout period can request a waiver to reenter the program.

In response to the COVID-19 PHE, the State suspended all cost-sharing policies. Effective April 1, 2020, members with copayments no longer have copayments, including pharmacy copayments. Further, the State waived all POWER Account Contributions starting March 1, 2020, until further notice. Members who made contributions during the COVID-19 PHE (since March 2020) had those payments applied as credits to their accounts (i.e., for use as POWER Account Contributions when the policy is reinstated).

Tobacco Cessation Initiative

As indicated previously, all HIP members must contribute to their POWER Account to maintain access to the enhanced HIP Plus benefit plan. To discourage tobacco use and to align with commercial market coverage policies, HIP includes a surcharge on top of the POWER Account Contribution for HIP Plus members who self-identify as tobacco users.[19] Tobacco use is defined as tobacco use four or more times a week in the last six months, including chewing tobacco, cigarettes, electronic cigarettes (including vaping), cigars, pipes, hookah, and snuff. The HIP tobacco initiative began in January 2018, with surcharges taking effect in January 2019.

The State assesses a surcharge on top of the POWER Account Contribution for members who continuously enroll for 12 months with the same MCE and self-identify as a tobacco user during this period. If the member continues to self-identify as using tobacco, the State increases monthly contributions by 50% beginning in the first month of their new benefit period. For example, the POWER Account Contribution for an individual with income less than 22% of the FPL would increase from $1.00 to $1.50 per month with the application of the tobacco surcharge. For married HIP members, only the tobacco user receives the tobacco surcharge.

MCEs separate the surcharge on the monthly POWER Account statements to highlight the additional cost of tobacco use for members. Some MCEs offer members MCE-specific incentives to participate in tobacco cessation services. Two of these tobacco cessation services include:

[18] Waiver 4 (related to eligibility) in HIP STC. Accessible from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/in-healthy-indiana-plan-support-20-ca-01012021.pdf

[19] Members may self-identify as tobacco users during their initial application, during MCE selection, or when a member notifies their MCE.

- **Indiana Tobacco Quitline:** Free phone-based counseling service administered by the State. Users can access services every day of the week in over 170 languages. The Quitline includes access to one-on-one coaching, resources for health care providers, and tools for other stakeholders to use for smoke-free and other smoking cessation programming.[20]
- **Baby and Me Tobacco Free:** Smoking cessation program for pregnant and postpartum women (up until 12 months postpartum). This program includes individualized education sessions, biochemical testing at visits, and several diaper vouchers.[21]

The State collects information on HIP member tobacco use during the HIP enrollment process (i.e., initial enrollment and when changing plans during open enrollment); members can also report changes in their tobacco use by calling their MCE or the State. While there are questions about tobacco use on the health needs assessment performed by the MCEs, these responses are not used to determine the tobacco surcharge due to concerns about members underreporting tobacco use during an assessment performed for clinical purposes. When a member changes MCEs during the MCE selection period or in the middle of the year, the tobacco indicator passes to the new MCE. However, the surcharge is based on 12 months of full eligibility and tracking of tobacco use, so the new MCE will not know the member's previous tobacco use indicator or be expected to apply a surcharge.

Since the State suspended all cost-sharing during the COVID-19 PHE, no surcharge is collected. The Tobacco surcharge policy will be reinstated, with an implementation process that aligns with the initial implementation after the COVID-19 PHE is lifted.

Preventive Service Incentive and Rollover

The State provides all HIP members with incentives to receive preventive services and manage their POWER Accounts via direct financial investment. Members have an opportunity to rollover any funds remaining in their POWER Account and apply the rollover as a credit toward their POWER Account Contribution in the next benefit period. For members that contribute to a POWER Account and use services, claims are paid from the account proportionally from State and member funds. If the member contributes $240 over the year out of the $2,500 limit, then 9.6% of every claim paid by the account is paid with member dollars; the rest is covered with State dollars. If the entire account is not spent, the member's remaining dollars can be rolled over to the next year or refunded if the member leaves the program.

The amount rolled over or discounted depends on whether the member received preventive care services and what program the member enrolled in on the last day of the benefit period:

- If HIP Plus members have funds remaining at year-end and received preventive services, the State matches the member rollover amount and provides extra funds to their POWER Account. These funds further reduce the amount owed for the current benefit period, but only after members use rollover funds.
- If HIP Basic members receive preventive services, they can offset the required contribution for HIP Plus by up to 50% the following year. However, members may not double their rollover as in HIP Plus. Members who choose to remain in HIP Basic will incur a penalty on any unused member rollover funds. HIP Basic members who do not receive preventive services will not earn

[20] Indiana.gov Quitline. (2019). Indiana's Tobacco Quitline. Retrieved from https://www.in.gov/quitline/

[21] Indiana State Department of Health: Maternal and Child Health Epidemiology Division. (2016). Infant Mortality: Year in Review. Retrieved from https://www.in.gov/fssa/files/Medicaid%20Advisory%20Board%208.16.pdf

the rollover discount. Members who choose to remain in HIP Basic will incur a penalty on any unused member rollover funds.

Exhibits A.4 and A.5 illustrate the rollover for HIP Plus and HIP Basic.

Exhibit A.4: HIP Rollover for HIP Plus Members

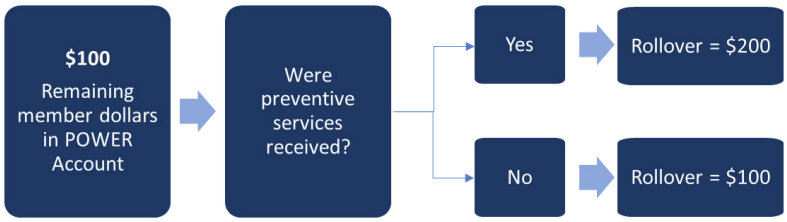
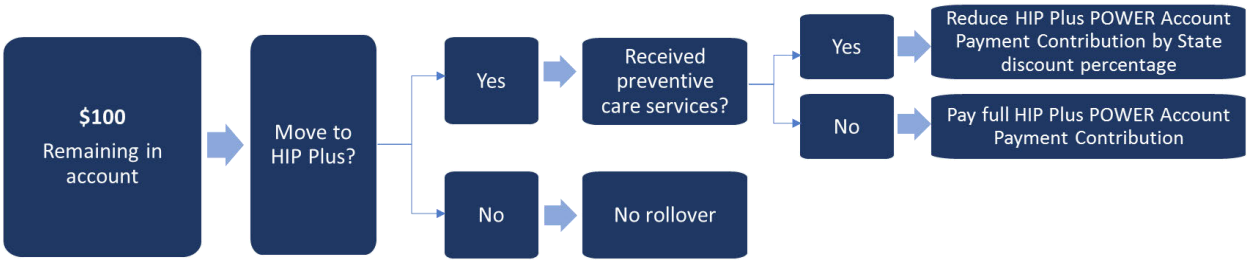


Exhibit A.5: HIP Rollover for HIP Basic Members



MCEs calculate the rollover 121 calendar days after the end of the benefit period to allow for a claims run-out period. The MCEs then submit this information to the State. For rollover, members can reuse these funds to reduce the amount owed for their current benefit period. HIP members who leave the program remain eligible to receive a refund for the unused portion of their contributions and rollover following the reconciliation of their POWER Account. State rollover funds never pay tobacco surcharge amounts, and unused funds return to the State at the end of the current benefit period.

During the COVID-19 PHE, rollover will not be impacted due to suspension of HIP policies and member contributions.

Workforce Bridge Account

Workforce Bridge Accounts (WBA) will become effective once the COVID-19 PHE restrictions are lifted. To receive a WBA, eligible individuals will be informed that they have access to financial resources, in an amount no greater than $1,000, to temporarily pay for health insurance premiums and cost-sharing, or for the direct costs of prescription drugs and services otherwise covered under Section 1905(a) of the Social Security Act. This assistance is expected to act as a bridge to commercial insurance coverage. While individuals would be made aware that this resource would be available to them if they took steps to raise their income enough to lose Medicaid eligibility, the accounts would only be activated when an individual is no longer Medicaid eligible. Individuals who recently disenrolled for failure to meet conditions of eligibility, such as payment of premiums, will not qualify.

This program will be available to eligible individuals based on the availability of State funding. Members eligible for WBA, once notified, must opt-in to the WBA program. To opt-in, the eligible individual must acknowledge an interest in participating by phone or mail to the state. Individuals will have 30 days once notified to opt-in to the account. As part of this 30-day opt-in process, individuals will have the

opportunity for referral to a "health care navigator" who will inform individuals about their health care options and provide choice counseling. Once individuals opt-in, the amount associated with the WBA will be available for 12 months or until the full amount has been expended, whichever comes first. Individuals can only use the account for premiums, cost-sharing, or the direct cost of services received within 12 months. Once the 12 months is finished, individuals will not be able to access the WBA. Reimbursement for health insurance premiums will be paid to the individual or at the request of the individual enrolled in a Marketplace health plan, the State will pay for the premiums directly on behalf of the individual to the health plan. In addition, beneficiaries of this program will receive an insurance card that will contain information for providers on how to submit a claim to the WBA for reimbursement of cost-sharing linked to the enrollees primary insurance or direct billing for enrollees who have not yet completed enrollment in primary insurance coverage. The funds available through the WBA can also be used for the direct payment of Medicaid-covered Section 1905(a) services that would otherwise be available to Medicaid beneficiaries. To receive reimbursement for these services, the services must be rendered by a Medicaid enrolled provider.

3. Population Groups Impacted by the Demonstration

Indiana will evaluate whether the HIP demonstration has the intended effects on the target population. HIP includes low-income, non-disabled adults ages 19 to 64. The other adults eligible for Medicaid in Indiana include individuals who are 65 and older, blind, or disabled and who are not eligible for Medicare. The other eligible adults in the State are low-income adults who can receive home and community-based services or who are in nursing homes and other facilities.

To gain eligibility for the WBA, an individual (1) must be fully enrolled in HIP[22] and (2) would otherwise be eligible for HIP except for the increase in income. For example, an individual that lost coverage due to being over income and moving out of state would not be eligible for the WBA, since they no longer meet the HIP eligibility criteria due to state residency. Multiple individuals in the same household, who meet the eligibility requirements, will have access to their own account. These qualified individuals will be notified of their eligibility and opt-in opportunity consecutive with their notice of disenrollment. Accounts may be closed if an individual moves out of state, voluntarily withdraws, ages out, becomes incarcerated, enrolls in Medicare, or regains Medicaid or Presumptive Medicaid eligibility. Eligibility for the WBA program is for one 12-month period and is not eligible for renewal. After lifting the COVID-19 PHE and policies are reinstated, the State anticipates a surge in WBA enrollment due to income disenrollment.

Exhibit A.6: Eligibility Groups Included in the WBA Amendment of the End-Stage Renal Disease (ESRD) Demonstration

Eligibility Group Name	FPL Level and/or other qualifying criteria
WBA	1902(a)(10)(A)(ii)(VII) 42 CFR §435.218

[22] Members conditionally eligible or presumptively eligible for HIP benefits will not qualify for the HIP WBA benefit, nor will individuals that are only eligible for emergency services.

B. Evaluation Questions and Hypotheses

The evaluation will focus on the demonstration policy goals described in **Section A**. This section provides the hypotheses and research questions (RQ) that correspond to each of the goals. Logic models are provided for Goals 2 and 3, which are focused on evaluating the impact of a specific policy change. Logic models are not provided for Goals 1, 4, 5, and 6, which are descriptive in nature.

As a result of the COVID-19 PHE, metrics for some hypotheses and research questions were not applicable during scheduled data collection. For example, key informant interviews for 2021 will not capture data specific to understanding the tobacco surcharge or POWER Account Contributions, given both were on hold in response to the COVID-19 PHE. More details on policy changes implemented by the State during the COVID-19 PHE are described in **Section A**.

1. Goal One – Improve health care access, appropriate utilization, and health outcomes among HIP members

The evaluation determines whether the HIP policies have the intended effects on members, including improving health care access, appropriate utilization, and health outcomes. **Exhibit B.1** below lists the hypotheses and research questions corresponding to this goal.

Exhibit B.1: Hypotheses and Research Questions for Goal 1

Hypotheses	Research Questions
Hypothesis 1 – Member use of preventive care, primary care, needed prescription drugs, chronic disease management care, and urgent care will be stable during the HIP demonstration period.	**Primary research question 1.1:** How has the following changed over time for HIP members? • Preventive, primary, urgent and specialty care • Prescription drug use • Chronic care management
Hypothesis 2 –Unnecessary ED services will not rise over time for HIP members.	**Primary research question 2.1:** How have avoidable ED visits among HIP members changed over time?
Hypothesis 3 – HIP members will report positive health outcomes.	**Primary research question 3.1:** How has reported health status for HIP members changed over time?
Hypothesis 4 – HIP members will report satisfaction with health care access.	**Primary research question 4.1:** What percentage of HIP members report getting health care as soon as needed? **Primary research question 4.2:** To what extent do HIP members receive coverage through Fast Track and presumptive eligibility policies?
Hypothesis 5 – The Indiana Medicaid enrollment rate will be comparable to other Medicaid expansion states.	**Primary research question 5.1:** How does the Indiana Medicaid coverage rate compare to other Medicaid expansion states?

2. Goal Two – Discourage tobacco use among HIP members through a premium surcharge and the utilization of tobacco cessation benefits

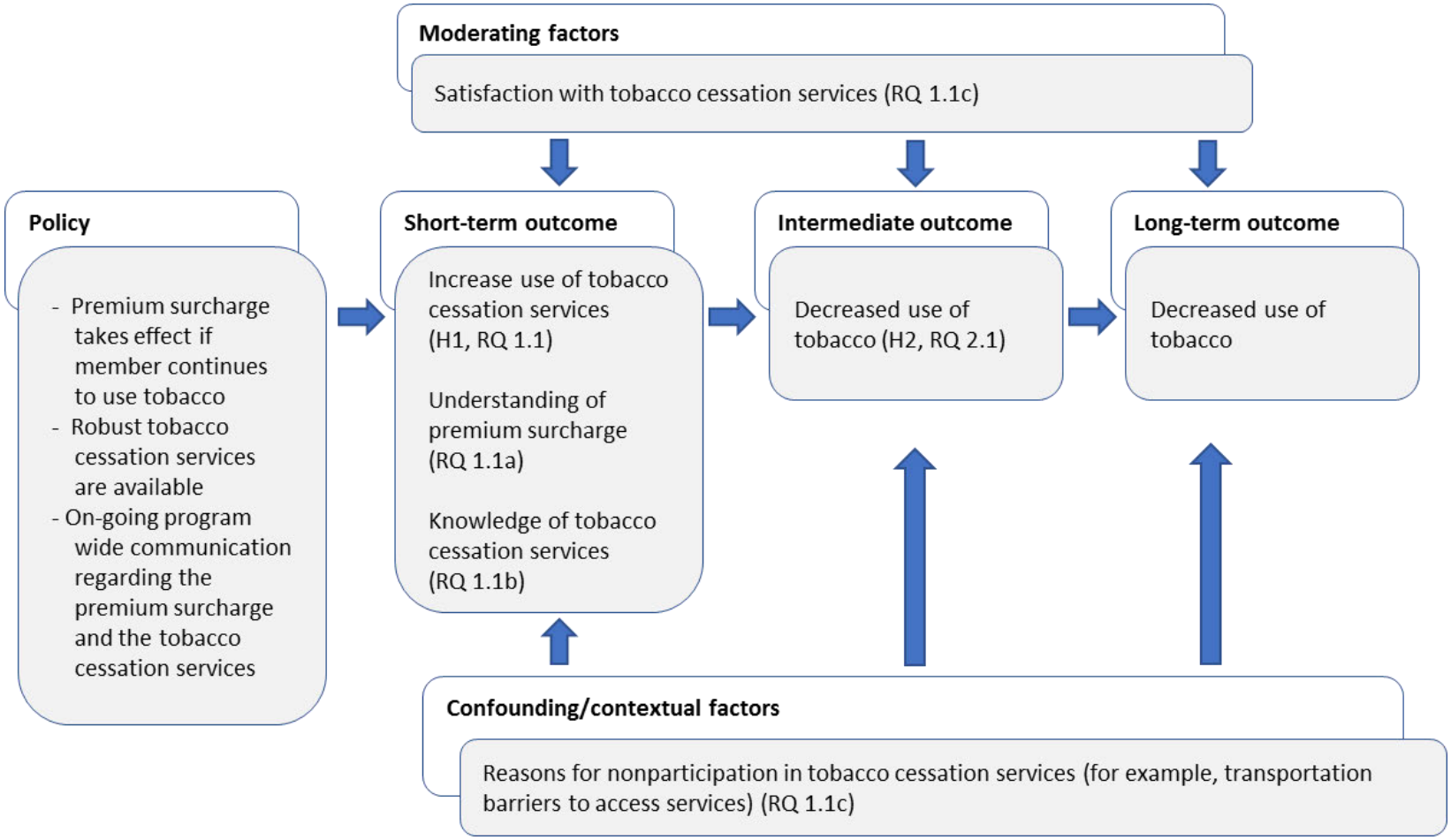
Indiana will test whether the POWER Account Contribution surcharge and utilization of tobacco cessation benefits will discourage tobacco use among HIP members. **Exhibit B.2** below lists the hypotheses and research questions corresponding to this goal. As State suspended all cost-sharing during the COVID-19 PHE (starting from March 2020), no surcharge will be collected during this time. The Tobacco surcharge policy will be reestablished after the COVID-19 PHE is lifted and all policies are reinstated.

Exhibit B.2: Hypotheses and Research Questions for Goal 2

Hypotheses	Research Questions
Hypothesis 1 – The tobacco premium surcharge will increase use of tobacco cessation services among HIP members.	**Primary research question 1.1:** What impact has the tobacco premium surcharge had on the use of tobacco cessation benefits for HIP members? **Subsidiary research question 1.1a:** Do HIP members understand the premium surcharge policy? **Subsidiary research question 1.1b:** Do HIP members know about the cessation services offered through HIP? **Subsidiary research question 1.1c:** Are HIP members satisfied with tobacco cessation services?
Hypothesis 2 – The tobacco premium surcharge and availability of tobacco cessation benefits will decrease tobacco use.	**Primary research question 2.1:** Has tobacco use decreased among the target population?

The logic model in **Exhibit B.3** depicts the expected short-term, intermediate, and long-term outcomes[23] for the premium surcharge and the utilization of tobacco cessation benefits.

Exhibit B.3: Logic Model for Goal 2



[23] Since we will be estimating the outcome measures based on data from the observation period (2015-2020), the evaluation will not provide conclusions about the long-term outcomes of the HIP program (e.g., related to health status, employment, and education level) beyond this period.

3. Goal Three – Promote member understanding and increase compliance with payment requirements by changing the monthly POWER Account payment requirement to a tiered structure.

Indiana will test whether the tiered POWER Account structure is easy to understand and increases compliance with payments[24] (**Subsection A.2** provides additional background on POWER Account policies). Research questions under Goal 1 cover the efficient use of health care services as defined by utilization. **Exhibit B.4** below lists the hypotheses and research questions corresponding to this goal. Members enrolled in HIP Basic prior to COVID-19 PHE could change to Plus. All new members were enrolled in HIP Plus irrespective of income status during the COVID-19 PHE, and members were not allowed to downgrade to Basic during the PHE. Additionally, the State suspended all cost-sharing during the COVID-19 PHE and thereby disenrollment due to non-payment of POWER Account Contribution. As no contribution was collected and other HIP policies were suspended, there will also be very limited dollars for rollover during the COVID-19 PHE. Starting from January 2021, the State suspended the six-month non-eligibility criterion pending resolution of the stay in the federal lawsuit and in compliance with the newly approved waiver terms and conditions.[25] Ability to analyze the research questions will depend on the timing of reinstatement of HIP policies.

