

## State Demonstrations Group

November 9, 2020

Maureen Corcoran  
Director  
Ohio Department of Medicaid  
50 W. Town Street, Suite 400  
Columbus, OH 43215

Dear Ms. Corcoran:

The Centers for Medicare & Medicaid Services (CMS) has completed its review of the state's Substance Use Disorder (SUD) Evaluation Design, which is required by the Special Terms and Conditions (STCs) for Ohio's "Section 1115 Demonstration for Substance Use Disorder Treatment" (Project No. 11-W-00330/5). CMS has determined that the evaluation design, submitted on March 21, 2020, meets the requirements set forth in the STCs and, therefore, hereby approves the state's SUD evaluation design.

The evaluation design is approved for the demonstration period through September 30, 2024, and is incorporated into the attached demonstration STCs as Attachment E. Per 42 CFR 431.424(c), the approved SUD monitoring protocol may now be posted to your state's Medicaid website. CMS will also post the approved evaluation design as a standalone document, separated from the STCs, on Medicaid.gov.

Please note that an interim evaluation report, consistent with the approved evaluation design is due to CMS one year prior to the expiration of the demonstration or at the time of the extension application if the state chooses to extend the demonstration. Likewise, a summative evaluation report, consistent with this approved design is due to CMS within 18 months of the end of the demonstration period.

Your CMS project officer, Ms. Rachel Nichols, is available to answer any questions concerning this approval or your section 1115 demonstration. Ms. Nichols may be reached by phone at 410-786-6269 or by email at [rachel.nichols@cms.hhs.gov](mailto:rachel.nichols@cms.hhs.gov). We look forward to our continued partnership on the Ohio Substance Use Disorder Treatment section 1115 demonstration.

Sincerely,



Danielle Daly  
Director  
Division of Demonstration Monitoring  
and Evaluation



Andrea Casart  
Director  
Division of Eligibility and Coverage  
Demonstrations

cc: Michael Kahnowitz, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

**CENTERS FOR MEDICARE & MEDICAID SERVICES  
EXPENDITURE AUTHORITY**

**NUMBER:** 11-W00330/5

**TITLE:** Section 1115 Substance Use Disorder Demonstration

**AWARDEE:** Ohio Department of Medicaid

Under the authority of section 1115(a)(2) of the Social Security Act (“the Act”), expenditures made by Ohio for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from October 1, 2019 through September 30, 2024, unless otherwise specified, be regarded as expenditures under the state’s title XIX plan.

The following expenditure authority may only be implemented consistent with the approved Special Terms and Conditions (STC) and shall enable Ohio to operate the above-identified section 1115(a) demonstration.

- 1. Residential Treatment for Individuals with Substance Use Disorder (SUD).**  
Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for SUD who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).

**CENTERS FOR MEDICARE & MEDICAID SERVICES  
SPECIAL TERMS AND CONDITIONS (STCs)**

**NUMBER:** 11-W00330/5

**TITLE:** Section 1115 Substance Use Disorder Demonstration

**AWARDEE:** Ohio Department of Medicaid

**I. PREFACE**

The following are the Special Terms and Conditions (STC) for the “Section 1115 Substance Use Disorder Demonstration” section 1115(a) Medicaid demonstration (hereinafter “demonstration”), to enable the Ohio Department of Medicaid (hereinafter “state”) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on the expenditure authority, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS related to the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted.

The STCs related to the programs for those state plan populations affected by the demonstration are effective from October 1, 2019 through September 30, 2024, unless otherwise specified.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Eligibility and Enrollment
- V. Demonstration Programs and Benefits
- VI. Cost Sharing
- VII. Delivery System
- VIII. General Reporting Requirements
- IX. Monitoring
- X. Evaluation of the Demonstration
- XI. General Financial Requirements Under Title XIX
- XII. Monitoring Budget Neutrality for the Demonstration
- XIII. Schedule of Deliverables for the Demonstration Period

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

- Attachment A: Developing the Evaluation Design
- Attachment B: Preparing the Interim and Summative Evaluation Reports
- Attachment C: SUD Implementation Plan

- Attachment D: Reserved for the SUD Monitoring Protocol
- Attachment E: Reserved for the SUD Evaluation Design

## II. PROGRAM DESCRIPTION AND OBJECTIVES

The goal of this demonstration is for the state to maintain and enhance critical access to Opioid Use Disorder (OUD) and other SUD services for Ohio Medicaid beneficiaries and continue delivery system improvements to provide more coordinated and comprehensive treatment of Medicaid beneficiaries with SUD. This demonstration will provide the state with authority to provide high-quality, clinically appropriate treatment to beneficiaries with a SUD diagnosis while they are short-term residents in residential and inpatient treatment settings that qualify as IMDs. This demonstration will also support state efforts to implement models of care focused on increasing support for individuals in the community and home, outside of institutions, and improve access to a continuum of SUD evidence-based services at varied levels of intensity. This continuum of care shall be based on the American Society of Addiction Medicine (ASAM) criteria and/or other nationally recognized assessment and placement tools that reflect evidence-based clinical treatment guidelines.

During the demonstration period, the state seeks to achieve the following goals:

1. Increased rates of identification, initiation, and engagement in treatment for SUD;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically 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 with SUD.

## III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).
- 2. Compliance with Medicaid and Child Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

- 3. Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.
- 4. Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
  - a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
  - b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.
- 5. State Plan Amendments.** The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.
- 6. Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

**7. Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

- a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
- b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
- c. A data analysis which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable “with waiver” and “without waiver” status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the “with waiver” expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
- d. An up-to-date CHIP allotment worksheet, if necessary;
- e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

**8. Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 42 CFR §431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit phase-out plan consistent with the requirements of STC 9.

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

- a. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration’s suspension or termination. Prior to submitting

- the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.
- b. Transition and Phase-out Plan Requirements: The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.
  - c. Transition and Phase-out Plan Approval: The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
  - d. Transition and Phase-out Procedures: The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210 and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).
  - e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g): CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
  - f. Enrollment Limitation during Demonstration Phase-Out: If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the

state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

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

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

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

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

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

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

**14. Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise

oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

**15. Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

**IV. ELIGIBILITY AND ENROLLMENT**

**16. Eligibility Groups Affected by the Demonstration.** Under the demonstration, there is no change to Medicaid eligibility. Standards and methodologies for eligibility remain set forth under the state plan and are subject to all applicable Medicaid laws and regulations.

**V. DEMONSTRATION PROGRAMS AND BENEFITS**

**17. Opioid Use Disorder/Substance Use Disorder Program.** Under this demonstration, Ohio Medicaid beneficiaries will have access to high quality, evidence-based OUD/SUD treatment and withdrawal management services ranging from medically supervised withdrawal management to on-going chronic care for these conditions in cost-effective community-based settings. The state will work to improve care coordination and care for co-occurring physical and behavioral health conditions. Ohio will be expected to achieve a statewide average length of stay of 30 days in residential and inpatient treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in STC 19 below.

The coverage of OUD/SUD treatment services and withdrawal management during short term residential and inpatient stays in IMDs will expand Ohio’s current OUD/SUD benefit package available to all Ohio Medicaid beneficiaries as outlined in Table 1 (see exceptions detailed in STC 45).

The state attests that the services indicated in Table 1 as being covered under the Medicaid state plan authority are currently covered in the Ohio Medicaid state plan.

<b>Table 1: Ohio Section 1115 Substance Use Disorder Benefits Coverage</b>			
<b>Benefit</b>	<b>Type</b>	<b>Medicaid Authority</b>	<b>Expenditure Authority</b>
Outpatient services	SUD	State plan (Individual	Services provided to individuals in IMDs

<b>Table 1: Ohio Section 1115 Substance Use Disorder Benefits Coverage</b>			
<b>Benefit</b>	<b>Type</b>	<b>Medicaid Authority</b>	<b>Expenditure Authority</b>
		services covered)	
Intensive outpatient services	SUD	State plan (Individual services covered)	Services provided to individuals in IMDs
Partial hospitalization services	SUD	State Plan (Individual services covered)	Services provided to individuals in IMDs
Inpatient services	SUD	State plan (Individual services covered)	Services provided to individuals in IMDs
Residential treatment services	SUD	State plan (Individual services covered)	Services provided to individuals residing in IMDs
Medically Monitored Withdrawal Management	SUD	State plan (Individual services covered)	Services provided to individuals in IMDs
Medication-Assisted Treatment (MAT)	SUD	State plan (individual services covered)	Services provided to individuals in IMDs

## 18. SUD Implementation Plan.

- a. The state must submit the SUD Implementation Plan within 90 calendar days after approval of this demonstration. The state may not claim FFP for services provided in IMDs to beneficiaries who are primarily receiving SUD treatment and withdrawal management services until CMS has approved the SUD Implementation Plan. Once approved, the SUD Implementation Plan will be incorporated into the STCs as Attachment C and, once incorporated, may be altered only with CMS approval. After approval of the applicable implementation plans required by these STCs, FFP will be available prospectively, not retrospectively.
- b. Failure to submit a SUD Implementation Plan will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SUD program under this demonstration. Failure to progress in meeting the milestones

agreed upon by the state and CMS will result in a funding deferral as described in STC 23.

- c. At a minimum, the SUD Implementation Plan must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:
  - i. **Access to Critical Levels of Care for OUD and other SUDs:** Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of SUD demonstration approval;
  - ii. **Use of Evidence-based SUD-specific Patient Placement Criteria:** Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as ASAM Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of demonstration approval;
  - iii. **Patient Placement:** Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of demonstration approval;
  - iv. **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities:** Currently, residential treatment service providers must be a certified organization, pursuant to the residential service provider qualifications described in OAC5122-29-09. The state must establish residential treatment provider qualifications in licensure, certification, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
  - v. **Standards of Care:** Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;

- vi. **Standards of Care:** Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of demonstration approval;
  - vii. **Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for SUD/OD:** An assessment of the availability of providers in the critical levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of demonstration approval;
  - viii. **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/OD:** Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;
  - ix. **Improved Care Coordination and Transitions between levels of care:** Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of demonstration approval; and
  - x. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in STC 18(d) or Attachment C.
- d. **SUD Health Information Technology Plan (“SUD Health IT Plan”).** The SUD Health IT Plan applies to all states where the Health IT functionalities are expected to impact beneficiaries within the demonstration. As outlined in SMDL #17-003, states must submit to CMS the applicable SUD Health IT Plan to be included as a section of the associated SUD Implementation Plan (see STC 18.a.), to develop infrastructure and capabilities consistent with the requirements of this SUD demonstration.

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

- i. The state must include in its SUD Monitoring Protocol (see STC 19) an approach to monitoring its SUD Health IT Plan which will include performance metrics, to be approved in advance by CMS.

- ii. The state must monitor progress, each demonstration year (DY), on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines – and report on its progress to CMS in an addendum to its Annual Report (see STC 27).
- iii. As applicable, the state should advance the standards identified in the ‘Interoperability Standards Advisory—Best Available Standards and Implementation Specifications’ (ISA) in developing and implementing the state’s SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.
- iv. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally-recognized standards, barring another compelling state interest.
- v. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling state interest.
- vi. Components of the SUD Health IT Plan include:
  - A. The SUD Health IT Plan must describe the state’s goals, each DY, to enhance the state’s prescription drug monitoring program (PDMP).<sup>1</sup>
  - B. The SUD Health IT Plan must address how the state’s PDMP will enhance ease of use for prescribers and other state and federal stakeholders.<sup>1</sup> This must also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance – and reviewing the patients’ history of controlled substance prescriptions – prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.
  - C. The SUD Health IT Plan will, as applicable, describe the state’s capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the SUD Health IT Plan must describe current and future

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

capabilities regarding PDMP queries – and the state’s ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.

