

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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State Demonstrations Group

JUN 06 2019

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

Dear Ms. Taylor:

On March 21, 2019, the state of Indiana submitted to the Centers for Medicare & Medicaid Services (CMS) a final evaluation design for the substance use disorder (SUD) component of the state's section 1115(a) demonstration, entitled "Healthy Indiana Plan (HIP)," (Project No. 11-W-00296/5), approved on February 1, 2018. The design, which responded to CMS comments provided to the state on March 1, 2019, was submitted in fulfillment of the requirement for an SUD evaluation design as described in the special term and condition (STC) #9 of section X.

I am pleased to inform you that CMS has approved Indiana's evaluation design for the SUD demonstration. The design is consistent with the requirements outlined in the applicable demonstration STCs and the State Medicaid Director Letter SMD # 17-003, "Strategies to Address the Opioid Epidemic". We sincerely appreciate the state's commitment to a rigorous evaluation approach of their initiative.

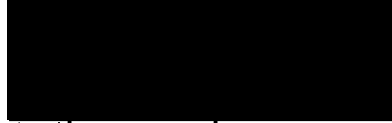
CMS has added the approved SUD evaluation design to the demonstration STCs as part of Attachment C. A copy of the STCs that includes the new attachment is enclosed with this letter. Per 42 CFR 431.424(c), the approved evaluation design may now be posted to the state's Medicaid website within thirty days of CMS approval. CMS will also post the approved evaluation design as a standalone document separate from the STCs on Medicaid.gov.

On May 14, 2019, CMS received Indiana's revised draft HIP evaluation design, which addresses the remaining components of the HIP demonstration, including community engagement. This deliverable was submitted in accordance with the requirements described in STCs #3 and #4 of section XV. The revisions are currently under review by CMS.

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We look forward to our continued partnership with you and your team on the Indiana HIP section 1115 demonstration evaluation. If you have any questions, please contact your project officer, Jennifer Maslowksi, at Jennifer.Maslowksi@cms.hhs.gov.

Sincerely,



Andrea J. Casart

Director

Division of Medicaid Expansion Demonstrations

Enclosure

cc: Ruth Hughes, Deputy Director of Field Operations North

**EVALUATION DESIGN PLAN
FOR INDIANA'S 1115 SUBSTANCE
USE DISORDER (SUD) WAIVER**



**FINAL DRAFT
MARCH 21, 2019**

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SECTION I: GENERAL BACKGROUND INFORMATION

I.A Introduction

Indiana, along with a number of states, is in the midst of a substantial drug abuse epidemic. The magnitude of the epidemic is demonstrated by the following facts:

- Nearly six times as many Hoosiers died from drug overdoses in 2014 as did in 2000, and the number of heroin overdose deaths increased by nearly 25 times between 2000 and 2014.¹
- In 2014, Indiana had the 16th highest drug overdose death rate in the nation, which represented a statistically significant increase in the rate from 2013.²
- Since 2009, more Hoosiers have lost their lives due to a drug overdose than in automobile accidents on state highways.³
- 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 2016.⁴

As an outgrowth of recommendations made by the State’s Taskforce on Drug Enforcement, Treatment, and Prevention, the Family and Social Services Administration (FSSA) requested a waiver from the Centers for Medicare and Medicaid (CMS) under the authority of section 1115(a) of the Social Security Act. The waiver request was to add new evidence-based substance use disorder (SUD) treatment services and to expand access to qualified providers through a waiver of the Institution for Mental Diseases (IMD) exclusion. As proposed, the SUD services would be available to all Medicaid beneficiaries, not just those eligible as a result of the demonstration waiver. The waiver application was submitted on January 31, 2017 and amended on July 20, 2017. CMS subsequently approved the extension request on February 1, 2018 (Project No. 11-W-00296/5). The approved waiver is effective from February 1, 2018 through December 31, 2020 and will provide access to the enhanced SUD benefit package for all Indiana Medicaid recipients. Services will be delivered through fee for service (FFS) and managed care delivery systems.

On February 1, 2018, Indiana also received approval of its SUD Implementation Protocol as required by special terms and conditions (STC) X.10 of the state’s section 1115 Health Indiana Plan (HIP)

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 R. Rudd et al., Increases in drug and opioid overdose deaths — United States, 2000–2014, 64(50) MORBIDITY AND MORTALITY WEEKLY REPORT 1378 (2016).

³ INDIANA STATE DEPARTMENT OF HEALTH, INDIANA: SPECIAL EMPHASIS REPORT, DRUG OVERDOSE DEATHS, 1999-2013 (2015), available at http://www.in.gov/isdh/files/2015_SER_Drug_Deaths_Indiana_Updated.pdf

⁴ State of Indiana 1115 SUD Waiver Implementation Plan, page 4, available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-sud-implementation-prtcl-appvl-02012018.pdf>

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demonstration. As set forth in the Implementation Plan, Indiana is aligning the six goals for the SUD waiver component with the milestones outlined by CMS as follows:⁵

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.

To accomplish these six goals, Indiana Medicaid is focusing on the three following areas⁶:

- 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 approved Implementation and Monitoring Plan, which include:⁷

1. Access to critical levels of care for SUD treatment;
2. Use of evidence-based SUD-specific patient placement criteria; prior-authorization, providers, payers; matching need to capacity
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.

⁵ State Medicaid Director Letter #17-003 RE: Strategies to Address the Opioid Epidemic, November 1, 2017, available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf>

⁶ Indiana 1115 SUD Waiver Implementation Plan, Updated January 2018, page 4, available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-sud-implementation-prtcl-appvl-02012018.pdf>

⁷ Indiana 1115 SUD Waiver Implementation Plan, Updated January 2018, pages 4 – 30, available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-sud-implementation-prtcl-appvl-02012018.pdf>

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I.B Indiana Medicaid's Six Milestones

A detailed description of activities related to each milestone are below.

1. Improve access to critical levels of care for SUD treatment

- Indiana will align current and expanded or new services along the American Society of Addiction Medicine (ASAM) level of care continuum.
- See Figure 1 for a summary of the ASAM levels of care and Figure 2 for a summary of the key SUD waiver policy changes to improve access, including the timing for implementation and populations impacted, by ASAM level of care.

2. Use of evidence-based SUD-specific patient placement criteria

- Patient Assessment
 - Individuals seeking treatment will be required to undergo a psychosocial assessment that will be used to develop a treatment plan.
 - Providers will be required to submit assessments that address the six dimensions of ASAM patient placement criteria which will be critical in determining the appropriate level of care.
- Utilization Management
 - ASAM levels 2 and above will require prior authorization through either the fee-for-service vendor or one of the managed care entities (MCEs).
 - A single prior authorization form will be developed to assist providers in requesting approval for the most appropriate level of care.

3. Use of nationally recognized SUD-specific program standards for residential treatment

- Develop new administrative rules that align residential facility certification with ASAM patient placement criteria for levels 3.1 and 3.5.
- Require residential facilities to offer medication assisted treatment (MAT) either on-site or through facilitated access off-site.

4. Sufficient provider capacity at critical levels of care

- Pursue stronger data analytics around provider capacity by creating reporting by provider specialty and ASAM level of care.
- Complete an assessment of ASAM providers and services, including availability of MAT.
- Create a new provider specialty for residential addictions facilities, and consider adding additional provider specialties to account for more mid-level practitioners.

5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse

- Governor's Task Force on Drug Enforcement, Treatment and Prevention
 - Established on September 1, 2015 to identify best practices and informed recommendations to policy makers.
 - Membership included the following: General Assembly; Governor's Office; State Department of Health; Department of Corrections; Department of Child Services; Family and Social Services Administration; and other organizations and associations.
 - Task force concluded its work on December 5, 2016, and issued a final report detailing findings and actionable recommendations:

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- 17 recommendations in total;
- 3 recommendations related to enforcement; and
- 14 recommendations related to treatment, including pursuit of a Medicaid 1115 Demonstration Waiver for individuals with SUD.
- Gold Card Program
 - Implemented late 2015.
 - Program allows qualified Medicaid prescribers to be exempt from prior authorization document submission requirements when prescribing buprenorphine and buprenorphine/naloxone.
- Buprenorphine Prior Authorization Criteria
 - Established specific prior authorization criteria for prescribers who are not Gold Card members.
 - Criteria is used by all of the MCEs' pharmacy benefit managers to allow for authorization up to six months at a time, and a 34-day supply at a time per member.
- Indiana Attorney General's Prescription Drug Abuse Prevention Task Force
 - Separate task force created in September 2012.
 - Published a four-year report in December 2016, with many of the same objectives identified by the Governor's Task Force acted upon by this task force.
- Prescribing Guidelines
 - Established standards and protocols (844 IAC 5-6) for physicians prescribing opioid controlled substances for pain management treatment.
 - Indiana Senate Enrolled Act 297 (2016) created clinical practice guidelines for office-based opiate treatment.
 - Indiana Senate Enrolled Act 226 (2017) limited prescription supply to seven days for first time opioid prescriptions for adults and children under age 18.
- Expanded Access to Naloxone
 - Indiana Senate Enrolled Act 406 (2015) expanded access to persons at risk for overdose or any individual who knows someone who may be at risk for overdosing.
 - Indiana Senate Enrolled Act 187 (2016) expanded access to allow any individual to walk into a pharmacy for a prescription of Naloxone without having to first see a prescriber.
- Prescription Drug Monitoring Program
 - On August 24, 2017, Governor Eric Holcomb announced a major statewide initiative to incorporate the State's prescription drug monitoring program (INSPECT) into health care systems' electronic health records.
 - Once fully integrated, practitioners will have a single portal to access information about prescribing and dispensing of a controlled substance.
 - Indiana hopes to have all of its hospitals fully integrated within three years.

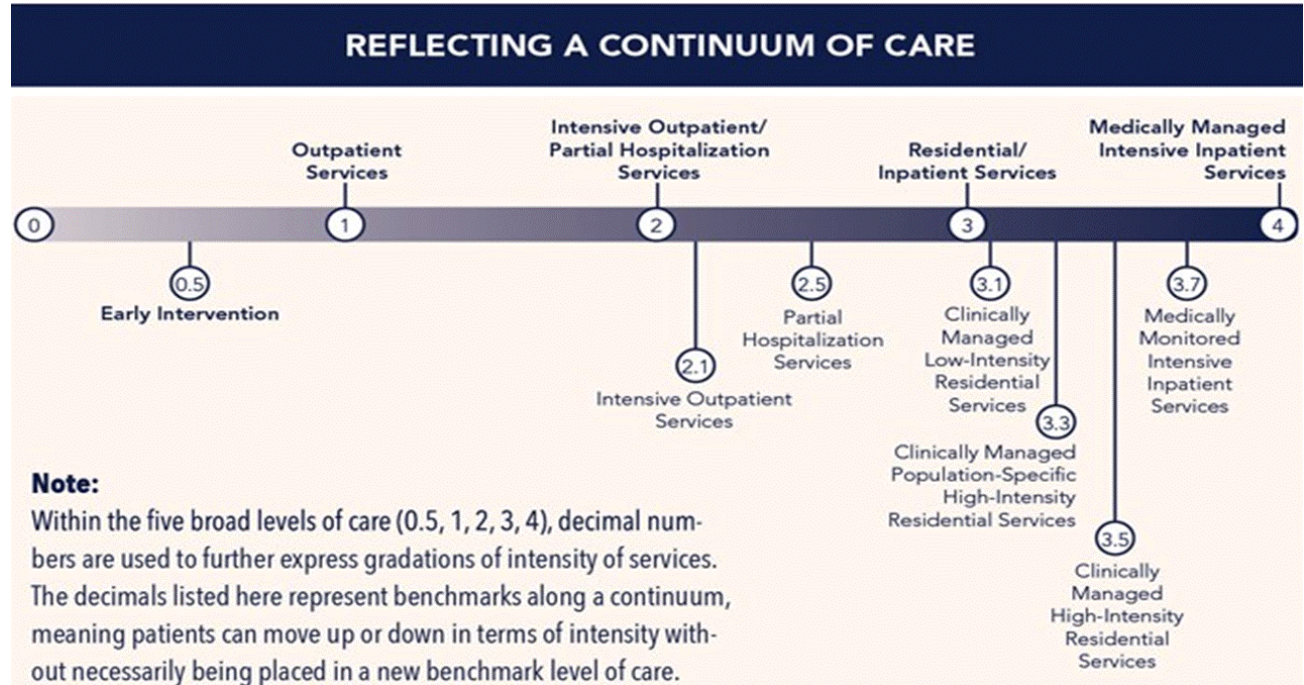
6. Improved care coordination and transitions between levels of care

- In addition to current MCE contractual requirements for case management, pursue extending the care settings transitioning from inpatient to include residential treatment facilities.
- Expand access to peer recovery coaches across delivery systems.

Since receiving approval of the SUD waiver, Indiana FSSA has been engaged in implementation activities as shown in Figure 3. Additionally, Indiana FSSA completed the procurement of an independent evaluator to develop the SUD Evaluation Design Plan, as required in STC X.9. Burns & Associates, Inc. (B&A), a health care consulting firm with headquarters in Phoenix, Arizona, was contracted by the FSSA to serve in that capacity and, as such, has led development of the initial draft of the Evaluation Design Plan.