Exhibit B.4: Hypotheses and Research Questions for Goal 3

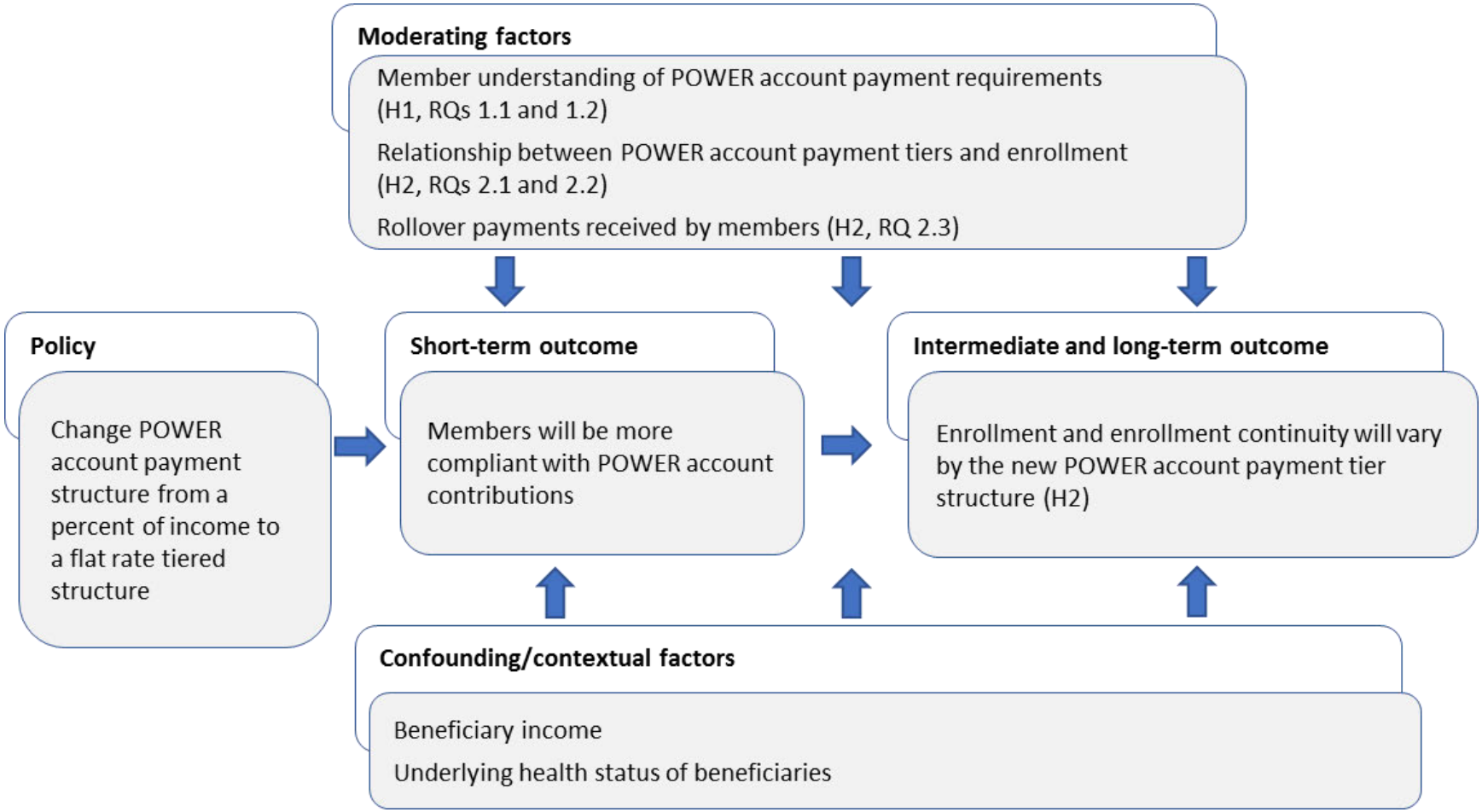
Hypotheses	Research Questions
Hypothesis 1 – HIP's new income tier structure for POWER Account Contributions will be clear to HIP members.	**Primary research question 1.1:** Do HIP members with POWER account payment requirements understand their payment obligations? **Primary research question 1.2:** Do HIP members with POWER Account payment requirements who initiate payments continue to make regular payments throughout their 12-month enrollment period?
Hypothesis 2 – Enrollment and enrollment continuity will vary for the POWER Account payment tiers.	**Primary research question 2.1:** Is there a relationship between POWER Account payment tiers and total and new enrollment in Medicaid? **Primary research question 2.2:** Is there a relationship between POWER Account payment tiers and continued enrollment in Medicaid? **Primary research question 2.3:** Do HIP members that receive rollover have greater coverage continuity than HIP members who do not receive rollover?

[24] Previous versions of this goal included a reference to "efficient use of services" consistent with the STCs. This wording is no longer included as efficient use of services is addressed under Goal 1.

[25] Waiver 4 (related to eligibility) in HIP STC. Accessible from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/in-healthy-indiana-plan-support-20-ca-01012021.pdf

The logic model in **Exhibit B.5** depicts the expected short-term, intermediate, and long-term outcomes[26] for the tiered structure of the monthly POWER Account payment.

Exhibit B.5: Logic Model for Goal 3



[26] Since we will be estimating the outcome measures based on data from the observation period (2015-2020), the evaluation will not provide conclusions about the long-term outcomes of the HIP program (e.g., related to health status, employment, and education level) beyond this period.

4. Goal Four – Ensure HIP program policies align with commercial policies, are understood by members, and promote positive member experience and minimize coverage gaps

Indiana will test whether the HIP policies align with commercial policies, use easy-to-understand language, and result in a positive member experience for all HIP members. **Exhibit B.6** below lists the hypotheses and research questions corresponding to this goal. Starting from January 2021, the State suspended the six-month non-eligibility criterion pending resolution of the stay in the federal lawsuit and in compliance with the newly approved waiver terms and conditions.[27] Members will not be "locked" out for non-payment of POWER Account Contributions. Research questions related to non-eligibility will be addressed and analyzed only if the State reinstates the policy (pending lawsuit decision). Additionally, as HIP policies were "turned off" during the COVID-19 PHE (starting March 2020), the ability to analyze research questions related to member knowledge on HIP policies on POWER Account Contribution, preventive care, and rollover will depend on the timing of reinstatement of HIP policies.

Exhibit B.6: Hypotheses and Research Questions for Goal 4

Hypotheses	Research Questions
Hypothesis 1 – Beneficiaries subject to HIP policies will understand program policies.	**Primary research question 1.1:** Are HIP members knowledgeable about policies on payment of POWER Account Contributions, preventive care and rollover? **Primary research question 1.2:** Do HIP members subject to non-eligibility periods understand program requirements and how to comply with them? **Primary research question 1.3:** Do HIP members subject to non-eligibility periods understand the non-eligibility period consequence for noncompliance with program requirements? **Primary research question 1.4:** What are common barriers to compliance with program requirements that have non-eligibility period consequences for noncompliance?
Hypothesis 2 – Beneficiaries will be satisfied with the HIP program.	**Primary research question 2.1:** What is the level of satisfaction with HIP among HIP members?
Hypothesis 3 – Individuals subject to the non-eligibility/"lockout" periods (payment and redetermination) and retroactive eligibility are no different from commercial market populations.[28]	**Primary research question 3.1:** Do HIP members that are subject to non-eligibility periods have similar demographic characteristics as the commercial market population? **Primary research question 3.2:** Do HIP members that are not retroactively eligible have similar demographic characteristics as the commercial market population?

[27] Waiver 4 (related to eligibility) in HIP STC. Accessible from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/in-healthy-indiana-plan-support-20-ca-01012021.pdf

[28] A core principal underlying HIP policy is that the program is designed for non-disabled working aged adults who may be moving between eligibility for HIP and eligibility for commercial coverage on a frequent basis and who are more closely aligned with commercial market populations than with traditional Medicaid populations. Thus, instead of mimicking traditional Medicaid, HIP pulls in elements of commercial market design including required cost sharing, lack of retroactive benefits, required monthly payments, enrollment periods, incentives, tobacco surcharges, and member accounts. This hypothesis looks to test the foundational theory of HIP that HIP enrollees are aligned with commercial market populations looking at enrollee's subject to non-eligibility periods and enrollees subject to the retroactive coverage waiver.

Hypotheses	Research Questions
Hypothesis 4 – Eliminating or reducing retroactive eligibility will not reduce member enrollment or access to health care; decrease health status; or have adverse financial impact[29]	**Primary research question 4.1:** Do eligible people subject to retroactive eligibility waivers enroll in Medicaid at the same rates as other eligible people who have access to retroactive eligibility? (CMS Guidance Hypothesis 1, RQ 1.1) **Primary research question 4.2:** Do beneficiaries subject to the retroactive eligibility waiver understand that they will not be covered during enrollment gaps? (CMS Guidance Hypothesis 1, Subsidiary RQ 1.2a) **Primary research question 4.3:** Do beneficiaries subject to the retroactive eligibility waiver have better health outcomes than other beneficiaries who have access to retroactive eligibility? (CMS Guidance Hypothesis 3, RQ 3.1) **Primary research question 4.4:** Does the retroactive eligibility waiver lead to changes in the incidence of beneficiary medical debt? (CMS Guidance Hypothesis 4, RQ 4.1)

[29] The hypothesis was included to address CMS' recommendation (received on 03/24/2020) to include analyses of the impact of the waiver of retroactive eligibility on member access and health.

5. Goal Five – Assess the costs to implement and operate HIP and other non-cost outcomes of the demonstration

Indiana's goal is to assess the costs to implement and operate HIP and other non-cost outcomes of the demonstration. **Exhibit B.7** below lists the hypotheses and research questions corresponding to this goal. To reduce the duplication of efforts, and thus cost, this analysis will be completed by Indiana's actuary, Milliman, Inc., and appended to the Interim Evaluation Report. The results will be incorporated into the overall evaluation analysis where relevant and as appropriate.

Exhibit B.7: Hypotheses and Research Questions for Goal 5

Hypotheses	Research Questions
Implementation Questions	**Primary research question 1.1:** What are the administrative costs incurred by the State to implement and operate the HIP demonstration? **Primary research question 1.2:** What are the short- and long-term effects of eligibility and coverage policies on Medicaid health care expenditures? **Primary research question 1.3:** What are the impacts of eligibility and coverage policies on provider uncompensated care costs?

C. Methodology

This section summarizes Indiana's evaluation design, including data sources, target and comparison populations, evaluation period, and analytic methods for the first Interim Evaluation Report scheduled for submission to CMS in June 2024.[30] Throughout the previous HIP demonstration, the State tracked meaningful measures of health care access, utilization, health outcomes, and member satisfaction. This Evaluation Plan builds on this tracking and expands the quantitative and qualitative data collection and analysis to reflect new program goals and to incorporate CMS' Section 1115(a) Eligibility and Coverage Evaluation Guidance,[31] most notably:

- Impact of tobacco surcharge – The evaluation includes interrupted time series (ITS) analyses of tobacco cessation service use and tobacco use among HIP members.
- HIP members' compliance with the tiered POWER Account structure – The evaluation includes analyses of enrollment outcomes pre/post-implementation of the new tiered account structure among HIP members.
- WBA – The evaluation includes descriptive statistics to analyze impact of WBA on continuity of coverage and benefit cliff among HIP members transitioning to commercial coverage.

Subsection C.1 describes the data sources and collection. **Subsection C.2** describes how Indiana identified comparison groups and determined when an ITS or pre/post analysis was appropriate for a particular research question. Appropriate matching techniques (e.g., propensity score or Mahalanobis distance) will be used as necessary to identify and develop comparison groups.

The observation period for the Interim evaluation, scheduled to be submitted to CMS in June 2024 (scope of this current Evaluation Plan) will be CYs 2015 to 2022. This time period includes three years before the HIP renewal took effect in 2018, all of the 2018-2020 waiver period, and two years of the 2021-2030 waiver renewal period. For some research questions and analyses, the time period is limited to fewer years. Since we will be estimating the outcome measures based on data from the observation period, the evaluation will not provide conclusions about the impact of the HIP program (e.g., related to health status, employment, and education level) beyond this period. The evaluation will include descriptive analysis of changes in the composition of the enrolled population and the evaluator will consider any findings from this analysis when interpreting the results of the analyses described in the Evaluation Plan.

Section F includes the analytic design tables for each goal, detailing the relevant hypotheses, research questions, data sources, outcome measures, analytic methods, and comparison group(s) (if applicable). These tables also specify the years of data to be used for individual research questions and the research questions to be addressed in the Interim Evaluation Report.

The ongoing COVID-19 PHE, which started in March 2020, continues to cause substantial changes to HIP policies, service utilization, and provider availability and will have both short- and long-term impacts on Indiana's health care system. Due to the COVID-19 PHE, the State suspended HIP policies including

[30] The State anticipates building on this plan to address any future programmatic changes. The analyses plan will be reviewed and updated, as required, for future evaluations (interims and summative) to incorporate any program changes and other specifications including intervention time period and analytic methods.

[31] CMS. 1115 Demonstration State Monitoring & Evaluation Resources. Released and Accessed March 13, 2019 at https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html

POWER Account payments, tobacco surcharge, and disenrollment, starting on March 17, 2020.[32] The policies are "turned off" as of the development of this Evaluation Plan, with an unknown timeline for reinstatement. This will likely impact the evaluation of HIP policies. **Section A** outlines the State's COVID-19 policy changes in more detail. Social distancing and prioritization of health care resources are anticipated to affect utilization of a wide variety of services in the immediate future, even as telehealth services increase. Additionally, Medicaid enrollment has increased substantially and is likely to continue to increase during the COVID-19 PHE[33]. Further, it is anticipated that some health care providers will experience financial stress resulting from PHE rules and changing utilization. Changes in payer mix are also expected as individuals lose employer-based coverage, while Medicaid enrollment and the number of uninsured increases. The ability to use data starting from CY 2020 to analyze the impact of the HIP policies will require careful consideration and be dependent on multiple factors including the timeframe for reinstatement of HIP policies and the economic impact of the COVID-19 PHE. During Interim Evaluation Report development, the evaluator will evaluate the research questions, data, and appropriate analytic methods.

1. Data Sources and Collection

The evaluator will compile data from federal surveys and state-specific surveys, claims, and enrollment data. The evaluator will also capture qualitative data via key informant interviews (i.e., members, FSSA officials, MCEs, and providers). **Exhibit C.1** summarizes the data sources anticipated to be used to evaluate each goal ("X" indicates relevant sources for each goal), followed by detailed descriptions of key data sources. **Section F** provides specific information regarding how these data sources will be used in the first Interim Report evaluation.[34]

[32] These policies were suspended March 17, 2020. Based on State "Medicaid Policy Changes: regarding COVID-19" updated on July 28, 2020 and in discussion with State as of May 2021.

[33] Based on enrollment summary report, there were approximately 583,000 members receiving HIP benefits end of December 2020. Member enrollment increased to 643,000 in May 2021 with an approximate 10,000 new members every month. Information retrieved from https://www.in.gov/fssa/ompp/forms-documents-and-tools2/medicaid-monthly-enrollment-reports/

[34] The data sources identified and information in Section F are specific to the first Interim Evaluation report for this demonstration. For future evaluations (two interims and a summative) the information will need to be reviewed and updated, as required, to incorporate any programmatic changes. The State does not anticipate significant changes to analytic data for future evaluations.

Exhibit C.1: Data Sources by Goal (Goal 1 to Goal 5)

Type	Data Sources	Goal 1 Access, Utilization, Health Outcomes	Goal 2 Tobacco Cessation	Goal 3 POWER Account	Goal 4 Positive Member Experience	Goal 5 Cost and Non-Cost
External – Quantitative	1. American Community Survey (ACS)	X	-	X	X	-
	2. Uncompensated care data as reported on Medicare cost reports	-	-	-	-	X
	3. Behavioral Risk Factor Surveillance System (BRFSS)	X	-	-	X	-
Indiana – Quantitative	1. Indiana Medicaid Historical Data *Note: Historical data will be leveraged as necessary for the goals.*	X	X	X	X	X
	2. Member Eligibility, Application, and Enrollment Data *Note: Enrollment data will be used to draw member survey samples that are applicable across goals.*	X	-	X	-	-
	3. Claims Data	X	X	-	-	-
	4. State administrative data – for example, POWER Account data, Gateway to Work data, POWER Account rollover data, data for tobacco use/cessation[35]	-	X	-	X	X
	5. Data reported by health plan, including Healthcare Effectiveness Data and Information Set (HEDIS) and annual chronic disease management program utilization	X	-	-	-	-
	6. Longitudinal Member Survey (2023, 2024)	X	X	X	X	-
	7. Leaver #1 – Income	-	-	-	X	-
	8. Leaver #2 – POWER Account Contribution non-payment (2024)	-	-	-	X	-

[35] Other sources of State administrative data may be leveraged as available.

Type	Data Sources	Goal 1 Access, Utilization, Health Outcomes	Goal 2 Tobacco Cessation	Goal 3 POWER Account	Goal 4 Positive Member Experience	Goal 5 Cost and Non-Cost
Indiana – Qualitative	1. Key Informant Interviews with FSSA Officials		X	X	X	-
	2. Key Informant Interviews with MCEs		-	X	X	-
	3. Key Informant Interviews with MCEs on Tobacco-Related Topics	-	X	-	-	-
	4. Key Informant Interviews with Providers	-	X	X	X	-
	5. Key Informant Interviews with Members	-	X	X	X	-

External Data Source Descriptions – Quantitative

American Community Survey (ACS): The ACS, sponsored jointly by the U.S. Census Bureau and the U.S. Department of Commerce, is a nationwide survey that collects and produces information on demographic, social, economic, and health insurance coverage characteristics of the U.S. population each year. See **Section E.4** for a description of key ACS variables.

Medicare Cost Report Data: Medicare cost report data contains provider information such as facility characteristics, utilization data and cost and charges by cost center. This data is available through the Healthcare Provider Cost Reporting Information System (HCRIS), which CMS maintains. Medicare cost report data include information on uncompensated care, bad debt and charity care.

Behavioral Risk Factor Surveillance System (BRFSS): The BRFSS is a nationwide survey operated jointly by the Centers for Disease Control and Prevention (CDC) and state health departments. The survey collects data on health status and health risk behaviors including chronic diseases, access to health care, and use of preventive health services related to the leading causes of death and disability for non-institutionalized population.

Internal Data Source Descriptions – Quantitative

Other applicable data sources may be included as available and validated. Current sources include:

- *Indiana Medicaid Historical Data:* Indiana Medicaid historical data refers to data that the State has summarized in previous assessments and evaluations, either directly or through contracted services for the previous HIP demonstration population. As necessary, the evaluation will use data summaries from previous HIP evaluations on various metrics, including POWER Account, enrollment, and utilization.
- *Member Eligibility, Application, and Enrollment Data:* Member application and enrollment data provide information on the size, location, and socio-demographic makeup of HIP enrollees (e.g., members with household income under 138% of the FPL).

- *Claims Data:* The claims records (encounter data) that the MCEs submit to the State provide information about all HIP enrollees' health care utilization patterns and identify enrolled HIP providers that are actively providing services.
- *State Administrative Data:* Program administrative data will include items related to POWER Accounts (e.g., member usage of POWER Account fund and POWER Account payments), Gateway to Work activities (if reinstated for e.g., reporting of qualifying activities and exemptions by member), tobacco use status and items related to the use of the WBA to pay for premiums for enrollment in commercial coverage. These data will permit identification of individuals that have had HIP eligibility closed due to non-payment of POWER Account Contributions or had a WBA.
- *HIP Surveys:* Surveys will capture the perspectives of members regarding HIP during the intervention time-period covered by the evaluation. Member responses will contribute to addressing research questions across different goals for the evaluation. **Exhibit C.2** describes, by survey, the type of individuals to be surveyed, key topics, process for selecting the sample, mode of data collection, the targeted number of respondents, and statistical power assumptions for the first Interim Evaluation Report. **Section F** provides additional information by research question. There will be three types of member surveys:
    - A longitudinal survey capturing HIP member experience at two points in time 12 months apart. The evaluator will field the first round of the survey in 2023 with a follow up in 2024.
    - Survey of previous HIP members (leavers) who disenrolled due to increase in income.
    - Survey of previous HIP members (leavers) who disenrolled due to non-payment of POWER Account.

As appropriate and feasible, selecting members for survey data collection will be based on probability sampling methods, such as simple random sampling or stratified random sampling, to ensure that the sample represents the larger population under study, reduces bias, and increases validity of study findings.

In implementing each survey, the State will ensure that all informed consent procedures are followed, so that respondents are aware of the reason for the survey and have the information they need to fully participate. The evaluator will leverage the most up-to-date contact information for sampled members using program administrative data to maximize the response rate.

All surveys will be administered using computer-assisted telephone interviewing (CATI) software to ensure data completeness and consistency. Prior to analysis, data will be weighted to adjust for sample design, non-response, and differences in characteristics between the survey respondents and the population. Participant rewards will not be provided.

The average survey length will be six minutes; a longer average survey length will result in a lower survey completion rate and strain existing evaluation resources. The evaluator will prioritize research questions within the available survey time and make adjustments to data collection accordingly.