- D. The SUD Health IT Plan will describe how the activities described in (i), (ii) and (iii) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.<sup>2</sup>
- E. The SUD Health IT Plan will describe the state’s current and future capabilities to support providers implementing or expanding Health IT functionality in the following areas: 1) Referrals, 2) Electronic care plans and medical records, 3) Consent, 4) Interoperability, 5) Telehealth, 6) Alerting/analytics, and 7) Identity management.
- F. In developing the SUD Health IT Plan, states should use the following resources:
  - 1. States may use federal resources available on Health IT.Gov (<https://www.healthit.gov/topic/behavioral-health>) including but not limited to “Behavioral Health and Physical Health Integration” and “Section 34: Opioid Epidemic and Health IT” (<https://www.healthit.gov/playbook/health-information-exchange/>).
  - 2. States may also use the CMS 1115 Health IT resources available on “Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability” at <https://www.medicare.gov/medicaid/data-and-systems/hie/index.html>. States should review the “1115 Health IT Toolkit” for health IT considerations in conducting an assessment and developing their Health IT Plans.
  - 3. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

**19. SUD Monitoring Protocol.** The state must submit a SUD Monitoring Protocol for the SUD program authorized by this demonstration within 150 calendar days after approval of the

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<sup>2</sup> Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017;66.

demonstration. The SUD Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs, as Attachment D. Progress on the performance measures identified in the SUD Monitoring Protocol must be reported via the quarterly and annual monitoring reports. Components of the SUD Monitoring Protocol must include:

- a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 18.c and reporting relevant information to the state's SUD Health IT Plan described in STC 18.d;
- b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section VIII of the demonstration; and
- c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

**20. Evaluation.** The SUD Evaluation is subject to the requirements as described in Sections VIII (General Reporting Requirements) and X (Evaluation of the Demonstration) of these STCs.

## **VI. COST SHARING**

**21. Cost Sharing.** Cost sharing requirements under the demonstration will not differ from the approved Medicaid state plan.

## **VII. DELIVERY SYSTEM**

**22. Delivery System.** Ohio currently utilizes both fee-for-service (FFS) and managed care delivery systems as specified under its state plan and 1915(b) waiver authority. Managed Care Organizations (MCOs) provide integrated physical and behavioral health services, including SUD services, to beneficiaries, with a small number of beneficiaries receiving services through FFS.

## **VIII. GENERAL REPORTING REQUIREMENTS**

**23. Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of \$5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

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

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
- b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request.
- c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
- d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released.
- e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

**24. Deferral of Federal Financial Participation (FFP) from IMD Claiming for Insufficient Progress Toward Milestones.** Up to \$5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones as evidenced by reporting on the milestones in the SUD Implementation Plan and the required performance measures in the SUD Monitoring Protocol agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to \$5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.

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

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

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

## **IX. MONITORING**

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

- a. Operational Updates. The operational updates will focus on progress toward meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
- b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance

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

- c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.
- d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.
- e. SUD Health IT. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 18.d.

**28. SUD Mid-Point Assessment.** The state must contract with an independent assessor to conduct an independent mid-point assessment by December 31, 2021. In the design, planning and conduction of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of managed care organizations (MCO), SUD treatment providers, beneficiaries, and other key partners.

The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 days after December 31, 2021. The state must brief CMS on the report.

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

Elements of the mid-point assessment include:

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

- b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;
- c. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets;
- d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's SUD Implementation Plan or to pertinent factors that the state can influence that will support improvement; and
- e. An assessment of whether the state is on track to meet the budget neutrality requirements.

**29. Corrective Action.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

**30. Close-Out Report.** Within 120 calendar days after the expiration of the demonstration, the state must submit a Draft Close-Out Report to CMS for comments.

- a. The draft close-out report must comply with the most current guidance from CMS.
- b. The state will present to and participate in a discussion with CMS on the close-out report.
- c. The state must take into consideration CMS' comments for incorporation into the final close-out report.
- d. The final close-out report is due to CMS no later than 30 calendar days after receipt of CMS' comments.
- e. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 23.

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

- a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, enrollment and access, budget neutrality, and progress on evaluation activities.
- b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.

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

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

## **X. EVALUATION OF THE DEMONSTRATION**

**33. Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors' in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 23.

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

**35. Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs.

The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the approval of the demonstration. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable.

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

- a. All applicable Evaluation Design guidance about SUD. Hypotheses applicable to the demonstration as a whole, and to all key policies referenced above, will include (but will not be limited to): the effects of the demonstration on health outcomes; the financial impact of the demonstration (for example, such as an assessment of medical debt and uncompensated care costs).
- b. Attachment A (Developing the Evaluation Design) of these STCs, technical assistance for developing SUD Evaluation Designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a Draft Evaluation Design.

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

**37. Evaluation Design Approval and Updates.** The state must submit the revised draft Evaluation Designs within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Designs, the documents will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) calendar days of CMS approval. The state must implement the evaluation designs and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the evaluation designs, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

**38. Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

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

- a. The Interim Evaluation Reports will discuss evaluation progress and present findings to date as per the approved evaluation design.
- b. For demonstration authority that expires prior to the overall demonstration’s expiration date, the Interim Evaluation Reports must include an evaluation of the authority as approved by CMS.
- c. If the state is seeking to renew or extend the demonstration, draft Interim Evaluation Reports is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses and a description of how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, Interim Evaluation reports are due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, draft Interim Evaluation Reports are due to CMS on the date that will be specified in the notice of termination or suspension.
- d. The state must submit final Interim Evaluation Reports 60 calendar days after receiving CMS comments on the draft Interim Evaluation Reports and post the document to the state’s website.
- e. The Interim Evaluation Report must comply with Attachment B of these STCs.

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

- a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within sixty (60) calendar days of receiving comments from CMS on the draft.
- b. The final Summative Evaluation Report must be posted to the state’s Medicaid website within thirty (30) calendar days of approval by CMS.

**41. Corrective Action Plan Related to Evaluation.** If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval.

These discussions may also occur as part of a renewal process when associated with the state's Interim Evaluation Report. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

- 42. State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.
- 43. Public Access.** The state shall post the final documents (e.g., Monitoring Reports, Close Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 calendar days of approval by CMS.
- 44. Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

## **XI. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX**

- 45. Allowable Expenditures.** This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS.
- 46. Unallowable Expenditures.** In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:
  - a. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.
  - b. Costs for services provided in a nursing facility as defined in section 1919 of the Act that qualifies as an IMD.
- 47. Standard Medicaid Funding Process.** The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this Medicaid section 1115 demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-

37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

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

- a. Administrative costs, including those associated with the administration of the demonstration;
- b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
- c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

**49. Sources of Non-Federal Share.** The state certifies that its match for the non-federal share of funds for this section 1115 demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

- a. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.
- b. The state acknowledges that any amendments that impact the financial status of this section 1115 demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

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

- a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.
- b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
- c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR §433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR §433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.
- d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
- e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR §447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

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

**52. Medicaid Expenditure Groups (MEG).** MEGs are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to

monitoring and tracking expenditures under the demonstration. The following table provides a master list of MEGs defined for this demonstration.

<b>Table 2: Master MEG Chart</b>					
<b>MEG</b>	<b>To Which BN Test Does This Apply?</b>	<b>WOW Per Capita</b>	<b>WOW Aggregate</b>	<b>WW</b>	<b>Brief Description</b>
Managed Care IMD Services	Hypo	X		X	See Expenditure Authority #1
FFS IMD Services	Hypo	X		X	See Expenditure Authority #1

**53. Reporting Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W00330/5). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

- a. Cost Settlements. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.
- b. Premiums and Cost Sharing Collected by the State. The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the

demonstration year for determination of the state's compliance with the budget neutrality limits.

- c. Pharmacy Rebates. Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.
- d. Administrative Costs. The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the table below, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.
- e. Member Months. As part of the Quarterly and Annual Monitoring Reports described in section IX, the state must report the actual number of “eligible member months” for all demonstration enrollees for all MEGs identified as WOW Per Capita, and as also indicated in the table below. The term “eligible member months” refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.
- f. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state’s Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

**Table 3: MEG Detail for Expenditure and Member Month Reporting**

<b>MEG (Waiver Name)</b>	<b>Detailed Description</b>	<b>Exclusions</b>	<b>CMS-64.9 Line(s) To Use</b>	<b>How Expend. Are Assigned to DY</b>	<b>MAP or ADM</b>	<b>Report Member Months (Y/N)</b>	<b>MEG Start Date</b>	<b>MEG End Date</b>
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Managed Care IMD Services	Managed care beneficiaries	Refer to STC #46 Unallowable Expenditures	Follow CMS-64.9 Base Category of Service Definitions	Date of service	MAP	Y	October 01, 2019	September 30, 2024
FFS IMD Services	Fee for service beneficiaries	Refer to STC #46 Unallowable Expenditures	Follow CMS-64.9 Base Category of Service Definitions	Date of service	MAP	Y	October 01, 2019	September 30, 2024

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

Table 4: Demonstration Years		
Demonstration Year 1	October 1, 2019 to September 30, 2020	12 months
Demonstration Year 2	October 1, 2020 to September 30, 2021	12 months
Demonstration Year 3	October 1, 2021 to September 30, 2022	12 months
Demonstration Year 4	October 1, 2022 to September 30, 2023	12 months
Demonstration Year 5	October 1, 2023 to September 30, 2024	12 months

**55. Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the “Schedule C Report” for comparing demonstration’s actual expenditures to the budget neutrality expenditure limits described in section XI. CMS will provide technical assistance, upon request.<sup>3</sup>

**56. Claiming Period.** The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar

<sup>3</sup> 42 CFR §431.420(a)(2) provides that states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and §431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS’s current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and in states agree to use the tool as a condition of demonstration approval.

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

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

- a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Social Security Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
- b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.
- c. The state certifies that the data it provided are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief.

## **XII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION**

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

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

**60. Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which projected fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

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

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

spending exceeds the supplemental test’s expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending by refunding the FFP to CMS.

**63. Hypothetical Budget Neutrality Test 1: SUD Initiative.** This includes expenditures for the costs of all current state plan medical assistance that could be covered, were it not for the Institution for Mental Diseases (IMD) prohibition—and provided to otherwise-eligible individuals receiving SUD treatment while residing in an IMD setting. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated “WOW Only” or “Both” are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as “WW Only” or “Both.” MEGs that are indicated as “WW Only” or “Both” are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

**64. Composite Federal Share.** The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration’s approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Main or

**Table 5: Hypothetical Budget Neutrality Test**

MEG	PC or Agg*	WOW Only, WW Only, or Both	BASE YEAR 2019	TREND	DY 1	DY 2	DY 3	DY 4	DY 5
Managed Care IMD Services	PC	Both	\$662.93	4.5%	\$685.18	\$716.02	\$748.24	\$781.91	\$817.10
FFS IMD Services	PC	Both	\$3,926.44	4.5%	\$4,103.13	\$4,287.77	\$4,480.72	\$4,682.35	\$4,893.06

Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

**65. Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from October 1, 2019 to September

30, 2024. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

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

**Hypothetical Budget Neutrality Test**

<b>Table 6: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations</b>		
	<b>Cumulative Target Definition</b>	<b>Percentage</b>
DY 1	Cumulative budget neutrality limit plus:	2.0 percent
DY 1 through DY 2	Cumulative budget neutrality limit plus:	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit plus:	1.0 percent
DY 1 through DY 4	Cumulative budget neutrality limit plus:	0.5 percent
DY 1 through DY 5	Cumulative budget neutrality limit plus:	0.0 percent

**XIII. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD**

<b>Table 7: Schedule of Deliverables for the Demonstration Period</b>		
<b>Date</b>	<b>Deliverable</b>	<b>STC</b>
30 calendar days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 calendar days after SUD program approval date	SUD Implementation Protocol	STC 18
150 calendar days after SUD implementation approval date	SUD Monitoring Protocol	STC 19
180 calendar days after approval date	Draft Evaluation Design	STC 35
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STC 37

30 calendar days after CMS Approval	Approved Evaluation Design published to state's website	STC 37
December 31, 2021	SUD Mid-Point Assessment	STC 28
September 30, 2023, or with renewal application	Draft Interim Evaluation Report	STC 39
60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 39 d
Within 18 months after September 30, 2024	Draft Summative Evaluation Report	STC 40
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 40 a
Monthly Deliverables	Monitoring Call	STC 31
Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4 <sup>th</sup> quarter, beginning March 2019.	Quarterly Progress Reports, including implementation updates	STC 27
	Quarterly Expenditure Reports	STC 27 c
Annual Deliverables - Due 90 calendar days after end of each 4 <sup>th</sup> quarter	Annual Reports	STC 27

# **ATTACHMENT A**

## **Developing the Evaluation Design**

### **Introduction**

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

### **Expectations for Evaluation Designs**

All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals.