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Figure 1. ASAM Levels Reflect a Continuum of Care⁸



⁸ State of Indiana 1115 SUD Waiver Implementation Plan, page 5, available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-sud-implementation-prtel-appvl-02012018.pdf>

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Figure 2. Current and Proposed Coverage for Indiana Medicaid, and Implementation Timeline, by ASAM level of care⁹

ASAM Level of Care	Service Title	Description	Current Coverage	Future Coverage	Implementation Timeline
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	December 31, 2018
0.5	Early Intervention	Services for individuals who are at risk of developing substance-related disorders	Currently covered for all	No change expected	
1	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	December 31, 2018
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	March 1, 2018
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	March 1, 2018
3.7	Medically Monitored Intensive Inpatient	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	Fall 2018
4	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	Fall 2018
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	December 31, 2018
Sub-Support	Supportive Housing Services	Services for individuals who are transitioning or sustaining housing.	No coverage	Explore options for coverage	Begin in 2018

⁹ State of Indiana 1115 SUD Waiver Implementation Plan, pages 5-30, available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-sud-implementation-prtcl-appvl-02012018.pdf>

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Figure 3. Indiana SUD Waiver Implementation Activities and Timeline¹⁰

Waiver Goal	Activities	Implementation Timeline
Improve access to critical levels of care for SUD treatment	Pursue Indiana Administrative Code (IAC) change for coverage and reimbursement of OTPs	Will be filed by December 31, 2018
	Pursue IAC amendments to Mental Health Services Rule for outpatient services	Will be filed by December 31, 2018
	Pursue IAC and SPA amendments to move IOT coverage from MRO to State Plan	IAC will be filed by December 31, 2018. SPA amendment filed by June 30, 2018.
	Pursue amendment to 1915(b)(4) waiver	Will be filed by June 30, 2018
	Make necessary systems changes to CoreMMIS related to IOT coverage change	Will be completed by June 30, 2018
	Develop provider communication over new IOT benefits	Contingent upon approval of SPA (formal notification will be delivered at least 30 days prior to launch)
	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 residential treatment facility benefits	Ongoing as part of roll-out; formal communication will be released with at least 30
	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
	Make necessary system changes to allow reimbursement for Addiction Recovery Management	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 IAC changes to add coverage of Addiction Recovery Management Services	Will be filed by December 31, 2018
Use of evidence-based SUD-specific patient placement criteria	Develop provider communication over new addiction recovery management benefits	Ongoing as part of roll-out; formal communication will be released with at least 30 days-notice ahead of launch
	Provider education on ASAM Criteria	Ongoing throughout 2018
	Development of standard prior authorization SUD treatment form	Will be completed by July 1, 2018
	Review contracts and pursue amendments where necessary	Will be filed by July 1, 2018
Use of nationally recognized SUD-specific program standards for residential treatment	Review CANS/ANSA for alignment with ASAM Criteria	Will be completed by December 31, 2018
	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	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	Consider options for emergency responder reimbursement of naloxone	Will be completed in early 2018

¹⁰ State of Indiana 1115 SUD Waiver Implementation Plan, pages 5-30, available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-sud-implementation-prtcl-appvl-02012018.pdf>

SECTION II: EVALUATION QUESTIONS AND HYPOTHESES

II.A Defining Relationships: Aims, Primary Drivers, and Secondary Drivers

B&A examined the relationships between the CMS goals and Indiana Medicaid-delineated interventions included in the 1115 waiver and approved Implementation Plan. As part of the examination of the relationships between goals and the interventions, B&A constructed two driver diagrams identifying primary and secondary drivers of two principle aims: 1) reducing overdose death; and 2) reducing costs. The driver diagrams are summarized in Figure 4 and Figure 5 on the following two pages of the Evaluation Design Plan.

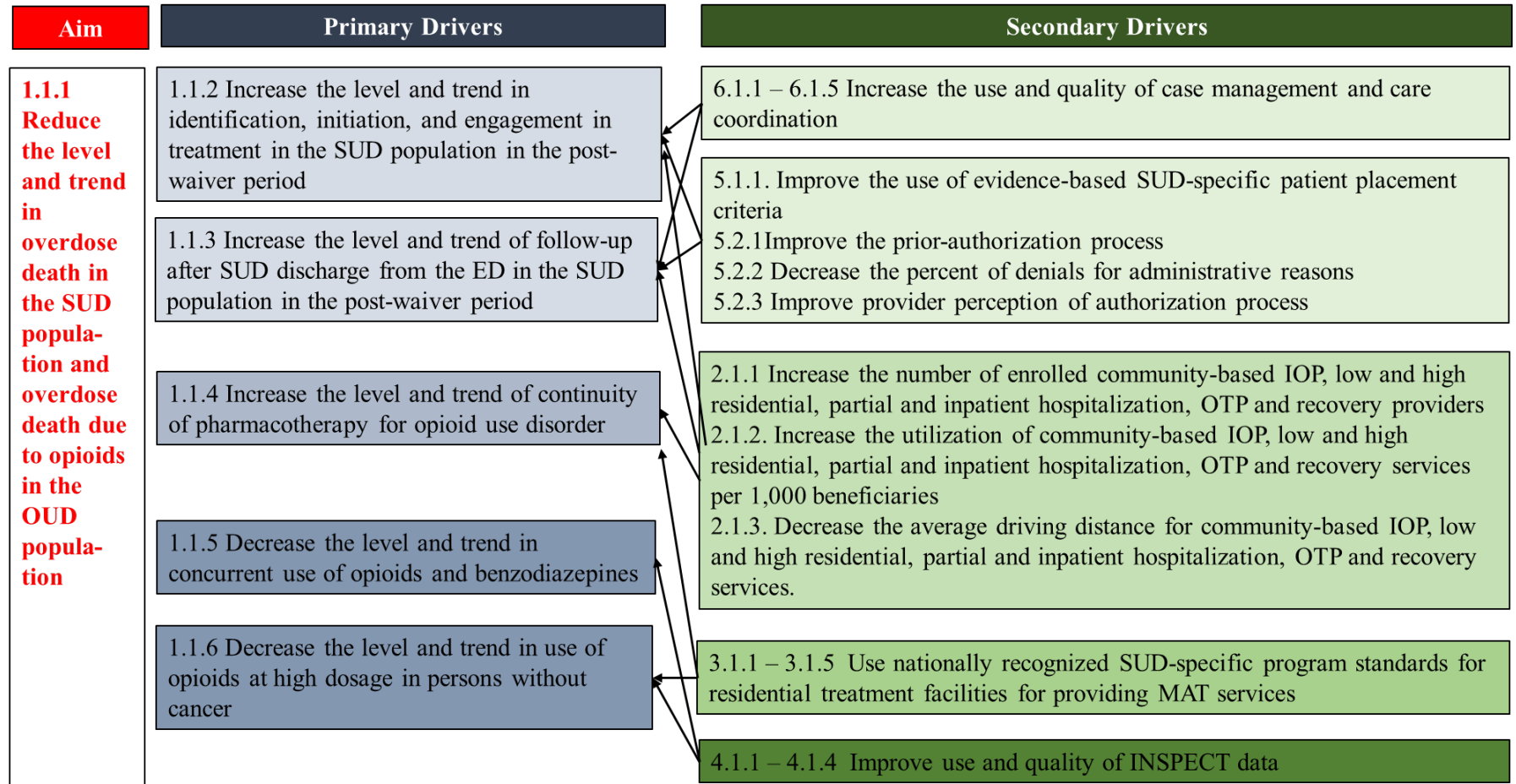
B&A chose overdose deaths as the first aim because it is a measurable health outcome. CMS goals related to improved quality of care were determined to all have the potential to contribute to a reduction in overdose deaths and therefore are included as primary drivers. And in turn, the specific actions described in the implementation plan, which would be designed to improve these measures of quality of care, were considered as secondary drivers.

Reductions in per capita costs of the SUD population is the second defined aim based on CMS interest on whether the investments in SUD services made as part of the waiver, result in demonstrable reductions in non-SUD services spending. Similar to the approach above, upon examination, B&A identified relationships between goals related to improving physical health and reductions in the use of acute care services as the key primary drivers of achieving a reduction in overall spending, net of SUD investments.

In order to translate these aims, and primary and secondary drivers into measurable results, we compared these items against the measures included in the Monitoring Plan and identified whether new measures may be needed. B&A found that existing, nationally recognized measures were available for the aims and primary drivers; moreover, the specifications and data sources were already described as part of Indiana Medicaid's CMS-approved Monitoring Plan. The one exception is that B&A will add two "potentially preventable" measures. To fill gaps in measuring secondary drivers, B&A added custom measures where needed. These measures, in the post-waiver period, will be used as targets such that performance in the post-waiver period will be considered positive should changes occur in the post- versus pre- waiver period.

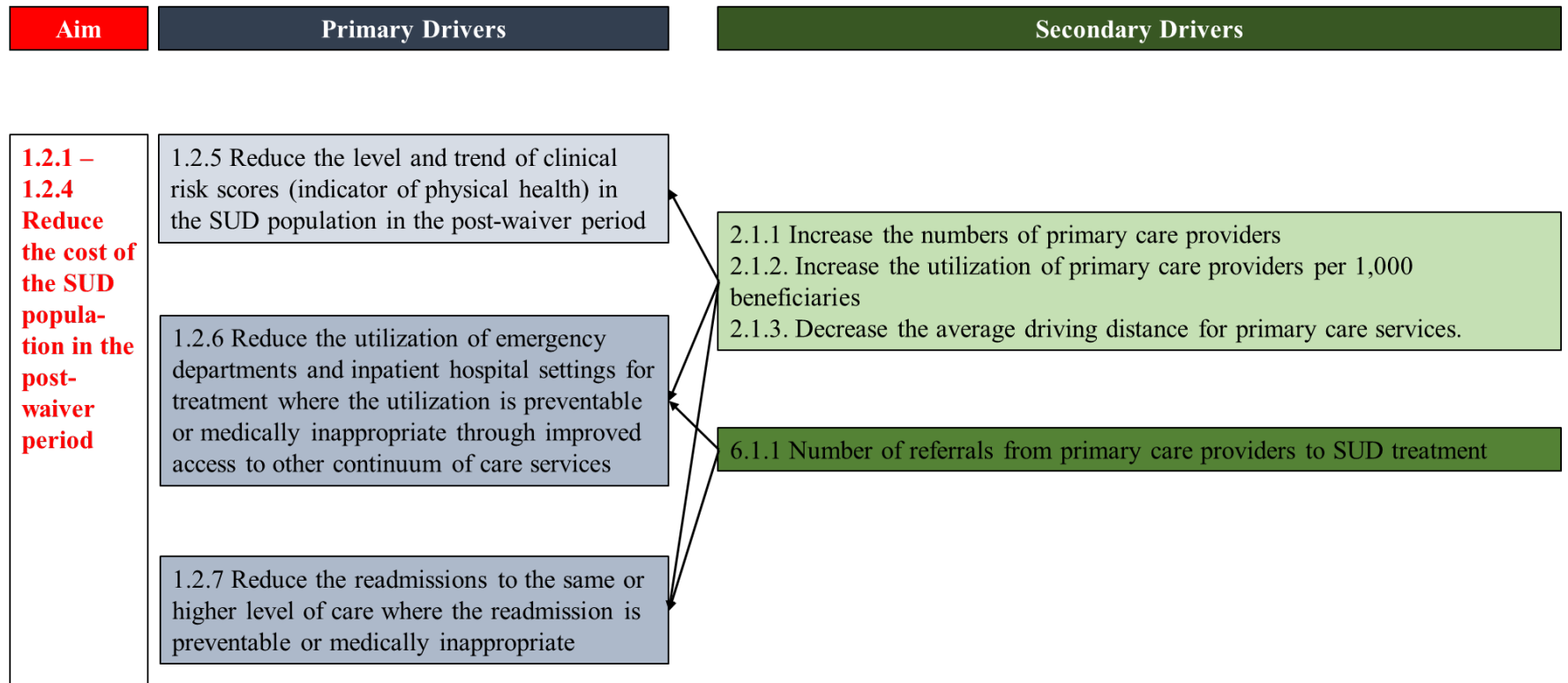
A more detailed description of the data, measures and analysis to be used are described in Section III. Methodology.

Figure 4. Driver Diagram 1.1 Target Health Outcome: Reductions in the Overdose Rate



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Figure 5. Driver Diagram 1.2 Target Health Outcome: Reductions in Per Capita Cost



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II.B Hypotheses (H) and Research Questions (Q)

Aims and Primary Drivers

The identified aims, primary and secondary drivers were converted into a series of hypotheses (H) and research questions (Q); and the latter each assigned measures and targeted analytic methodology, described in detail in Section III. Methodology.