Exhibit C.2: Summary of Indiana-Specific Surveys*

Area	Longitudinal Member Survey	Leaver Survey – POWER Account Contribution non-payment	Leaver Survey – Increased Income
Individuals Surveyed	Members having HIP Basic or HIP Plus coverage in a specific month. The coverage status of these individuals will vary between the 2023 and 2024 surveys; some will continue to be HIP members while others may leave the program.	Individuals who had been fully enrolled in HIP but who left the program (i.e., coverage is closed) due to not paying the POWER Account Contribution.	Individuals who had been fully enrolled in HIP but who left the program (i.e., coverage is closed) due to changes in income eligibility. The survey sample will include individuals participating in the WBA program and individuals who are not participating.
Timeframe	2023, 2024	2024	2024
Topics	• Access to care • Health status • Tobacco use and related surcharge • Satisfaction with HIP and knowledge of HIP policies • POWER Accounts • Medical debt • WBA	• Reasons for leaving HIP • Current insurance coverage/ employer coverage • Knowledge of HIP policies • Access to care • Satisfaction with HIP	• Reasons for leaving HIP • Current insurance coverage/employer offer of coverage • Knowledge of HIP policies • Access to care • WBA
Mode of Administration	Telephone Up to three attempts in 2023 and update five attempts in 2024	Telephone Up to three attempts	Telephone Up to three attempts
Sampling Strategy	Stratified Random	Random	Random
Anticipated Timeline (May change depending on data availability or other program nuances and changes)	• Sampling Universe: All members enrolled with HIP Basic or HIP Plus in February 2023 • Select sample: April 2023 • Survey instrument test: May (2023, 2024) • Conduct survey: June – July 2023, June 2024	• Sampling Universe: HIP members who disenrolled between January 1, 2023 and December 31, 2023 • Select sample: March 2024 • Survey instrument test: April 2024 • Conduct survey: May – June 2024	Same as Leaver Survey – POWER Account Contribution non-payment

Area	Longitudinal Member Survey	Leaver Survey – POWER Account Contribution non-payment	Leaver Survey – Increased Income
Estimated number of completed surveys	2023: 4,500 2024: 650 to 900 (dependent on response rate among respondents in 2023)	250	400
Statistical power assumptions	Assuming a population of 400,000, this sample size will allow for estimating population metrics (e.g., proportion has access to care) with 95% confidence level with a margin of error of +/-1.38% for 2023 and 3.8% for 2024. The evaluator anticipates contacting all respondents in the 2023 survey for purposes of the 2024 longitudinal survey. The adequacy of the resulting 2024 sample for subgroup analysis will be assessed prior to analysis. The adequacy of the sample size for conducting subgroup analyses was assessed for one outcome of interest (high HIP satisfaction). The sample size supports comparisons (detectable difference of 10% or more with confidence level of 95% and power level of 80%) between HIP Basic and HIP Plus members and between members who are below and above 100% FPL.	Assuming a population of 5,000, this sample size will allow for estimating population metrics (e.g., proportion has access to care) with 95% confidence level with a margin of error of +/-6.05%. Subgroup analysis may be limited due to sample size. The adequacy of the sample for subgroup analysis will be assessed prior to analysis and provided in the Interim Evaluation Report.	Assuming a population of 28,000, this sample size will allow for estimating population metrics (e.g., proportion has access to care) with 95% confidence level with a margin of error of +/-4.86%. Subgroup analysis may be limited due to sample size. The adequacy of the sample for subgroup analysis will be assessed prior to analysis and provided in the Interim Evaluation Report.

*Note: The table includes details for surveys planned for the first Interim Evaluation report scheduled to be submitted to CMS in June 2024. This table (including information on type of surveys, sample sizes, time frame) will need to be updated in future for the other interim reports and summative evaluation.

(1) The population for sampling will depend on the timing of reinstatement of HIP policies and potential long term impact of the COVID-19 PHE.

(2) Due to the small population size and anticipated high non-response, the survey process will involve calling all available individuals until the target sample size has been achieved or until the evaluator has reached the maximum number of dialing attempts. The completed number of responses may be lower than the target.

Internal Data Source Descriptions – Qualitative

In addition to quantitative data collection and analysis, Indiana will conduct key informant interviews to capture member and provider experience and evaluate other outcomes related to each goal. Participant responses to targeted questions will provide an opportunity to explore trends and outliers in the quantitative data, and allow participants to use their own words to describe their experiences. Indiana will identify potential participants based on existing contacts and other member and provider lists including enrollment data. Indiana is not planning to use any monetary incentives for recruitment and participation will not affect member enrollment status. **Exhibit C.3** describes the targeted number of interviewees, timeframe, and potential topics.

For the first Interim Evaluation Report, the evaluator anticipates leveraging the results from interviews conducted in 2021 under the pending 2018-2020 Summative Report and will conduct one round of key informant interviews in CY 2024. Key informant interview specifications including type of interviews, targeted number of interviewees and schedule of interview will be updated and included in future interim and summative evaluation reports for this demonstration.

Exhibit C.3: Summary of Indiana-Specific Qualitative Data Collection – Key Informant Interviews

Type	Potential Topics	Targeted Number of Interviewees
FSSA Officials	• Implementation of HIP POWER Account changes, tobacco surcharge, and WBA • Identification of factors related to member enrollment and participation in/compliance with policy changes • Member satisfaction	8 semi-structured interviews (including group interviews) each year
MCEs	• Implementation of HIP POWER Account changes, tobacco surcharge, and WBA • Identification of factors related to member enrollment and participation in/compliance with policy changes ○ Member satisfaction	4 semi-structured interviews with representatives from the four MCEs
Provider/Other Associations	• Understanding of and experience with HIP policies – POWER Accounts, tobacco surcharge, tobacco cessation services, and WBA ○ Member satisfaction with HIP	20 interviews *Note: To be determined based on provider/other association availability. Interviews will include provider associations and certified navigators*
HIP Members	• Access to care • Tobacco use • Satisfaction with HIP • Knowledge of HIP policies – POWER Accounts, tobacco surcharge, tobacco cessation services, and WBA	30 interviews *Note: To be determined based on member availability.*

Type	Potential Topics	Targeted Number of Interviewees
Other Stakeholders	• Topics to be determined based on key areas of interest from the State	5 to 8 interviews *Note: To be determined based on stakeholder availability. This will include an individual with a WBA.*

2. Target and Comparison Populations

The target population for analysis is all beneficiaries covered by HIP or – where applicable and possible – the HIP member sub-population specific to the research question and related outcome measure(s). HIP includes low-income, non-disabled adults ages 19 to 64. The other adults eligible for Medicaid in Indiana include individuals who are 65 and older, blind, or disabled and who are also not eligible for Medicare, or low-income adults who can receive home and community-based services or who are in nursing homes and other facilities.

During the development of strategies for comparative analyses, both within-state and other-state comparison groups who are similar to HIP members but not subject to the policies being evaluated were considered. Ideally, a comparison group used to evaluate the impact of program implementation is a population with similar demographics but without comparable program or policy changes.

CMS' guidance outlined several possible within-state comparison groups,[36] which are not feasible or ideal for this evaluation due to specific aspects of Indiana HIP, specifically:

- The State includes all eligible non-elderly, non-disabled adults in HIP. The unique characteristics of other Medicaid-eligible adults in the state (e.g., individuals with disabilities and children less than 19 years of age) limits the availability of appropriate within-state comparison groups for the HIP evaluation.
- HIP does not involve random assignment and the State has not staged HIP policy implementation based on beneficiary characteristics. Changes to POWER Account Contribution payment tiers apply to all HIP members interested in enrolling in HIP Plus.

For these reasons, depending on the research question, Indiana's Evaluation Plan uses two types of comparison groups: (1) HIP population prior to policy implementation, and (2) other state Medicaid populations, with a particular focus on states that did not implement any comparable demonstrations during the evaluation period and have populations with similar demographic characteristics.

In instances when adequate data are available before and after policy implementation, the evaluator will develop quasi-experimental analyses (e.g., ITS). For such analyses, the HIP population post-policy implementation is the target while the member population prior to policy implementation is the comparison group. As necessary, the evaluator will explain in the Interim Evaluation Reports why regression discontinuity designs using age, medical frailty, or parents with dependents were not used.

[36] Feedback received previously from CMS included considering use of regression discontinuity (RD) designs using age and medical frailty cutoffs, where feasible.

Exhibit C.4 summarizes a preliminary set of states to be considered for comparison based on select characteristics. Prior to developing the relevant analyses for the Interim Evaluation Report,[37] the evaluator will refine this set to two to three states, taking into account recent state-specific policy changes, if the state has a retroactive eligibility waiver in place, and/or data challenges that might make comparisons challenging. The evaluator may choose to vary the final states selected by research question. The below parameters were used to select the preliminary set of states:

- Expanded Medicaid to childless adults, have similar eligibility for childless adults as Indiana, and expansion did not take place during the evaluation time period.
- Have not implemented the 1115(a) waiver policy under study (e.g., community engagement requirements) but are similar to Indiana in other Medicaid policies.
- Have similar population characteristics.
- Have sufficient sample size for analysis.

Depending on the research question, ACS or BRFSS will be used for cross-state or cross-coverage type (Medicaid versus commercial) comparisons. In addition to age (19-64), income (138% FPL or less using FPL or reported income) the evaluator will leverage other available variables to approximate the HIP population (e.g., Medicaid eligible population). However, there are limitations to the ability to define these comparison groups, and Indiana's Interim Evaluation Report will include discussion of how these limitations affect the interpretation of the results.

Indiana anticipates identifying the ACS sample size by including individuals that:

- Live in households with income less than 138% of the FPL (Integrated Public Use Microdata Series (IPUMS) ACS variable POVERTY)
- Are 19-64 years old (IPUMS ACS variable AGE)
- Are not covered by Medicare (IPUMS ACS variable HINSCARE)
- Are not receiving social security income (IPUMS ACS variable INCSUPP)

The definition of the study population may be based on either (1) likely eligible or (2) Medicaid-enrolled individuals. The sample representing the likely eligible population can be identified in ACS using the variables listed above, while the "Have Medicaid coverage (IPUMS ACS variable HINSCAID)" variable can be used in addition to the others listed to identify the sample representing the potential Medicaid enrolled population. The evaluator will explore and assess the use of analysis results based on both approaches and include a comprehensive rationale and relevant analyses in Interim Evaluation Report on the choice of a specific population definition (e.g., why the enrolled population was used instead of the eligible population or vice-versa).

[37] Comparison group analyses are only included in the Summative Evaluation Report due to the timeframe of data required for analysis.

Exhibit C.5 provides the anticipated sample sizes for ACS for both definitions of the study population under consideration. Once the Indiana and other state samples are identified from the ACS, the evaluator will conduct descriptive analyses to assess the similarities and differences in the Indiana sample compared to the other state samples in terms of key characteristics (e.g., age, race, sex). The evaluator will consider the need to leverage appropriate matching techniques (e.g., propensity score or Mahalanobis distance) to identity a matching comparison group of beneficiaries similar to the Indiana sample members. The evaluator will apply this same approach as appropriate when using other data sources to perform cross-state comparisons; the Interim Evaluation Report will include a description of the approach(es) and the rationale for selection.

The evaluator will use BRFSS data to analyze health status and medical debt of the Medicaid-eligible population as indicated in Section F (Goal 1 and Goal 4) for the Interim Evaluation Report. BRFSS data will only allow for the identification of the likely eligible Medicaid population; it is not possible to identify the enrolled Medicaid population. Indiana anticipates identifying the likely eligible Medicaid population using the following criteria:

- Include respondents age between 18 and 64 (AGE65YR – Reported age in five-year age categories)
- Exclude respondents that report household income of more than $15,000 (INCOME2 – income is reported in income categories such as “less than $10,000” instead of by FPL)
- Exclude respondents with self-reported employment status of “unable to work” (EMPLOY1)
- Exclude pregnant women (variable “PREGNANT)

Exhibit C.6 provides the anticipated sample sizes for likely eligible Medicaid population in BRFSS. The evaluator will explore additional options to identify the samples representing the likely eligible Medicaid population during Interim Evaluation Report development.

Section F provides additional detail regarding how these comparison groups will be used and also identifies unique within-state comparison groups pertinent to specific research questions.[38]

[38] Goal 4, Primary Research Question 2.3 (HIP members who do not receive rollover) and Subsidiary Research Question 3.1 (Low-income adults in Indiana enrolled in commercial coverage)

Exhibit C.4: Summary of Key State Characteristics

Characteristic	Indiana	Colorado	Minnesota	New Mexico	Pennsylvania	Washington
Non-Elderly Adult Expansion FPL Percent[39]	138%	138%	138%	138%	138%	138%
Percent Unemployed[40]	3.6%	3.5%	3.2%	5.1%	3.9%	4.6%
Minimum Wage[41]	$7.25	$11.10	$9.86/$8.04[42]	$7.25	$7.25	$12.00
Percent Rural Households[43]	31%	24%	35%	35%	17%	16%
Percent Uninsured[44]	8.2%	7.6%	4.5%	9.1%	5.5%	6.1%
Percent Employees with Employer Offer[45]	82%	83%	83%	80%	88%	85%
Race (selected)[46]	79% White 9% Black 7% Hispanic 2% Asian	68% White 4% Black 22% Hispanic 3% Asian	80% White 6% Black 5% Hispanic 5% Asian	37% White 2% Black 49% Hispanic 1% Asian	77% White 11% Black 7% Hispanic 3% Asian	69% White 3% Black 13% Hispanic 9% Asian
Type of Marketplace[47]	Federally-facilitated	State-based	State-based	State-based with Federal Platform[48]	Federally-facilitated	State-based

Note: All of the states listed expanded their Medicaid programs prior to 2015.

39 Henry J. Kaiser Family Foundation. Medicaid and CHIP Eligibility, Enrollment, and Cost Sharing Policies as of January 2019: Findings from a 50-State Survey. Retrieved May 3, 2019 from https://www.kff.org/medicaid/report/medicaid-and-chip-eligibility-enrollment-and-cost-sharing-policies-as-of-january-2019-findings-from-a-50-state-survey/

40 Bureau of Labor Statistics. Local Area Unemployment Statistics for March 2019. Retrieved May 3, 2019 from https://www.bls.gov/web/laus/laumstrk.htm

41 National Conference of State Legislatures State 2019. Minimum Wages by State. Retrieved May 3, 2019 from http://www.ncsl.org/research/labor-and-employment/state-minimum-wage-chart.aspx#Table

42 For large employers, with an annual sales volume of $500,000 or more, the minimum wage is currently $9.50; for small employers, those with an annual sales volume of less than $500,000, the minimum wage is $7.75.

43 University of Minnesota. 2017 American Community Survey accessed through IPUMS USA. Retrieved May 3, 2019 from https://usa.ipums.org/usa/

44 Ibid.

45 Medical Expenditure Panel Survey. Insurance Component 2017 Chartbook, Exhibit 1.3. Retrieved May 3, 2019 from https://meps.ahrq.gov/data_files/publications/cb22/cb22.pdf

46 Henry J. Kaiser Family Foundation. Population Distribution by Race/Ethnicity, 2017. Retrieved May 11, 2019 from https://www.kff.org/other/state-indicator/distribution-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

47 Henry J. Kaiser Family Foundation. State Insurance Marketplace Types 2018. Retrieved May 3, 2019 from https://www.kff.org/health-reform/state-indicator/state-health-insurance-marketplace-types/

48 While New Mexico has a state-based marketplace with a federal platform, the state component of the marketplace only applies to small employers/employees.

Exhibit C.5: ACS Sample Sizes for Key States

Note: The adequacy of the sample sizes for testing Medicaid uptake in comparison to other states was assessed; the sample sizes support comparisons (detectable difference of 5% or more with confidence level of 95% and power level of 80%) between Indiana and other states.[49]

Definition	Year	Indiana	Colorado	Minnesota	New Mexico	Pennsylvania	Washington
Likely Eligible for Medicaid	**2015**	7,773	5,103	4,168	2,990	12,472	6,692
	2016	7,216	5,135	4,075	2,750	12,370	6,490
	2017	7,065	5,096	3,957	2,843	11,936	6,186
Medicaid Enrolled	**2015**	2,069	2,018	1,879	1,414	3,952	2,848
	2016	2,328	1,839	1,847	1,449	4,564	2,898
	2017	2,378	1,923	1,775	1,534	4,680	2,715

Exhibit C.6: BRFSS Sample Sizes for Key States

Note: The adequacy of the sample sizes for testing medical debt and health status in comparison to other states was assessed; the sample sizes support comparisons (detectable difference of 10% or more with confidence level of 95% and power level of 80%) between Indiana and other states. Current sample sizes will not allow for any robust statistical tests of differences between subgroups within a state.[50]

Definition	Year	Indiana	Colorado	Minnesota	New Mexico	Pennsylvania	Washington
Likely Eligible for Medicaid	**2015**	137	400	415	188	176	423
	2016	190	319	360	152	183	330
	2017	336	322	497	243	225	458

[49] University of Minnesota. 2017 American Community Survey accessed through IPUMS USA. Retrieved May 3, 2019 from https://usa.ipums.org/usa/

[50] Behavioral Risk Factor Surveillance System (BRFSS), Retrieved May 7, 2020 from https://nccd.cdc.gov/weat/#/analysis

3. Analytic Methods

Indiana will use a mixed-methods approach employing both quantitative and qualitative analyses to answer the research questions in this evaluation (first Interim Evaluation).[51] Qualitative analyses will support stakeholders' perspectives related to context, implementation, and outcomes and will identify contextual factors that help explain outcomes. Quantitative analyses will examine changes in outcomes and estimate the impact of policy changes, as demonstration design and data permit. Quantitative and qualitative analyses will reinforce each other and contribute to understanding context, implementation, impact, and variation.

The evaluation will employ a convergent approach incorporating mixed methods. With a convergent approach, qualitative data and analysis may inform the collection, analysis, and interpretation of quantitative data, and quantitative data and analysis can inform the collection, analysis, and interpretation of qualitative data. For example, interviews with HIP members will provide important contextual information that may help explain the results of claims analysis. The claims analyses may inform the development of survey and interview protocols. Both quantitative and qualitative data will be used throughout the course of the evaluation. Any quantitative analyses that leverages survey sample data will apply appropriate sample weights and weighting techniques.

Qualitative Analyses: Qualitative data collected through interviews will be analyzed using thematic analysis, a systematic data coding and analysis process during which information is categorized with codes developed iteratively to reflect themes or patterns within the data.

Quantitative Descriptive and Trend Analyses: Descriptive statistics (e.g., total, average, proportion) will be calculated to summarize the characteristics of HIP members (across time where necessary) as well as observational inference on trends in outcomes of interest. The analyses will leverage data visualizations to identify underlying trends, seasonal patterns, and outliers where feasible (e.g., line chart showing disenrollment rate over time, clustered bar chart showing member composition over time). Where applicable and feasible, we will leverage appropriate statistical tests (e.g., Chi-Square test for independence) to test for differences between HIP members and comparison groups or to test for differences between subgroups of interest. These tests will use, as appropriate, regression based adjustments to control for changes in member characteristics to estimate changes in measures of interest across time. The descriptive statistics and related statistical analyses (test for difference or regression adjustments as appropriate) will be used to analyze the impact of HIP 2021 policies on member utilization of health care, health status, tobacco cessation services, and compliance with program policies.

Cross-Sectional Analyses: We will use cross-sectional models to assess associations and compare risk-adjusted outcomes for HIP members to comparison beneficiaries. Standard power calculations will be conducted to ensure adequacy of sample sizes in available data for model development. A variety of parametric models and techniques are available to estimate the models. The outcome variable characteristics, for example type (e.g., categorical or continuous) and distribution (e.g., normal, skewed), will be used to determine the model specifications (e.g., logistic, linear, log-linear). Models will include beneficiary and geographic-level covariates to control for differences between the groups of interest.

[51] The analytic methods for future evaluations (two interims and a summative) will need to be reviewed and updated, as required, to incorporate any programmatic changes. The State does not anticipate significant changes to analytic methods for future evaluations.

The covariates will include demographic characteristics, income level, health status, regional characteristics, and other variables that are relevant and available within the data sources used.

Quantitative Impact Analyses: Because the implementation of Indiana's policy changes did not involve a randomized control design (as discussed in *Target and Comparison Population* section), the evaluation will use quasi-experimental approaches to estimate the impact of policy changes. Specifically, the evaluation will use a difference in differences (DiD) approach to address several research questions. DiD is a regression technique that measures the impact of the model by comparing changes in risk-adjusted outcomes for the target population to changes in outcomes in a comparison group, between the baseline and intervention periods. Standard power calculations will be conducted to assess adequacy of sample size in available data for model development. We will ensure model specifications are appropriate for the outcome variable (e.g., logit for dichotomous outcomes) of interest. Models will include beneficiary and geographic-level covariates to control for differences between the groups of interest. The covariates will include demographic characteristics, income level, health status, regional characteristics, and other variables that are relevant and available in the data sources used. The validity of the DiD approach relies on the assumption that the intervention and comparison groups were on parallel trends in the baseline. Tests for parallel trends in the baseline period for key outcomes will be conducted using statistical testing and visual trend analysis.

When a comparison group is not available but multiple years of data (before and after the policy change) are available for HIP members, the evaluation will rely on an ITS design (or a pre/post design if only two points in time are available) to assess change in an outcome before and after the policy change. To strengthen this analysis, multivariate regression analysis will be used to control for possible confounders. Prior to implementing these analyses, pre-implementation trends will be evaluated and comparability in samples over time will be assessed, relying on appropriate methods (e.g., matching) to address sample differences.