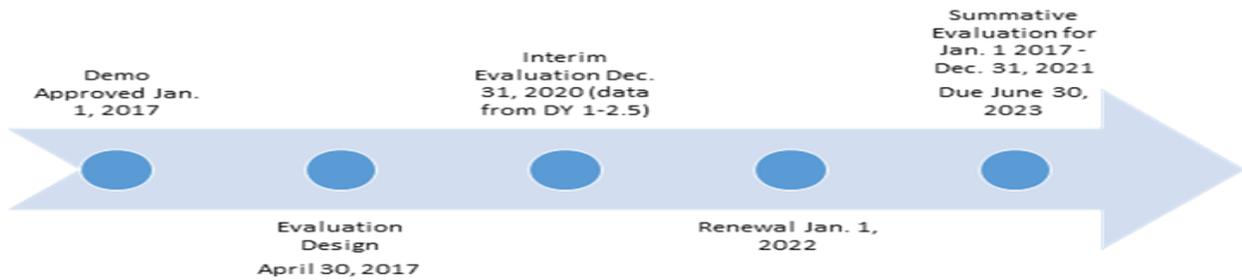
### **The format for the Evaluation Design is as follows:**

General Background Information;  
Evaluation Questions and Hypotheses;  
Methodology;  
Methodological Limitations;  
Attachments.

### **Submission Timelines**

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

## ATTACHMENT A Developing the Evaluation Design



### Required Core Components of All Evaluation Designs

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

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

- 1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
- 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
- 3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;
- 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.
- 5) Describe the population groups impacted by the demonstration.

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

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

**ATTACHMENT A**  
**Developing the Evaluation Design**

- 2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams:  
<https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf>
- 3) Identify the state’s hypotheses about the outcomes of the demonstration:
- 4) Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
- 5) Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

**C. Methodology** – In this section, the state is to describe in detail the proposed research methodology.

The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

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

- 1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?
- 2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.
- 3) *Evaluation Period* – Describe the time periods for which data will be included.

**ATTACHMENT A**  
**Developing the Evaluation Design**

- 4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by “owning”, defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
- a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
  - b. Qualitative analysis methods may be used, and must be described in detail.
  - c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
  - d. Proposed health measures could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
  - e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
  - f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

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

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

- 6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
- a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.

**ATTACHMENT A**  
**Developing the Evaluation Design**

- b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
  - c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
  - d. The application of sensitivity analyses, as appropriate, should be considered.
- 7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

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

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
<b>Hypothesis 1</b>				
Research question 1a	-Measure 1 -Measure 2 -Measure 3	-Sample e.g. All attributed Medicaid beneficiaries -Beneficiaries with diabetes diagnosis	-Medicaid fee-for-service and encounter claims records	-Interrupted time series
Research question 1b	-Measure 1 -Measure 2 -Measure 3 -Measure 4	-sample, e.g., PPS patients who meet survey selection requirements (used services within the last 6 months)	-Patient survey	Descriptive statistics
<b>Hypothesis 2</b>				
Research question 2a	-Measure 1 -Measure 2	-Sample, e.g., PPS administrators	-Key informants	Qualitative analysis of interview material

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

- 1) When the state demonstration is:
  - a. Long-standing, non-complex, unchanged, or
  - b. Has previously been rigorously evaluated and found to be successful, or
  - c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)
- 2) When the demonstration is also considered successful without issues or concerns that

**ATTACHMENT A**  
**Developing the Evaluation Design**

would require more regular reporting, such as:

- a. Operating smoothly without administrative changes; and
- b. No or minimal appeals and grievances; and
- c. No state issues with CMS-64 reporting or budget neutrality; and
- d. No Corrective Action Plans (CAP) for the demonstration.

**E. Attachments**

- 1) **Independent Evaluator.** This includes a discussion of the state’s process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include “No Conflict of Interest” signed by the independent evaluator.
- 2) **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.
- 3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

## **ATTACHMENT B**

### **Preparing the Interim and Summative Evaluation Reports**

#### **Introduction**

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

#### **Expectations for Evaluation Reports**

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

#### **Intent of this Guidance**

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

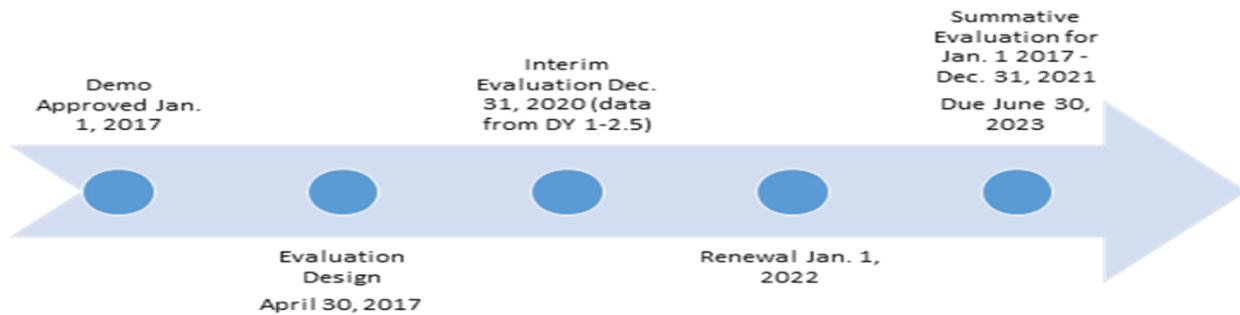
**ATTACHMENT B**  
**Preparing the Interim and Summative Evaluation Reports**

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

- A. Executive Summary;
- B. General Background Information;
- C. Evaluation Questions and Hypotheses;
- D. Methodology;
- E. Methodological Limitations;
- F. Results;
- G. Conclusions;
- H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
- I. Lessons Learned and Recommendations; and
- J. Attachment(s).

**Submission Timelines**

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



**ATTACHMENT B**  
**Preparing the Interim and Summative Evaluation Reports**

**Required Core Components of Interim and Summative Evaluation Reports**

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

- A. Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.
  
- B. General Background Information about the Demonstration** – In this section, the state should include basic information about the demonstration, such as:
  - 1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
  - 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
  - 3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
  - 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
  - 5) Describe the population groups impacted by the demonstration.
  
- C. Evaluation Questions and Hypotheses** – In this section, the state should:
  - 1) Describe how the state’s demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

**ATTACHMENT B**  
**Preparing the Interim and Summative Evaluation Reports**

- 2) Identify the state’s hypotheses about the outcomes of the demonstration;
  - a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
  - b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
  - c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

**D. Methodology** – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design.

The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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

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

1. *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?
2. *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected
4. *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?
5. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.
6. *Analytic methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

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

## ATTACHMENT B

### Preparing the Interim and Summative Evaluation Reports

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

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

- 1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
- 2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
  - a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

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

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

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

**F. Attachment** - Evaluation Design: Provide the CMS-approved Evaluation Design

**ATTACHMENT C**  
**SUD Implementation Plan**



# **Section 1115 Substance Use Disorder Demonstration Implementation Plan**

Submitted by the

Ohio Department of Medicaid

Version updated 08/26/2019

## Ohio Section 1115 Substance Use Disorder (SUD) Demonstration: Implementation Plan

Nationwide, deaths due to opioids continue to increase, are under-reported and have great variability in the specificity of how they are recorded across the country.<sup>1</sup> Contributing factors to the difficulty of verifying these opioid-related deaths are that a specific drug or cause of death may not be identified or reported, multiple drugs may be listed instead of one, or the primary cause of death may be listed with another diagnosis such as anoxic brain injury or congestive heart failure. From 1999 to 2015, the number of overdose deaths involving opioids in the United States has quadrupled.

### Section I – Milestone Completion

After taking office in January 2019, one of Governor Mike DeWine’s first actions was to launch the Recovery Ohio initiative which built on the eight year history of former Governor Kasich’s Governor’s Cabinet Opiate Action Team in continuing to fight all substance use disorders and promote recovery. (See Attachment B on page 53 for a summary of the accomplishments of former Governor Kasich’s Cabinet Opiate Action Team (GCOAT). Recovery Ohio will assist local schools, law enforcement, businesses, and other agencies who face the consequences of this critical public health concern. Through the Recovery Ohio initiative ODM, other state agencies and state and local partners remain dedicated to improving mental health and substance use prevention, treatment, and recovery support efforts that address the state’s substance abuse crisis.



More detailed information about the Recovery Ohio Initiative as well as its initial action recommendations can be found here:

<https://governor.ohio.gov/wps/portal/gov/governor/media/executive-orders/2019-08d>

Ohio has remained especially vigilant in tracking and fighting opioid use disorders and deaths from opioid overdoses. Opioids deaths in Ohio rose from 1,914 in 2012 to 4,050 in 2016.<sup>2</sup> See Figure 1 for maps outlining the growth in number of unintentional opioid drug-related deaths in Ohio counties between calendar year (CY) 2012 and CY 2017.<sup>3</sup>

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<sup>1</sup> Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010– 2015. MMWR Morb Mortal Wkly Rep 2016;65:1445–1452. DOI: <http://dx.doi.org/10.15585/mmwr.mm655051e1>

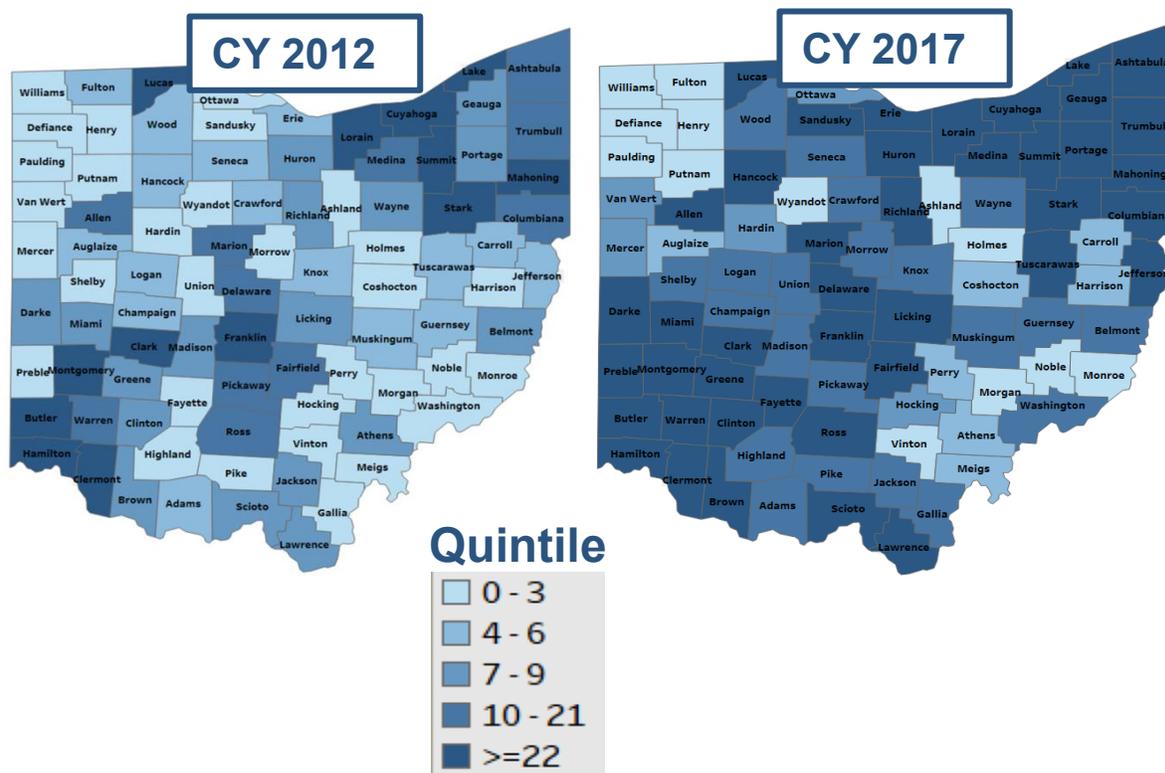
Ruhm, CJ. Geographic Variation in Opioid and Heroin Involved Drug Poisoning Mortality Rates. American Journal of Preventive Medicine, Volume 53, Issue 6, 745 - 753

<sup>2</sup> Mortality data can be found at the following website:

<http://publicapps.odh.ohio.gov/EDW/DataBrowser/Browse/Mortality>

<sup>3</sup> “Governor’s Cabinet Opiate Action Team Dashboard” (slide 9)