Hypothesis 1.1 and 1.2 focus on the aims and primary drivers depicted in the revised driver diagrams. These are the targets for testing using interrupted time series (ITS) as described in Section III. Methodology. The two aims and eight primary drivers will be tested in order to detect statistically significant changes in the pre- and post-waiver period.

The hypotheses and research questions specific to the aims and primary drivers include:

H 1.1 Key health outcomes improve in the SUD population in the post-waiver period.

- Q 1.1.1 Does the level and trend of overdose deaths and overdose due to opioids decrease among the SUD population in the post-waiver period?
- Q 1.1.2 Does the level and trend of initiation and engagement in treatment increase in the SUD population in the post waiver period?
- Q 1.1.3 Does the level and trend of follow-up after discharge from the Emergency Department (ED) for SUD increase among the SUD population in the post waiver period?
- Q 1.1.4 Does the level and trend in continuity of pharmacotherapy for opioid use disorder increase among the OUD population in the post waiver period?
- Q 1.1.5 Does the level and trend in concurrent use of opioids and benzodiazepines decrease in the OUD population in the post waiver period?
- Q 1.1.6 Does the level and trend in the rate of use of opioids at high dosage in persons without cancer decrease in the post waiver period?

H 1.2 Costs of care decreases in the SUD population in the post waiver period.

- Q 1.2.1 Does the level and trend in overall spending for the SUD population decrease in the post waiver period?
- Q 1.2.2 Does the level and trend in SUD service spending for the SUD population increase in the post waiver period?
- Q 1.2.3 Does the level and trend in non-SUD service spending for the SUD population decrease in the post waiver period?
- Q 1.2.4 Does the level and trend in the percentage of SUD facilities who report they accept Medicaid as a payer increase in the post waiver period?
- Q 1.2.5 Does the level and trend in Clinical Risk Group (CRG) risk scores decrease among the SUD population in the post waiver period?
- Q 1.2.6 Does the level and trend in acute utilization for SUD, potentially preventable emergency department or potentially preventable hospital readmissions decrease in the SUD population in the post waiver period?

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Secondary Drivers

Hypotheses 2.1 through 6.1 focus on the secondary drivers as depicted in the revised driver diagram and are organized to be consistent with Indiana Medicaid's CMS-approved Implementation Plan. Unlike those aims and primary drivers in Hypothesis 1.1 and 1.2, the secondary drivers are targets for continuous monitoring and quality improvement, and require information beyond what is available in claims or other public data sets, nationally recognized measures, and thus, performance will be assessed using a set of mixed methods to evaluate progress on the secondary drivers. Where possible, measures will be incorporated into a reporting dashboard of the pre- and the to-date post-waiver periods and reported on a quarterly basis, with a refresh every six months. A summary of methods is detailed in Section III. Methodology.

The hypotheses and research questions specific to the secondary drivers include:

H 2.1 Access to care improved in the SUD population in the post-waiver period.

- Q 2.1.1. Does the level and trend in the number of SUD and primary care providers and the number of providers per capita in the SUD population increase in the post waiver period for each ASAM level of care?
- Q 2.1.2 Does the utilization per 1,000 of SUD services and primary care in the SUD population increase in the post waiver period for each ASAM level of care?
- Q 2.1.3 Does the average driving distance for SUD services and primary care decrease in the SUD population in the post waiver period for each ASAM level of care?

H 3.1 Implementing residential treatment facility provider certification requirements based on ASAM level 3.1 and 3.5 criteria will improve provision of care.

- Q 3.1.1 Does provider certification shift from resident and facility-based criteria to treatment-based certification criteria using ASAM level of care over the length of the waiver?
- Q 3.1.2 Does the ability to measure utilization by ASAM facility level improve program monitoring?
- Q 3.1.3 Does provider awareness and use of ASAM Patient Placement Criteria increase over the length of the waiver?
- Q 3.1.4 Do providers offer medication-assisted treatment (MAT)?
- Q 3.1.5 Do residential facilities not currently enrolled in Indiana Medicaid have the opportunity to meet standards for enrollment leading to increased enrollment of residential addictions facilities?

H 4.1 The quality and use of INSPECT data will improve in the post waiver period.

- Q 4.1.1 Were changes to INSPECT made according to the Implementation Plan?
- Q 4.1.2 Did changes to INSPECT result in meaningful reporting capabilities?
- Q 4.1.3 Has the number of prescribers using INSPECT increased over time?
- Q 4.1.4 Has the volume of inquiries into the INSPECT database increased over time?

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H 5.1 The Child and Adolescent Needs and Strengths (CANS) and Adult Needs and Strengths Assessment (ANSA) tools are being used to place beneficiaries in ASAM levels of care.

- Q 5.1.1 Are clinical criteria for authorization review for services delivered to beneficiaries with SUD being applied consistently across Indiana's Health Coverage Programs (Hoosier Healthwise, Healthy Indiana Plan, Hoosier Care Connect, and Traditional Medicaid)?

H 5.2 Prior authorization (PA) requirements do not negatively impact access to residential or inpatient services (ASAM 3.1, 3.5 and 4.0).

- Q 5.2.1 Are the rates of prior authorizations (PAs) submitted and PA requests that are denied in the SUD population, controlling for volume, relatively consistent by MCE and over time?
- Q 5.2.2 Are prior authorization (PA) denials predominately for reasons directly related to not meeting clinical criteria as opposed to administrative reasons such as lack of information submitted?
- Q 5.2.3 Is provider administrative burden associated with PA requests cited as a perceived barrier to access to care?

H 6.1 Care coordination and transitions between ASAM levels of care will increase in the post-waiver period.

- Q 6.1.1 Does the proportion of beneficiaries receiving ASAM designation who had a claim in that ASAM level within the next two consecutive months following the month of ASAM assignment increase over time?
- Q 6.1.2 Does the proportion of beneficiaries with a SUD diagnosis who are receiving care coordination increase over time?
- Q 6.1.3 Do Indiana's MCEs facilitate more active engagement in the case/care management process between behavioral health/substance abuse providers and primary care/other physical health providers for their patients with a SUD diagnosis?

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. B&A tailored the evaluation approach for each research question described in Section II, Evaluation Hypothesis and Research Questions. The evaluation plan reflects a range of data sources, measures and perspectives. It also defines the most appropriate study population and sub-populations, as well as describes the six analytic methods included in the evaluation design.

The six analytic methods proposed for use across the six goals include:

1. single segment interrupted time series (ITS),
2. descriptive statistics (DS),
3. provider surveys (PS)
4. onsite reviews (OR)
5. desk reviews (DR) and,
6. facilitated interviews (FIs) and/or focus groups (FGs).

Figure 6 on the next page presents a chart displaying which method(s) are used for each hypothesis. It also includes a brief description of the indicated methods, as well as the sources of data on which they rely. The six methods are ordered and abbreviated as described in the first sentence of this paragraph.

As described in Section II.B, the first two hypothesis [1.1. and 1.2.] and the 12 associated research questions focus on whether the 1115 SUD waiver provision made an impact on key CMS goals (i.e., aims and primary drivers). In order to facilitate evaluation on whether a statistically significant difference between the pre- and post- waiver period can be detected, the data, measures and methods for these research questions will be tested using healthcare claims and enrollment data, nationally recognized measure specifications, and ITS.

For the remainder of the hypotheses (2.1 – 6.1) and the associated research questions, the focus will shift to the secondary drivers. Given these are targets for continuous monitoring and quality improvement, and require information beyond what is available in claims or other public data sets, this section draws upon a set of mixed methods to evaluate progress on the secondary drivers. Where possible, measures will be incorporated into a reporting dashboard of the pre- and the to-date post-waiver periods and reported on a quarterly basis, with refreshes every six months.

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Figure 6. Summary of Six Methods by Hypotheses

Hypotheses	Method						Description
	1	2	3	4	5	6	
	ITS	DS	PS	OR	DR	FI/FG	
1.1 – 1.2	X	X					ITS will be used. Data sources primarily include claims and enrollment data. The National Survey of Substance Abuse Treatment Services (N-SSATS) data will be used in one instance. As part of the ITS model specification, descriptive statistics will be generated and reported as well.
2.1		X					Claims data will be used to compute a set of access to care measures and reported descriptively and stratified by region, managed care plan or fee for service, and by ASAM level.
3.1		X	X	X	X	X	An onsite and a desk review, coupled with the residential provider survey will be used.
4.1		X			X	X	This study question will be evaluated using a desk review of externally provided descriptive studies on number of INSPECT users and queries.
5.1 – 5.2		X	X	X		X	Onsite reviews will be used to assess the adoption of ANSA and assignment to ASAM by MCEs and FFS. MCE and FFS-supplied data will be used to review prior authorizations for residential and inpatient hospital levels of care. This summary will include: the rate of prior authorization, the rate of prior authorization denials, and the frequency of authorization denial reason code by MCE. A residential and inpatient provider survey will be used to collect data on overall provider perceptions as well as information specific to prior authorization and adoption of ANSA criteria.
6.1		X	X	X		X	Claims data and MCE and FFS-supplied care coordination data will be used to calculate descriptive statistics. A cross-sectional provider survey and an onsite review of MCEs and the OMP will also be used to evaluate care coordination activities.

ITS = Interrupted Time Series; DS = Descriptive Statistics; PS = Provider Survey; OR = Onsite Review; DR = Desk Review; FI/FG = Facilitated Interviews and/or Focus Groups

Italics indicate the method will be used “as needed”

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III.B Target and Comparison Populations

Target Population

The target population is any Indiana Medicaid beneficiary with Substance Use Disorder (SUD) in the study period. B&A will use the approved specification, described in the CMS-approved Monitoring Plan, for identification of beneficiaries with SUD. Having a positive SUD Indicator Flag will serve as an indicator of exposure to the changes in the waiver. The specification to be used to create the SUD Indicator Flag is included in Attachment D.

While the key study population is the overall SUD population, a standardized set of sub-populations will be identified and examined. B&A will sub-set the SUD population at minimum, by common demographic groups, payer (i.e., MCE or OMPP), and geographic regions. In addition, there are nuances in the 1115 waiver changes, which warrant identification and stratification of the data into a number of sub-populations. See Figure 2 in Section I of the evaluation plan for a summary of the waiver policy changes.

- ASAM Levels: 2.1; 3.1; 3.5; 4; OTP; RS. It is possible that outcomes may differ among the SUD population based on their access to services. B&A 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-waiver period.
- Risk Scores: Similarly, outcomes may differ among the SUD population for some types of clinically similar groups compared to others. Therefore, B&A will examine outcomes by categorized groups of clinically similar beneficiaries based on the 3M™ Clinical Risk Groups (CRG) to examine whether there are differences in health outcomes or cost among clinically similar groups of SUD beneficiaries.
- ASAM 2.1 Intensive Outpatient Services: coverage is expanding beyond the community-based treatment or Medicaid Rehabilitation Option (MRO); those previously receiving IOP via the MRO option therefore, may not be impacted as much as others not previously eligible for MRO.
- Opioid Use Disorder (OUD): It is likely that those 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 and those beneficiaries will be identified and examined as a sub-population. B&A will use the specification for OUD described in the CMS-approved Monitoring Plan.

To fully study the secondary drivers, three surveys will target all identified Indiana Medicaid enrolled providers. In addition, B&A will use Indiana-specific N-SSATS data, which is self-reported provider survey data collected nationally, to explore statewide, multi-payer trends.

The matrices included in Section III.G identify the target population and stratification proposed for each hypothesis and research question.

Comparison Groups

Two ideal comparison groups described in the CMS technical advisory guidance on selection of comparison groups include another state Medicaid population and/or prospectively collected information

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prior to the start of the intervention.¹¹ Specifically, a SUD population with similar demographics, in another state without those waiver flexibilities described in Indiana, would be an ideal comparator. However, identifying whether such a state exists or that data could be obtained given the sensitivity of SUD privacy concerns as it relates to data sharing is outside the scope of the evaluation and therefore not feasible. Similarly, the other example of a control from the design guide is to collect prospective data and to our knowledge, there is no known prospective data collection on which to build baselines.

One exception to this would be for the three reported measures using N-SSATS data, which are collected nationally and reported at a statewide level. In this case, comparator states could be identified and possibly included within the analysis. B&A will compare these trends for up to two other states if desired; the two states will be chosen in consultation with Indiana Medicaid, CMS and other stakeholders.

Given the lack of an available and appropriate comparison group, B&A will use an analytic method which creates a pre- and post- waiver (intervention) group upon which to compare outcomes. See Section III.F for more details on the analytic methods.

III.C Evaluation Period

A pre- and post- waiver period will be defined as three calendar years before and three calendar years after waiver implementation. The waiver period is three years and therefore, the pre-period will also be for three years. The pre-waiver period, therefore, is defined as enrollment or dates of service of January 1, 2015 through December 31, 2017. The post-waiver period is defined as enrollment or dates of service of January 1, 2018 through December 31, 2020. Also, in support of the analytic methods described in Section III.F, the calendar year data will be sub-set into both monthly and quarterly segments such that both the pre- and post- waiver periods will include 12 quarters or 36 months each.