Subgroup Analysis: These analyses will be conducted as part of descriptive, cross-sectional, and interrupted time-series analyses (as listed in Section F). The type and number of subgroup analyses will be determined by appropriateness for the research question, and as data and sample sizes allow. The primary ITS or DiD analysis will produce estimates of the average impact of a policy change. However, the impact may vary by beneficiary subgroups (e.g., by older and younger HIP members, by length of enrollment, by income, by region within state). To inform the selection of characteristics that will define subgroups, information gathered through interviews as well as through the descriptive analysis will be considered. The evaluator will first test whether subgroups of HIP and comparison beneficiaries are adequately balanced across key characteristics. If necessary, matching methods will be used to develop subgroup-specific comparison groups, so that intervention and comparison groups are balanced in observed characteristics. The ability to look at subgroups and differentiated effects is ultimately limited by the number of beneficiaries in each group and the variability in the data. The independent evaluator will weigh the value of testing for differences among subgroups against having adequate sample size and power to do so precisely.

The evaluation will consider the impact of the COVID-19 PHE when looking at trends over time, with specific analysis related to the time period when the COVID-19 PHE declaration was in effect. Sensitivity analyses (e.g., regression, analysis of variance, predictive validity analysis) are typical analytical techniques leveraged to study the impact of specific factors or occurrence of events on outcome(s) of interest. As part of the analytics to evaluate the impact of the HIP demonstration on utilization of health care services for HIP beneficiaries (and other outcomes), the evaluator anticipates performing sensitivity

analyses to explore (or possibly somewhat parse out) the confounded impact of the COVID-19 PHE and suspension of HIP policies. The evaluator will determine the possible inclusion of data from the COVID-19 PHE time period for any quantitative analytics (e.g., estimated change of ED use over time, disenrollment rate) based on this sensitivity analyses.

D. Methodological Limitations

Exhibit D.1 describes the known limitations of the evaluation and anticipated approaches to minimizing those limitations and/or acknowledges where limitations might preclude casual inferences about the effects of demonstration policies. **Section C** contained information on limitations regarding identifying comparison groups and the potential impact of the COVID-19 PHE on the use of 2020 data for evaluation purposes. The Interim Evaluation Report will describe limitations of the evaluation, which may include data and methodological challenges and other limitations identified during the evaluation process that are not described below. The report will acknowledge approaches taken by the evaluator and necessary modifications made to the Evaluation Plan to address these challenges and limitations.

Exhibit D.1: Summary of Methodological Limitations and Approach to Minimizing Limitations

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Overall issues	Impact of the COVID-19 PHE	The ongoing COVID-19 PHE, which started in March 2020, is anticipated to cause substantial changes to: • HIP policies (e.g., all members were enrolled in HIP Plus irrespective of income, cost-sharing has been suspended) • Service utilization • Medicaid enrollment • Provider networks	• Use and inclusion of data from CY 2020 and beyond to analyze the impact of HIP policies will require careful analyses and be dependent on multiple factors, including the time frame for reinstatement of HIP policies, phase-in time period once the COVID-19 PHE is lifted, policies reinstated and COVID-19's economic impact.
	Limited ability to control for differences between states when using other State Medicaid populations as a comparison group	State Medicaid populations are different in observable and unobservable ways. For example, state-specific policies and economies vary from state to state. Available variables and sample sizes in proposed federal data sources (e.g., ACS) limit the ability to control for these differences.	• Select states for comparison that: ○ Did not implement comparable demonstrations during the evaluation period ○ Implemented Medicaid expansion prior to 2015 ○ Have similar Medicaid eligibility FPL requirements for adults ages 19-64 ○ Have similar geographic variation ○ Have sufficient sample sizes • Include a description of the differences that cannot be accounted for given available evaluation resources and data limitations. • Use appropriate methods (e.g., matching) to account for observable differences.

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Overall issues, continued	Quality of provider contact information for key informant interviews	Provider contact information reliability made completing provider key informant interviews challenging. For example, provider email addresses and phone numbers listed in the MCE provider list often provided only generic office email addresses.	• Obtain support from key provider associations to identify providers for key informant interview purposes. • Use interviews with key provider associations in lieu of individual providers as necessary
	Ability to identify HIP members within ACS survey data	HIP members include low-income (<138% FPL), non-disabled adults aged 19-64; HIP members also include the medically frail, TMA participants, and low-income parents and caretakers. Available fields within ACS will limit the ability to identify all of these groups.	• Use available survey fields related to Medicaid coverage, income, disability, and age. • Highlight in the evaluation narrative what HIP member characteristics could not be taken into account.
	Ability to use BRFSS data to identify individuals enrolled in HIP and potentially eligible for HIP	BRFSS data does not allow for identification of individuals in the sample enrolled in Medicaid. Additionally, BRFSS data fields do not allow for a full identification of individuals that are potentially eligible for HIP. HIP members include low-income (<138% FPL), non-disabled adults aged 19-64; HIP members also include the medically frail, TMA participants, and low-income parents and caretakers.	• Use available survey fields related to income, disability, and age (Medicaid enrollment is not an available field). • Include in the evaluation narrative that BRFSS survey data can only identify individuals that are potentially eligible for HIP; describe related limitations for analyses.
	Impact of changes in case-mix over time	Changes in HIP case mix over time may have an impact on a variety of areas of this evaluation, including service utilization, prevalence of medical frailty exemptions for the Gateway to Work program, and member preference for the HIP Plus versus HIP Basic benefit plan.	• Use regression-based adjustments as data is available and appropriate and necessary for analyses across time.
	Number of respondents for leaver surveys (due to increased income, due to non-payment of POWER Account Contribution)	The completed number of responses may be lower than the target sample size. Obtaining responses from previous members is dependent on the non-response rate and total population of leavers. Additionally, the population size of leaver for sampling will depend on the timing of reinstatement of HIP policies and potential long term impact of the COVID-19 PHE.	• The survey process will involve calling all available individuals until the target sample size has been achieved or until the evaluator has reached the maximum number of dialing attempts.

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Overall issues, continued	Survey length/ respondent burden and corresponding response rates for member surveys	The average survey length will be six minutes; a longer average survey length will result in a lower survey completion rate and strain existing evaluation resources.	• Prioritize research questions within the available survey time and make adjustments to data collection accordingly.
	Quality of MCE encounter data	MCE encounter data is self-reported, and the procedure codes and units recorded in the encounter data available for the evaluation of the demonstration can be incomplete and/or inaccurate.	• Perform data checks on key variables (e.g., expected versus populated values). • Adjust or eliminate analyses as necessary if data are not reliable.
	Identification of unique HIP members	Recipient identification numbers can change over time and the State performs on-going adjustments to data so that each member has only one active recipient identification number.	• Confirm whether data received from the State is fully adjusted for duplicate members. • Request a mapping of duplicate recipient identification numbers, if applicable. • Indicate in the reports if there is a possibility that data analyzed contains duplicated HIP members.

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Overall issues, continued	Identification of FPL	Member income can change throughout the year and as often as monthly. We anticipate defining member FPL based on the first enrollment month in the CY under analysis (based on analyses of the income in enrollment data and feedback from the State). There may be FPL amounts in the data that appear inconsistent with HIP policies (e.g., a small number of HIP Plus members with income at or less than 100% had disenrollments with non-payment as a reason). Based on discussions with the State for the 2018 – 2020 waiver evaluation, there are several possible reasons for inconsistencies, for example: • The member changed income after the first HIP Plus enrollment month in the CY under analysis. • Interplay between the required member notification for coverage changes (e.g., HIP Plus to HIP Basic) and when the State/MCE received and updates data, in conjunction with member changes in FPL across months. • Inconsistencies in FPL data transfer between eligibility and the Medicaid Management Information System that resulted in null FPL values on disenrollment, which appear as zero in provided enrollment data and in some cases in the application of updated FPL numbers to prior months. The State has indicated that this data issue is resolved, but on a minority of historical records included in this analyses these data artifacts remain.	• Do not place restrictions on FPL when identifying HIP Plus members for analysis. • Provide context for interpretation of results.

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Overall issues, continued	Limitations of interrupted time series (ITS) and pre/post analyses	ITS involves estimating the impact of an intervention based on pre/post analyses of an outcome of interest based on a longitudinal measure of outcome. Use of this approach can be unsuitable to measure the impact of intervention in certain situations, including: • Intervention is introduced gradually or at multiple points in time, making it difficult to identify and quantify for pre/post measures. • Characteristics of the population with intervention changes across time. • Underlying trend is not linear; other factors are also impacting the population (e.g., simultaneous implementation of a different).	• Perform checks of population differences over time; consider matching or other appropriate methods to address observed differences. • Use regression analysis to control for potential confounders to the extent possible.
	Distinguishing the impacts of overlapping initiatives	Multiple policy changes have been implemented under the 2018 – 2020 renewal. As such, distinguishing the impacts of the individual initiatives becomes challenging. In addition to the HIP waiver policies, non-waiver operational items have overlapping impacts, for example: • Implementation of a new Medicaid Management Information System in 2017. • Updates to verification policies over time.	• Provide context for interpretation of results in the report, including the need for caution in interpreting and presenting results for take-up and continued enrollment in HIP.
Goal 1: Improve health care access, appropriate utilization, and health outcomes among HIP members	Variations in health care utilization based on time of enrollment	Members may experience higher utilization of service when first enrolled in Medicaid based on previously unmet health care needs. This higher utilization may make identification of trends in the use of preventative, primary, urgent and specialty care challenging.	• Use members continuously enrolled for at least one year to calculate the participation rate for each service type.

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Goal 2: Discourage tobacco use among HIP members, through a premium surcharge and the utilization of tobacco cessation benefits	Tobacco surcharge is only assessed on members who self-report tobacco use via defined channels	The tobacco surcharge determination relies on reporting of tobacco use by members during the MCE selection period, when changing MCEs, or if members otherwise voluntarily contact the MCE to report their tobacco use status. This underestimates the number of members who continue to use tobacco.	• Provide context for this issue in the Interim and Summative Evaluation Reports.
	Members may under-report tobacco use	Members may have an incentive to refrain from reporting tobacco use if they want to avoid the related premium surcharge increase.	• Provide context in the evaluation narrative for this issue.
	Medicaid encounter data may not fully reflect use of tobacco cessation services	Encounter data will not have codes for all tobacco cessation service since some programs will not be reimbursable by the provider.	• Ask questions about MCE tobacco cessation initiatives during key informant interviews with MCEs • Ask questions about cessation services received during member key informant interviews
Goal 3: Promote member understanding and increase compliance with payment requirements by changing the monthly POWER Account payment requirement to a tiered structure	Ability to use ACS data to identify Medicaid populations in other states that match Indiana's HIP program members subject to POWER Account payment policies	ACS data are limited in regards to excluding populations that are exempt from the HIP POWER Account non-payment penalty, specifically individuals who are: • Medically frail • Living in a domestic violence shelter • In a state-declared disaster area	• Include a description of limitations of the comparisons in the Summative Evaluation Report and potential impact on the interpretation of the results
	Variability in FPL amounts	Discussed as an overall methodological limitation above	• Refer to description above.

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Goal 4: Ensure that HIP policies promote a positive member experience for all HIP members	Distinguishing impact of retroactive eligibility waiver	• Due to the inclusivity of HIP coverage, there is no comparable in-state population that can be used to measure the impact of the retroactive eligibility waiver. HIP 2.0 has covered all non-disabled, low-income adults between 19 and 64 years old with household income at or below 138% of the FPL since 2015. During that same time period, only pregnant women and individuals with disabilities have retroactive coverage. • Medicaid programs across states can be very different in policies and implementation. Any differences in measures of interest when comparing with other states will likely not purely be due to the impact of the retroactive eligibility waiver and may include the impact of other policy differences. • Comparing program experience pre- and post-2015 will likely not capture impact of retroactive eligibility waiver due to the multiple program policies that have been implemented over time.	Provide context for interpretation of results in the Summative Evaluation Reports, including the need for caution in interpreting and presenting results for impact of retroactive eligibility waiver on member access to care, health status and medical debt.
Goal 5: Assess the costs to implement and operate HIP and other non-cost outcome of the demonstration	Expenditures and enrollment may be affected by factors other than eligibility and coverage policies	Neglecting to control for other factors such as changes in the economy, demographic shifts, individual market changes, or coverage changes in other Medicaid programs could result in mistakenly attributing their impact to that of the demonstration.	• Per Member Per Month (PMPM) expenditures will be normalized for changes in population mix • Additional variables will be considered in the difference-in-differences regression model to control for alternative factors • Model results and residuals will be iteratively examined to determine if other significant factors may have been omitted and can be added

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Goal 5, continued	Difficulty in controlling for factors related to the reporting of hospital uncompensated care	There are many factors that affect the reporting of hospital uncompensated care, including if HCRIS Worksheet S-10 is relied upon for payment purposes in the State (if not, hospitals may not report data fully), hospital reporting practices, state-specific Medicaid shortfalls, and the proportion of uninsured or underinsured individuals in a state.	• Control for the proportion of uninsured and underinsured individuals in the state • Include a discussion in the Summative Evaluation Report of the potential impact of aspects of hospitals' uncompensated care reporting that are not easy to measure • Evaluate if Worksheet S-10 data are used for payment purposes in the comparison states (which would suggest that they are more fully completed by hospitals)

E. Attachments

Attachment E.1. Summary of Independent Evaluator Approach

Due to the COVID-19 PHE issued in Indiana, and the impact of COVID-19 on the State's budget, an independent evaluator was not procured in time for the initial Evaluation Design submission. However, Indiana has selected an independent evaluator and is in the process of finalizing a contract. The State is committed to securing an independent evaluator in a timely fashion to work through iterations of this Plan with CMS. Indiana will ensure no conflicts of interest as stated in Section XVI, Paragraph 1 of CMS' STCs for this Waiver Evaluation.

To ensure an independent evaluation, the evaluation process will be independent of any process involving program policy-making, management, or activity of the waiver demonstration implementation. The State's responsibility towards an independent evaluation is the assurance of quality data to the evaluator, support in understanding program context of any data anomalies, and identifying the program components important for the evaluation.

CMS recommended inclusion of cost analysis to understand how the demonstration affected health care spending. Accordingly, analyses developed by the State's actuary, Milliman Inc., will be included for this portion of the evaluation.

Exhibit E.1: Organizational Conflict of Interest

Indiana Department of Administration
Healthy Indiana Plan 1115 Waiver Evaluation

Professional Services Contract #00000000000000000000029036

Organizational Conflict of Interest Disclosure

The Lewin Group, Inc. ("Lewin") is performing Professional Services Contract #00000000000000000000029036 entitled, "Health Indiana Plan 1115 Waiver Evaluation" ("Contract"), for the Indiana Department of Administration, Indiana Family and Social Services Administration ("FSSA").

In accordance with the Centers for Medicare and Medicaid ("CMS") Special Terms and Conditions ("STC") 11-W-00296/5 (as extended through December 31, 2030), Attachment A-Developing the Evaluation Design, Section F-Conflict of Interest, FSSA is required to assure CMS that it will obtain an Independent Evaluator which will "conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest." These types of COIs are normally referred to as Organizational Conflicts of Interest ("OCI"). Accordingly, what follows in this OCI disclosure ("Disclosure") is an explanation of why Lewin's performance as the HIP Evaluation Contractor under the Contract does not create an actual or potential OCI. This Disclosure is organized to describe; 1) Lewin's relevant corporate affiliates and, 2) Lewin's OCI analysis.

I. Lewin's Affiliate Interests

Lewin is part of UnitedHealth Group, Incorporated ("UHG"), a diversified health and well-being company dedicated to improving the health care system in the United States. UHG is organized into six businesses. Three of those businesses — UnitedHealthcare Community & State, UnitedHealthcare Medicare & Retirement and UnitedHealthcare Employer & Individual — provide network-based health care benefits and related services under the "UnitedHealthcare" brand. The other three businesses operate under the "Optum" brand and include OptumHealth, OptumRx, and OptumInsight. Amongst its services, the Optum businesses offer a large variety of services that include but are not limited to third party administration of specialty benefits, pharmacy benefit management, disease and care management, direct care delivery, consulting, health technology and innovation support to government agencies and external third party insurers and health plans as well as to UnitedHealthcare plans. Although UHG provides certain shared services across the enterprise, Optum and UnitedHealthcare operate as separate businesses with separate operational structures and separately reported financial results. For more information, please see www.unitedhealthgroup.com and www.optum.com.

In conducting a current OCI analysis, Lewin identified three (3) affiliated businesses relevant for discussion, and are as follows:

- *UnitedHealthcare Community and State ("UHC C&S"):* UHC C&S is one of the nation's largest health benefits companies dedicated to providing diversified solutions to states that care for the economically disadvantaged, the medically underserved and those without employer-funded health care coverage. C&S Managed Care Organizations ("MCOs") contract with networks of participating providers and facilities to serve more than 5 million beneficiaries covered under Medicaid (Title 19), CHIP (the Title 21, Children's Health Insurance Program), Dually Eligible (Medicaid-Medicare enrollees), Long Term Care and Children with Special Care Needs (a Title V Program) and other federal and state health care programs. UHC C&S is also a government programs Administrative Services Organization where it acts in the capacity of an administrator on a non-risk basis. C&S participates in Medicaid programs throughout the country. Presently, UHC C&S is not an MCO in the State of Indiana. However, UHC C&S is intending to bid on FSSA Request for Proposal RFP #22-68152 Risk-Based Managed Care Services for Medicaid Beneficiaries (Hoosier Healthwise and Healthy Indiana Plan Programs) (hereby referred to as the "RFP") for which proposals are due August 9, 2021.

- *MedExpress:* MedExpress, which is part of OptumHealth, includes primary and urgent care centers in multiple states that provide walk-in neighborhood care, wellness and prevention service. MedExpress

currently provides services to eligible Indiana Medicaid recipients in seven (7) locations throughout the State which include Anderson, Bloomington, Indianapolis, Kokomo, Lafayette, and Muncie.

- *OptumRx:* OptumRx is one of the three largest pharmacy benefit managers and specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. OptumRx provides full-service pharmacy benefits management services, including mail order and specialty pharmacy benefits, and a synchronized pharmacy care experience that combines member engagement with health data and analytics. Its additional services include claims processing, retail network contracting, rebate contracting and management, and clinical programs, such as step therapy, formulary management and disease/drug therapy management programs. OptumRx serves customers in multiple markets and government programs, including commercial, managed care, Medicaid, Medicare, labor and trust, workers compensation and others. OptumRx is presently under contract with FSSA to provide pharmacy benefit management services for the Indiana Health Coverage Program.

II. Lewin's OCI Analysis

For the purpose of this OCI Analysis, Lewin refers to the Federal Acquisition Regulation Part 9.5 which defines three types of conflicts. Upon review, Lewin is not aware of any facts or circumstances that would create an actual or potential OCI. To the extent that an OCI may be perceived to exist, Lewin will explain how the OCI is avoided, neutralized, or mitigated. These conclusions are based on the following:

A. Biased Ground Rules

A Biased Ground Rules OCI arises where a company, as part of its performance of a government contract, sets the ground rules for a later government procurement by, for example, writing the statement of work or the specifications. The primary concern is that the company could create an unfair competitive advantage by biasing the competition in favor of itself or its affiliate. Neither Lewin nor any of its affiliates developed or assisted FSSA in the procurement of the Contract. Accordingly, no Biased Ground Rules OCI exists.

B. Impaired Objectivity

An Impaired Objectivity OCI commonly occurs when a company's work under one government contract could require the company to evaluate the work that company itself or its affiliates performed under a separate government contract. The primary concern is that the company's ability to render impartial advice to the government could be impaired, where that advice involves the use of subjective judgment, and where the advice could affect the economic interests of the company as broadly construed.

Lewin has not identified any situation while performing work as the contracted Independent Evaluator under the Contract would create an actual or potential Impaired Objectivity OCI. Where it might be perceived that the risk of a potential OCI might exist, Lewin will explain why that perceived risk would not become an actual or potential OCI.

Lewin's OCI analysis determined that primary purpose of proposed evaluation is to determine the impact of HIP with regard to eligible Indiana Medicaid recipients and their access to health care services, utilization of those services, and health outcomes. Lewin's OCI analysis concluded that Optum's MedExpress and OptumRx affiliates do not present any risk of an Impaired Objectivity OCI in the conduct of this evaluation. Lewin also established that should its UHC C&S affiliate be awarded a future roles as a Managed Care Entity ("MCE") it might be perceived that Lewin would conduct the HIP evaluation in such a manner that could financially and/or contractually benefit UHC C&S. However, after conducting a thorough review of the facts surrounding the scope of Lewin's evaluation support to FSSA, it was determined that no such OCI risk would be created for the following reasons:

- *The Objective Focus of the Evaluation:* The evaluation of the HIP is to support FSSA's continuous effort to assure Indiana Medicaid recipients are receiving the best possible health care as defined by CMS' Triple Aim for better access to care, better health care outcomes, and reduced cost to beneficiaries. At no time during the course of the evaluation will Lewin be required to evaluate the performance of any HIP MCE including its UCH C&S affiliate as an awarded MCE under the RFP.