**Figure 1: Map of the rate of Unintentional Opioid Deaths per 100,000 people in Ohio Counties**



ODM has been particularly assertive in this work as the Centers for Disease Control and Prevention (CDC) reported individuals enrolled in Medicaid were prescribed opioids at more than twice the rate as those with commercial insurance and were at greater risk for opioid abuse and death.<sup>4</sup>

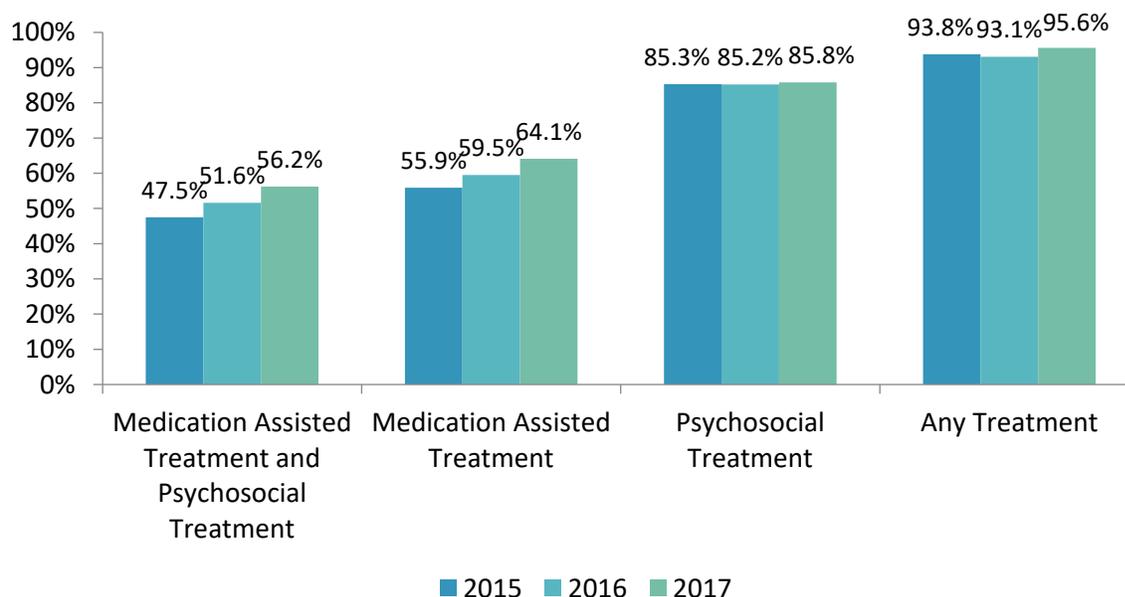
As of August 2018, Ohio averaged about three million individuals enrolled in Medicaid a month. The number of Medicaid individuals with SUD diagnoses continues to grow. The largest increase in the number of Medicaid individuals with SUD occurred between 2014 and 2015 with the implementation of the Medicaid Expansion. The expansion saw a 23 percent increase in the number of Medicaid individuals with a SUD diagnosis. Following expansion, Ohio Medicaid has continued to see increases in SUD each year, with an 8% increase in 2015-2016 and a 4% increase in 2016-2017. Currently 8% of the total population has a primary SUD diagnosis.

According to Medicaid claims, one tenth (9.8%) of Medicaid individuals enrolled in Group VIII received a primary SUD diagnosis and 7.9% enrolled in Group VIII received

<sup>4</sup> CDC. Overdose deaths involving prescription opioids among Medicaid enrollees. *Morbidity and Mortality Weekly Report*. 2009; 58:1171-1175, and CDC. Patient review and restriction programs: Lessons learned from state Medicaid programs. *CDC Expert Panel Meeting Report*. Aug 27-28, 2012; Atlanta, GA).

an opioid use disorder (OUD) primary diagnosis in 2017.<sup>5</sup> Among those with a primary diagnosis of OUD diagnosis in 2017, 64.1% received pharmacy-dispensed or office-administered Medication Assisted Treatment (MAT), 85.8% received psychosocial treatment, 95.6% received at least one treatment, and 56.2% received both MAT and psychosocial treatment (Figure 2). This reflects an increase in the utilization of treatment from 2015, during which only 47.5% of individuals with an OUD primary diagnosis received both MAT and psychosocial treatment.

**Figure 2: Percentage of Medicaid individuals enrolled in Group VIII with a Primary OUD Diagnosis Receiving Treatment, 2015–2017**



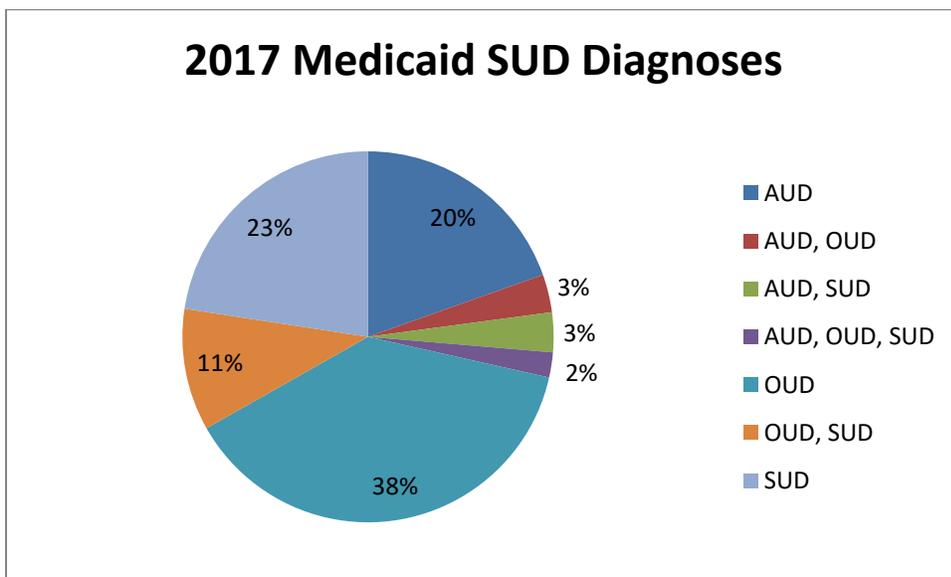
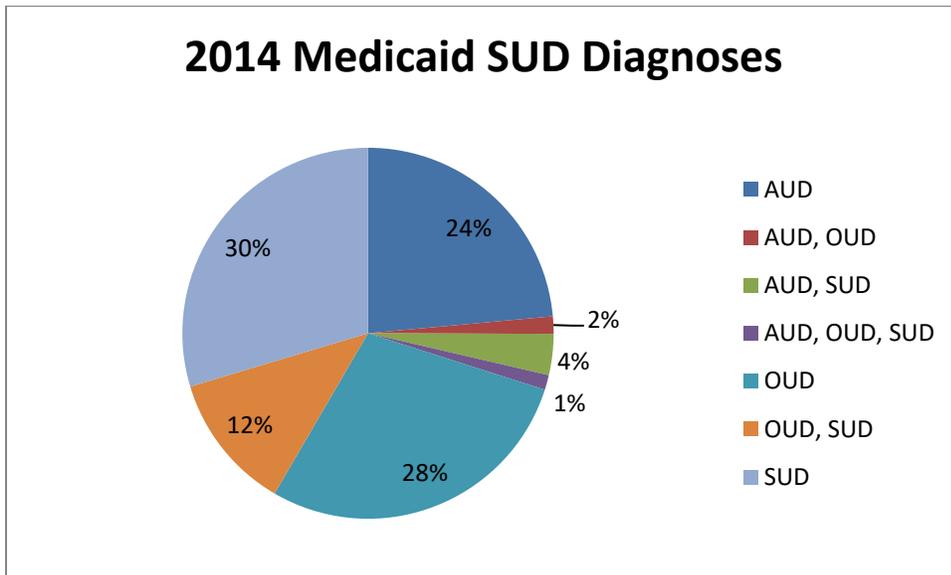
Source: Medicaid Administrative Data

Billing codes used to define MAT and psychosocial treatment are in the Methodological Report

The type of SUD diagnosis for the Medicaid population varies widely and includes alcohol, opiates and combinations of those drugs and other drugs. Since 2014, as the number of individuals with SUD diagnoses has increased, the proportion of individuals with any given diagnosis has changed over time. Specifically, individuals in Medicaid with an OUD diagnosis have increased as a proportion of the population. See tables below.

<sup>5</sup> This finding is based on diagnosed opioid use disorder, which is likely to be an underestimate of the actual prevalence of opioid use disorder.

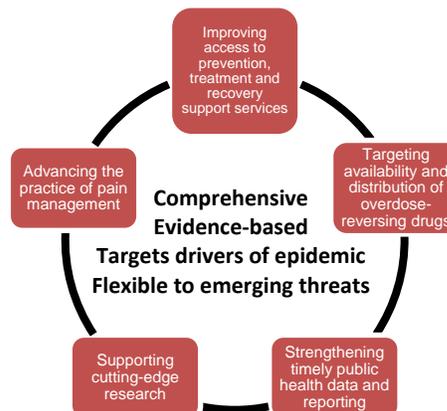
**Tables: The type of SUD diagnosis for the Medicaid population**



AUD – Alcohol Use Disorder  
OUD – Opioid Use Disorder  
SUD – Substance Use Disorder

Figure 3: HHS Opioid strategy

ODM efforts have primarily focused on the five prongs of the Health and Human Services (HHS) Opioid Strategy (see Figure 3 for a visual of the HHS Opioid strategy) including:



1. Improving access to prevention, treatment and recovery support services.
2. Targeting distribution of overdose-reversing drugs.
3. Advancing the practice of pain management.
4. Supporting cutting-edge research.
5. Strengthening timely public health data and reporting.

A summary of how Ohio already meets each milestone and actions needed is included in the 1115 waiver application.

Table: Summary of Actions Needed

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
None	Milestone 1	
Review plan policies for utilization review and prior authorization for compliance.	Milestone 2	12 to 24 months
Review plan delivery for program compliance (e.g., treatment plan, provider qualifications, etc.).	Milestone 2	12 to 24 months
Collect, review, and analyze utilization Management information for CY2018.	Milestone 2	12 to 24 months
Based upon review and analysis, develop changes to the utilization management approach that reflects analysis and ensure compliance with ASAM and MHPAEA.	Milestone 2	12 to 24 months
Develop necessary guidance to plans and providers regarding the new UM process.	Milestone 2	12 to 24 months
Update the State requirements to reflect residential requirements for the types of services, hours of clinical care, and credentials of staff for each ASAM residential LOC.	Milestone 3	12 to 24 months

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
Require the plans to comply with updated ASAM residential requirements.	Milestone 3	12 to 24 months
Implement a standardized State on-site review process of residential provider qualifications against State requirements for ASAM including the types of services, hours of clinical care and credentials of staff for each ASAM residential LOC.	Milestone 3	12 to 24 months
Implement a single statewide vendor to survey Ohio SUD residential providers to assure they meet certain standards and manage provider enrollment on an on-going basis.	Milestone 3	24 months
Require the plans to comply with State processes for credentialing SUD residential providers.	Milestone 3	12 to 24 months
Educate abstinence-based residential providers on benefits of MAT accessibility and begin cultural shift toward acceptance of MAT as a complementary treatment.	Milestone 3	24 months
Require SUD treatment providers to offer access and to facilitate patient access to MAT while in residential settings.	Milestone 3	12 to 24 months
Require the FFS delivery system and the plans to monitor access to MAT in residential settings including access to MAT counseling.	Milestone 3	24 months
Create a comprehensive access assessment baseline of all SUD providers and all SUD LOC including MAT capacity.	Milestone 4	12 months
ODM will create access standards for SUD LOC.	Milestone 4	12 months
Require MCPs to update their SUD network development and management plan to specifically focus on SUD provider capacity by LOC, including MAT.	Milestone 4	12-18 months

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
Add an indicator for providers accepting new patients to the plan quarterly network adequacy reports.	Milestone 4	12 to 24 months
Require the plans to adopt access requirements to all ASAM LOC.	Milestone 4	12 months
Continue to onboard new electronic health record (EHR) and pharmacy dispensing system vendors.	Milestone 5	12 to 24 months
Explore the possibility of analysis to correlate long-term opioid use directly to clinician prescribing patterns in conjunction with the ODM (Action item for the Board of Pharmacy).	Milestone 5	12 to 24 months
Implement enhanced information within the Ohio Automated Rx Reporting System (OARRS) including: OARRS flags for individuals who are participating in one of Ohio's drug court programs; non-fatal overdose deaths, and naltrexone identification to identify individuals treated for SUD.	Milestone 5	Over the duration of the waiver
Implement an enforcement plan to minimize the risk of inappropriate overprescribing consistent with prescribing guidelines.	Milestone 5	Over the duration of the waiver
Review data and conduct analysis of individuals with SUD	Milestone 6	12 to 24 months
Based upon data analysis develop care coordination model(s) specific to identified populations	Milestone 6	12 to 24 months
Implement care coordination for identified populations	Milestone 6	12 to 24 months

## Milestone 1: Access to Critical LOC for OUD and Other SUDs

### CMS Specifications:

Coverage of: (a) outpatient services, (b) intensive outpatient services, (c) MAT (medications as well as counseling and other services with sufficient provider capacity)

to meet the needs of individuals enrolled in Medicaid in the state), (d) intensive LOC in residential and inpatient settings and (e) medically supervised withdrawal management.