To simplify the analytic plan, B&A is making an assumption about the first month of 2018. Although CMS approved the SUD provisions of Indiana’s 1115 waiver in February 2018, not in January 2018, waiver-related activities were moving forward in anticipation of approval and for ease of conducting and describing the analysis, the evaluation period will include the one month of the post-intervention period following submission of the waiver but prior to February 2018 approval.

Similarly, while this is the expected post-evaluation period, modifications may be warranted to better reflect differences in the time period upon which one would expect to see a change in outcome resulting from waiver activities. At this time, there was little data or similar studies on which to base specific alternatives to the proposed post-evaluation period. B&A will therefore, examine time series data in order to identify whether the post-evaluation period should be delayed. For example, if review of the data shows a distinctive change in the third quarter of 2018, the post-period would be adjusted such that the first and second quarter data would not be considered in the interrupted time series analysis described in Section III.F.

III.D Evaluation Measures

The measures included in the evaluation plan directly relate to the aims, primary and secondary drivers described in Section II. The measures fall into three primary domains: quality, access and financial. All

¹¹ Comparison Group Evaluation Design. <https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/comparison-grp-eval-dsgn.pdf>.

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the measures in Indiana’s existing Monitoring Plan are included as well as additional measures including average driving distance, potentially preventable emergency department visits and hospital readmissions.

Figure 7 summarizes the list of measures included in the evaluation plan. A comprehensive summary of measures, which includes measure stewards as well as a description of numerators and denominators can be found in the detailed matrices in Section III.G.

Figure 7. List of Measures by Domain

Quality

- Potentially Preventable Emergency Department Visits
- Potentially Preventable Re-Admissions
- Initiation and Engagement of Alcohol and Other Drug (AOD) Dependence Treatment
- Follow-Up After Discharge from the ED for Alcohol or Other Drug Dependence
- Use of Opioids at High Dosage in Persons Without Cancer
- Concurrent Use of Opioids and Benzodiazepines
- Continuity of Pharmacotherapy for Opioid Use Disorder
- Emergency Department Utilization for SUD Per Member Month
- Inpatient Admissions for SUD Per Member Month
- Readmissions for SUD
- Overdose Deaths
- Opioid Overdose Deaths
- Average Clinical Risk Group (CRG) Score

Access

- Utilization of ASAM-specific Services per 1,000
- Count of ASAM-specific Providers
- Average Driving Distance for ASAM-specific Services
- Number of Prior Authorizations
- Number and Reason for Denial of Prior Authorization

Financial

- Total costs
- Total federal costs
- SUD-IMD
- SUD-other
- Non-SUD
- Outpatient costs – non ED
- Outpatient costs – ED
- Inpatient costs
- Pharmacy costs
- Long-term care costs

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III.E Data Sources

As described in section III.A, Evaluation Design, B&A 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, i.e., enrollment, claims and encounter data. Supplemental administrative data, such as prior approval denials and authorizations, will also be incorporated. Primary data will be limited and include data created by surveys, desk review and facilitated interview instruments. A brief description of these data and their strengths and weaknesses are below.

Indiana Medicaid Administrative Data

Claims and encounters with dates of service (DOS) from January 1, 2015 – December 31, 2020 will be collected from the OMPP Enterprise Data Warehouse (EDW), facilitated by OMPP's EDW vendor, Optum. Managed care encounter data has the same record layout as fee-for-service, 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, including SUD and related services payments. Three of the four MCEs in Indiana were contracted through the entire study period, with the fourth, CareSource, added effective January 1, 2017.

A data request specific to the 1115 SUD Evaluation Design Plan, will be given to Optum and the data will be delivered to B&A in an agreed upon format. The initial EDW data set will include historical data up to the point of the delivery, with subsequent data sent on a monthly basis. All data delivered to B&A from the OMPP will come directly from the EDW. B&A will leverage all data validation techniques used by Optum before the data is submitted to the EDW. When additional data is deemed necessary for the evaluation, B&A will outreach directly to the MCEs to obtain the necessary data for the evaluation, including running the required data validations. A refresh of the EDW for additional claims with these dates of services will be done at six month and twelve-month intervals; the last query of the EDW will occur on January 1, 2022 for claims with DOS in the study period.

Additional data from the MCEs and the State will be collected on prior authorizations, denials, 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. That being said, we will use a standard quality review and data cleaning protocol in order to validate these data, as well as 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.

Survey and Facilitated Interview Data

N-SSATS

The National Survey of Substance Abuse Treatment Services (N-SSATS) is an annual survey of service providers. This data is reported at a statewide level and therefore, this data does not allow states to isolate demonstration populations. Moreover, the CMS technical guidance states that this survey is known to undercount Medicaid providers. Therefore, this data is used as supplement and will be used to review for descriptive trends over time.

Provider Survey or Interview Guides

B&A will construct standardized instruments in order to create primary data. The instruments will be provided to CMS for their feedback in advance of fielding. The instruments will be created after doing preliminary desk reviews and analysis, and therefore, are not included in the evaluation plan. It is

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anticipated that once the survey instruments are approved by CMS, they will be fielded for one month before initial results would be tabulated. Where focused interviews are used to collect data, B&A will hold a sufficient number of sessions to collect the required data in accordance with the research question and CMS deliverable. Figure 8 contains the proposed primary data collection activities by source, year, and hypotheses. Figure 9 demonstrates the proposed primary data collection timeline by type, year, and hypotheses.

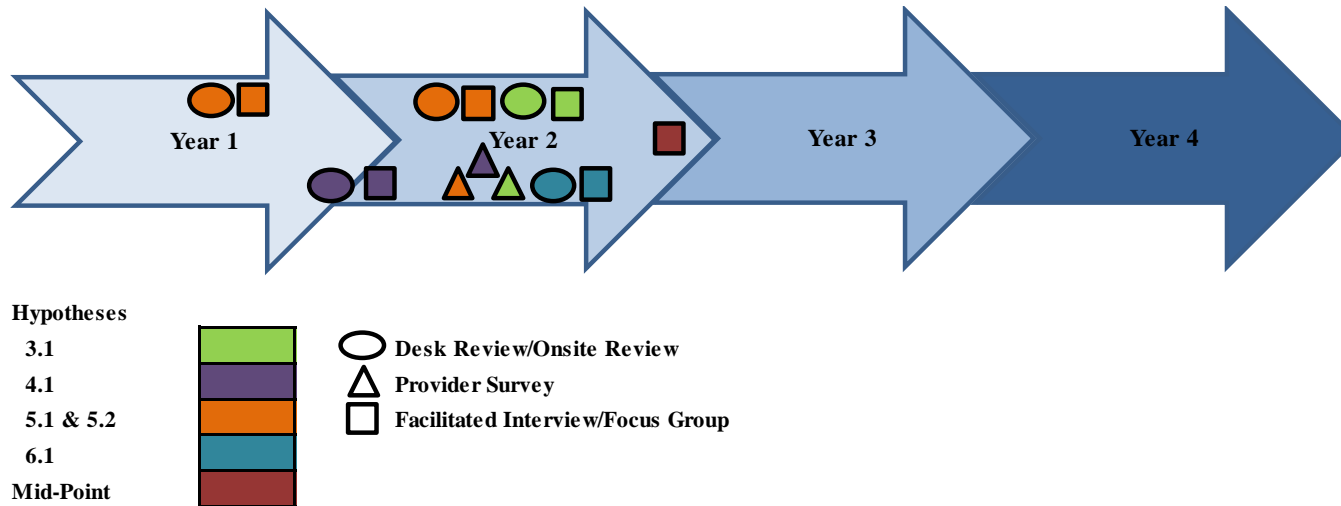
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Figure 8. Proposed Primary Data Collection Activities, by Source, Year and Hypotheses

	Source	Desk / Onsite Review			Survey	Facilitated Interviews / Focus Groups			
		MCEs	CMCS	State Agencies	Providers	Beneficiaries	Providers	CMCS	MCEs
Hypotheses	Contract Year 1								
	3.1	X		X					
	4.1			X					
	5.1 and 5.2	X	X	X				X	X
	6.1								
	Contract Year 2								
	3.1				X		X		
	4.1				X		X		
	5.1 and 5.2	X	X	X	X			X	X
	6.1	X		X			X		X
Mid-Point Assessment						X	X		X

* Years correspond to B&A contract, and run June 1 through May 30. Year 1 began in 2018.

Figure 9. Proposed Primary Data Collection Timeline, by Type, Year and Hypotheses



* Years correspond to B&A contract, and run June 1 through May 30. Year 1 began in 2018.

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III.F Analytic Methods

Figure 6 in Section III.A, Evaluation Design, depicts the six analytic methods to be used in the analysis. A detailed review of each are included in this section.

Method 1: Interrupted Time Series (ITS)

Interrupted time series (ITS) is a quasi-experimental method used to evaluate health interventions and policy changes when randomized control trials (RTC) are not feasible or appropriate.^{12,13,14} As it would not be ethical or consistent with Medicaid policy to withhold services resulting from waiver changes from a sub-set of SUD beneficiaries for purposes of evaluation, an RTC is therefore, not possible. Per CMS technical guidance, the ITS is the preferred alternative approach to RTC in the absence of an available, adequate comparison group. And finally, the ITS method is particularly suited for interventions introduced at the population level which have a clearly defined time period and targeted health outcomes.^{15,16,17}

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.

While there are no fixed limits regarding the number of data points because statistical power depends on a number of factors like variability of the data and seasonality, it is likely that a small number of observations paired with small expected effects may be underpowered.¹⁸ The expected change in many outcomes included in the evaluation are likely to be small and therefore, B&A will use 72 monthly observations where possible and 24 quarterly observations where monthly are not deemed reliable.

In order to determine whether monthly or quarterly observations will be created, a reliability threshold of having a denominator of a minimum number of 100 observations at the monthly or quarterly level will be used. If quarterly reporting is not deemed reliable under this threshold, the measure and/or stratification will not be tested using interrupted time series and instead, these measures will be computed using calendar year data in the pre- and post-period and reported descriptively.

¹² Bonell CP, Hargreaves J, Cousens S et al.. Alternatives to randomisation in the evaluation of public health interventions: Design challenges and solutions. *J Epidemiol Community Health* 2009;65:582-87.

¹³ Victora CG , Habicht J-P, Bryce J. Evidence-based public health: moving beyond randomized trials. *Am J Public Health* 2004;94:400–05.

¹⁴ Campbell M , Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. . Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;321:694.

¹⁵ Soumerai SB. How do you know which health care effectiveness research you can trust? A guide to study design for the perplexed. *Prev Chronic Dis* 2015;12:E101.

¹⁶ 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.

¹⁷ 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>

¹⁸ 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>

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ITS Descriptive Statistics

All demographic, population flags, and measures will be computed and basic descriptive statistics created: mean, median, minimum, maximum, standard deviation. These data will be inspected for identification of anomalies and trends.

To identify underlying trends, seasonal patterns and outliers, scatter plots of each measure will be created and examined. 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 as¹⁹:

$$\hat{Y}_t = \beta_0 + \beta_1 * time_t + \beta_2 * intervention_t + \beta_3 * time_after_intervention_t + e_t$$

Where: 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

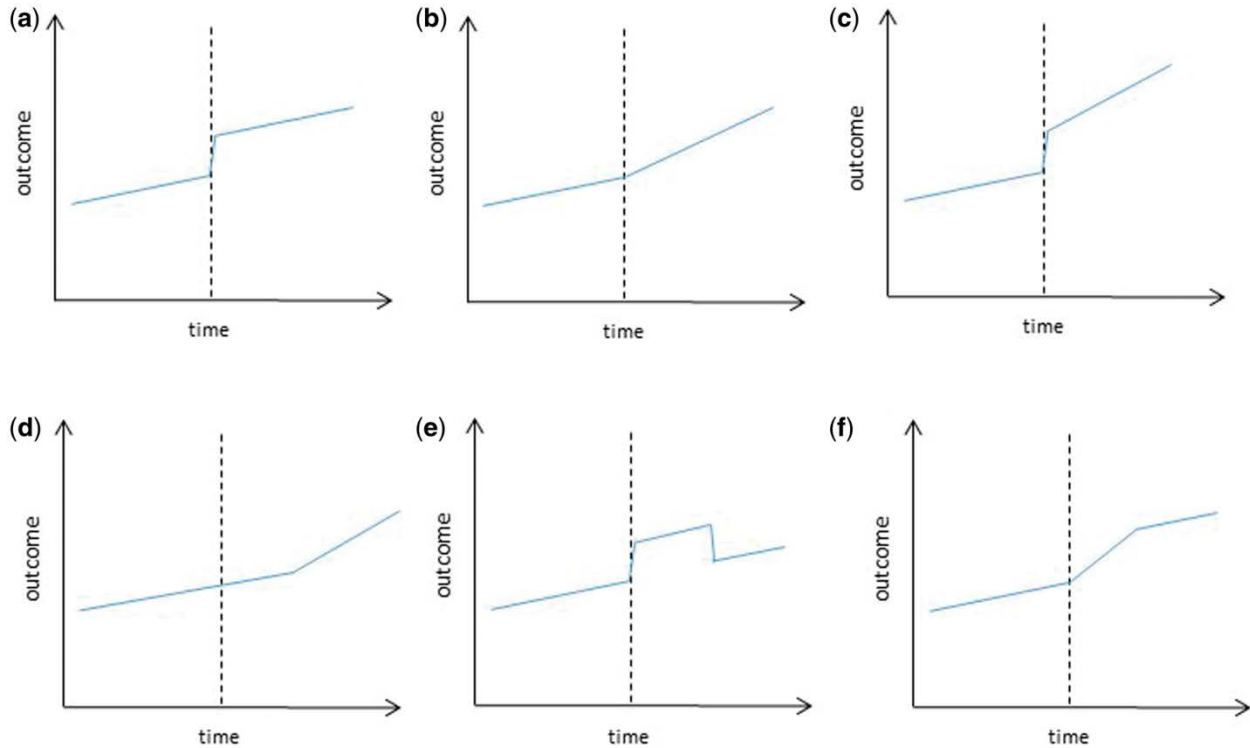
β_3 estimates the change in trend in the post-intervention segment

e_t estimates the error

Visualization and interpretation will be done as depicted in the Figure 10. Each outcome will be assessed for one of the following types of relationships in the pre- and post- wavier 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.