- *Lewin's Significant Limitations to Exercise Subjective Judgment:* Lewin will execute all evaluation tasks under an FSSA/CMS-approved evaluation design in accordance with evaluation guidance set forth in CMS STC 11-W-00296/5. Data for the evaluation data is collected from FSSA-directed sources to include statewide Medicaid member surveys, focus groups, key informant interviews, and prescribed data sets from the Indiana Medicaid Management Information System ("MMIS"). Data sets required by Lewin for analysis from state MCOs are provided to Lewin directly from state staff members. Any recommended changes to the evaluation design made by Lewin must go through a review by FSSA and its stakeholders and must be approved by CMS. Combined, these FSSA/CMS mandated requirements and parameters, significantly restricts Lewin from exercising subjective judgment. Furthermore, there is no nexus between the outcomes of Lewin's evaluation of this demonstration and the financial interests of Lewin or any of its affiliates providing healthcare services to Indiana Medicaid recipients. As such, no Impaired Objectivity OCI exists.

- *Transparency:* FSSA will have complete oversight of Lewin's in-progress work and through the review of required evaluation deliverables. Additionally, FSSA has final approval of all Lewin's work with CMS being the ultimate approver.

Given these facts and circumstances as they have been presented above, Lewin's ability to perform its HIP evaluation work will not create any risk of an actual or potential Impaired Objectivity OCI should UHC C&S serve FSSA as an MCE under the RFP.

C. Unequal Access to Information

An Unequal Access to Information OCI exists where a company has access to non-public information as part of its performance of a government contract and that information may provide the company with an unfair competitive advantage in a later competition for a government contract.

In the performance of the Contract, Lewin has access to non-public and confidential information such as claims and benefit data from Indiana MCOs. If this information was inadvertently accessed by Lewin's UHC C&S affiliate it could conceivably generate an unfair competitive advantage under the current RFP and future MCE bid opportunities. However, any such OCI concerns are unfounded because Lewin understands and complies with its obligation to handle non-public and confidential information in accordance with applicable laws, regulations, and contract requirements. As a result, in the regular course if its business, Lewin has implemented measures that would prospectively prevent any Unequal Access to Information OCI from occurring and that includes the following:

- *Information and Security Firewalls:* Lewin has established effective firewalls to prevent unauthorized use or disclosure of protected information and to guard against the risk of even inadvertent disclosure of such information. These firewalls provide an information disclosure barrier between Lewin and other business units and employees of UHG, including without limitation MedExpress, OptumRx, and UHC C&S. All protected program information in electronic form will be maintained on a secure, password-protected server that is dedicated to Lewin. Electronic documents or data files containing protected information area accessible only to Lewin employees on a need to know basis.

- *Separate Staffing:* The personnel that Lewin uses for the Contract are separate and distinct from the staff used by Lewin's MedExpress, OptumRx, and C&S affiliates. There is no overlap of staffing in this regard between the very separate businesses.

- *Information Security Policies and Procedures:* Lewin has implemented numerous policies and procedures regarding the way employees are to handle and disclose confidential information. This includes, a "need-to-know" policy, which provides that individual employees have access to the minimal amount of confidential information necessary to perform his or her work on the specific project to which the employee is assigned. Furthermore, Lewin employees are annually trained on the firewall and its policies and have a continuing obligation to report suspected violations of the policy, including any suspected violations of the

information firewall. This obligation is emphasized as part of their training on the enterprise Code of Conduct. The policy identifies the company hotline and other means through which they may make such a report (anonymously, if desired). Employees are advised that violations could result in consequences such as termination of employment.

- *Contract Requirements:* In accordance with Section 12 of the Contract (Confidentiality, Security and Privacy of Personal Information), Lewin is required to abide by HIPAA Rules as such Rules apply to Business Associates.

IV. Conclusion

For all the foregoing reasons, Lewin's continued performance of the Contract does not create an actual or potential OCI nor adversely affect or impact FSSA. Lewin understands that there is a continuing obligation to provide assurance to FSSA that no OCIs arise in the course of performing the work. In the event there is a change in facts that would give rise to an actual or significant, potential OCI, Lewin will promptly disclose the circumstances to FSSA, along with a mitigation plan, and Lewin will not proceed with performing the conflicted work until a mutually acceptable mitigation plan is in place.

Attachment E.2. Evaluation Budget

The budget for the Independent Evaluation from the awarded evaluator contract is included below. Since the State is bounded by three-year contracts, the evaluation budget includes costs through 2023 and does not account for costs for the entire waiver evaluation period. Oversight and support of this contract and provision of data to the evaluator on behalf of the state are considered to be encompassed in general program administrative costs and are not reported in this document. The State will leverage its existing contract with Milliman Inc. for the required cost analysis (Goal 5).

Exhibit E.2: Evaluation Budget-Total Costs

Deliverable / Payment Schedule	SFY 2021	SFY 2022	SFY 2023	SFY 2024	SFY 2025	Total
Task 1: Conduct Project Kick-off and Project Management and Status Meetings						
Subtotal	*$ 6,883*	*$ 6,874*	*$ 7,166*	*$ 25,668*	*$ 31,378*	**$ 77,969**
Task 2:Develop Draft and Final Evaluation Plan for DYs 2021-2030						
Subtotal	*$ 53,001*					**$ 53,001**
Task 3: Perform Key Informant Interviews for the 2021-2023 Interim Evaluation Report						
SFY 2024 (August/Sept of 2023				$ 127,619		$ 127,619
Subtotal		$ -	$ -	$ 127,619	$ -	**$ 127,619**
Task 4: Perform HIP Beneficiary Surveys for the 2021-2023 Interim Evaluation Report						
1st Longitudinal Survey		$ 5,464	$ 418,527			$ 423,992
2nd Longitudinal Survey and Two Leaver Surveys				$ 178,630		$ 178,630
Subtotal		*$ 5,464*	*$ 418,527*	*$ 178,630*	$ -	**$ 602,621**
Task 5: Develop Draft 2021-2023 Interim Evaluation Report						
Subtotal					*$ 725,688*	**$ 725,688**
Task 6: Incorporate CMS Feedback into 2021-2023 Interim Evaluation Report						
Final Interim Evaluation Report for CMS					$ 171,455	$ 171,455
Subtotal					*$ 171,455*	***$ 171,455***
Task 7: Support FSSA in Presenting the Team's Findings and Recommendations						
Subtotal					*$ 42,646*	***$ 42,646***
Task 8: Conduct Ad Hoc Analyses						
Ad Hoc Analyses		$ 76,199	$ 78,485	$ 161,680	$ 166,530	$ 482,895
Subtotal		*$ 76,199*	*$ 78,485*	*$ 161,680*	*$ 166,530*	***$ 482,895***
Total without Optional tasks 7 and 8	**$ 59,884**	**$ 12,338**	**$ 425,693**	**$ 331,917**	**$ 928,520**	**$ 1,758,353**
Total with Optional Tasks 7 and 8	**$ 59,884**	**$ 88,538**	**$ 504,179**	**$ 493,596**	**$ 1,137,697**	**$ 2,283,894**

Attachment E.3. Timeline and Major Milestones

Exhibit E.3: Timeline and Milestones

	State Fiscal Year	2021				2022				2023				2024				2025				2026
	Calendar year	2021				2022				2023				2024				2025				
Task / SubTask		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Task 1	**Conduct Project Kick-off and Project Management and Monitoring Activities**																					
1.1	Conduct project kick off meeting																					
1.2	Provide updated workplan																					
1.3	Conduct status meetings																					
1.4	Provide monthly progress reports	*Covered under base HIP contract*																				
Task 2	**Develop Draft and Final Evaluation Plan for DYs 2021-2030**																					
2.1	Develop draft 2021-2030 Evaluation Plan for FSSA review																					
2.2	Revise draft 2021-2030 Evaluation Plan based on FFSA review (for submission to CMS)																					
2.3	Revise draft 2021-2030 Evaluation Plan based on CMS feedback and provide final version for CMS approval																					
Task 3	**Perform Key Informant Interviews for the 2021-2023 Interim Evaluation Report**																					
3.1	Develop interview guides																					
3.2	Perform key informant interivews																					
3.3	Provide summaries of key informant interviews																					
Task 4	**Perform HIP Beneficiary Surveys for the 2021-2023 Interim Evaluation Report**																					
4.1	Submit member data request to draw survey samples																					
4.2	Develop survey guides																					
4.3	Conduct surveys																					
4.4	Summarize survey 2023 survey results																					
4.5	Summarize 2024 survey results as part of the draft Interim Report development																					
Task 5	**Develop Draft 2021-2023 Interim Evaluation Report**																					
5.1	Collect and prepare data for analysis																					
5.2	Conduct data analyses																					
5.3	Review results of data analytics with FSSA																					
5.4	Develop draft outline for FSSA review; incorporate feedback																					
5.5	Develop draft 2021-2023 Interim Evaluation Report for FSSA review																					
5.6	Provide revised draft 2021-2023 Interim Evaluation Report for public commnet																					
5.7	Provide revised draft 2021-2023 Interim Evaluation Report for submission to CMS																					
Task 6	**Incorporate CMS Feedback into 2021-2023 Interim Evaluation Report**																					
6.1	Develop revised 2021-2023 Interim Evaluation Report for FSSA review																					
6.2	Provide revised 2021-2023 Interim Evaluation Report for submission to CMS																					
Task 7	**Support FSSA in Presenting Findings and Recommendations**																					
7.1	Presentation #1																					
7.2	Presentation #2																					
Task 8	**Conduct Ad Hoc Analyses**																					
8.1	Conduct ad hoc analysis (1)																					
8.2	Conduct ad hoc analysis (1)																					
8.3	Conduct ad hoc analyses (2)																					
8.4	Conduct ad hoc analyses (2)																					

Attachment E.4. Variable Descriptions for ACS Data to be Used in this Evaluation

Exhibit E.4: American Community Survey Variable Descriptions[52]

Domain	Name	Variable	Description
Age	AGE	Age	Person's age in years as of the last birthday.
Children	CHBORN	Children Ever Born	Number of children ever born to each woman. Women report all live births by all fathers, whether or not the children were still living; they exclude stillbirths, adopted children, and stepchildren.
Citizenship	CITIZEN	Citizenship Status (U.S. Citizenship Status)	Citizenship status of respondents, distinguishing between naturalized citizens and non-citizens. Respondents were asked to select one of five categories: (1) born in the United States, (2) born in Puerto Rico, Guam, the U.S. Virgin Islands, or Northern Marianas, (3) born abroad of U.S. citizen parent or parents, (4) U.S. citizen by naturalization, or (5) not a U.S citizen. Respondents indicating they are a U.S. citizen by naturalization also are asked to print their year of naturalization.
Disability Status	DISABWRK	Disability Status	Per the Institute of Medicine (IOM) and the International Classification of Functioning, Disability, and Health (ICF), disability is defined as the product of interactions among individuals' bodies; their physical, emotional, and mental health; and the physical and social environment in which they live, work, or play. Disability exists where this results in limitations of activities and restrictions to full participation at school, at work, at home, or in the community
Education	EDUC	Educational Attainment	Indicates respondents' educational attainment, as measured by the highest year of school or degree completed. Note that completion differs from the highest year of school attendance; for example, respondents who attended 10th grade but did not finish were classified in EDUC as having completed 9th grade.
Education	SCHLTYPE	Type of School	Indicates whether respondents attending school were enrolled in a public or a private school.
Education	SCHOOL	Attending School	Indicates whether the respondent attended school at the time of interview in the past three months.
Education	GRADEATT	Level attending	Reports the grade or level of recent schooling for people who attended "regular school or college" at the time of interview in the past three months. "Regular school or college" includes only nursery school or preschool, kindergarten, elementary school, and schooling that leads to a high school diploma or a college/graduate degree.

[52] University of Minnesota. IPUMS USA Variables. Retrieved April 19, 2019 from https://www.usa.ipums.org/usa-action/variables

Domain	Name	Variable	Description
Health Coverage	HCOVANY	Any Health Insurance Coverage	Indicates whether the respondent had any health insurance coverage at the time of interview, including employer-provided insurance, privately purchased insurance, Medicare, Medicaid or other governmental insurance, TRICARE or other military care, or Veterans Administration-provided insurance.
Health Coverage	HINSCAID	Health Insurance through Medicaid	Indicates whether, at the time of interview, the respondent was covered by Medicaid, Medical Assistance, or any other kind of government-assistance plan for those with low incomes or a disability.
Health Coverage	HINSCARE	Health insurance through Medicare	Indicates whether, at the time of interview, the respondent was covered by Medicare.
Income	INCWAGE	Wage and salary income	Respondent's total pre-tax wage and salary income (e.g., money received as an employee) for the previous year. For the ACS and the Puerto Rican Community Survey (PRCS), the reference period was the past 12 months. Sources of income include wages, salaries, commissions, cash bonuses, tips, and other money income received from an employer. Payments-in-kind or reimbursements for business expenses are not included.
Income	INCSUPP	Supplementary Security income	Reports how much pre-tax income (if any) the respondent received from Supplemental Security Income (SSI) during the previous year. Amounts are expressed in contemporary dollars, and users studying change over time must adjust for inflation.
Income	INCSS	Social Security income	Reports how much pre-tax income (if any) the respondent received from Social Security pensions, survivors benefits, or permanent disability insurance, as well as U.S. government Railroad Retirement insurance payments, during the previous year. Amounts are expressed in contemporary dollars, and users studying change over time must adjust for inflation.
Income	HHINCOME	Income of Households	The total money income of all household members age 15 years old and over during the previous year. The amount should equal the sum of all household members' individual incomes, as recorded in the person-record variable INCTOT. The persons included were those present in the household at the time of the census or survey. People who lived in the household during the previous year but who were no longer present at census time are not included, and members who did not live in the household during the previous year but who had joined the household by the time of the census or survey, are included. Note that household income differs from family income. The family income variable only reports the incomes of household members related to the head, while HHINCOME includes the incomes of all household members.

Domain	Name	Variable	Description
Income	FTOTINC	Income of Families	The incomes of all members 15 years old and over related to the household head are summed and treated as a single amount. Although the family income statistics cover the past 12 months, the characteristics of individuals and the composition of families refer to the time of interview.
Income	INCTOT	Income of Individuals	Reports each respondent's total pre-tax personal income or losses from all sources for the previous year. The censuses collected information on income received from these sources during the previous CY; for the ACS and the PRCS, the reference period was the past 12 months. Amounts are expressed in contemporary dollars, and users studying change over time must adjust for inflation.
Income	INCWELFR	Pre-tax income from public assistance programs	Reports how much pre-tax income (if any) the respondent received during the previous year from various public assistance programs commonly referred to as "welfare." Assistance from private charities was not included. The censuses collected information on income received from these sources during the previous CY; for the ACS and the PRCS, the reference period was the past 12 months. The following are included within INCWELFR: • Federal/State SSI payments to elderly (age 65+), blind, or disabled persons with low incomes. (In the 2000 census, the ACS, and the PRCS, SSI payments are specified in INCSUPP only, not in INCWELFR); • Aid to Families with Dependent Children (AFDC); and • General Assistance (This does not include separate payments for hospital or other medical care).
Income	POVERTY	Poverty Status in the Past 12 Months	Each family's total income for the previous year as a percentage of the poverty thresholds established by the Social Security Administration in 1964 and subsequently revised in 1980, adjusted for inflation. Assigns all members of each family (not each household) the same code. Whether an individual falls below the official "poverty line" depends not only on total family income, but also on the size of the family, the number of people in the family who are children, and the age of the household head (under/over age 65).
Marital Status	MARST	Marital Status	Each individual’s marital status, including married, spouse present; married, spouse absent; separated; divorced; widowed; never married/single.

Domain	Name	Variable	Description
Race	RACE	Race	The racial categories included in the census questionnaire generally reflect a social definition of race recognized in this country and not an attempt to define race biologically, anthropologically, or genetically. Includes white, black/African American, American Indian or Alaskan Native, Chinese, Japanese, other Asian or Pacific Islander, other race, two major races, three or more major races.
Residence	MIGCITY1	Residence 1 Year Ago	For respondents who lived in a different residence one year before the survey date, identifies the city of residence at that time, if the prior residence was in an identifiable city. Cities are not directly identified in the source Integrated Public Use Microdata Series (IPUMS) files, so IPUMS bases MIGCITY1 coding on relationships between cities and the Migration Public Use Microdata Areas.
Sex	SEX	Sex	Either “male” or “female.”
Work Status	EMPSTAT	Work Status in the Past 12 Months	Whether the respondent was a part of the labor force (e.g., working or seeking work) and, if so, whether the person was currently unemployed.
Work Status	WKSWORK1	Weeks Worked in the Past 12 Months	The number of weeks that the respondent worked for profit, pay, or as an unpaid family worker during the previous year. Weeks of active service in the Armed Forces are also included.
Work Status	UHRSWORK	Usual Hours Worked Per Week Worked in the Past 12 Months	The usual hours worked per week worked in the past 12 months. This question was asked of people 16 years old and over who indicated that they worked during the past 12 months. The respondent was to report the number of hours worked per week in the majority of the weeks he or she worked in the past 12 months. If the hours worked per week varied considerably during the past 12 months, the respondent was to report an approximate average of the hours worked per week.
Work Status	CLASSWKR	Class of Worker	The type of ownership of the employing organization. These categories are: 1. An employee of a private for-profit company or business, or of an individual, for wages, salary, or commissions. 2. An employee of a private not-for-profit, tax-exempt, or charitable organization. 3. A local government employee (e.g., city, county). 4. A state government employee. 5. A Federal government employee. 6. Self-employed in own not incorporated business, professional practice, or farm. 7. Self-employed in own incorporated business, professional practice, or farm. 8. Working without pay in a family business or farm.

Domain	Name	Variable	Description
Work Status	IND	Industry	A 4-digit un-recoded variable reporting the work setting and economic sector, as opposed to the worker's specific technical function, or "occupation." Respondents unsure about this were to report the industry in which they spent the most time. For persons listing more than one industry, the samples use the first one listed. Persons not currently employed were to give their most recent industry.
Work Status	OCC	Occupation	The person's primary occupation, coded into a contemporary census classification scheme. Generally, the primary occupation is the one from which the person earns the most money; if respondents were not sure about this, they were to report the one at which they spent the most time. Unemployed persons were to give their most recent occupation. For persons listing more than one occupation, the samples use the first one listed.
Work Status	LABFORCE	Labor Force Status	Participation in the civilian labor force (e.g., working or seeking work) and, if so, whether the person was currently unemployed, or participation in the U.S. Armed Forces (i.e., people on active duty with the United States Army, Air Force, Navy, Marine Corps, or Coast Guard).

F. Analytic Tables

The reporting schedule and data source timeline included in the tables in this Section are related to the 2024 Interim Evaluation Report. The analysis plan for future intervention periods will be revisited and additional detail will be included for subsequent reporting.

Goal 1: Improve health care access, appropriate utilization, and health outcomes among HIP members

Due to COVID-19 PHE, starting March 2020, all new members were enrolled in HIP Plus benefit plan irrespective of income status and the State suspended any disenrollment. Additionally, due to COVID-19 PHE and requirement for social distancing, certain services were not accessible. Analysis of impact of HIP policies on access to care, utilization and health outcome will require careful consideration.

Exhibit F.1: Goal 1[53]

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.1 – Member use of preventive care, primary care, needed prescription drugs, chronic disease management care, and urgent care will be stable during the HIP demonstration period.	**Primary RQ 1.1—** How has the following changed over time for HIP members?[54] • Preventive, primary, urgent and specialty care • Prescription drug use • Chronic care management	Outcome measures will reflect utilization of the types of service during defined time frame as described in the research question and are anticipated to include for instance based on yearly utilization: • Proportion of members receiving qualifying preventive care services[55] • Proportion of members using primary care[56] • Proportion of members using specialty care[57] • Enrollment in disease management programs by MCE • Adherence to prescription drugs • Proportion of members with urgent care visits[58] • Proportion of members with ED visit	• Claims data (2015-2022) • Annual MCE reporting on enrollment in chronic disease management programs (2015-2022)	Descriptive quantitative analysis with subgroup analysis	n.a.	Interim Evaluation 2024

[53] For the evaluation, outcome measures will include the time frame component, for example, the proportion of members using primary care within a 6-month period or enrollment in disease management within 12 months. The exact definition of the measures will be included in the evaluation report.