#### Current and Future State:

Ohio currently covers all the critical LOC identified in Milestone 1. Ohio administers its Medicaid SUD treatment services based on the ASAM Patient Placement Criteria.<sup>6</sup> No additional actions are needed to meet Milestone 1. The below table identifies the ASAM level-brief descriptions of services currently offered, and associated state plan authorities.

**Table: SUD service coverage in the Medicaid State Plan**

Existing ASAM LOC Coverage	Description	Adult/Adolescent Specific Criteria	State Plan Authority
ASAM Level 0.5	Early Intervention	Both	State Plan Authority items 13 c and 13 d.
ASAM Level 1	Outpatient Services	Both	Rehabilitation Authority Item 13-d-2 Page 2 of 9
ASAM Level 1 Opioid Treatment Services	Opioid Treatment Programs (OTPs)	Both	Rehabilitation Authority Item 13-d-2 Page 2 of 9
ASAM Level 1 Opioid Treatment Services	Medically Managed Opioid Treatment	Both	Physician Authority Item 5-a
ASAM Level 2.1	Intensive Outpatient	Both	Rehabilitation Authority Item 13-d-2 Page 2 of 9
ASAM Level 2.5	Partial Hospitalization	Both	Rehabilitation Authority Item 13-d-2 Page 2 of 9
ASAM Level 2-WM	Ambulatory Withdrawal Management with Extended Onsite Monitoring	Single set of criteria	Rehabilitation Authority Item 13-d-2 Page 2 of 9
ASAM Level 3.1	Clinically Managed Low-Intensity Residential Treatment	Single set of criteria	Rehabilitation Authority Item 13-d-2 Page 4 of 9
ASAM Level 3.2-WM	Clinically Managed Residential	Single set of criteria	Rehabilitation Authority

<sup>6</sup> The MCP provider agreement, July 1, 2018, (Appendix G.1.u) requires managed care plans to provide behavioral health services in accordance with state regulations (OAC 5160-27). State regulations (OAC 5160-27-09) requires SUD treatment services to be defined by and provided according to ASAM treatment criteria for addictive, substance related and co-occurring conditions for admission, continued stay, discharge, or referral to each level of care.

Existing ASAM LOC Coverage	Description	Adult/Adolescent Specific Criteria	State Plan Authority
	Withdrawal Management		Item 13-d-2 Page 4 of 9
ASAM Level 3.3	Clinically Managed Population-Specific High Intensity Residential Treatment	Single set of criteria	Rehabilitation Authority Item 13-d-2 Page 5 of 9
ASAM Level 3.5	Clinically Managed High Intensity (adults) Residential Treatment and Medium Intensity (adolescents)	Single set of criteria	Rehabilitation Authority Item 13-d-2 Page 5 of 9
ASAM 3.7	Medically Monitored Intensive Inpatient Treatment (Adults)/ Medically Monitored High Intensity Inpatient Treatment Services (Adolescent)	Both	Rehabilitation Authority Item 13-d-2 Page 5 of 9
ASAM 3.7-WM	Medically Monitored Inpatient Withdrawal Management.	Single set of criteria	Rehabilitation Authority Item 13-d-2 Page 5 of 9
ASAM 4 and ASAM-4-WM	Medically Managed Intensive Inpatient Treatment	Single set of criteria	Hospital Authority Item 1

Approximately 90% of all individuals in Ohio Medicaid are enrolled in managed care. MyCare Ohio is Ohio's dual-eligible demonstration waiver covering individuals in certain counties. Ohio's plans, both MCOPs and MCPs, currently include all the above LOCs in their contracts. SUD residential LOC in large facilities may be covered under the "in lieu of" authority under managed care rate setting rules.

The Ohio Medicaid covered opioid pharmaceutical therapies are listed below.<sup>7</sup> Beginning January 1, 2019, the State, in partnership with MCPs, eliminated prior authorization in most instances for MAT for opioid use disorder. All MCPs and FFS will have the same coverage and limitations for these prescribed drugs. Medicare covers prescription drugs for individuals enrolled in MCOPs, so this does not apply to those plans.

<sup>7</sup>Ohio Medicaid prescription fee schedule and authorization:  
<https://druglookup.ohgov.changehealthcare.com/DrugSearch>

**The Ohio MAT preferred drug list includes:**

- Bunavail® buccal film (buprenorphine/naloxone)
- Buprenorphine SL tablets (generic of Subutex®)
- Buprenorphine/Naloxone SL tablets
- Suboxone® SL film (buprenorphine/naloxone)
- Zubsolv® SL tablets (buprenorphine/naloxone)

**The current Medicaid prescription coverage includes:**

- Buprenorphine
- Buprenorphine-Naloxone [Suboxone]
- Buprenorphine-Naloxone [Bunavail]
- Buprenorphine-Naloxone [Zubsolv]
- Buprenorphine Implant [Probuphine]
- Sublingual Suboxone
- Naloxone Injectable
- Naloxone Nasal Spray [Narcan]
- Oral Naltrexone Tab
- Naltrexone ER Injectable [Vivitrol]

As part of MAT, individuals prescribed one of the opioid pharmaceutical therapies listed above, and/or are accessing Methadone through OTPs, have access to counseling and other behavioral health (BH) therapies through the ASAM levels covered under the Medicaid State Plan according to the level of counseling that the individual requires.

Beginning January 1, 2020, ODM will implement a unified preferred drug list that will be required of both FFS and the managed care plans.

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
None	Milestone 1	

**Milestone 2: Use of Evidence-based, SUD-specific Patient Placement Criteria**

**CMS Specifications:**

Implementation of evidence-based, SUD-specific patient placement criteria is identified as a critical milestone that states are to address as part of the demonstration. To meet this milestone, states must ensure that the following criteria are met:

1. Providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools, e.g., the ASAM Criteria, or other patient placement assessment tools that reflect evidence-based clinical treatment guidelines; and
2. Utilization management (UM) approaches are implemented to ensure that (a) individuals enrolled in Medicaid have access to SUD services at the appropriate LOC, (b) interventions are appropriate for the diagnosis and LOC and (c) there is an independent process for reviewing placement in residential treatment settings.

***Implementation of requirement that providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools that reflect evidence-based clinical treatment guidelines***

**Current State:**

The State requires all SUD treatment providers to assess and provide services using ASAM criteria. Ohio Department of Mental Health and Addiction Services (OhioMHAS) requires all certified SUD treatment providers to use multi-dimensional assessments based on the six dimensions of care as outlined in ASAM.

***Implementation of a UM approach such that (a) individuals enrolled in Medicaid have access to SUD services at the appropriate LOC***

**Current State:**

Ohio Administrative Code (OAC) [5160-27-09](#) describes SUD treatment services provided to all individuals in Medicaid. This regulation requires the use of the ASAM treatment criteria for addictive, substance related and co-occurring conditions for admission, continued stay, discharge or referral to each LOC. All plans are required to follow OAC 5160-27-09 in providing BH services under the plan provider agreement.<sup>8</sup> ODM requires FFS providers and plans to provide the current SUD service array using ASAM requirements for assessments, admission and discharge criteria for each SUD outpatient and residential LOC.

The Medicaid Behavioral Health Provider manual, which also applies to plan service decisions, does not describe the responsibilities for screening, assessment and treatment plan review, including the requirements to substantiate appropriate patient placement at each LOC.

**Future State:**

For each ASAM level, the Medicaid Behavioral Health Provider Manual, managed care provider agreement, and/or OAC will be modified to describe the responsibilities for screening, assessment and treatment plan review, including the requirements to substantiate appropriate patient placement using the ASAM dimensions in assessments, admission and discharge criteria for each SUD outpatient and residential LOC.

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
Currently meeting	Milestone 2	

***Implementation of a UM approach such that (b) interventions are appropriate for the diagnosis and LOC***

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<sup>8</sup> Appendix G.1.u

## Current State:

As of July 1, 2019, SUD treatment services provided in the managed care and the FFS delivery systems are required to comply with ASAM criteria for all prior authorization and utilization review decisions resulting in continuity across the Medicaid delivery systems.

Plans are responsible for implementing a UM approach consistent with Milestone #2. The plans perform UM for all LOCs. Services may be subject to outlier review, practice management or other UM strategies. Plans are required to implement “clearly defined structures and processes” on UM programs in accordance with OAC 5160-26-03.1.<sup>9</sup> OAC 5160-26-03.1 requires a plan’s UM program to ensure care decisions are based on medical necessity. The State requirement also outlines additional standards for the UM program policies and procedures, including the following:<sup>10</sup>

- The information sources used to make determinations of medical necessity.
- The criteria, based on sound clinical evidence, to make UM decisions and the specific procedures for appropriately applying the criteria.
- A specification that written UM criteria will be made available to both contracting and non-contracting providers.
- A description of how the plan will monitor the impact of the UM program to detect and correct potential under- and over-utilization.

The UM program must ensure and document the following:

- An annual review and update of the UM program.
- The involvement of a designated senior physician in the UM program.
- The use of appropriate qualified licensed health professionals to assess the clinical information used to support UM decisions.
- The use of board-certified consultants to assist in making medical necessity determinations, as necessary.
- That UM decisions are consistent with clinical practice guidelines as specified in rule 5160-26-05.1 of the Ohio Administrative Code. A plan may not impose conditions around the coverage of a medically necessary Medicaid-covered service unless they are supported by such clinical practice guidelines.
- The reason for each denial of a service, based on sound clinical evidence.
- That compensation by the plan to individuals or entities that conduct UM activities does not offer incentives to deny limit or discontinue medically necessary services to any member.

The State Plan establishes coverage using the ASAM LOC. The State also requires, through OAC 5160-27-09, that SUD treatment services are defined by and provided according to ASAM treatment criteria for addictive, substance related co-occurring conditions for admission, continued stay, discharge or referral to each LOC. Plans are

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<sup>10</sup> <http://codes.ohio.gov/oac/5160-26-03.1>

required to comply with this requirement through the provider agreement, and as such, service authorization criteria must meet this same standard in each plan’s policies and procedures. However, the ASAM criteria for admission, continued stay, discharge or referral to each LOC are not defined in the plan contract or OAC rules with specific instructions to plans. Additionally, the plans are required to take steps to ensure adoption of the clinical practice guidelines by specialized BH care providers, and to measure compliance with the Provider Agreement, OAC and other ODM guidelines. The plans are contractually encouraged to employ substantive provider motivational incentive strategies, such as financial and non-financial incentives, to improve compliance. Additionally, the plans are required to perform record reviews.

Plans are required to have a Behavioral Health (BH) Clinical Director as part of its key staff. The BH Clinical Director, a dedicated part-time staff member, must currently be practicing within the scope of his/her license as either a clinical psychologist or board-certified psychiatrist with a minimum of three years of experience in a clinical setting. Each plan must have at least one board certified psychiatrist who is a prescriber and performs BH Clinical Director functions like monitoring overall safety of patients with a BH diagnosis with a special focus on safe prescribing. The BH Clinical Director duties also include: <sup>11</sup>

- BH coverage determination for UM to ensure individuals receive appropriate and medically necessary care in the most cost-effective setting.
- Oversight and quality improvement activities associated with care management activities.
- Providing guidance to BH orientation and network development/ recruitment in conjunction with provider relations, value-based contracting, support of episodes of care and full integration of BH services.
- Assisting in the review of utilization data to identify variances in patterns and providing feedback and education to plan staff and providers as appropriate.
- Representing the plan as the primary clinical liaison to individuals, providers and ODM.