¹⁹ 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.

Figure 10. Illustration of Potential ITS Relationships²⁰



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 thereby controlling 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, B&A 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 versus predicted values. If the points are not symmetrically distributed around a horizontal line, with roughly constant

²⁰ From: Interrupted time series regression for the evaluation of public health interventions: a tutorial
Int J Epidemiol. 2016;46(1):348-355. doi:10.1093/ije/dyw098. Int J Epidemiol.

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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, B&A 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, B&A 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, the regression analysis will be run both on the entire SUD target population and stratified by relevant sub-populations. The sub-population level analysis may reveal waiver effects that would otherwise be masked if only run on the entire SUD population. Similarly, common demographic covariates such as age, gender, and race will be included in these models to the extent they improve the explanatory power of the ITS models.

Method #2: Descriptive Statistics

In order to facilitate ongoing monitoring, all measures will be summarized on an ongoing basis over the course of the waiver. The descriptive statistics will be stratified by ASAM level of care, by MCE and FFS delivery systems, and/or by region where possible. For reporting purposes, the descriptive studies will be subject to determination of a minimum number of beneficiaries in an individual reported cell (i.e., minimum cell size) and subject to blinding if the number falls below this threshold. While a conventional threshold is 10 or fewer observations, given the sensitivity of SUD and the public dissemination of report findings, a higher threshold may be established by B&A upon review of the final data.

Results will primarily be reported in terms of longitudinal descriptive statistics of defined groups of SUD beneficiaries and using regional maps where possible.

Method #3: Provider Surveys (PS)

In order to fill gaps and address questions for which claims-based data is insufficient, one-time, cross-sectional provider surveys will be fielded. The surveys will be sent via an online survey tool. The survey will be sent to 100 percent of targeted providers. The provider groups include residential providers, inpatient providers and those serving patients with SUD who are receiving care coordination.

The surveys will collect anonymous information related to perceptions of barriers, value and efficiency of improvements under the waiver. Dissemination of the survey and efforts to improve response rates will be coordinated with the OMPP and applicable Indiana provider and/or professional associations. The response rate will be clearly stated and considered when evaluating and/or presenting any findings. The survey questions will be presented to CMS in advance of fielding for their feedback and approval.

A detailed overview of each survey along the dimensions of interest to CMS (defining cohort, study period, analytics, etc.) are included for each research question using survey findings in Section III.G.

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Method #4: Onsite Reviews (OR)

In order to fill gaps and address questions for which claims-based data and provider surveys are insufficient, a number of onsite reviews are proposed. These onsite reviews will seek to gain insight on nuanced differences in approach, use and effectiveness of different MCE and FSSA approaches to the following topics:

- Adoption of ANSA screening criteria and subsequent ASAM placement
- Credentialing of residential providers
- SUD care coordination activities

The onsite reviews rely on creating a standardized set of questions that will capture information on process, documentation and medical records. The questions may include onsite documentation gathering and data validation related to those topics described above.

In some cases, the onsite reviews will employ a sampling approach whereby a limited number of beneficiaries are selected based on a set of criteria, and internal records specific to those beneficiaries will be reviewed. The sample criteria would be developed to reflect the representativeness with the SUD population served by each MCE, which will help aid in the comparability of the results of the onsite across MCEs. Finally, the same reviewer (or group of reviewers) will be used for all MCE reviews, strengthening inter-reliability.

A detailed overview of each onsite review along the dimensions of interest to CMS (defining cohort, study period, analytics, etc.) are included for each research question using onsite review findings in Section III.G.

Method #5: Desk Reviews (DR)

A limited number of desk reviews will supplement the other study methods included in the evaluation. These reviews will focus on hypotheses which are directed at assessment of process outcomes like avoidance of implementation delays, system changes according to schedules, transparency of policy and rates, and utility of stakeholder tools and analytics. Each desk review will use a questionnaire that asks for the information sought, the documentation reviewed, and the finding. Any gaps in information will also be noted as findings. The evaluator will review publicly available information and/or documentation specifically requested from the OMPP and/or the MCEs.

A detailed overview of each survey along the dimensions of interest to CMS (defining cohort, study period, analytics, etc.) are included for each research question using desk review findings in Section III.G.

Method #6 Facilitated and/or Focus Group Interviews (FI/FG)

As needed, the evaluator will supplement all study methods using facilitated interviews and/or focus groups. Like the onsite reviews, facilitated interviews and focus groups will be done by first creating a standardized questionnaire that will be used to validate or elucidate gaps in information related to findings of any of the study methods. Since these would be done on an ad-hoc basis, no sampling design would be used; however, at minimum, the evaluator will ensure a broad representation of perspectives when doing additional research about a particular topic. An independent focus group facilitator has been engaged by the evaluation team to conduct these focus groups.

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III.G Other Additions

Starting on the next page, a matrix summarizing the methods for each hypothesis and research question described in Section III.A – III.F is presented.

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1.1 Key health outcomes improve in the SUD population in the post-waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
<p>1.1.1. Does the level and trend of overdose deaths and overdose due to opioids decrease among the SUD population in the post-waiver period?</p>	<ul style="list-style-type: none"> Overdose Deaths <i>Opioid Overdoes Deaths</i> <p><u>Description</u> The number of overdose deaths per 1,000 Medicaid beneficiaries</p> <p><u>Description</u> <i>The number of opioid overdose deaths per 1,000 Medicaid beneficiaries</i></p> <p>Computed Monthly or Quarterly <i>*if denominator is <100 at this level, compute annual and use for descriptive analysis only</i></p>	<p><u>Numerator</u> 1. Members who died of overdose in month or quarter.</p> <p><u>Denominator</u> Number of beneficiaries eligible in month or quarter/1000</p> <p><u>Age</u> 18 years and older</p> <p><u>Numerator</u> 1. Members who died of overdose due to opioid in month or quarter.</p> <p><u>Denominator</u> Number of beneficiaries eligible in month or quarter/1000</p> <p><u>Age</u> 18 years and older</p>	<p>OMPP Enterprise Data Warehouse (EDW)</p> <p>Vital Statistics/Indiana State Department of Health (ISDH)</p>	<ul style="list-style-type: none"> Interrupted Time Series <ul style="list-style-type: none"> Examine whether statistically significant differences exist in the rates of change in overdose deaths in the pre- and post-intervention periods. <p><u>Pre-intervention Timeframe</u> Monthly or Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Monthly or Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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1.1 Key health outcomes improve in the SUD population in the post-waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
1.1.2 Does the level and trend of initiation and engagement in treatment increase in the SUD population in the post waiver period?	<ul style="list-style-type: none"> Initiation and Engagement of Alcohol and Other Drug (AOD) Dependence Treatment <p><u>Description</u> Number of Indiana Medicaid members who have initiated treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter, or partial hospitalization within 14 days of a diagnosis (or two or more additional services within 30 days of the visit).</p> <p>Computed Monthly or Quarterly <i>*if denominator is <100 at this level, compute annual and use for descriptive analysis only</i></p>	<p><u>Numerator</u> 1. Members who initiated treatment within 14 days of the diagnosis 2. Members who initiated treatment and who had two or more additional services with a diagnosis within 30 days of the initiation visit</p> <p><u>Denominator</u> Individuals who were diagnosed with alcohol or drug dependency during a visit within the previous rolling 11 months</p> <p><u>Age</u> 18 years and older</p>	OMPP Enterprise Data Warehouse (EDW) NCQA	<ul style="list-style-type: none"> Interrupted Time Series <ul style="list-style-type: none"> Examine whether statistically significant differences exist in the rates of change in initiation and engagement in the pre- and post- intervention periods. <p><u>Pre-intervention Timeframe</u> Monthly or Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Monthly or Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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1.1 Key health outcomes improve in the SUD population in the post-waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
<p>1.1.3 Does the level and trend of follow-up after discharge from the ED for SUD increase among the SUD population in the post waiver period?</p>	<ul style="list-style-type: none"> Follow-Up After Discharge from the Emergency Department for Alcohol or Other Drug (AOD) Dependence <p><u>Description</u> The percentage of ED visits for members 18 years of age and older with a primary diagnosis of alcohol and other drug (AOD) dependence, who had an outpatient visit, an intensive outpatient encounter, or a partial hospitalization for AOD.</p> <p>Computed Monthly or Quarterly <i>*if denominator is <100 at this level, compute annual and use for descriptive analysis only</i></p>	<p><u>Numerator</u> 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. 2. Members who had a follow-up visit to and ED visit with a SUD indicator within 30 days of Discharge within the previous rolling 12 months.</p> <p><u>Denominator</u> Individuals with an ED visit (with SUD indicator) within the previous rolling 12 months</p> <p><u>Age</u> 18 years and older</p>	<p>OMPP Enterprise Data Warehouse (EDW)</p> <p>NCQA</p>	<ul style="list-style-type: none"> Interrupted Time Series <ul style="list-style-type: none"> Examine whether statistically significant differences exist in the rates of change in follow up after discharge in the pre- and post- intervention periods. <p><u>Pre-intervention Timeframe</u> Monthly or Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Monthly or Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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1.1 Key health outcomes improve in the SUD population in the post-waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
<p>1.1.4 Does the level and trend in continuity of pharmacotherapy for opioid use disorder increase among the OUD population in the post waiver period?</p>	<ul style="list-style-type: none"> Continuity of Pharmacotherapy for Opioid Use Disorder <p><u>Description</u> The percentage of adults (18 through 64) with pharmacotherapy for opioid use disorder who have at least 180 days of continuous treatment.</p> <p>Computed Monthly or Quarterly <i>*if denominator is <100 at this level, compute annual and use for descriptive analysis only</i></p>	<p><u>Numerator</u> Individuals who have had at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than seven days</p> <p><u>Denominator</u> Individuals with a diagnosis of opioid use disorder and at least one claim for opioid use disorder medication in the previous rolling 12 months.</p> <p><u>Age</u> 18 – 64 years and older</p>	<p>OMPP Enterprise Data Warehouse (EDW)</p> <p>RAND</p>	<ul style="list-style-type: none"> Interrupted Time Series <ul style="list-style-type: none"> Examine whether statistically significant differences exist in the rates of change of continuity of pharmacotherapy for opioid use disorder in the pre- and post-intervention periods. <p><u>Pre-intervention Timeframe</u> Monthly or Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Monthly or Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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1.1 Key health outcomes improve in the SUD population in the post-waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
1.1.5 Does the level and trend in concurrent use of opioids and benzodiazepines decrease in the OUD population in the post waiver period?	<ul style="list-style-type: none"> Concurrent Use of Opioids and Benzodiazepines <p><u>Description</u> The percentage of beneficiaries 18 years and older with concurrent use of prescription opioids and benzodiazepines.</p> <p>Computed Quarterly <i>*if denominator is <100 at this level, compute annual and use for descriptive analysis only</i></p>	<p><u>Numerator</u> The number of individuals with:</p> <ol style="list-style-type: none"> 2 or more prescription claims for any benzodiazepine filled on two or more separate days; AND Concurrent use of opioids and benzodiazepines for 30 or more cumulative days <p><u>Denominator</u> Any member with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days supply is ≥ 15</p> <p><u>Age</u> 18 years and older</p>	OMPP Enterprise Data Warehouse (EDW) PQA/CMT –Measure 903	<ul style="list-style-type: none"> Interrupted Time Series <ul style="list-style-type: none"> Examine whether statistically significant differences exist in the rates of change of concurrent opioid and benzodiazepines in the pre- and post- intervention periods. <p><u>Pre-intervention Timeframe</u> Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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1.1 Key health outcomes improve in the SUD population in the post-waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
<p>1.1.6 Does the level and trend in the rate of use of opioids at high dosage in persons without cancer decrease in the post waiver period?</p>	<ul style="list-style-type: none"> Use of Opioids at High Dosage in Persons Without Cancer <p><u>Description</u> The proportion (out of 1,000) of beneficiaries without cancer receiving a daily dosage of opioids greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer with and without a SUD diagnosis.</p> <p>Computed Quarterly <i>*if denominator is <100 at this level, compute annual and use for descriptive analysis only</i></p>	<p><u>Numerator</u> Any member in the denominator with greater than 120 MME for >= 90 days in the quarter.</p> <p><u>Denominator</u> Any member with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days supply is >= 15 in the quarter.</p> <p><u>Age</u> Ages 18 years and older</p>	<p>OMPP Enterprise Data Warehouse (EDW)</p> <p>PQA, CMT-884</p>	<ul style="list-style-type: none"> Interrupted Time Series <ul style="list-style-type: none"> Examine whether statistically significant differences exist in the rates of change of the use of opioids at a high dosage in the pre- and post- intervention periods. <p><u>Pre-intervention Timeframe</u> Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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1.2 Costs of care decreases in the SUD population in the post waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
1.2.1. Does the level and trend in overall spending for the SUD population decrease in the post waiver period?	<ul style="list-style-type: none"> • Total Spending <ul style="list-style-type: none"> ○ Estimated State and Federal Share • Per Capita Spending <ul style="list-style-type: none"> ○ Estimated State and Federal Share <p><u>Description</u> Total spending and per capita total spending broken down by estimated federal and state share using an average FMAP for the study period.</p> <p>Computed Quarterly <i>*if denominator is <100 at this level, compute annual and use for descriptive analysis only</i></p>	<p><u>Numerator</u> All paid claims based on service date for any beneficiary with SUD indicator in month or quarter. Excludes crossovers.</p> <p><u>Denominator (Per Capita)</u> Number of enrolled beneficiaries in month or quarter</p> <p><u>Age</u> All ages</p>	<p>OMPP Enterprise Data Warehouse (EDW)</p> <p>B&A</p>	<ul style="list-style-type: none"> • Interrupted Time Series <ul style="list-style-type: none"> ○ Examine whether statistically significant differences exist in the rates of change of total and per capita spending in the pre- and post- intervention periods. <p><u>Pre-intervention Timeframe</u> Monthly or Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Monthly or Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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1.2 Costs of care decreases in the SUD population in the post waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
1.2.2 Does the level and trend in SUD service spending for the SUD population increase in the post waiver period?	<ul style="list-style-type: none"> Any SUD Spending SUD Spending in IMDs Per Capita Any SUD Spending Per Capita SUD Spending in IMDs <p><u>Description</u> Any SUD and IMD spending in total and per capita.</p> <p>Computed Monthly or Quarterly <i>*if denominator is <100 at this level, compute annual and use for descriptive analysis only</i></p>	<p><u>Numerator</u> All SUD and IMD paid claims based on service date for any beneficiary with SUD indicator in month or quarter. Excludes crossovers.</p> <p><u>Denominator (Per Capita)</u> Number of enrolled individuals in month or quarter.</p> <p><u>Age</u> All ages</p>	<p>OMPP Enterprise Data Warehouse (EDW)</p> <p>B&A</p>	<ul style="list-style-type: none"> Interrupted Time Series <ul style="list-style-type: none"> Examine whether statistically significant differences exist in the rates of change of total SUD and SUD per capita spending in the pre- and post- intervention periods. <p><u>Pre-intervention Timeframe</u> Monthly or Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Monthly or Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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1.2 Costs of care decreases in the SUD population in the post waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
1.2.3. Does the level and trend in non-SUD service spending for the SUD population decrease in the post waiver period?	<ul style="list-style-type: none"> • Any non-SUD Spending • Per Capita non-SUD Spending <ul style="list-style-type: none"> ○ Non-emergency Outpatient ○ Emergency Department Outpatient ○ Inpatient ○ Pharmacy ○ Long Term Care ○ Professional Services: Primary versus Specialty ○ Other <p><u>Description</u> Any non-SUD spending in total and per capita. Broken down by key categories of services.</p> <p>Computed Monthly or Quarterly <i>*if denominator is <100 at this level, compute annual and use for descriptive analysis only</i></p>	<p><u>Numerator</u> All non-SUD paid claims based on service date for any beneficiary with SUD indicator in month or quarter. Excludes crossovers.</p> <p><u>Denominator (Per Capita)</u> Number of enrolled individuals in month or quarter.</p> <p><u>Age</u> All ages</p>	<p>OMPP Enterprise Data Warehouse (EDW)</p> <p>B&A</p>	<ul style="list-style-type: none"> • Interrupted Time Series <ul style="list-style-type: none"> ○ Examine whether statistically significant differences exist in the rates of change of total SUD and SUD per capita spending in the pre- and post- intervention periods. <p><u>Pre-intervention Timeframe</u> Monthly or Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Monthly or Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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1.2 Costs of care decreases in the SUD population in the post waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
1.2.4. Does the level and trend in the percentage of SUD facilities who report they accept Medicaid as a payer increase in the post waiver period?	<ul style="list-style-type: none"> Proportion of SUD Providers Who Report Accepting Medicaid <p><i>If Quarterly reporting not available, this measure will be reported annually and use for descriptive analysis only</i></p>	Indiana SUD providers who respond to N-SSATS survey.	National Survey of Substance Abuse Treatment Services (N-SSATS)	<ul style="list-style-type: none"> Interrupted Time Series/<i>Descriptive</i> <ul style="list-style-type: none"> Examine whether statistically significant differences exist in the rates of change of total SUD and SUD per capita spending in the pre- and post- intervention periods. <p><u>Pre-intervention Timeframe</u> Quarterly or Annually CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Quarterly or Annually CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> N/A</p>