[54] CMS' premium-related research question 2.2a (Are beneficiaries with accounts equally likely to receive preventive care, which does not draw down beneficiary accounts, compared to beneficiaries who do not have accounts?) is not included here because all HIP members (HIP Plus and HIP Basic) have accounts. As noted in the Evaluation Plan narrative, non-HIP members vary substantively from HIP members and comparing preventive care use between these two populations is problematic.

[55] The evaluator anticipates using the Center for Disease Control (CDC) list of preventive care procedures, identified by Current Procedural Terminology (CPT) codes and accompanying diagnosis.

[56] The evaluator anticipates identifying primary care office and ambulatory care visits using (1) primary care provider specialties and (2) evaluation and management (E&M) procedures, International Classification of Diseases (ICD)-9 and ICD-10 codes, and institutional revenue codes.

[57] The evaluator anticipates identifying these services using provider specialty.

[58] The evaluator anticipates identifying these services using the urgent care "Place of Service" code on the professional medical claim in addition to an accompanying ambulatory or outpatient procedure code, diagnosis code or revenue code from the HEDIS® value set directory for "Ambulatory Visits Value Set."

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.1, continued	**Primary RQ 1.1, continued**	Proportion of members: • Receiving breast cancer screening (BCS) • Receiving cervical cancer screening (CCS) • Receiving adult body mass index assessment (ABA) • Controlling high blood pressure (CBP) • Receiving comprehensive diabetes care hemoglobin A1c (HbA1c) testing (CDC) • On persistent medications that receive annual monitoring (MPM) • With an appropriate type of asthma medication (MMA)	HEDIS data as summarized by health plan in existing Indiana HEDIS reports (2015-2022)[59]	n.a.	n.a.	Interim Evaluation 2024
H.2 – Unnecessary ED services will not rise over time for HIP members.	**Primary RQ 2.1** – How have avoidable ED visits among HIP members changed over time?	Proportion of members with preventable/avoidable ED visits in a year[60]	Claims data (2015-2022)	Descriptive quantitative analysis; identification of visits based on the New York University (NYU) ED algorithm	n.a.	Interim Evaluation 2024
H.3 – HIP members will report positive health outcomes.	**Primary RQ 3.1 –** How has reported health status for HIP members changed over time?	Proportion of members reporting excellent/very good, good, or fair/ poor health	Longitudinal Member Survey and Leaver Survey (2023,2024)	Descriptive quantitative analysis across time	n.a.	Interim Evaluation 2024

[59] Indiana's 2018 HEDIS measures, for example, can be found online at: https://www.in.gov/fssa/ompp/5534.htm (accessed May 9, 2019).
[60] The evaluator anticipates using place of service and revenue code to identify ED visits.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.3, continued		Reported health status	BRFSS (2015 – 2022)[61]	Descriptive quantitative analysis Interrupted time series analysis of health status among likely eligible population in Indiana[62]	n.a.	Interim Evaluation 2024
				Findings from Goal 4, Primary RQ 4.3 difference-in-difference estimation of impact of HIP on member health status compared to Medicaid members in other states	Low-income adults (19-64) enrolled in/eligible for Medicaid in Indiana compared to similar adults during the same time period in states that provide retroactive coverage[63]	Interim Evaluation 2024

[61] BRFSS data does not allow for identification of individuals in the sample enrolled in Medicaid. Additionally, limited availability of fields in BRFSS will limit the ability to identify individuals that are potentially eligible for HIP (low-income (<138% FPL), non-disabled adults aged 19-64; medically frail, TMA participants, and low-income parents and caretakers). As such, analyses will reflect changes among the likely eligible population rather than changes among HIP enrolled members.

[62] The objective of the hypothesis and the research question is to assess impact of HIP policy on HIP member health status over time (not as compared to other states). As such, the primary analytic approach will use an interrupted time series to assess changes in HIP member health status over time.

[63] Goal 4 primary RQ 4.3 is "Do beneficiaries subject to the retroactive eligibility waiver have better health outcomes than other beneficiaries who have access to retroactive eligibility?" For purposes of this question, we plan to analyze the impact of HIP demonstration using a difference-in-difference estimation technique comparing reported health status of Medicaid covered members in Indiana during same period to states that provide retroactive coverage. HIP 2.0 demonstration included retroactive coverage

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.4 – HIP members will report satisfaction with health care access.	**Primary RQ 4.1** – What percentage of HIP members report getting health care as soon as needed?	Proportion of members reporting that they access care as soon as needed *Note: Survey length constraints will determine how many questions might be asked to determine access by type of service*	Member Survey (2023, 2024)	Descriptive quantitative analysis	n.a.	Interim Evaluation 2024
	Primary RQ 4.2 – To what extent do HIP members receive coverage through Fast Track and presumptive eligibility policies?	Proportion of members receiving coverage under Fast Track and presumptive eligibility policies, by ranges of months	Enrollment data (2017-2022)	Descriptive quantitative analysis by number of months	n.a.	Interim Evaluation 2024

waiver from its inception in 2015 (this evaluation is for demonstration period 2021-2030). It is to be noted that there is variance in Medicaid program policy, member composition and state healthcare systems and economies across states. Hence, differences in outcome measure using a difference-in-difference approach can be due to multiple reasons that might be inextricably linked. The details associated with the analytics will be included in Goal 4. The Goal 4 RQ 4.3 findings will be leveraged in conjunction with ITS analyses proposed for this research questions to provide a response to primary RQ3.1.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.5 – The Indiana Medicaid enrollment rate will be comparable to other Medicaid expansion states.	**Primary RQ 5.1** – How does the Indiana Medicaid coverage rate compare to other Medicaid expansion states?	Proportion of eligible population enrolled in Medicaid	IPUMS ACS data, variables HINSCAID, HCOVANY and HINSCARE (2012-2022)	Difference in differences regression model of eligible population enrolling in Medicaid	Low-income Indiana adults (19-64) enrolled in/eligible for Medicaid from 2016/2017 and 2019/2020 compared to similar adults enrolled in/eligible for Medicaid during the same time period in selected Medicaid expansion states (27) and selected states without a Medicaid expansion (17). The evaluator will assess use of the Medicaid-enrolled versus the Medicaid-eligible population prior to deciding which population to use.	Interim Evaluation 2024

Goal 2: Reduce tobacco use among HIP members, through a premium surcharge and the utilization of tobacco cessation benefits

As the State suspended all cost-sharing during the COVID-19 PHE (starting from March 2020), no surcharge will be collected during this time. The tobacco surcharge policy will be reestablished after COVID-19 PHE is lifted and all policies are reinstated. The ability to develop analysis for this goal will depend on the lift of the COVID-19 PHE and reinstatement of HIP policies.

Exhibit F.6: Goal 2[64]

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.1 – The tobacco premium surcharge will increase use of tobacco cessation services among HIP members.	**Primary RQ 1.1 –** What impact has the tobacco premium surcharge had on the use of tobacco cessation benefits for HIP members?	Proportion of members using tobacco cessation services by year	Longitudinal Member Survey (2023, 2024)	Descriptive quantitative analysis	n.a.	Interim Evaluation 2024
			Claims data (2015-2022)	ITS analysis of tobacco cessation services among likely eligible population in Indiana	n.a.[65]	Interim Evaluation 2024
	Subsidiary RQ 1.1a – Do HIP members understand the premium surcharge policy?	Themes related to member knowledge of surcharge	Key informant interviews with members (2021, 2024)	Descriptive qualitative analysis	n.a.	Interim Evaluation 2024
		Proportion of members who are tobacco users and report knowledge of the premium surcharge	Longitudinal Member Survey (2023, 2024)	Descriptive quantitative analysis on proportion of tobacco users reporting knowledge of premium surcharge.	n.a.	Interim Evaluation 2024

[64] For the evaluation, outcome measures will include time frame component, for example, the proportion of members using primary care within a 6-month period or enrollment in disease management within 12 months. The exact definition of the measures will be included in the Interim and Summative report.

[65] CMS's guidance outlined several possible within-state comparison groups, which are not possible for this evaluation due to specific aspects of Indiana HIP. HIP does not involve random assignment to the tobacco surcharge, and Indiana has not staged implementation based on beneficiary characteristics. For these reasons, this Evaluation Plan focuses on an interrupted time series analysis of outcomes within Indiana.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.1, continued	**Subsidiary RQ 1.1b** – Do HIP members know about the cessation services offered through HIP?	Themes related to member knowledge of cessation services offered through HIP	Key informant interviews with members (2021, 2024)	Descriptive qualitative analysis	n.a.	Interim Evaluation 2024
		Proportion of members who are tobacco users and report knowledge of cessation services offered through HIP	Longitudinal Member Survey (2023, 2024)	Descriptive quantitative analysis	n.a.	Interim Evaluation 2024
	Subsidiary RQ 1.1c – Are HIP members satisfied with tobacco cessation services?	Themes related to satisfaction with tobacco cessation services	Key informant interviews with members, providers, MCEs and State officials (2021, 2024)	Descriptive qualitative analysis	n.a.	Interim Evaluation 2024
		Themes related to reasons for nonparticipation in cessation services	Key informant interviews with members, providers, MCEs, and State officials (2021, 2024)	Descriptive qualitative analysis	n.a.	Interim Evaluation 2024

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.2 – The tobacco premium surcharge and availability of tobacco cessation benefits will decrease tobacco use.	**Primary RQ 2.1 –** Has tobacco use decreased among the target population?	Proportion of members using tobacco by year	• Longitudinal Member Survey (2023, 2024) • State administrative data (2018-2022)	Quantitative descriptive analyses of proportion of respondents identifying as using tobacco across time. *Note: Analyses based on member survey data will provide a point in time estimate. Analyses of use across time will be based on State administrative data.*	n.a.	Interim Evaluation 2024

Goal 3: Promote member understanding and increase compliance with payment requirements by changing the monthly POWER Account payment requirement to a tiered structure

Members enrolled in HIP Basic prior to COVID-19 PHE could change to Plus. All new members were enrolled in HIP Plus irrespective of income status during COVID-19 PHE and members were not allowed to change to Basic. Additionally, the State suspended all cost-sharing during the COVID-19 PHE and thereby disenrollment due to non-payment of POWER Account Contribution. As no contribution was collected and other HIP policies were suspended, there will also be limited rollovers during the COVID-19 PHE. Starting from January 2021, the State suspended the six-month non-eligibility criterion pending resolution of the stay in the federal lawsuit and in compliance with the newly approved waiver terms and conditions.[66] Ability to analyze the research questions will depend on timing of reinstatement of HIP policies.

Exhibit F.7: Goal 3[67,68,69]

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.1 – HIP's new income tier structure for POWER Account Contributions	**Primary RQ 1.1 –** Do HIP members with POWER account payment requirements understand their payment obligations?[71]	Themes regarding member understanding of payment obligations	Key informant interviews with members, providers, MCEs, and State officials (2021, 2024)	Descriptive qualitative analysis	n.a.	Interim Evaluation 2024

[66] Waiver 4 (related to eligibility) in HIP STC. Accessible from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/in-healthy-indiana-plan-support-20-ca-01012021.pdf

[67] To evaluate HIP's new tiered POWER account payment structure, CMS's evaluation guidance for premium and account payments has been consulted. Some of CMS's hypotheses and research questions within this guidance have been excluded or reworded because they pertain to impact of premium accounts in general and not to Indiana's new tiered structure, which involves multiple payment amounts. CMS items that have been excluded for this reason are research questions 3.1 and 3.2. Items that have been retained but reworded are noted in this document.

[68] For the purposes of this goal, Indiana has operationalized efficient use of health care services as continuity in coverage. For this reason, Hypothesis 2 and affiliated research questions from CMS's guidance is not included. However, Indiana's Goal 1 includes an analysis of health care utilization under the HIP program.

[69] For the evaluation, outcome measures will include time frame component, for example, the proportion of members using primary care within a 6-month period or enrollment in disease management within 12 months. The exact definition of the measures will be included in the Interim and Summative report.

[71] CMS's research question 1.1 ("Do beneficiaries with premium or beneficiary account payment requirements understand their payment obligations?") has been reworded slightly to reflect the Indiana policy.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
will be clear to HIP members.[70]	*Note: Goal 4, H.1, RQ 1.2 also addresses this question.*	Proportion of members who are knowledgeable of payment obligations	Longitudinal Member Survey (2023, 2024)	Descriptive quantitative analysis	n.a.	Interim Evaluation 2024
H.1, continued	**Subsidiary RQ 1.1a** – Do HIP members that are subject to POWER Account payment requirements have different disenrollment compared to other HIP members?	Proportion of members who disenroll overall, and by: • Plan type (Basic versus Plus) • Under and over 100% of the FPL for HIP Plus members • HIP Plus with and without medically frail status	Enrollment data (2015-2022)	Descriptive quantitative analyses across time for disenrollment overall and by relevant reason codes, and by: • Plan type • Under and over 100% of the FPL for HIP Plus members • HIP Plus with and without medically frail status Interrupted time series analyses of disenrollment pre- and post-2021 – evaluator will develop approach based on results of descriptive analyses.	n.a.	Interim Evaluation 2024

[70] This hypothesis differs from Hypothesis 1 in CMS's evaluation guidance for premiums and account payments, which states "Beneficiaries who are required to make premium payments, including beneficiary account contributions, will gain familiarity with a common feature of commercial health insurance." This change more closely aligns the hypothesis with Indiana's stated goal and with the research questions included to address this hypothesis.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.1, continued	**Primary RQ 1.2 –** Do HIP members with POWER account payment requirements who initiate payments continue to make regular payments throughout their 12-month enrollment period?[72]	• Proportion of members with payment obligations who make a contribution before end of grace period by year • Proportion of members with payment obligations who are disenrolled due to non-payment by year[73] • Proportion of members that moved from HIP Plus to HIP Basic due to nonpayment by year	Enrollment data (2015-2022)	Descriptive quantitative analysis	n.a.	Interim Evaluation 2024

[72] CMS's research question 1.2 ("Do beneficiaries with premium or beneficiary account obligations who initiate payments continue to make regular payments throughout their 12-month enrollment periods?") has been reworded slightly to reflect the Indiana policy.

[73] Disenrollment reason 001 is "Nonpayment of Initial POWER Account Contribution (PAC) (i.e., never fully enrolled in HIP Plus)." Disenrollment reason 002 is "Nonpayment of PAC (i.e., disenrolled from HIP Plus WITH 6-month lockout)." Disenrollment reason 003 is "Increased Income + Nonpayment of PAC (i.e., disenrolled from HIP Basic WITHOUT 6-month lockout).

Exhibit F.8: Goal 3, Hypothesis 2[74]

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.2 – Enrollment and enrollment continuity will vary for the POWER Account payment tiers.[75]	**Primary RQ 2.1 –** Is there a relationship between POWER Account payment tiers and total and new enrollment in Medicaid?[76]	Reported enrollment in Medicaid among the likely eligible population (take-up)	IPUMS ACS, variable HINSCAID (2015-2022)	Descriptive analysis by income level[77]	n.a.	Interim Evaluation 2024
			IPUMS ACS, variable HINSCAID (2015-2022)[78]	Interrupted time series analyses of enrollment pre and post 2018[79]	n.a.[80]	Interim Evaluation 2024
		• Number of individuals enrolled in Medicaid annually • Number of new enrollees in Medicaid annually	Enrollment data (2015-2022)	Descriptive analysis of enrollment	n.a.	Interim Evaluation 2019 Interim Evaluation 2024

[74] For the evaluation, outcome measures will include time frame component, for example, the proportion of members using primary care within a 6-month period or enrollment in disease management within 12 months. The exact definition of the measures will be included in the Interim and Summative report.

[75] This hypothesis in the CMS guidance was phrased "Premium requirements, including beneficiary account contributions, will reduce the likelihood of enrollment and enrollment continuity." This hypothesis has been revised to focus on the new POWER account tiered structure. In addition, multiple program changes have occurred along with the implementation of the tiered structure and there are limitations in the ability to attribute impact to the change in beneficiary account payment amount.

[76] This question is research question 3.3 in the CMS guidance for premiums and account payments. It has been reworded slightly to reflect the Indiana policy.

[77] Initial analyses of the data indicate sufficient sample size by income level within Indiana.

[78] This analysis will leverage data from 2015 to 2020 for Medicaid uptake. Enrollment in 2019 and onwards can be impacted by other policy changes that have taken/will take effect in 2019 and 2020. Enrollment in 2020 may also be affected by the COVID-19 PHE.

[79] Evaluator will explore the appropriateness of the model based on the ability to control for differences in beneficiary characteristics between the two years. If resources permit, the evaluator will also explore the combined use of ACS and enrollment data to examine take-up rate on a monthly basis using a regression discontinuity design to examine results at different tier cutoffs in income.

[80] CMS's guidance outlined several possible within-state comparison groups, which are not possible for this evaluation due to specific aspects of Indiana HIP. Indiana has not staged implementation of the tiered payment structure based on beneficiary characteristics. For this reason, this Evaluation Plan focuses on alternative analyses of outcomes within Indiana.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.2, continued	**Primary RQ 2.2 –** Is there a relationship between POWER Account payment tiers and continued enrollment in Medicaid?[81]	Probability of disenrollment due to non-payment[82]	Enrollment data (2015-2022)	Descriptive quantitative analysis of disenrollment	n.a.	Interim Evaluation 2024
			Enrollment data (2015-2022)[83]	Regression model of outcome controlling for enrollment year[84]	n.a.[85]	Interim Evaluation 2024
		Probability of moving from HIP Plus to Basic	Enrollment data (2015-2022)	Descriptive analysis of movement to Basic	n.a.	Interim Evaluation 2024
			Enrollment data (2015-2022)[86]	Regression model of outcome controlling for enrollment year[87]	n.a.[88]	Interim Evaluation 2024

81 This question is research question 3.4 in the CMS guidance for premiums and account payments: "Is there a relationship between payment amounts and continued enrollment in Medicaid, as reflected by mid-year disenrollments and renewal decisions?" It has been reworded to reflect the Indiana policy and the outcomes identified.

82 Disenrollment reason 001 is "Nonpayment of Initial PAC (i.e., never fully enrolled in HIP Plus)." Disenrollment reason 002 is "Nonpayment of PAC (i.e., disenrolled from HIP Plus WITH 6-month lockout)." Disenrollment reason 003 is "Increased Income + Nonpayment of PAC (i.e., disenrolled from HIP Basic WITHOUT 6-month lockout).

83 This analysis will leverage available data (2015 – 2022) to account for the trend in disenrollment across time, even prior to 2018 implementation of POWER Account tiered payment, due to other policy or program changes.

84 Prior to implementing these analyses, comparability in samples between the two periods will be assessed. Evaluator will explore the appropriateness of the model based on the ability to control for differences in beneficiary characteristics between the two years.

85 CMS's guidance outlined several possible within-state comparison groups, which are not possible for this evaluation due to specific aspects of Indiana HIP. Indiana has not staged implementation of the tiered payment structure based on beneficiary characteristics. For this reason, this Evaluation Plan focuses on alternative analyses of outcomes within Indiana.

86 This analysis will leverage available data (2015 – 2022) to account for trend in disenrollment across time, even prior to 2018 implementation of POWER Account tiered payment, due to other policy or program changes.

87 Prior to implementing these analyses, the evaluator will assess comparability in samples between the two periods. Evaluator will explore the appropriateness of the model based on the ability to control for differences in beneficiary characteristics between the two years.

88 CMS's guidance outlined several possible within-state comparison groups, which are not possible for this evaluation due to specific aspects of Indiana HIP. Indiana has not staged implementation of the tiered payment structure based on beneficiary characteristics. For this reason, this Evaluation Plan focuses on alternative analyses of outcomes within Indiana.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.2, continued	**Primary RQ 2.2, continued**	Probability of moving from HIP Basic to Plus	Enrollment data (2015-2022)	Descriptive analysis of movement to Plus	n.a.	Interim Evaluation 2024
			Enrollment data (2015-2022)[89]	Regression model of outcome controlling for enrollment year[90]	n.a.[91]	Interim Evaluation 2024
		Number of months with Medicaid coverage during year	Enrollment data (2015-2022)	Descriptive analysis of coverage months	n.a.	Interim Evaluation 2024
			Enrollment data (2015-2022)[92]	Regression model of outcome controlling for enrollment year[93]	n.a.[94]	Interim Evaluation 2024
	Primary RQ 2.3 – Do HIP members who receive rollover have greater coverage continuity than HIP members who do not receive rollover?[95]	• Number of months with Medicaid coverage • Probability of disenrollment	Enrollment data (2018-2022)	Regression model of outcomes controlling for enrollment year	Members who do not receive rollover	Interim Evaluation 2024

89 This analysis will leverage available data (2015 – 2020) to account for trend in disenrollment across time, even prior to 2018 implementation of POWER Account tiered payment, due to other policy or program changes.

90 Prior to implementing these analyses, the evaluator will assess comparability in samples between the two periods. Evaluator will explore the appropriateness of the model based on the ability to control for differences in beneficiary characteristics between the two years.