**Future State:**

The state continually seeks to improve its review and monitoring of its MCOs relative to UM. In keeping with the State’s commitment to improve the use of the ASAM criteria by both providers and plans, ODM will conduct reviews of provider and plan utilization management processes and make necessary adjustments to the UM program as the waiver demonstration evolves.

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
Review plan policies for utilization review and prior authorization for compliance.	Milestone 2	12 to 24 months
Review plan delivery for program compliance (e.g., treatment plan, provider qualifications, etc.).	Milestone 2	12 to 24 months

<sup>11</sup> Appendix C.8.d

**Implementation of a UM approach such that (c) there is an independent process for reviewing placement in residential treatment settings**

**Current State:**

As of July 1, 2019, plans and FFS were required to utilize ASAM and have an independent process for reviewing all placements in residential treatment settings. Currently the provider agreement requires all plans to follow the prior authorization standards established under BH Redesign for both the FFS and managed care delivery systems. Consistent with 5160-27-09, the FFS delivery system and all MCPs use ASAM for continued stay criteria for residential treatment after 30 days and/or to prior authorize three or more admissions to a residential treatment facility. The provider agreement requires plans to authorize a stay in a SUD residential treatment facility as expeditiously as the member’s health condition requires, but no later than 48 hours after receipt of the prior authorization request.<sup>12</sup> Magellan Clinical Guidelines and InterQual guidelines are utilized by some MCPs in addition to ASAM.

**Future State:**

The State will maintain the current prior authorization process as described above, and, within 24 months of the approval of the 1115 SUD Waiver Demonstration, will collect, review, and analyze the data regarding residential utilization management from the implementation of the redesign of the behavioral health benefit package on January 1, 2018. Based upon the analysis of the current residential treatment authorization processes, the state will develop appropriate authorization approaches that ensure compliance with ASAM and MHPAEA.

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
Collect, review, and analyze utilization management information for CY2018.	Milestone 2	12 to 24 months
Based upon review and analysis, develop changes to the utilization management approach that reflect analysis and ensure compliance with ASAM and MHPAEA.	Milestone 2	12 to 24 months
Develop necessary guidance to plans and providers regarding the new UM process.	Milestone 2	12 to 24 months

**Milestone 3: Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities**

**CMS Specifications:**

<sup>12</sup> Appendix C.66.c

- Implementation of residential treatment provider qualifications (in licensure requirements, provider manuals, managed care contracts or other guidance) that meet the ASAM criteria or other nationally recognized, SUD-specific program standards regarding the types of services, hours of clinical care and credentials of staff for residential treatment settings.
- Implementation of a state process for reviewing residential treatment providers to ensure compliance with these standards.
- Implementation of a requirement that residential treatment facilities offer MAT on-site or facilitate access off site.

*Implementation of residential treatment provider qualifications in licensure requirements, policy manuals, managed care contracts, or other guidance. Qualification should meet program standards in the ASAM criteria or other nationally recognized, SUD-specific program standards regarding, in particular, the types of services, hours of clinical care and credentials of staff for residential treatment settings*

**Current State:**

OAC 5122-29-09 describes OhioMHAS provider certification requirements. OhioMHAS certification requirements define specific LOCs. These requirements apply to facilities providing residential services under both the managed care and FFS delivery systems.<sup>13</sup>

OAC 5122-29-09 requires residential, withdrawal management and inpatient SUD treatment services to be provided in accordance with ASAM Level 3, ASAM Level 3-WM, and associated sub-levels as appropriate to the needs of the individual being served, as published in the ASAM criteria, third edition, 2013. However, the licensing regulations, Ohio Medicaid regulations and the publicly available published Medicaid provider manuals do not detail the service definitions, program requirements, eligibility criteria and detailed provider requirements/qualifications for each level. Providers must purchase the ASAM criteria and interpret the particular types of services, hours of clinical care and credentials of staff for each of the ASAM residential treatment settings and LOC.

**Future State:**

Ohio will strengthen the Medicaid provider qualification requirements, based on ASAM criteria, for SUD residential treatment providers through Medicaid provider manuals, OAC and managed care provider manuals. Ohio will align all service definitions, the Medicaid program requirements, eligibility criteria, and detailed provider requirements/qualifications for each level with ASAM in the published Medicaid provider manual. The Medicaid provider manuals will include more detail about the ASAM residential program standards including the particular types of services, hours of clinical care, and credentials of staff for residential treatment settings.

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<sup>13</sup> <http://codes.ohio.gov/oac/5122-29-09v1>

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
Update the State requirements to reflect residential requirements for the types of services, hours of clinical care and credentials of staff for each ASAM residential LOC.	Milestone 3	12 to 24 months
Require the plans to comply with updated ASAM residential requirements.	Milestone 3	12 to 24 months

***Implementation of a state process for reviewing residential treatment providers to ensure compliance with these standards***

**Current State:**

There is currently no standardized state process for the review of residential provider qualifications against state requirements for ASAM Level 3, ASAM Level 3-WM and associated sub-levels. Current standards are not enforced through consistent onsite reviews of residential facilities.

**Future State:**

Medicaid will implement a process for reviewing residential treatment providers to ensure compliance with these standards. Providers will be held compliant by onsite and administrative reviews, which will include reviews of records and observations and interviews with staff and clients, as appropriate to the process. All visits, except for the initial review, will be unannounced. To ensure compliance, reviews will be conducted during application, renewal, complaints, onsite and administrative reviews such as desk reviews.

Residential providers contracting to provide Medicaid services as part of the plan networks will be held to certain standards in their plan contracts and will be required to be credentialed by the plans prior to participating in the network. The plans also will ensure compliance with program standards outlined in the ODM provider manuals by monitoring their provider networks via credentialing, monitoring complaints and during the provider re-credentialing cycle.

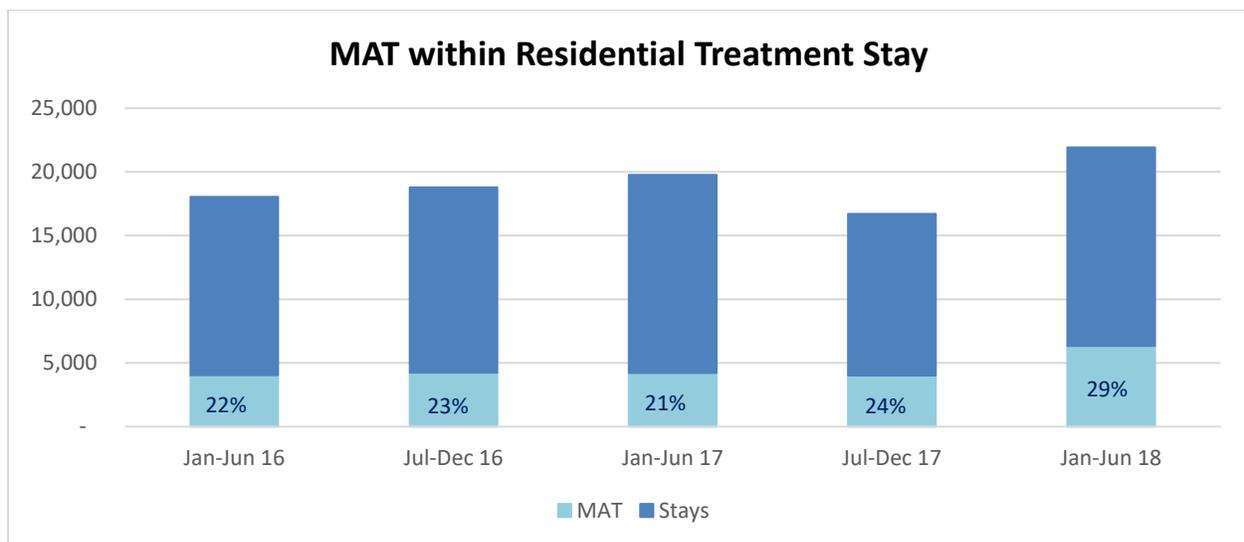
In addition, ODM intends to procure a single, statewide vendor to perform SUD treatment provider management including a qualification and verification function to assure statewide standards are met. It is intended that this will achieve a single, reliable provider registry. This new provider enrollment and qualification system is anticipated to be activated during CY2020. Plans will then be limited to credentialing providers from the state's single source for provider enrollment, allowing ODM to appropriately identify SUD treatment providers in encounter data.

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
Implement a standardized State on-site review process of residential provider qualifications against State requirements for ASAM including the types of services, hours of clinical care and credentials of staff for each ASAM residential LOC.	Milestone 3	12 to 24 months
Implement a single statewide vendor to survey Ohio SUD residential providers to assure they meet certain standards and manage provider enrollment on an on-going basis.	Milestone 3	12 to 24 months
Require the plans to comply with State processes for credentialing SUD residential providers.	Milestone 3	12 to 24 months

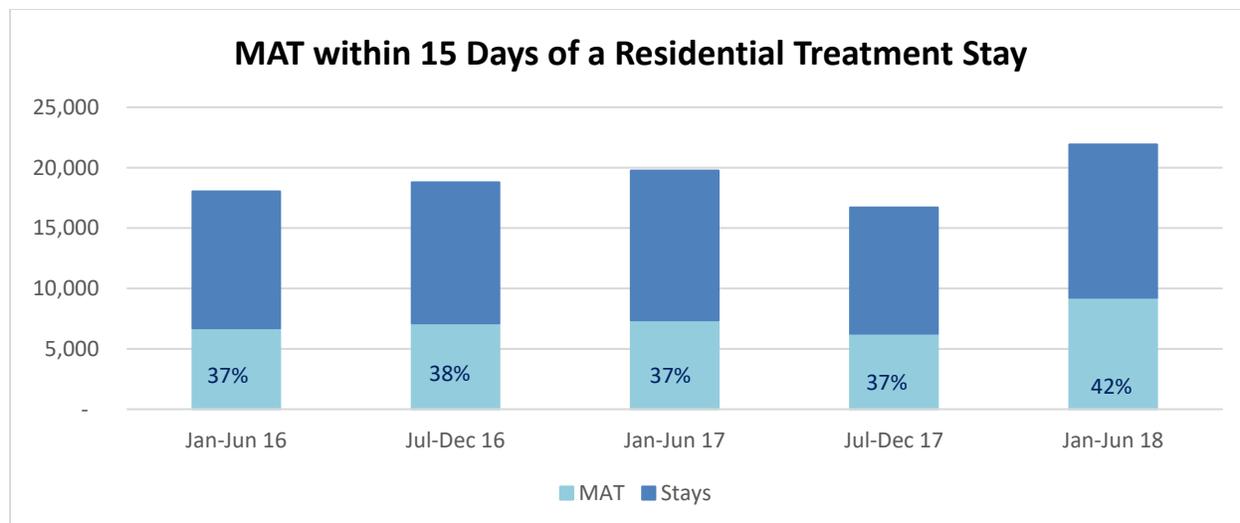
**Implementation of requirement that residential treatment facilities offer MAT on-site or facilitate access off-site**

**Current State:**

Finally, there are no requirements for residential providers to arrange for or provide MAT to their residents. Currently, many residential providers utilize abstinence-based care models and do not provide MAT onsite or facilitate offsite access to MAT. However, by the first half of CY 2018, 29% of individuals received MAT during their SUD residential stay.



Because medication in MAT can remain effective for up to 15 days, Ohio also tracks the number of Medicaid individuals who received MAT within 15 days of a residential stay. The number of Medicaid residential stays where the individual was prescribed MAT within 15 days of a residential stay increased to 42% by the first half of CY 2018.



**Future State:**

The updated Medicaid provider standards will include a requirement that residential treatment facilities offer MAT on-site or facilitate access off-site.

OhioMHAS will modify the OAC section 5122-40-15 governing OTPs to add certified SUD residential/withdrawal management providers to the types of permitted providers under this section.