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1.2 Costs of care decreases in the SUD population in the post waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
1.2.5. Does the level and trend in average CRG risk scores decrease among the SUD population in the post-waiver period?	<ul style="list-style-type: none"> Average Clinical Risk Group (CRG) Score <p><u>Description</u> The average CRG score for Medicaid beneficiaries with a SUD diagnosis in the month or quarter.</p> <p>Computed Monthly or Quarterly <i>*if denominator is <100 at this level, compute annual and use for descriptive analysis only</i></p>	<p><u>Numerator</u> Total CRG risk score for members with SUD in month or quarter.</p> <p><u>Denominator</u> Members with SUD in month or quarter.</p> <p><u>Age</u> 18 – 64 years and older</p>	OMPP Enterprise Data Warehouse (EDW) 3M/B&A	<ul style="list-style-type: none"> Interrupted Time Series <ul style="list-style-type: none"> Examine whether statistically significant differences exist in the level and trend in average CRG risk score in the pre- and post- intervention periods. <p><u>Pre-intervention Timeframe</u> Monthly or Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Monthly or Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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1.2 Costs of care decreases in the SUD population in the post waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
1.2.6 Does the level and trend in acute utilization for SUD, potentially preventable emergency department or potentially preventable hospital readmissions decrease in the SUD population in the post waiver period?	<ul style="list-style-type: none"> PPVs and PPRs <p><u>Description</u> Rate of potentially preventable emergency department visits (PPVs) and hospital readmissions (PPRs) among Indiana Medicaid members with SUD.</p> <ul style="list-style-type: none"> ED, Admission and Readmission per member month <p><u>Description</u> The total number of emergency department visits, hospital admissions and readmissions for SUD diagnosis in the reporting month (per 1,000 enrolled Medicaid members) in previous three months (separate count for each month).</p> <p>Computed Quarterly <i>*if denominator is <100 at this level, compute annual and use for descriptive analysis only</i></p>	<p><u>Numerator</u> Number of potentially preventable visits and/or readmissions</p> <p><u>Denominator</u> Individuals who were diagnosed with alcohol or drug dependency during the calendar year.</p> <p><u>Age</u> 18 – 64 years and older</p> <p><u>Numerator</u> Number of ED visits, hospital admissions, and readmissions with SUD diagnosis.</p> <p><u>Denominator</u> Enrolled Medicaid members/1000</p> <p><u>Age</u> 18 – 64 years and older</p>	<p>OMPP Enterprise Data Warehouse (EDW)</p> <p>3M PPV and PPR Software</p> <p>B&A</p>	<ul style="list-style-type: none"> Interrupted Time Series <ul style="list-style-type: none"> Examine whether statistically significant differences exist in the rates of change in acute utilization in the pre- and post-intervention periods. <p><u>Pre-intervention Timeframe</u> Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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2.1 Access to care improved in the SUD population in the post-waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
2.1.1. Does the level and trend in the number of SUD and primary care providers and the number of providers per capita in the SUD population increase in the post waiver period for each ASAM level of care?	<ul style="list-style-type: none"> Count of ASAM-specific Medicaid enrolled providers Number of ASAM-specific Medicaid enrolled providers per 1,000 SUD population <p>Computed Quarterly</p> <ul style="list-style-type: none"> Count of ASAM-specific statewide self-reported provider (N-SSATS) 	<p><u>Numerator</u> Number of providers enrolled as of last day of quarter.</p> <p><u>Denominator</u> Individuals with SUD as of the last day of the quarter.</p> <p><u>Age</u> 18 and older</p> <p>Indiana SUD providers who respond to N-SSATS survey.</p>	<p>OMPP Enterprise Data Warehouse (EDW)</p> <p>National Survey of Substance Abuse Treatment Services (N-SSATS)</p>	<ul style="list-style-type: none"> Descriptive Statistics <ul style="list-style-type: none"> Examine trends in counts of Medicaid-enrolled providers by ASAM level and per capita in the SUD population, MCE and region. <p><u>Pre-intervention Timeframe</u> Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p> <ul style="list-style-type: none"> Descriptive Statistics <ul style="list-style-type: none"> Examine changes in statewide trends in counts of providers by ASAM level, MCE and region.

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2.1 Access to care improved in the SUD population in the post-waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
2.1.2 Does the utilization per 1,000 of SUD services and primary care in the SUD population increase in the post waiver period for each ASAM level of care?	<ul style="list-style-type: none"> Utilization of ASAM-specific services per 1,000 Utilization of primary care services per 1,000 <p>Computed Quarterly</p>	<p><u>Numerator</u> Number of unique SUD and primary care services as of last day of quarter.</p> <p><u>Denominator</u> Individuals with SUD as of the last day of the quarter.</p> <p><u>Age</u> 18 and older</p>	OMPP Enterprise Data Warehouse (EDW)	<ul style="list-style-type: none"> Descriptive Statistics <ul style="list-style-type: none"> Examine trends in utilization of services per 1,000 SUD population by ASAM level, MCE and region. <p><u>Pre-intervention Timeframe</u> Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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2.1 Access to care improved in the SUD population in the post-waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
2.1.3. Does the average driving distance for SUD services and primary care decrease in the SUD population in the post waiver period for each ASAM level of care?	<ul style="list-style-type: none"> Average driving distance for ASAM-specific services Average driving distance for primary care <p>Computed Quarterly</p>	<p><u>Numerator</u> Number of unique SUD and primary care services as of last day of quarter.</p> <p><u>Denominator</u> Individuals with SUD as of the last day of the quarter.</p> <p><u>Age</u> 18 and older</p>	<p>OMPP Enterprise Data Warehouse (EDW)</p> <p>B&A</p>	<ul style="list-style-type: none"> Descriptive Statistics <ul style="list-style-type: none"> Examine trends in the average driving distance to SUD and primary care services by ASAM level, MCE and region. <p><u>Pre-intervention Timeframe</u> Quarterly CY2015-CY2017</p> <p><u>Post-intervention Timeframe</u> Quarterly CY2018-CY2020* <i>*refreshed every six months until after six months following run-out.</i></p> <p><u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]</p>

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3.1 Implementing residential treatment facility provider certification requirements based on ASAM level 3.1 and 3.5 criteria will improve provision of care.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
3.1.1. Does provider certification shift from resident and facility-based criteria to treatment-based certification criteria using ASAM level of care over the length of the waiver?	<ul style="list-style-type: none"> • Document process to phase in and adopt certification criteria based on ASAM level of care • Number of providers pre-waiver • Number of providers certified • Number of providers denied certification and why 	<p>OMPP and DMHA certification policies and procedures.</p> <p>MCEs credentialing policies and procedures</p>	Desk Review of OMPP, DMHA, MCE	<ul style="list-style-type: none"> • Descriptive Statistics <ul style="list-style-type: none"> ○ Examine results of process review and measures and develop trend over waiver
3.1.2. Does the ability to measure utilization by ASAM facility level will improve program monitoring?	<ul style="list-style-type: none"> • Document that ASAM level captured in EDW • Document reports created to track by ASAM level of care and by which metrics • Document use of reports through waiver period to monitor 	<p>OMPP and DMHA reporting measures</p> <p>MCEs reporting measures</p>	Desk Review of OMPP, DMHA, MCE	<ul style="list-style-type: none"> • Descriptive Statistics <ul style="list-style-type: none"> ○ Examine results of process review and measures and develop trend over waiver