91 CMS's guidance outlined several possible within-state comparison groups, which are not possible for this evaluation due to specific aspects of Indiana HIP. Indiana has not staged implementation of the tiered payment structure based on beneficiary characteristics. For this reason, this Evaluation Plan focuses on alternative analyses of outcomes within Indiana.

92 This analysis will leverage available data (2015 – 2020) to account for trend in disenrollment across time, even prior to 2018 implementation of POWER Account tiered payment, due to other policy or program changes.

93 Prior to implementing these analyses, the evaluator will assess comparability in samples between the two periods. The evaluator will explore the appropriateness of the model based on the ability to control for differences in beneficiary characteristics between the two years.

94 CMS's guidance outlined several possible within-state comparison groups, which are not possible for this evaluation due to specific aspects of Indiana HIP. Indiana has not staged implementation of the tiered payment structure based on beneficiary characteristics. For this reason, this Evaluation Plan focuses on alternative analyses of outcomes within Indiana.

95 This is a state-specific question that is not included in CMS guidance.

Goal 4: Ensure HIP program policies align with commercial policies, are understood by members, and promote positive member experience and minimize coverage gaps

Starting from January 2021, the State suspended the six-month non-eligibility criterion pending resolution of the stay in the federal lawsuit and in compliance with the newly approved waiver terms and conditions.[96] Members will not be "locked" out for non-payment of POWER Account Contribution. Research questions related to non-eligibility will be addressed and analyzed only if State reinstates the policy (pending decision on lawsuit). Additionally, as HIP policies were turned off during COVID-19 PHE (starting March 2020), ability to analyze for the research questions related to member knowledge on HIP policies on POWER Account Contribution, preventive care, rollover will depend on timing of reinstatement of HIP policies.

[96] Waiver 4 (related to eligibility) in HIP STC. Accessible from https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/in-healthy-indiana-plan-support-20-ca-01012021.pdf

Exhibit F.9: Goal 4[97,98]

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.1 – Beneficiaries subject to HIP policies will understand program policies.[99]	**Primary RQ 1.1 –** Are HIP members knowledgeable about policies on payment of POWER Account Contributions, preventive care and rollover?[100]	Proportion of members who are knowledgeable about HIP policies related to payment of POWER Account Contributions Themes related to knowledge of POWER Account Contributions, preventive care and rollover	• Longitudinal Member Survey (2023, 2024) • Program administrative data (2017-2022) • Key informant interview with members (2021, 2024)	Descriptive quantitative and qualitative analysis (depending on data source)	n.a.	Interim Evaluation 2024
	Primary RQ 1.2 – Do HIP members subject to non-eligibility periods understand program requirements and how to comply with them? *Note: Goal 3, H.1, RQ 1.1 also addresses this question.*	Reported knowledge of program requirements and how to comply with them	• Key informant interview with members (2021, 2024) • Longitudinal Member Survey (2023, 2024)	Descriptive quantitative and qualitative analysis (depending on data source)	n.a.	Interim Evaluation 2024

97 Indiana does not have specific goals regarding non-eligibility periods. Furthermore, due to budget constraints and concerns about beneficiary burden, the member survey planned for the evaluation is limited in size, and Indiana has prioritized other topics for this survey. However, for Indiana's Goal 4, CMS' evaluation guidance for non-eligibility periods was reviewed and this Evaluation Plan includes research questions that are applicable to the State's goal that fall within the evaluation scope. Specifically, CMS questions related to beneficiary understanding of and experiences with these policies have been included. The hypotheses and research questions from CMS guidance that have been omitted are Hypothesis 1 (1.1, 1.1c), Hypothesis 2 (2.1, 2.1a-2.1d), and Hypothesis 3 (3.1, 3.1a, 3.1b).

98 For the evaluation, outcome measures will include time frame component, for example, the proportion of members using primary care within a 6-month period or enrollment in disease management within 12 months. The exact definition of the measures will be included in the Interim and Summative report.

99 This is a state-specific hypothesis. The research questions included here focus on non-eligibility periods. Goals 2 and 3 address member understanding of and experiences with policies related to the tobacco surcharge and POWER accounts.

100 This question takes the place of CMS' premium-related subsidiary research question 2.2b (Do beneficiaries with monthly account payments understand what services result in debits from their accounts and how their service use impacts account balances?).

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.1, continued	**Primary RQ 1.3 –** Do HIP members subject to non-eligibility periods understand the consequence for noncompliance with program requirements?	Reported knowledge of non-eligibility period consequence for noncompliance with program requirements	• Key informant interview with members (2021, 2024) • Longitudinal Member Survey (2023, 2024)	Descriptive quantitative and qualitative analysis (depending on data source)	n.a.	Interim Evaluation 2024
	Primary RQ 1.4 – What are common barriers to compliance with program requirements that have non-eligibility period consequences for noncompliance?	Reported barriers to complying with program requirements	• Key informant interview with members, MCE and FSSA officials interviews (2021, 2024)	Descriptive qualitative analysis	n.a.	Interim Evaluation 2024
H.2 – Beneficiaries will be satisfied with the HIP program.[101]	**Primary RQ 2.1 –** What is the level of satisfaction with HIP among HIP members?[102]	Themes related to member satisfaction	• Key informant interview with members, provider, MCE and FSSA officials interviews (2021, 2024)	Descriptive qualitative analysis	n.a.	Interim Evaluation 2024

[101] This is a State-specific hypothesis.
[102] This is a State-specific question.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.2, continued		• Proportion of members having high satisfaction with the program • Proportion of members considering HIP a good value relative to its costs	• Longitudinal Member Survey (2023, 2024) • All Leaver Surveys (Non-payment of POWER Account Contribution, income) (2024)	Descriptive quantitative analysis	n.a.	Interim Evaluation 2024
H.3 – Individuals subject to the non-eligibility/lockout periods (payment and redetermination) and retroactive eligibility are no different from commercial market populations.[103]	**Primary RQ 3.1** – Do HIP members that are subject to non-eligibility periods have similar demographic characteristics as the commercial market population?	Distribution of demographic characteristics by year such as the following: • Gender • Age • Educational level • Income • Race and ethnicity	IPUMS ACS data, variables SEX, AGE, EDUC, INCTOT, RACE, and HISPAN (2015-2022) Program administrative data (2015-2022)	Descriptive quantitative analysis	Adults ≤138% FPL enrolled in commercial coverage (2015-2022)	Interim Evaluation 2024
	Primary RQ 3.2 – Do HIP members that are not retroactively eligible have similar demographic characteristics as the commercial market population?	Distribution of demographic characteristics by year such as the following: • Gender • Age • Educational level • Income • Race and ethnicity	IPUMS ACS data, variables SEX, AGE, EDUC, INCTOT, RACE, HISPAN (2015-2022) Program administrative data (2015-2022)	Descriptive quantitative analysis	Adults ≤138% FPL enrolled in commercial coverage (2015-2022)	Interim Evaluation 2024

[103] This hypothesis pertains to three distinct HIP populations: 1) members subject to non-payment eligibility periods, 2) members subject to redetermination non-eligibility periods, and 3) individuals who do not receive retroactive eligibility.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.4 – Eliminating or reducing retroactive eligibility will not reduce member enrollment or access to health care; decrease health status; or have adverse financial impact	**Primary RQ 4.1** – Do eligible people subject to retroactive eligibility waivers enroll in Medicaid at the same rates as other eligible people who have access to retroactive eligibility? (CMS Guidance Hypothesis 1, RQ 1.1)	Proportion of eligible population enrolled in Medicaid	IPUMS ACS data, variables HINSCAID, HCOVANY and HINSCARE (2012-2022)	Regression model of eligible population enrolling in Medicaid (IN and other selected states with expansion)	Low-income adults (19-64) enrolled in/eligible for Medicaid in Indiana compared to similar adults during the same time period in selected Medicaid expansion states that provide retroactive coverage[104]	Interim Evaluation 2024
	Primary RQ 4.2 – Do beneficiaries subject to the retroactive eligibility waiver understand that they will not be covered during enrollment gaps? (CMS Guidance Hypothesis 1, Subsidiary RQ 1.2a)	Reported knowledge of consequence due to coverage gaps for not renewing in a timely manner	Longitudinal Member Survey (2023, 2024)	Descriptive quantitative analysis	n.a.	Interim Evaluation 2024

[104] Indiana has retroactive waiver from 2015. Only pregnant women and individuals with disability have retroactive coverage. Hence, there are no comparable beneficiary group for Indiana HIP, given how inclusive eligibility is for this program. Comparing program experience pre- and post-2015 will likely not capture impact of retroactive eligibility waiver as multiple changes were implemented in Medicaid coverage for HIP 2.0.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.4, continued	**Subsidiary RQ 4.2a** – What are common barriers to timely renewal for those subject to the retroactive eligibility waiver? (CMS Guidance Hypothesis 1, Subsidiary RQ 1.2b)	Reported barriers to timely renewal	Key informant interview with members, provider, MCE and FSSA officials interviews (2021, 2024)	Qualitative descriptive analysis	n.a.	Interim Evaluation 2024
	Primary RQ 4.3 – Do beneficiaries subject to the retroactive eligibility waiver have better health outcomes than other beneficiaries who have access to retroactive eligibility? (CMS Guidance Hypothesis 3, RQ 3.1)	Reported health status	BRFSS (2013 – 2022)[Error! Bookmark not defined.] Variable GENHLTH	Difference-in-differences regression model of self-reported health status/healthy days among the likely eligible population[105]	Low-income adults (19-64) enrolled in/eligible for Medicaid in Indiana compared to similar adults during the same time period in states that provide retroactive coverage	Interim Evaluation 2024

[105] Differences in outcome measure between low-income adults (19-64) enrolled in/eligible for Medicaid in Indiana compared to similar adults during the same time period in states that provide retroactive coverage can be due to multiple reasons including differences in Medicaid coverage policies across states (including retroactive waiver).

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.4, continued	**Primary RQ 4.4** – Does the retroactive eligibility waiver lead to changes in the incidence of beneficiary medical debt? (CMS Guidance Hypothesis 4, RQ 4.1)	Reported medical debt (medical bills)	BRFSS (2013 – 2022)[Error! Bookmark not defined.], variable MEDBILL1	Difference-in-differences regression model of medical debt among the likely eligible population[105]	Low-income adults (19-64) enrolled in/eligible for Medicaid in Indiana compared to similar adults during the same time period in states that provide retroactive coverage	Interim Evaluation 2024

Goal 5: Assess the costs to implement and operate HIP and other non-cost outcomes of the demonstration

Exhibit F.10: Goal 5[106]

Note: In order to reduce the duplication of efforts, and thus cost, Goal 5 analyses will be completed by Indiana's actuary, Milliman, Inc., and appended to the Interim Evaluation Report. The results where relevant will be incorporated into overall evaluation analysis, as appropriate.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
n.a.	**Primary RQ 1 –** What are the administrative costs incurred by the State to implement and operate the HIP demonstration?	• Annual administrative costs to implement and operate the demonstration • Contracts or contract amendments to implement, monitor, and evaluate demonstration policies • Annual staff time equivalents needed to implement, administer, and communicate with members about demonstration policies • Annual Medicaid agency staff time for those hired to support the demonstration, and time redirected from other Medicaid operations • Identified costs or cost savings accruing to other state agencies that partner with Medicaid (i.e., increased state spending for job readiness programs	State administrative records for 2018-2022	Descriptive analysis of administrative costs	n.a.	Interim Evaluation 2024

[106] For the evaluation, outcome measures will include time frame component, for example, the proportion of members using primary care within a 6-month period or enrollment in disease management within 12 months. The exact definition of the measures will be included in the interim and Summative report.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
n.a.	**Primary RQ 2 –** What are the short- and long-term effects of eligibility and coverage policies on Medicaid health care expenditures?	• Total annual health service expenditures for demonstration population • Change in annual PMPM health service expenditures	CY 2016-2022 Medicaid funded-health care expenditures (in total and PMPM): • All HIP members • Expansion members only • Basic members • Plus members New adult group enrollment from the Medicaid Budget and Expenditure System (MBES) and expenditures from Transformed Medicaid Statistical Information System (T-MSIS) Medicaid Analytic Extracts (MAX)—pending CMS approval for research • Indiana, Ohio, and Kentucky (two comparable states)	• Difference-in-differences regression model of total service expenditures • Difference-in-differences regression model of PMPM service expenditures	Compare health service expenditures for the demonstration population to health service expenditures for a similar population in two comparison states (total and PMPM)	Interim Evaluation 2024

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
n.a.	**Primary RQ 3 –** What are the impacts of eligibility and coverage policies on provider uncompensated care costs?	Change in total uncompensated care costs annually	HCRIS data: • Worksheet S-10, line 31 • 2013-2014 (before HIP 2.0) vs 2018-2022 • Indiana, Ohio, and Kentucky (two comparable states) and South Carolina (non-expansion "control" state)	Difference-in-differences regression model of uncompensated care costs	Two comparable states that have similar Medicaid eligibility criteria but do not operate a similar demonstration	Interim Evaluation 2024

G. Goal Six – Workforce Bridge Account Evaluation Questions, Hypotheses, and Analytic Tables

G. Goal Six – Workforce Bridge Account Evaluation Questions, Hypotheses, and Analytic Tables

Workforce Bridge Account Background Information

Workforce Bridge Accounts (WBA) will become effective once the COVID-19 PHE restrictions are lifted. To receive a WBA, eligible individuals will be informed that they have access to financial resources, in an amount no greater than $1,000, to temporarily pay for health insurance premiums and cost-sharing, or for the direct costs of prescription drugs and services otherwise covered under Section 1905(a) of the Social Security Act. This assistance is expected to act as a bridge to commercial insurance coverage. While individuals would be made aware that this resource would be available to them if they took steps to raise their income enough to lose Medicaid eligibility, the accounts would only be activated when an individual is no longer Medicaid eligible. Individuals who recently disenrolled for failure to meet conditions of eligibility, such as payment of premiums, will not qualify.

This program will be available to eligible individuals based on the availability of State funding. Members eligible for WBA, once notified, must opt-in to the WBA program. To opt-in, the eligible individual must acknowledge an interest in participating by phone or mail to the state. Individuals will have 30 days once notified to opt-in to the account. As part of this 30-day opt-in process, individuals will have the opportunity for referral to a "health care navigator" who will inform individuals about their health care options and provide choice counseling. Once individuals opt-in, the amount associated with the WBA will be available for 12 months or until the full amount has been expended, whichever comes first. Individuals can only use the account for premiums, cost-sharing, or the direct cost of services received within 12 months. Once the 12 months is finished, individuals will not be able to access the WBA. Reimbursement for health insurance premiums will be paid to the individual or at the request of the individual enrolled in a Marketplace health plan, the State will pay for the premiums directly on behalf of the individual to the health plan. In addition, beneficiaries of this program will receive an insurance card that will contain information for providers on how to submit a claim to the WBA for reimbursement of cost-sharing linked to the enrollees primary insurance or direct billing for enrollees who have not yet completed enrollment in primary insurance coverage. The funds available through the WBA can also be used for the direct payment of Medicaid-covered Section 1905(a) services that would otherwise be available to Medicaid beneficiaries. To receive reimbursement for these services, the services must be rendered by a Medicaid enrolled provider.

Population Groups Impacted by the Demonstration

To gain eligibility for the WBA, an individual (1) must be fully enrolled in HIP[107] and (2) would otherwise be eligible for HIP except for the increase in income. For example, an individual that lost coverage due to being over income and moving out of state would not be eligible for the WBA, since they no longer meet the HIP eligibility criteria due to state residency. Multiple individuals in the same household, who meet the eligibility requirements, will have access to their own account. These qualified individuals will be notified of their eligibility and opt-in opportunity consecutive with their notice of disenrollment. Accounts may be closed if an individual moves out of state, voluntarily withdraws, ages out, becomes incarcerated, enrolls in Medicare, or regains Medicaid or Presumptive Medicaid eligibility. Eligibility for the WBA program is for one 12-month period and is not eligible for renewal. After lifting the COVID-19

[107] Members conditionally eligible or presumptively eligible for HIP benefits will not qualify for the HIP WBA benefit, nor will individuals that are only eligible for emergency services.

PHE and policies are reinstated, the State anticipates a surge in WBA enrollment due to income disenrollment.

Exhibit G.1: Eligibility Groups Included in the WBA Amendment of the End-Stage Renal Disease (ESRD) Demonstration

Eligibility Group Name	FPL Level and/or other qualifying criteria
WBA	1902(a)(10)(A)(ii)(VII) 42 CFR §435.218

WBA Evaluation Questions and Hypotheses

Goal 6 – WBA will support HIP members transitioning to commercial with continuity of coverage, reduce benefit cliff, and churn

The WBA program is included in the Section 1115(a) demonstration waiver entitled "End Stage Renal Disease (ESRD)" as of January 2021. Indiana is currently working with CMS to move the WBA program into the HIP waiver with similar evaluation report timeframes and requirements. At the time of submitting this evaluation draft plan, the WBA was not approved beyond December 31, 2021. The State anticipates receiving approval by the time the COVID-19 PHE is lifted, and all HIP policies are reinstated; hence the reason for inclusion in the draft Evaluation Plan. Ability to analyze any of the research questions will depend on implementation of the WBA.

Goal 6.1. Reduce the benefit cliff faced by individuals transitioning from HIP to commercial coverage

The evaluation determines whether the WBA had an impact in reducing the benefit cliff faced by individuals transitioning from HIP to commercial coverage. **Exhibit G.2** below lists the hypothesis and research questions corresponding to this goal.

Exhibit G.2: Hypothesis and Research Questions for Goal 6.1

Hypotheses	Research Questions
Hypothesis 1 – The HIP WBA will reduce the amount of out-of-pocket costs (copayments, coinsurance, deductible, and premium costs) for individuals who transition into commercial health insurance	**Primary RQ 1.1:** Does the WBA result in reductions of out-of-pocket costs for individuals who transition into commercial health insurance?
Hypothesis 2 –The HIP WBA will support members who face a coverage gap when transitioning to commercial insurance	**Primary RQ 2.1:** Does the WBA support members when transiting to commercial insurance?

Goal 6.2. Support successful uptake of and continued enrollment in commercial coverage

This evaluation explores the impact of the WBA to increase uptake of, and continued enrollment in, commercial insurance. **Exhibit G.3** below lists the hypothesis and research questions corresponding to this goal.

Exhibit G.3: Hypothesis and Research Questions for Goal 6.2

Hypotheses	Research Questions
Hypothesis 1 – The HIP WBA will increase the number of successful enrollments in Marketplace insurance among individuals leaving HIP and eligible for the Account.	**Primary research question 1.1:** Does the WBA increase the number of successful enrollments in Marketplace insurance?
Hypothesis 2 – The HIP WBA and contribution policies will increase the number of successful enrollments in employer-sponsored insurance among individuals leaving HIP and eligible for the WBA	**Primary research question 2.1:** Does the WBA increase the number of successful enrollments in employer-sponsored insurance among individuals who disenroll HIP due to increased income?

Goal 6.3. Increase insurance uptake and reduce the number of individuals who leave HIP and are uninsured

This evaluation explores the impact of the WBA to increase insurance uptake and reduce the number of individuals who leave HIP and are uninsured. **Exhibit G.4** below lists the hypotheses and research questions corresponding to this goal.

Exhibit G.4: Hypothesis and Research Questions for Goal 6.3

Hypotheses	Research Questions
Hypothesis 1 – The HIP WBA will reduce the number of individuals who disenroll due to increased income and are uninsured following disenrollment	**Primary RQ 1.1:** Does the WBA reduce the number of individuals who disenroll due to increased income and are uninsured following disenrollment?

Goal 6.4. Reduce churn between HIP and commercial coverage or uninsured status

This evaluation explores the impact of the WBA to reduce churn between HIP and commercial coverage or uninsured status. **Exhibit G.5** below lists the hypotheses and research questions corresponding to this goal.

Exhibit G.5: Hypothesis and Research Questions for Goal 6.4

Hypotheses	Research Questions
Hypothesis 1 – The HIP WBA will reduce churn back to HIP among eligible individuals	**Primary RQ 1.1:** Does the WBA reduce churn back to HIP among eligible members?
Hypothesis 2 – Individuals with a WBA will report satisfaction of health care access	**Primary RQ 2.1:** What percentage of HIP members report getting care as soon as needed after they disenrolled from HIP?