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3.1 Implementing residential treatment facility provider certification requirements based on ASAM level 3.1 and 3.5 criteria will improve provision of care.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
3.1.3. Does provider awareness and use of ASAM Patient Placement Criteria increase over the length of the waiver?	<ul style="list-style-type: none"> • Document knowledge of criteria • Number of providers using criteria 	Residential services providers	Provider Focus Study or Provider Survey* *subject to CMS approval	<ul style="list-style-type: none"> • Cross-sectional, online, census provider survey. <ul style="list-style-type: none"> ○ Examine results of provider focus study or online provider survey and measures and develop trend over waiver
3.1.4. Do providers offer medication-assisted treatment (MAT)?	<ul style="list-style-type: none"> • Document process to phase in and adopt MAT. • Number of providers pre-waiver • Number of providers offering MAT onsite. • Number of providers offering access to MAT at an affiliated location 	Residential services provider	Provider Survey* or Onsite *subject to CMS approval	<ul style="list-style-type: none"> • Cross-sectional, online, census provider survey. <ul style="list-style-type: none"> ○ Examine results of provider focus study or online provider survey and measures and develop trend over waiver

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3.1 Implementing residential treatment facility provider certification requirements based on ASAM level 3.1 and 3.5 criteria will improve provision of care.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
3.1.5. Do residential facilities not currently enrolled in Indiana Medicaid have the opportunity to meet standards for enrollment leading to increased enrollment of residential addictions facilities?	<ul style="list-style-type: none"> • Document process to outreach to unenrolled providers to make them aware of the new enrollment opportunities. • Number of known providers who were not enrolled pre-waiver • Number of providers that enrolled during the waiver period • Number of providers denied enrollment and why 	<p>OMPP and DMHA certification policies and procedures.</p> <p>MCEs credentialing policies and procedures</p>	Desk Reviews of OMPP, DMHA, MCE	<ul style="list-style-type: none"> • Descriptive Statistics <ul style="list-style-type: none"> ○ Examine results of process review and measures and develop trend over waiver

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4.1 The quality and use of INSPECT data will improve in the post waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
4.1.1. Were changes to INSPECT made according to the Implementation Plan?	<ul style="list-style-type: none"> • Number of Changes Implemented as Expected • Number of Changes Implemented, but with less than a year delay • Number of Changes Not Implemented or delayed > 1 year 	INSPECT	Desk Review of admin documentation and interview notes	<ul style="list-style-type: none"> • Desk review of administrative documentation between proposed and actual implementation dates • As needed, conduct supplemental facilitated interviews with OMPP staff, fiscal agent staff, and/or INSPECT users
4.1.2. Did changes to INSPECT result in meaningful reporting capabilities?	<ul style="list-style-type: none"> • Perceptions of Usefulness of INSPECT Reporting Capabilities • Estimated Frequency of Use • Recommended Improvements 	INSPECT	Facilitated Interviews	<ul style="list-style-type: none"> • Review findings of facilitated interviews with IPLA and Indiana Board of Pharmacy staff. • As needed, conduct supplemental facilitated OMPP interviews with broader group of stakeholders including INSPECT users.
4.1.3. Has the number of prescribers using INSPECT increased over time?	<ul style="list-style-type: none"> • Number of prescribers using INSPECT 	All providers using inspect	INSPECT	<ul style="list-style-type: none"> • Descriptive Statistics <ul style="list-style-type: none"> ○ Review trends in use number of prescribers using INSPECT over time.
4.1.4. Has the volume of inquiries into the INSPECT database increased over time?	<ul style="list-style-type: none"> • Number of queries against INSPECT 	All providers using inspect	INSPECT	<ul style="list-style-type: none"> • Descriptive Statistics <ul style="list-style-type: none"> ○ Review trends in use of querying of INSPECT over time.

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5.1 The Child and Adolescent Needs and Strengths (CANS) and Adult Needs and Strengths Assessment (ANSA) tools are being used to place beneficiaries in ASAM levels of care.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
5.1.1. Are clinical criteria for authorization review for services delivered to beneficiaries with SUD being applied consistently across Indiana’s Health Coverage Programs (Hoosier Healthwise, Healthy Indiana Plan, Hoosier Care Connect, and Traditional Medicaid)?	<ul style="list-style-type: none"> • Average turnaround time for authorization decisions • For denied authorizations, the percentage of denials based on application of medical necessity criteria • For denied authorizations, the percentage of denials in which the specific reason/criteria were cited to the requesting provider 	MCE and FFS	Onsite Review of MCE and FFS Documentation and System B&A	<ul style="list-style-type: none"> • Develop standardized data request to the MCEs/OMPP to analyze all authorization records related to SUD services • Develop standardized tool with which to evaluate a sample of authorization records related to SUD services in the field at each MCE and at OMPP • In person interviews with the MCE/OMPP (or its contractor) staff who review authorization requests for SUD services to assess their capacity and training

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5.2 Prior authorization (PA) requirements do not negatively impact access to residential or inpatient services (ASAM 3.1, 3.5 and 4.0).				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
5.2.1. Are the rates of prior authorizations (PAs) submitted and PA requests that are denied in the SUD population, controlling for volume, relatively consistent by MCE and over time?	<ul style="list-style-type: none"> • Number of Prior Authorizations (PA) for ASAM 3.1, 3.5 and 4.0 • Number of PA Denials for ASAM 3.1, 3.5 and 4.0 • Rate of Approved and Denied SUD Authorizations for ASAM 3.1, 3.5 and 4.0 	<p><u>Numerator</u> The total number of prior approved and denied authorizations for ASAM 3.1, 3.5 and 4.0 in a calendar year.</p> <p><u>Denominator</u> Total number of authorizations for ASAM 3.1, 3.5 and 4.0 in a calendar year.</p> <p><u>Age</u> All ages</p>	OMPP Enterprise Data Warehouse (EDW)/OMPP Data B&A	<ul style="list-style-type: none"> • Descriptive Statistics <ul style="list-style-type: none"> ○ Examine trends in the rate of prior authorizations and denials among stratified populations, over time and by region and MCE.
5.2.2. Are prior authorization denials predominately for reasons directly related to not meeting clinical criteria as opposed to administrative reasons such as lack of information submitted?	<ul style="list-style-type: none"> • Frequency of Denial Reasons Codes for ASAM 3.1, 3.5 and 4.0 • Percent of Total Denials for ASAM 3.1, 3.5 and 4.0 	<p><u>Numerator</u> Count of denials with each reason for denial for ASAM 3.1, 3.5 and 4.0 in a calendar year.</p> <p><u>Denominator</u> Total number of denials for ASAM 3.1, 3.5 and 4.0 in a calendar year.</p> <p><u>Age</u> All ages</p>	OMPP Enterprise Data Warehouse (EDW)/OMPP Data B&A	<ul style="list-style-type: none"> • Descriptive Statistics <ul style="list-style-type: none"> ○ Examine the frequency of denial codes among stratified populations over time and by region and MCE.

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5.2 Prior authorization (PA) requirements do not negatively impact access to residential or inpatient services (ASAM 3.1, 3.5 and 4.0).				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
5.2.3. Is provider administrative burden associated with PA requests cited as a perceived barrier to access to care?	<ul style="list-style-type: none"> • Rate of participation in the FSSA Gold Card program (status to reduce burden on authorization requests) • Provider satisfaction rates with the Gold Card application process 	Residential and inpatient service providers.	Online Survey	<ul style="list-style-type: none"> • Cross-sectional, census provider of survey. <ul style="list-style-type: none"> ○ Examine rate of growth among participating providers in the Gold Card program ○ Examine results of point in time survey of provider perceptions

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6.1 Care coordination and transitions between ASAM levels of care will increase in the post-waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
6.1.1. Does the proportion of beneficiaries receiving ASAM designation who had a claim in that ASAM level within the next two consecutive months following the month of ASAM assignment increase over time?	<ul style="list-style-type: none"> Rate of beneficiaries who received ASAM service within two months following screening and ASAM designation 	<p><u>Numerator</u> Number of beneficiaries who received an ASAM in a given calendar year and received a service within two months within that ASAM level.</p> <p><u>Denominator</u> Number of beneficiaries who received each ASAM designation in a calendar year.</p> <p><u>Age</u> All ages</p>	<p>OMPP Enterprise Data Warehouse (EDW)</p> <p>B&A</p>	<ul style="list-style-type: none"> Descriptive Statistics <ul style="list-style-type: none"> Examine changes in statewide, regional and payer trends in proportion of beneficiaries with an ASAM designation receiving that level of care within the two following months.

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6.1 Care coordination and transitions between ASAM levels of care will increase in the post-waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
6.1.2. Does the proportion of beneficiaries with a SUD diagnosis who are receiving care coordination increase over time?	<ul style="list-style-type: none"> Number of beneficiaries receiving care coordination Proportion of SUD population receiving care coordination Percent of all SUD providers reporting using case management (N-SSATS) 	<p><u>Numerator</u> Number of beneficiaries who received care coordination in a calendar year.</p> <p><u>Denominator</u> Number of beneficiaries with SUD in a calendar year.</p> <p><u>Age</u> All ages</p> <p><u>Numerator</u> Number of providers reporting offering case management services.</p> <p><u>Denominator</u> Number of SUD providers who responded to the survey.</p>	<p>OMPP Enterprise Data Warehouse (EDW)</p> <p>B&A</p> <p>N-SSATS</p>	<ul style="list-style-type: none"> Descriptive Statistics <ul style="list-style-type: none"> Examine the absolute number of beneficiaries receiving care by MCE over time Examine the proportion of the SUD population receiving care by ASAM and MCE over time. Compare Medicaid trends to those reported in all-payer survey. Stratify SUD and OUD populations if feasible.

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6.1 Care coordination and transitions between ASAM levels of care will increase in the post-waiver period.				
Research Question	Evaluation Measure(s)	Study Population	Data Sources and Measure Steward	Analytic Methods
6.1.3. Do Indiana’s MCEs facilitate more active engagement in the case/care management process between behavioral health/substance abuse providers and primary care/other physical health providers for their patients with a SUD diagnosis?	<ul style="list-style-type: none"> • Number of care plan meetings between the MCE, primary care and BH/SA providers for patients with a SUD diagnosis • Number of protocols in place for coordination between providers (required by OMPP contract) • Number of referrals from primary care providers for treatment for SUD members • Number of behavioral health provider notifications to the MCE (required by contract) 	MCE and OMPP	Onsite Review of MCE and FFS Documentation and Systems	<ul style="list-style-type: none"> • Descriptive Statistics <ul style="list-style-type: none"> ○ Examine trends in reports of count of care plan meetings documented ○ Examine trends in behavioral health provider reports submitted per SUD member per year ○ Examine trends in referrals from primary care providers for treatment for SUD

SECTION IV: METHODODOLOGICAL 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 provider surveys, onsite reviews, desk reviews, and facilitated interviews/focus groups are proposed to provide a more holistic and comprehensive evaluation.

Another limitation is the length of time of the evaluation period. It is not expected that a two-year evaluation period, assuming year one is the benchmark period, would be sufficient time to observe changes in all measures of interest. 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 Considerations, will summarize the unique challenges in this study, reemphasizing the need for a mix-methods approach.

SECTION V: SPECIAL METHODOLOGICAL CONSIDERATIONS

Given that the waiver is new, and there are no identified implementation delays, or any other outstanding concerns, 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 detail in Section IV, Methodological Limitations, the study mitigates known limitations to the extent feasible drawing upon the range of options to fill gaps in the observational study design. Moreover, this Evaluation Design Plan is consistent with, and expands upon, CMS approved 1115 demonstration waiver SUD evaluation plans available on the CMS State Waivers List.²¹

Another special consideration is in the case of residential treatment in IMDs. While the waiver change is stated as “no coverage” to “coverage for all”, B&A identified that IMD residential services may have been provided in the pre-waiver period, but these would be funded by 100% state funds as opposed to matched federal dollars. Therefore, it is unclear whether a detectable change will be seen related to IMDs specifically, or whether change is created by the availability of new funds to be invested in other waiver services. This nuance will be considered when evaluating the results.

²¹ Medicaid State Waivers List can be accessed at: <https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/index.html>

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ATTACHMENT A: INDEPENDENT EVALUATOR

Process

On February 8, 2018, the Indiana Department of Administration, on behalf of Indiana Family and Social Services Administration, issued a Request for Proposal (RFP) 18-061 to solicit responses from vendors experienced in performing large-scale health care program evaluations to provide an evaluation of Indiana’s 1115 Substance Use Disorder (SUD) Waiver based upon the criteria set forth in the waiver’s Special Terms and Conditions as approved by the Centers for Medicare and Medicaid Services (CMS). A total of five vendors submitted proposals. After evaluation, and a request for a best and final offer from respondents, Burns & Associates, Inc. (B&A) was selected to act as the independent evaluator based on scores determined by the state review team on April 23, 2018.