WBA Methodology

For goals related to WBA, the target population for analyses are HIP beneficiaries that would opt-in to receiving the WBA after being disenrolled from HIP solely due to increased income. In 2018, the State estimated 27,000 individuals would qualify for the WBA. The WBA program has not been implemented at the time of this Evaluation Plan development. Indiana anticipates a higher number of HIP members will be eligible for WBA following the COVID-19 PHE and upon reinstatement of all HIP policies. With this in mind, the state will explore the use of a quasi-experimental design, including difference-in-difference and interrupted time series (ITS) with comparison groups. Potential comparison populations of interest would be: those individuals who disenrolled from HIP for any other reason except increased income, or; HIP members who were eligible for WBA but did not opt-in, or; if the HIP had more individuals disenroll solely for increased income than the available number of WBA accounts. Comparison groups will be carefully considered and revisited if the amendment were extended after the current demonstration approval period ends. **Exhibit G.6** identifies the data sources for Goal 6 and **Exhibit G.7** provides a summary of the anticipated quantitative surveys. The Longitudinal Member Survey, Leaver #1 – Income Survey, and Leaver #2 – POWER Account Contribution Non-Payment Survey will include sub-questions related to the WBA. These will not be separate or additional surveys to what was described in the HIP Evaluation Plan. **Exhibit G.8** includes a summary of the key informant interviews. Note that the WBA questions will be embedded within the existing key informant interviews as described in the HIP Evaluation Plan.

Exhibit G.6: Data Sources for Goal 6

Type	Data Sources	Goal 6.1 Reduce Benefit Cliff	Goal 6.2 Enrollment and Uptake of Commercial Insurance	Goal 6.3 Increase Insurance Uptake	Goal 6.4 Reduce Churn and Access
Indiana – Quantitative	1. Member Eligibility, Application, and Enrollment/Disenrollment Data *Note: Enrollment data will be used to draw member survey samples that are applicable across goals.*	X	X	-	X
	2. Claims Data	X	X	-	X
	3. State administrative data—for example, WBA information, POWER Account contributions, etc. [108]	X	X	X	-
	4. Longitudinal Member Survey (2023, 2024)*	X	-	X	X
	5. Leaver #1 – Income*	X	-	X	X
	6. Leaver #2 – POWER Account Contribution non-payment (2024)*	X	-	X	X

[108] Other sources of State administrative data may be leveraged as available.

Type	Data Sources	Goal 6.1 Reduce Benefit Cliff	Goal 6.2 Enrollment and Uptake of Commercial Insurance	Goal 6.3 Increase Insurance Uptake	Goal 6.4 Reduce Churn and Access
Indiana – Qualitative	7. Key Informant Interviews with HIP members[109]	X	X	X	X
	8. Key Informant Interviews with State Officials	X	X	X	X
	9. Key Informant Interviews with MCEs	X	-	X	-
	10. Key Informant Interviews with Other Stakeholders (including consumer advocates)	X	X	X	X
	11. Key Informant Interviews with Providers	X	X	X	X

*Availability of data will depend on multiple factors including sample size, number of individuals having WBA in the study period, response received from leaver who had WBA and implementation timing of WBA

Exhibit G.7: Summary of Indiana-Specific Surveys*

Area	Longitudinal Member Survey	Leaver Survey – POWER Account Contribution non-payment	Leaver Survey – Increased Income
Individuals Surveyed	Members having HIP Basic or HIP Plus coverage in a specific month. The coverage status of these individuals will vary between the 2023 and 2024 surveys; some will continue to be HIP members while others may leave the program.	Individuals who had been fully enrolled in HIP but who left the program (i.e., coverage is closed) due to not paying the POWER Account Contribution.	Individuals who had been fully enrolled in HIP but who left the program (i.e., coverage is closed) due to changes in income eligibility. The survey sample will include individuals participating in the WBA program and individuals who are not participating.
Timeframe	2023, 2024	2024	2024
Topics	• Access to care • Health status • Tobacco use and related surcharge • Satisfaction with HIP and knowledge of HIP policies • POWER Accounts • Medical debt • WBA	• Reasons for leaving HIP • Current insurance coverage/ employer coverage • Knowledge of HIP policies • Access to care • Satisfaction with HIP	• Reasons for leaving HIP • Current insurance coverage/employer offer of coverage • Knowledge of HIP policies • Access to care • WBA

[109] HIP member focus groups may also be utilized in qualitative data research

Area	Longitudinal Member Survey	Leaver Survey – POWER Account Contribution non-payment	Leaver Survey – Increased Income
Mode of Administration	Telephone Up to three attempts in 2023 and update five attempts in 2024	Telephone Up to three attempts	Telephone Up to three attempts
Sampling Strategy	Stratified Random	Random	Random
Anticipated Timeline (May change depending on data availability or other program nuances and changes)	• Sampling Universe: All members enrolled with HIP Basic or HIP Plus in February 2023 • Select sample: April 2023 • Survey instrument test: May (2023, 2024) • Conduct survey: June – July 2023, June 2024	• Sampling Universe: HIP members who disenrolled between January 1, 2023 and December 31, 2023 • Select sample: March 2024 • Survey instrument test: April 2024 • Conduct survey: May – June 2024	Same as Leaver Survey – POWER Account Contribution non-payment
Estimated number of completed surveys	2023: 4,500 2024: 650 to 900 (dependent on response rate among respondents in 2023)	250	400

Area	Longitudinal Member Survey	Leaver Survey – POWER Account Contribution non-payment	Leaver Survey – Increased Income
Statistical power assumptions	Assuming a population of 400,000, this sample size will allow for estimating population metrics (e.g., proportion has access to care) with 95% confidence level with a margin of error of +/-1.38% for 2023 and 3.8% for 2024. The evaluator anticipates contacting all respondents in the 2023 survey for purposes of the 2024 longitudinal survey. The adequacy of the resulting 2024 sample for subgroup analysis will be assessed prior to analysis. The adequacy of the sample size for conducting subgroup analyses was assessed for one outcome of interest (high HIP satisfaction). The sample size supports comparisons (detectable difference of 10% or more with confidence level of 95% and power level of 80%) between HIP Basic and HIP Plus members and between members who are below and above 100% FPL.	Assuming a population of 5,000, this sample size will allow for estimating population metrics (e.g., proportion has access to care) with 95% confidence level with a margin of error of +/-6.05%. Subgroup analysis may be limited due to sample size. The adequacy of the sample for subgroup analysis will be assessed prior to analysis and provided in the Interim Evaluation Report.	Assuming a population of 28,000, this sample size will allow for estimating population metrics (e.g., proportion has access to care) with 95% confidence level with a margin of error of +/-4.86%. Subgroup analysis may be limited due to sample size. The adequacy of the sample for subgroup analysis will be assessed prior to analysis and provided in the Interim Evaluation Report.

*Note: The table includes details for surveys planned for the first Interim Evaluation report scheduled to be submitted to CMS in June 2024. This table (including information on type of surveys, sample sizes, time frame) will need to be updated in future for the other interim reports and summative evaluation.

(1) The population for sampling will depend on the timing of reinstatement of HIP policies and potential long term impact of the COVID-19 PHE.

(2) Due to the small population size and anticipated high non-response, the survey process will involve calling all available individuals until the target sample size has been achieved or until the evaluator has reached the maximum number of dialing attempts. The completed number of responses may be lower than the target

Exhibit G.8: Summary of Indiana-Specific Qualitative Data Collection – Key Informant Interviews

Type	Potential Topics	Targeted Number of Interviewees
FSSA Officials	• Implementation of HIP POWER Account changes, tobacco surcharge, and WBA • Identification of factors related to member enrollment and participation in/compliance with policy changes • Member satisfaction	8 semi-structured interviews (including group interviews) each year
MCEs	• Implementation of HIP POWER Account changes, tobacco surcharge, and WBA • Identification of factors related to member enrollment and participation in/compliance with policy changes ○ Member satisfaction	4 semi-structured interviews with representatives from the four MCEs
Provider/Other Associations	• Understanding of and experience with HIP policies –POWER Accounts, tobacco surcharge, tobacco cessation services, and WBA ○ Member satisfaction with HIP	20 interviews *Note: To be determined based on provider/other association availability. Interviews will include provider associations and certified navigators*
HIP Members	• Access to care • Tobacco use • Satisfaction with HIP • Knowledge of HIP policies – POWER Accounts, tobacco surcharge, tobacco cessation services, and WBA	30 interviews *Note: To be determined based on member availability.*
Other Stakeholders	• Topics to be determined based on key areas of interest from the State	5 to 8 interviews *Note: To be determined based on stakeholder availability. This will include an individual with a WBA.*

WBA Methodological Limitations

Exhibit G.9 describes the known limitations of the evaluation and anticipated approaches to minimizing those limitations and/or acknowledges where limitations might preclude casual inferences about the effects of demonstration policies.

Exhibit G.9: Summary of Methodological Limitations and Approach to Minimizing Limitations

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Overall issues	Impact of the COVID-19 PHE	The ongoing COVID-19 PHE, which started in March 2020, is anticipated to cause substantial changes to: • HIP policies (e.g., all members were enrolled in HIP Plus irrespective of income, cost-sharing has been suspended) • Service utilization • Medicaid enrollment • Provider networks	• Use and inclusion of data from CY 2020 and beyond to analyze the impact of HIP policies will require careful analyses and be dependent on multiple factors, including the time frame for reinstatement of HIP policies, phase-in time period once the COVID-19 PHE is lifted, policies reinstated and COVID-19's economic impact.
	Limited ability to control for differences between states when using other State Medicaid populations as a comparison group	State Medicaid populations are different in observable and unobservable ways. For example, state-specific policies and economies vary from state to state. Available variables and sample sizes in proposed federal data sources (e.g., ACS) limit the ability to control for these differences.	• Select states for comparison that: ○ Did not implement comparable demonstrations during the evaluation period ○ Implemented Medicaid expansion prior to 2015 ○ Have similar Medicaid eligibility FPL requirements for adults ages 19-64 ○ Have similar geographic variation ○ Have sufficient sample sizes • Include a description of the differences that cannot be accounted for given available evaluation resources and data limitations. • Use appropriate methods (e.g., matching) to account for observable differences.
	Quality of provider contact information for key informant interviews	Provider contact information reliability made completing provider key informant interviews challenging. For example, provider email addresses and phone numbers listed in the MCE provider list often provided only generic office email addresses.	• Obtain support from key provider associations to identify providers for key informant interview purposes. • Use interviews with key provider associations in lieu of individual providers as necessary

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Overall issues, continued	Ability to identify HIP members within ACS survey data	HIP members include low-income (<138% FPL), non-disabled adults aged 19-64; HIP members also include the medically frail, TMA participants, and low-income parents and caretakers. Available fields within ACS will limit the ability to identify all of these groups.	• Use available survey fields related to Medicaid coverage, income, disability, and age. • Highlight in the evaluation narrative what HIP member characteristics could not be taken into account.
	Ability to use BRFSS data to identify individuals enrolled in HIP and potentially eligible for HIP	BRFSS data does not allow for identification of individuals in the sample enrolled in Medicaid. Additionally, BRFSS data fields do not allow for a full identification of individuals that are potentially eligible for HIP. HIP members include low-income (<138% FPL), non-disabled adults aged 19-64; HIP members also include the medically frail, TMA participants, and low-income parents and caretakers.	• Use available survey fields related to income, disability, and age (Medicaid enrollment is not an available field). • Include in the evaluation narrative that BRFSS survey data can only identify individuals that are potentially eligible for HIP; describe related limitations for analyses.
	Impact of changes in case-mix over time	Changes in HIP case mix over time may have an impact on a variety of areas of this evaluation, including service utilization, prevalence of medical frailty exemptions for the Gateway to Work program, and member preference for the HIP Plus versus HIP Basic benefit plan.	• Use regression-based adjustments as data is available and appropriate and necessary for analyses across time.
	Number of respondents for leaver surveys (due to increased income, due to non-payment of POWER Account Contribution)	The completed number of responses may be lower than the target sample size. Obtaining responses from previous members is dependent on the non-response rate and total population of leavers. Additionally, the population size of leaver for sampling will depend on the timing of reinstatement of HIP policies and potential long term impact of the COVID-19 PHE.	• The survey process will involve calling all available individuals until the target sample size has been achieved or until the evaluator has reached the maximum number of dialing attempts.
	Survey length/ respondent burden and corresponding response rates for member surveys	The average survey length will be six minutes; a longer average survey length will result in a lower survey completion rate and strain existing evaluation resources.	• Prioritize research questions within the available survey time and make adjustments to data collection accordingly.

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Overall issues, continued	Quality of MCE encounter data	MCE encounter data is self-reported, and the procedure codes and units recorded in the encounter data available for the evaluation of the demonstration can be incomplete and/or inaccurate.	• Perform data checks on key variables (e.g., expected versus populated values). • Adjust or eliminate analyses as necessary if data are not reliable.
	Identification of unique HIP members	Recipient identification numbers can change over time and the State performs on-going adjustments to data so that each member has only one active recipient identification number.	• Confirm whether data received from the State is fully adjusted for duplicate members. • Request a mapping of duplicate recipient identification numbers, if applicable. • Indicate in the reports if there is a possibility that data analyzed contains duplicated HIP members.

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Overall issues, continued	Identification of FPL	Member income can change throughout the year and as often as monthly. We anticipate defining member FPL based on the first enrollment month in the CY under analysis (based on analyses of the income in enrollment data and feedback from the State). There may be FPL amounts in the data that appear inconsistent with HIP policies (e.g., a small number of HIP Plus members with income at or less than 100% had disenrollments with non-payment as a reason). Based on discussions with the State for the 2018 – 2020 waiver evaluation, there are several possible reasons for inconsistencies, for example: • The member changed income after the first HIP Plus enrollment month in the CY under analysis. • Interplay between the required member notification for coverage changes (e.g., HIP Plus to HIP Basic) and when the State/MCE received and updates data, in conjunction with member changes in FPL across months. • Inconsistencies in FPL data transfer between eligibility and the Medicaid Management Information System that resulted in null FPL values on disenrollment, which appear as zero in provided enrollment data and in some cases in the application of updated FPL numbers to prior months. The State has indicated that this data issue is resolved, but on a minority of historical records included in this analyses these data artifacts remain.	• Do not place restrictions on FPL when identifying HIP Plus members for analysis. • Provide context for interpretation of results.

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Overall issues, continued	Limitations of interrupted time series (ITS) and pre/post analyses	ITS involves estimating the impact of an intervention based on pre/post analyses of an outcome of interest based on a longitudinal measure of outcome. Use of this approach can be unsuitable to measure the impact of intervention in certain situations, including: • Intervention is introduced gradually or at multiple points in time, making it difficult to identify and quantify for pre/post measures. • Characteristics of the population with intervention changes across time. • Underlying trend is not linear; other factors are also impacting the population (e.g., simultaneous implementation of a different).	• Perform checks of population differences over time; consider matching or other appropriate methods to address observed differences. • Use regression analysis to control for potential confounders to the extent possible.
	Distinguishing the impacts of overlapping initiatives	Multiple policy changes have been implemented under the 2018 – 2020 renewal. As such, distinguishing the impacts of the individual initiatives becomes challenging. In addition to the HIP waiver policies, non-waiver operational items have overlapping impacts, for example: • Implementation of a new Medicaid Management Information System in 2017. • Updates to verification policies over time.	• Provide context for interpretation of results in the report, including the need for caution in interpreting and presenting results for take-up and continued enrollment in HIP.
	Members may under-report tobacco use	Members may have an incentive to refrain from reporting tobacco use if they want to avoid the related premium surcharge increase.	• Provide context in the evaluation narrative for this issue.
	Medicaid encounter data may not fully reflect use of tobacco cessation services	Encounter data will not have codes for all tobacco cessation service since some programs will not be reimbursable by the provider.	• Ask questions about MCE tobacco cessation initiatives during key informant interviews with MCEs • Ask questions about cessation services received during member key informant interviews
	Variability in FPL amounts	Discussed as an overall methodological limitation above	• Refer to description above.

WBA Analytic Tables

Goal 6: WBA will support HIP members transitioning to commercial with continuity of coverage, reduce benefit cliff, and churn

Exhibit G.10: Goal 6.1

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.1 – The HIP WBA will reduce the amount of out-of-pocket costs (copayments, coinsurance, deductible, and premium costs) for individuals who transition into commercial health insurance	**Primary RQ 1.1**: Does the WBA result in reductions of out-of-pocket costs for individuals who transition into commercial health insurance?	• Number and percentage of members with WBA expenditures paid with coordination of benefits to a primary commercial plan by month of Bridge Account enrollment (month 1 to 12)	• Enrollment data (2015-2022) • Claims data (2015-2022)	• Descriptive quantitative analysis	n.a.	Interim Evaluation Report 2024
		• Amount paid from WBA for member claims and premiums • Amount paid from WBA by category of service	• State Administrative data for WBA	• Descriptive quantitative analysis	n.a.	Interim Evaluation Report 2024

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.2 –The HIP WBA will support members who face a coverage gap when transitioning to commercial insurance	**Primary RQ 2.1** – Does the WBA support members when transiting to commercial insurance?	• Number and percentage of members with WBA expenditures paid without coordination of benefits to a primary commercial plan by month of Bridge Account enrollment (month 1 to 12) • Number of claims applied to accounts without coordination of benefits	• Enrollment data (2015-2022) • Claims data (2015-2022)	• Descriptive quantitative analysis	n.a.	Interim Evaluation Report 2024
		• Member perceptions of access and affordability of coverage when in a coverage gap. • Member knowledge and perceptions of the WBA • WBA impact on access and affordability. • Member decisions to seek or delay health care, or enroll in health insurance, as a result of HIP WBA access.	• Key informant interviews with WBA holders, State staff, MCOs, providers, and other stakeholders (including consumer advocates)	• Qualitative analysis to identify themes associated with the effectiveness of demonstration activities for reducing the benefit cliff faced by individuals transition from HIP to commercial coverage.	n.a.	Interim Evaluation Report 2024

Exhibit G.11: Goal 6.2

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.1 – The HIP WBA will increase the number of successful enrollments in Marketplace insurance among individuals leaving HIP and eligible for the Account.	**Primary RQ 1.1:** Does the WBA increase the number of successful enrollments in Marketplace insurance?	• Track use of Account to pay for premiums for enrollment in commercial insurance	• Claims/encounter data • Enrollment data	• Descriptive quantitative analysis of trends over time during the demonstration	n.a.	Interim Evaluation Report 2024
		• Member self-report of Marketplace health insurance coverage *Note: Analysis will depend on number of respondents having a WBA*	• Member survey data	• Descriptive quantitative analysis	n.a.	Interim Evaluation Report 2024
H.2 – The HIP WBA and contribution policies will increase the number of successful enrollments in employer-sponsored insurance among individuals leaving HIP and eligible for the Account.	**Primary RQ 2.1 –** Does the WBA increase the number of successful enrollments in employer-sponsored insurance among individuals who disenroll HIP due to increased income?	• Track use of Account to pay for premiums for enrollment in commercial insurance • Number of third-party coverage policies that allow individuals that already have other coverage to request contrition waivers.	• Claims/encounter data • Enrollment data • State administrative data	Descriptive quantitative analysis of trends over time during the demonstration	n.a.	Interim Evaluation Report 2024

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.2, continued		• Member self-report of employer health insurance coverage *Note: Analysis will depend on number of respondents having a WBA*	• Member survey data	Qualitative analysis to identify associated themes	n.a.	Interim Evaluation Report 2024

Exhibit G.12: Goal 6.3

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.1 – The HIP WBA will reduce the number of individuals who disenroll due to increased income and are uninsured following disenrollment.	**Primary RQ 1.1:** Does the WBA reduce the number of individuals who disenroll due to increased income and are uninsured following disenrollment?	• Number of payments from WBA for health services incurred without coordination of benefits	State administrative data	Descriptive quantitative analysis of trends over time during the demonstration	Baseline assessment at the start of the demonstration	Interim Evaluation Report 2024
		• Member self-report of health insurance coverage *Note: Analysis will depend on number of respondents having a WBA*	Member survey data	Qualitative analysis to identify associated themes	n.a.	Interim Evaluation Report 2024

Exhibit G.13: Goal 6.4

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy	Reporting Schedule
H.1 – The HIP WBA will reduce churn back to HIP among eligible individuals.	**Primary RQ 1.1:** Does the WBA reduce churn back to HIP among eligible members?	• Number and percentage of individuals who return to HIP after disenrollment due to increased income	• Claims/encounter data • Enrollment data	ITS, analyzing churn pre and post WBA implementation	n.a.	Interim Evaluation Report 2024
		• Member perceptions of the causes of churn *Note: Analysis will depend on number of respondents having a WBA*	• Member survey data	• Qualitative analysis to identify associated themes	n.a.	Interim Evaluation Report 2024
H.2 – Individuals with a WBA will report satisfaction of health care access	**Primary RQ 2.1 –** What percentage of HIP members report getting care as soon as needed after they disenrolled from HIP?	Proportion of members reporting that they access care as soon as needed *Note: Analysis will depend on number of respondents having a WBA. Also, Survey length constraints will determine how many questions might be asked to determine access by type of service*	• Member survey data	Descriptive quantitative analysis of trends over time during the demonstration	n.a.	Interim Evaluation Report 2024