Vendor Qualifications

B&A has served as the evaluator for the Independent Assessment for Indiana’s 1915(b) waiver for Hoosier Care Connect and has served as the External Quality Review Organization (EQRO) for Indiana since 2007. B&A has written an External Quality Review (EQR) report each year since that time which has been submitted to CMS. With this experience, the B&A team is very familiar with the Indiana Medicaid program, the managed care entities (MCEs) under contract with the Office of Medicaid Policy and Planning (OMPP), and the unique issues related to SUD treatment. The team that developed the Evaluation Design Plan has also worked on numerous EQRs, including a baseline study on the initiation and engagement of treatment for SUD for Indiana Medicaid as part of the EQR 2015 report.

Assuring Independence

As the State EQRO, B&A has already established its independence as required of all EQROs for this engagement. Additionally, in accordance with standard term and condition (STC) Attachment A – Developing the Evaluation Design, B&A has signed “No Conflict of Interest” statements regarding its work as the selected independent evaluator.

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ATTACHMENT B: EVALUATION BUDGET

As part of the procurement process, respondents to RFP 18-061 were required to submit a best and final offer. Figure 1 summarizes the total amount agreed to between the State and B&A for each deliverable due to CMS. Figure 2 enumerates the proposed staffing, level of effort by labor category, and total budget. The total estimated cost of the Evaluation Design Plan is \$1,196,180.

Figure 1. Cost Proposal Summary

Summary of Cost Proposal Deliverable (Draft and Final)	Costs					Hours
	Contract Year 1	Contract Year 2	Contract Year 3	Contract Year 4	Contract Year 5	Contract Years 1-5
2.4.1 Evaluation Design	\$ 27,500.00					132.00
2.4.2 Quarterly Monitoring Reports - Q1		\$ 57,325.00	\$ 57,325.00			578.00
2.4.2 Quarterly Monitoring Reports - Q2	\$ 57,325.00	\$ 57,325.00	\$ 57,325.00			867.00
2.4.2 Quarterly Monitoring Reports - Q3	\$ 57,325.00	\$ 57,325.00	\$ 57,325.00			867.00
2.4.3 Annual Monitoring Reports		\$ 105,595.00	\$ 105,595.00	\$ 105,595.00		1,620.00
2.4.4 Mid-Point Assessment		\$ 121,830.00				621.00
2.4.5 Interim Evaluation Report		\$ 132,485.00				663.00
2.4.6 Final Summative Evaluation Report					\$ 138,990.00	693.00
Total for all Deliverables	\$ 142,150.00	\$ 531,885.00	\$ 277,570.00	\$ 105,595.00	\$ 138,990.00	6,041.00

Total Bid Amount	\$ 1,196,190.00	Blended Hourly Rate	\$ 198.01
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Figure 2. Proposed Staffing Costs and Hours Allocation

Position Title	Staff Member	Hourly Rate	Hours	Pct of Hours	Dollars
Project Director	Mark Podrazik	\$ 250.00	897.00	15.1%	\$224,250
Project Manager	Debbie Saxe	\$ 230.00	986.00	16.6%	\$226,780
Senior Data Scientist	Kara Morgan, PhD.	\$ 255.00	106.00	1.8%	\$27,030
Senior Policy Analyst	Kara Suter	\$ 230.00	800.00	13.5%	\$184,000
Data Manager	Ryan Sandhaus	\$ 210.00	756.00	12.8%	\$158,760
SAS Programmer	Jesse Eng, Akhilesh Pasupulati	\$ 210.00	418.00	7.1%	\$87,780
Consultant	Barry Smith	\$ 190.00	261.00	4.4%	\$49,590
Validation Testing Manager	Bruce Newcome	\$ 180.00	50.00	0.8%	\$9,000
Validation Testing Programmer	Business Analyst	\$ 110.00	676.00	11.4%	\$74,360
Business Analyst	Programmer	\$ 80.00	200.00	3.4%	\$16,000
Policy Analyst / WBE Subcontractor	Kristy Lawrance	\$ 190.00	521.00	8.8%	\$98,990
Data Analyst / Veteran Subcontractor	Daniel Traub	\$ 180.00	148.00	2.5%	\$26,640
Focus Group Facilitator / Veteran Subcontractor II	Fred Bingle	\$ 125.00	104.00	1.8%	\$13,000
			5923.00	100.0%	\$1,196,180

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ATTACHMENT C: TIMELINE AND MILESTONES

As part of the procurement process, respondents to RFP 18-061 were required to submit a work plan, including major tasks and milestones to complete the scope of work. B&A submitted a work plan which has been agreed to by the FSSA team. The work plan is divided into Sections A, B and C and has 31 tasks. Following is a high-level summary of each section of the work plan.

- Section A, Project Initiation and Ongoing Project Management, includes Tasks 1, 2 and 3.
- Section B, Ongoing Tasks to Support Deliverables to CMS, includes Tasks 4 through 16. This is where most of the work will occur. Included in these tasks are data analytics, measure development, computing measure results ongoing, and specific focus studies related to aspects of the FSSA SUD Implementation that will be important to the overall waiver evaluation.
- Section C, Prepare Deliverable to CMS, include Tasks 17 through 31 representing each of the deliverables to CMS. It should be noted that B&A intends to build upon the cumulative work captured to date at the time that each CMS deliverable is due.

A listing of the 31 tasks with the timeframe anticipated to perform each task appears in Figure 1.

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Figure 1. Proposed Timeline and Milestones

Task Number	Task Name	Contract Year(s)	Estimated Timeframe	CMS Due Date
SECTION A: PROJECT INITIATION AND ONGOING PROJECT MANAGEMENT				
1	Kickoff Meeting	Year 1	1 month	
2	Project Management	Years 1 through 4	Weekly	
3	Obtain and Read in Data for Project	Years 1 through 4	Monthly	
SECTION B: ONGOING TASKS TO SUPPORT DELIVERABLES TO CMS				
4	Introductory Meetings with Stakeholders	Year 1	2 Months	
5	Ongoing Meetings with Stakeholders	Years 1 through 4	1 Month	
6	Track and Maintain Library of Actions within Indiana and Other States	Years 1 through 4	Weekly	
7	Build Databook of Utilization, Members, Provider Network	Years 1 and 2	7 Months	
8	Develop Measures	Year 1	3 Months	
9	Compute Measures and Ongoing Peer Review	Years 1 through 4	3 Months	
10	Systems Testing	Years 1 and 2	4 Months	
11	Focus Study: Review Gold Card Program	Year 1	2 Months	
12	Focus Study: Review Authorization Criteria	Year 1	3 Months	
13	Focus Study: Revisions to Assessment Tools	Years 1 and 2	6 Months	
14	Focus Study: Care Management	Year 2	6 Months	
15	Focus Study: INSPECT	Year 2	6 Months	
16	Focus Study: Reimbursement	Year 2	3 Months	
SECTION C: PREPARE DELIVERABLES TO CMS				
17 - draft	Develop Evaluation Design - draft	Year 1	6 Months	7/31/2018
17 - final	Develop Evaluation Design - final	Year 1	6 Months	60 days after CMS feedback
18	Prepare Quarterly Report DY4 Q2	Year 1	4 Months	8/31/2018
19	Prepare Quarterly Report DY4 Q3	Year 1	4 Months	11/30/2018
20	Prepare Quarterly Report DY5 Q1	Year 2	4 Months	9/30/2019
21	Prepare Quarterly Report DY5 Q2	Year 2	4 Months	10/31/2019
22	Prepare Quarterly Report DY5 Q3	Year 2	4 Months	11/30/2019
23	Prepare Quarterly Report DY6 Q1	Year 3	4 Months	5/31/2020
24	Prepare Quarterly Report DY6 Q2	Year 3	4 Months	8/31/2020
25	Prepare Quarterly Report DY6 Q3	Year 3	4 Months	11/30/2020
26	Prepare Annual Report DY4	Years 1 to 2	6 Months	8/30/2019
27	Prepare Annual Report DY5	Years 2 to 3	6 Months	3/31/2020
28	Prepare Annual Report DY6	Years 3 to 4	6 Months	3/31/2021
29	Prepare Mid Point Assessment	Year 2	8 Months	1/31/2020
30 - draft	Prepare Interim Evaluation - draft	Year 2	6 Months	1/31/2020
30 - final	Prepare Interim Evaluation - final	Year 2	6 Months	60 days after CMS feedback
31 - draft	Prepare Summative Evaluation - draft	Years 4 and 5	10 Months	7/31/2022
31 - final	Prepare Summative Evaluation - final	Years 4 and 5	10 Months	60 days after CMS feedback

ATTACHMENT D: SUD INDICATOR FLAG DEVELOPED BY FSSA WITH BURNS & ASSOCIATES

Category	Code	Description
ICD-9 Diagnosis		
	303	Alcohol dependence syndrome
	304	Drug dependence
	305	Nondependent abuse of drugs
ICD-10 Diagnosis		
	F10	Alcohol related disorders
	F11	Opioid related disorders
	F12	Cannabis related disorders
	F13	Sedative, hypnotic, or anxiolytic related disorders
	F14	Cocaine related disorders
	F15	Other stimulant related disorders
	F16	Hallucinogen related disorders
	F18	Inhalant related disorders
	F19	Other psychoactive substance related disorders
Revenue Codes		
	116	Detox/Private Room
	126	Detox/Two Beds
	136	Detox/Three to Four Beds
	146	Detox/Deluxe Private Room
	156	Detox/Ward
	906	Behavioral Health Treatment-Intensive Outpatient Services Chemical Dependency
	944	Other Therapeutic Services - Drug Rehabilitation
	945	Other Therapeutic Services - Alcohol Rehabilitation
	1002	Behavioral Health Accomodation Residential Chemical Dependency
ICD-9 Procedure Codes		
	94.61	Alcohol rehabilitation
	94.62	Alcohol detoxification
	94.63	Alcohol rehabilitation and detoxification
	94.64	Drug rehabilitation
	94.65	Drug detoxification
	94.66	Drug rehabilitation and detoxification
	94.67	Combined alcohol and drug rehabilitation
	94.68	Combined alcohol and drug detoxification
	94.69	Combined alcohol and drug rehabilitation and detoxification
ICD-10 Procedure Codes		
	HZ2xx	Detoxification Services
	HZ3xx	Individual Counseling
	HZ4xx	Group Counseling
	HZ5xx	Individual Psychotherapy
	HZ6xx	Family Counseling
	HZ8xx	Medication Management
	HZ9xx	Pharmacotherapy

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Category	Code	Description
HCPCS/CPT Procedure Codes		
	G0396	Alcohol and/or substance abuse (other than tobacco) structured assessment, 15-30 minutes
	G0397	Alcohol and/or substance abuse (other than tobacco) structured assessment, >30 minutes
	G0443	Behavioral counseling for alcoholic misuse, 15 mins
	H0001	Alcohol and/or drug assessment
	H0004	Behavioral health counseling and therapy, per 15 mins
	H0005	Alcohol and/or drug services; Group counseling by a clinician
	H0006	Alcohol and/or drug services; case management
	H0007	Alcohol and/or drug services; crisis intervention (outpatient)
	H0008	Alcohol and/or drug services; sub-acute detox (hospital inpatient)
	H0009	Alcohol and/or drug services; Acute detox (hospital inpatient)
	H0010	Alcohol and/or drug services; Sub-acute detox (residential addiction program inpatient)
	H0011	Alcohol and/or drug services; acute detox (residential addiction program inpatient)
	H0012	Alcohol and/or drug services; Sub-acute detox (residential addiction program outpatient)
	H0013	Alcohol and/or drug services; acute detox (residential addiction program outpatient)
	H0014	Alcohol and/or drug services; ambulatory detox
	H0015	Alcohol and/or drug services; intensive outpatient
	H0016	Alcohol and/or drug services; medical intervention in ambulatory setting
	H0017	Behavioral health; residential wout room & board
	H0018	Behavioral health; short-term residential
	H0019	Behavioral health; long-term residential
	H0020	Alcohol and/or drug services; methadone administration and/or service (provisions of the drug by a licensed program)
	H0022	Alcohol and/or drug interven
	H2034	Alcohol and/or Drug Service, Halfway House, per diem
	H2035	Alcohol and/or drug treatment program, per hour
	H2036	Alcohol and/or drug treatment program, per diem
	J0572	BUPRENORPHINE/NALOXONE, <= 3 mg
	J0573	BUPRENORPHINE/NALOXONE, 3- 6 mg
	J0574	BUPRENORPHINE/NALOXONE, 6-10 mg
	J0575	BUPRENORPHINE/NALOXONE, > 10 mg
	J0592	Buprenorphine hydrochloride
	J2315	Naltrexone, depot form
	T1006	Alcohol and/or substance abuse services, family/couple counseling
	T1012	Alcohol and/or substance abuse services, skill development

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Category	Code	Description
Generic Product Codes - Pharmacy		
		Vivitrol
		Suboxone
		Subutex
		Acamprosate
		Disulfiram
		Methadone (methadose)
DRG Codes		
	770	Drug & Alcohol Abuse or Dependence. Left Against Medical Advise
	772	Alcohol & Drug Dependence with Rehab or Rehab/Detox Therapy
	773	Opioid Abuse & Dependence
	774	Cocaine Abuse & Dependence
	775	Alcohol Abuse & Dependence
	776	Other Drug Abuse & Dependence