Over the next 24 months, Ohio will seek to change the culture and attitudes among SUD residential treatment providers to accept and integrate MAT for their residents who choose MAT as a part of their treatment plan. Individuals will continue to have a choice in treatment, but all residential providers will be required to offer MAT on site or facilitate access to MAT off-site. ODM and OhioMHAS will work together to provide outreach and education to abstinence-based programs about the importance of adding MAT as a treatment option.

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
Educate abstinence-based residential providers on benefits of MAT accessibility and begin cultural shift toward acceptance of MAT as a complementary treatment.	Milestone 3	24 months
Require SUD treatment providers to offer access and to facilitate patient access to MAT while in residential settings.	Milestone 3	12 to 24 months
Require the FFS delivery system and the plans to monitor access to MAT in residential settings including access to MAT counseling.	Milestone 3	12 to 24 months

## Milestone 4: Sufficient Provider Capacity at Critical LOC including for MAT for OUD

### CMS Specifications:

- To meet this milestone, states must complete an assessment of the availability of providers enrolled in Medicaid and accepting new patients in the critical LOC listed in Milestone 1. This assessment must determine availability of treatment for individuals enrolled in Medicaid in each of these LOCs, as well as availability of MAT and medically supervised withdrawal management, throughout the state. This assessment should help to identify gaps in availability of services for individuals in the critical LOCs.

*Completion of assessment of the availability of providers enrolled in Medicaid and accepting new patients in the following critical LOC throughout the state (or at least in participating regions of the state) including those that offer MAT: Outpatient Services, Intensive Outpatient Services, MAT (medications as well as counseling and other services), Intensive Care in Residential and Inpatient Settings, Medically Supervised Withdrawal Management.*

### Current State:

Ohio has 4,135 SUD residential treatment beds in 178 SUD treatment facilities that might meet the definition of an Institute for Mental Disease (IMD). The number of residential days for each residential LOC based on 2014 data can be seen in the Table below:

**Table: Estimated 2014 Residential LOC days**

State Fiscal Year 2014	Adult Days	Child Days	Total Estimated Days
ASAM 3.1 (H2034)	0	0	0
ASAM 3.2 WM (H0010)	371	35	406
ASAM 3.3 (H2036 HI)	22,061	0	22,061
ASAM 3.5 (H2036)	70,759	39,171	109,930
ASAM 3.7(H2036 TG)	5,404	1,868	7,272
ASAM 3.7 WM(H0011)	3,947	563	4,510
<b>Total</b>	<b>102,542</b>	<b>41,637</b>	<b>144,179</b>

As described in the Milestone #1 section, MCPs are required to contract with a minimum number of certified SUD treatment providers for each designated Ohio MCP region and must maintain provider panel capacity so that enrolled individuals have access to comprehensive SUD treatment services. Ohio monitors compliance with these provider sufficiency requirements through MCP reporting. The network access monitoring reports for SUD treatment providers are still being developed because SUD treatment was first included in the MCP network on July 1, 2018. As noted above, the State will be developing access standards for each ASAM LOC.

When preparing for the inclusion of BH in the MCP benefit package on July 1, 2018, ODM conducted readiness reviews of the MCPs to ensure the panel requirements were met. This included ensuring each MCP had at least a minimum number of comprehensive alcohol and drug treatment providers in each region (see table below). If a covered Medicaid service is not available in network, the MCP must arrange for that service to be provided out-of-network at no additional charge to the member.

The State ensures sufficient coverage by contractually requiring the MCPs to meet network adequacy standards for services. MCPs are required to contract with any willing opioid treatment provider who is appropriately licensed and certified. This includes Methadone providers licensed by OhioMHAS and Buprenorphine-based medications providers certified by Substance Abuse and Mental Health Services Administration (SAMHSA) and/or possessing a Federal DEA waiver. MCPs must also contract with a minimum number of SUD treatment providers determined at the county level (described in table below). MCPs must maintain provider panel capacity so that enrolled individuals have access to the following services with reasonable and timely access:<sup>14</sup>

- Alcohol/drug screening analysis/lab urinalysis
- Ambulatory detoxification
- Assessment
- Case management
- Crisis intervention
- Individual counseling
- Group counseling
- Induction of buprenorphine
- Injection of naltrexone (for addiction treatment)
- Intensive outpatient (for addiction treatment) and
- Medical somatic services

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<sup>14</sup> MCP provider agreement, July 1, 2018, [Appendix H 4.c.ix. Behavioral Healthcare Providers](#)

**Table: Managed Care Plan Contract Standards for OhioMHAS-certified SUD treatment Providers in Each County**

Minimum SUD Provider Agencies for MCPS to Contract by County								
Region	County	SUD	Region	County	SUD	Region	County	SUD
W	ADAMS	-	W	GREENE	1	CEN/SE	NOBLE	1
W	ALLEN	2	CEN/SE	GUERNSEY	1	W	PAULDING	-
NE	ASHLAND	1	W	HAMILTON	15	CEN/SE	PERRY	1
NE	ASHTABULA	3	W	HANCOCK	1	CEN/SE	PICKAWAY	1
CEN/SE	ATHENS	2	CEN/SE	HARDIN	1	CEN/SE	PIKE	1
W	AUGLAIZE		W	HENRY	1	NE	PORTAGE	3
CEN/SE	BELMONT	1	W	HIGHLAND	1	W	PREBLE	1
W	BROWN		NE	HOCKING	1	W	PUTNAM	1
W	BUTLER	4	NE	HURON		NE	RICHLAND	10
W	CHAMPAIGN		CEN/SE	JACKSON	1	CEN/SE	ROSS	3
W	CLARK	2	CEN/SE	JEFFERSON	1	W	SANDUSKY	1
W	CLERMONT	2	CEN/SE	KNOX	1	CEN/SE	SCIOTO	7
W	CLINTON		NE	LAKE	5	W	SENECA	-
NE	COLUMBIANA	1	CEN/SE	LAWRENCE	4	W	SHELBY	1
CEN/SE	COSHOCTON	1	CEN/SE	LICKING	1	NE	STARK	6
CEN/SE	CRAWFORD	1	CEN/SE	LOGAN	1	NE	SUMMIT	9
NE	CUYAHOGA	29	NE	LORAIN	4	NE	TRUMBULL	1
W	DARKE	1	W	LUCAS	11	NE	TUSCARAWAS	1
W	DEFIANCE	1	CEN/SE	MADISON		CEN/SE	UNION	-
CEN/SE	DELAWARE	1	NE	MAHONING	8	W	VANWERT	1
NE	ERIE	2	CEN/SE	MARION	1	W	WARREN	1
CEN/SE	FAIRFIELD	2	NE	MEDINA	3	CEN/SE	WASHINGTON	1
CEN/SE	FAYETTE		W	MERCER	1	NE	WAYNE	4
CEN/SE	FRANKLIN	19	W	MIAMI	1	W	WILLIAMS	-
W	FULTON		W	MONTGOMERY	10	W	WOOD	1
CEN/SE	GALLIA	5	CEN/SE	MORGAN	1			
NE	GEAUGA	3	CEN/SE	MUSKINGUM	1			

The readiness reviews found that the MCPs had differing levels of access compared to the standard. See table below:

**Table: MCP capacity analysis as of September 10, 2018**

MCP	Number of Counties Meeting Network Standard for SUD	Percent of Counties* Meeting Network Standard for SUD
Buckeye Health Plan	81	92%
CareSource	88	100%
Molina	88	100%
Paramount	86	98%
United Healthcare	88	100%

\*Percent of 88 counties

The MCPs are tasked with monitoring provider capacity of their networks. Each MCP develops and maintains a provider Network Development and Management Plan, which ensures the provision of core benefits, and services will occur. It includes the MCP's process to develop, maintain and monitor an appropriate provider network that is supported by written agreements and is sufficient to provide adequate access of all required services. The plan demonstrates access to BH services, identifies gaps in network and describes the process to ensure services are delivered. The plan provides geo-mapping of providers to geographically demonstrate network capacity. The plan has policies detailing how it will provide or arrange for medically necessary covered services should the network become temporarily insufficient and will monitor the adequacy, accessibility and availability of its provider network to meet the needs of enrolled individuals. MCP Network Development and Management Plans are updated at least annually or more often as needed to reflect material changes in network status.

The MyCare Ohio contracts (both the Provider Agreement and the three-way contract) do not define specific SUD network requirements like those described above. However, MCOPs are held to the same standard of "assuring access to all-Medicaid covered BH services."<sup>15</sup> The MCOPs are also required to demonstrate an adequate provider network "sufficient in number, mix, and geographic distribution" to ensure access to BH services.<sup>16</sup> MCOPs as described in the Provider Agreement are required to evaluate each region's network capacity of BH services using the minimum capacity standards located in the table below:

**Table: MyCare Ohio Contract Standards for OhioMHAS-certified SUD treatment Providers in each region**

Region	OMHAS SUD Provider Agencies
Central	8
East Central	8
Northeast	8
Northeast Central	6

<sup>15</sup> Section 2.7.10 of the three-way contract

<sup>16</sup> Section 2.6.1.1 of the three-way contract

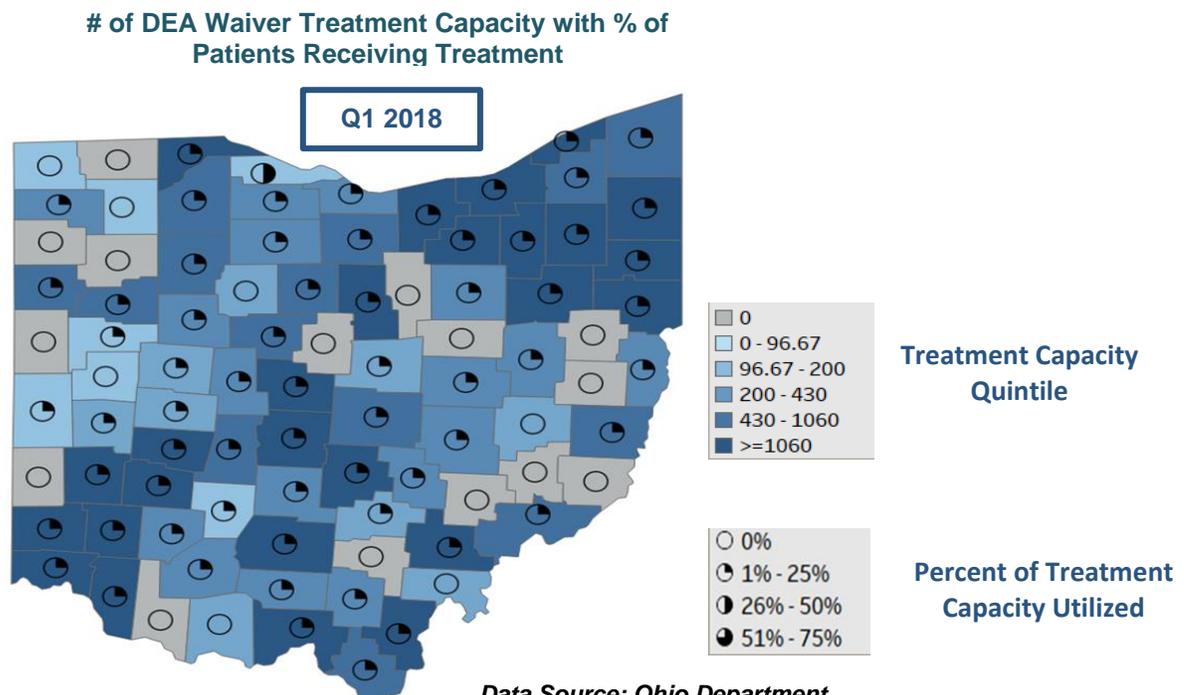
Region	OMHAS SUD Provider Agencies
Northwest	6
Southwest	8
West Central	6

The number of individuals receiving SUD treatment continues to grow. Ohio has tracked the increased capacity in the system through the increased number of individuals in treatment and the improved treatment rates of this population (i.e., increase SUD services penetration rate). See table below:

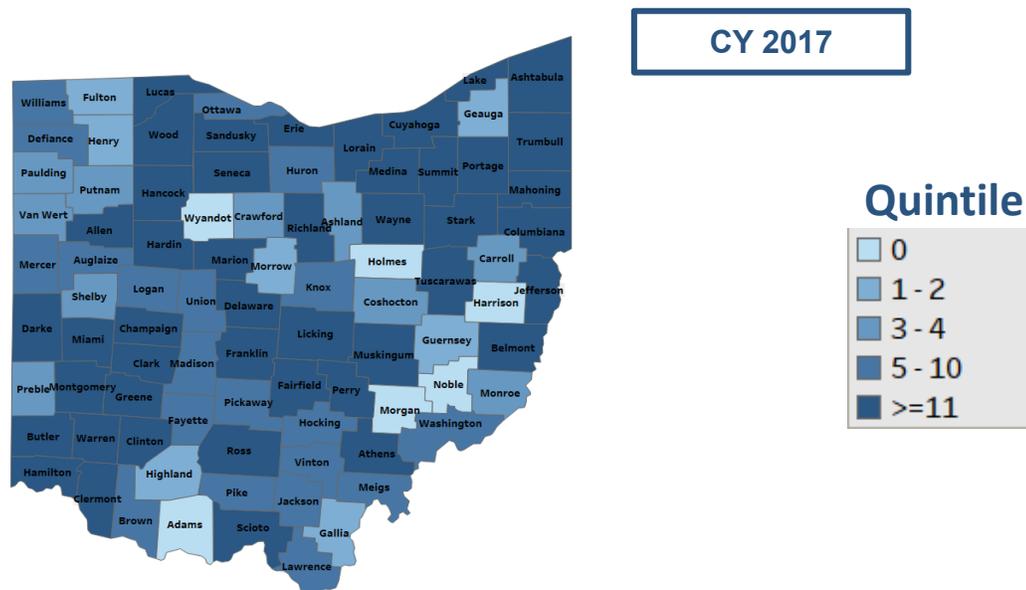
**Table: Increased SUD treatment capacity, penetration rate and MAT usage 2014–2017.**

Year	Any Primary SUD Diagnosis	Any SUD Diagnosis	General SUD Treatment	Appropriate MAT Usage	Population with any SUD diagnoses receiving SUD services (Penetration Rate)
2014	103,144	183,598	107,300	27,559	58%
2015	129,767	225,684	134,075	37,653	59%
2016	147,519	244,384	151,572	48,531	62%
2017	161,034	254,925	165,642	56,982	65%

The State also monitors MAT providers. The State trends the number of providers with Drug Enforcement Agency (DEA) waivers as well as the capacity of those providers. Monitoring also includes the number of providers prescribing Vivitrol. See figures below:



### Number of Providers Prescribing 1 or more Vivitrol



*Data Source: Ohio Department of Mental Health & Addiction Services*

Per the current MCP contract, MCPs are allowed to provide mental health services to members ages 21 through 64 for up to 15 days per calendar month while receiving inpatient treatment in designated IMDs. Medicaid does not compensate the MCP for the provision of such services beyond 15 days per calendar month either through direct payment or considering any associated costs in Medicaid rate setting. The MCPs are required to report quarterly on stays in designated IMDs that exceed 15 days per calendar month per ODM’s specifications. Future MCP contracts will outline requirements for provision of services to individuals with SUD receiving services in residential settings or facilities as described in the Summary of Actions outlined in Milestones 2, 3, and 4.

#### Future State:

Ohio will create an assessment of the availability of SUD treatment providers enrolled in Medicaid that are accepting new patients in the critical LOCs<sup>17</sup> throughout the state including those that offer MAT. The State expects to be able to develop the assessment within 12 months of demonstration approval. This assessment will include:

- Whether facilities accept clients funded through the managed care, FFS or both delivery systems.

<sup>17</sup> ASAM 1: Outpatient Services; ASAM 2.1/2.5: Intensive Outpatient Services/Partial Hospitalization; ASAM 1-WM/2-WM: Medication Assisted Treatment (medications as well as counseling and other services); ASAM 3.1/3.3/3.5/3.7/4: Intensive Care in Residential and Inpatient Settings; ASAM 3.2-WM/3.7-WM: Medically Supervised Withdrawal Management

- Anticipated penetration rate and geographic distributions of providers at each LOC.
- Plans for enhancement of capacity based on assessments of provider availability.

ODM will establish updated access standards for the new array of BH State Plan services including all SUD ASAM LOC. MCPs will be required to meet the new access standards and to report on their SUD treatment provider network development and management plans, specifically focusing on SUD treatment provider capacity, including MAT. Geo-mapping will also be expanded to monitor access to MAT inclusive of a reporting mechanism to monitor the number and location of providers accepting new patients.

MCPs will submit network adequacy reports to ODM on a quarterly basis inclusive of counts of available network providers by LOC and by provider type. The quarterly network report package will include GeoAccess mapping for all SUD network providers by ASAM LOC capacity. Should gaps in access or adequacy be identified, the MCPs are required to submit gap analyses and ad hoc network development plans with their quarterly report package.

The MCOP contract currently specifies that each MCP must have 6–8 SUD providers in each region’s network. Future plan contracts will outline geographic access requirements for maximum travel time and/or distance requirements for each ASAM LOC.

As an additional treatment strategy, physicians, advanced practice registered nurses and physician assistants will be encouraged to become certified dispensers. According to the Drug Addiction Treatment Act of 2000 (DATA 2000), which expands the clinical context of medication-assisted treatment for persons with OUD, certified practitioners (including MDs, DOs, Advanced Practice Nurses and Physician Assistants) are permitted to dispense or prescribe specifically approved Schedule III, IV and V narcotic medications such as buprenorphine, Suboxone, and Subutex in settings other than an OTP. DATA 2000 reduces the regulatory burden on physicians who choose to practice OUD treatment by permitting qualified physicians to apply for and receive waivers of the special registration requirements defined in the Controlled Substances Act.

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
Create a comprehensive access assessment baseline of all SUD providers and all SUD LOC, including MAT capacity.	Milestone 4	12 months
ODM will create access standards for SUD LOC.	Milestone 4	12 months
Require MCPs to update their SUD network development and management plan to specifically focus on SUD provider capacity by LOC, including MAT.	Milestone 4	12 to 18 months

Add an indicator for providers accepting new patients to the plan quarterly network adequacy reports.	Milestone 4	12 to 24 months
Require the plans to adopt access requirements for all ASAM LOC.	Milestone 4	12 months

## Milestone 5: Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD

### CMS Specifications:

- Implementation of opioid prescribing guidelines, along with other interventions to prevent opioid abuse.
- Expanded coverage of and access to, naloxone for overdose reversal.
- Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs (PDMPs).

### *Implementation of opioid prescribing guidelines, along with other interventions to prevent opioid abuse*

#### Current and Future State:

#### Opioid Prescribing Guidelines

Since 2012, Ohio has implemented five sets of opiate prescribing guidelines as part of GCOAT. This multi-pronged approach has advanced Ohio's fight against the opioid epidemic. (See Attachment B) Changes in prescribing guidelines addressed the easiest sources of uncoordinated prescription medications including prescriptions obtained via hospital emergency departments. The State also included guidelines for patients already taking opioid medications and safeguards for the highest doses of prescription opioids. The updated guidelines include:

- The first Emergency and Acute Care Facility Opioid and Other Controlled Substances Prescribing Guideline was released in April 2012 for hospital emergency departments and acute care facilities to address the large proportion of opioids prescribed from these settings, disconnected from routine sources of care for chronic pain conditions.
- In October 2013, GCOAT introduced Opioids Prescribing Guidelines for Treatment of Chronic, Non-terminal Pain for Ohio's opiate prescribers as the risk for overdose became increasingly apparent across the country.
- In January 2016, GCOAT launches Guidelines for the Management of Acute Pain *Outside* of Emergency Departments and acute care facilities. These guidelines addressed "new starts" and to further encourage non-opioid therapies and pain medications for the management of acute pain expected to resolve within 12 weeks.
- In August 2017, Ohio implemented prescribing limits for acute pain (seven days for adults and five days for minors). In order to be able to monitor adherence to these requirements, in December 29, 2017 prescribers were required to include

the first four alphanumeric characters of the diagnosis code or full procedure code on opioid prescriptions. The inclusion of a diagnosis/procedure code (CDT) was required for all other controlled substance prescriptions on June 1, 2018. The final requirement was a days’ supply limit on all controlled substance and gabapentin prescriptions.

- A final unifying guideline was rolled out in 2018, emphasizing the need for vigilance and persistence in ensuring safety and screening for misuse and abuse. Documentation recommendations were delineated, with a “press pause” at the lower threshold of 50 Morphine Equivalency Dosage (MED) instead of the 80 MED described in prior chronic pain guidelines.

### Progressive Opioid Prescribing Guidelines for a Safer Ohio

	Emergency Department & Acute Care Facilities	For Chronic, Non-Terminal Pain	For Acute Pain Outside of Emergency Department	Prescribing Limits For Acute Pain	For Subacute Pain
<b>Effective Date</b>	April 2012	October 2013	January 2016	August 2017	October 2018
<b>Specific Goals</b>	Stop inappropriate prescribing from ED & Urgent Care Centers	Ensure long-term patient safety	Limit first use of opioids and decrease availability of unused opioid medications	Limit type & amount of opioids for acute pain	Establish a continuum of safe prescribing with express informed consent
<b>Prescribing Limitations</b>	<ul style="list-style-type: none"> <li>• No more than 3 day supply</li> <li>• No recurrent refills for chronic conditions</li> <li>• No long-acting opioids</li> <li>• Connect to usual source of chronic care</li> </ul>	<ul style="list-style-type: none"> <li>• At ≥ 80 mg MED “press pause”</li> <li>• Caution with co-prescribing of benzodiazepines</li> <li>• Mandatory written agreement</li> <li>• Prescribe Naloxone</li> <li>• Mandatory OARRS checks and monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Discuss pain management expectations</li> <li>• First consider non-pharmacologic and non-opioid therapies</li> <li>• Limit pills per script</li> <li>• No Long-acting opioids</li> <li>• 2 week check point</li> </ul>	<ul style="list-style-type: none"> <li>• 7 day supply for adults</li> <li>• 5 day supply for youth</li> <li>• 30 MED average</li> </ul>	<ul style="list-style-type: none"> <li>• At ≥ 50 MED, “press pause”</li> <li>• Informed consent</li> <li>• Screen for OUD</li> <li>• At ≥80 MED, subspecialty consultation</li> <li>• At 120MED, pain medicine specialist</li> </ul>

1

MCPs implemented state-standardized claim edits requiring prior authorization for short-acting opioid prescriptions as well as prior authorization for all long-acting opioids. These claim edits were designed to help “enforce” the board’s guidelines.

### Other Statewide interventions

Additional interventions included:

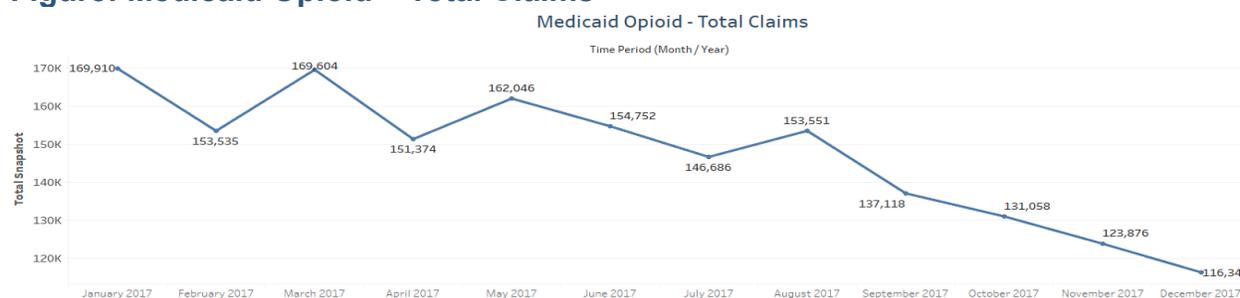
1. Closed “pill mills” in 2012.
2. Eliminated the authority of physicians to telephone in prescriptions for Schedule II drugs such as hydrocodone (Vicodin®).
3. Reduced the number of patients starting their first opioid.
4. Required Medicaid MCPs put edits in place within their pharmacy programs to support prescribing guidelines.
5. Required MCPs to implement Medication Therapy Management (MTM) for those with problematic polypharmacy and a Coordinated Services Program (CSP) to provide care management services for members who overuse or misuse services (described in greater detail below).

6. Implemented acupuncture as a covered Medicaid service as an evidence-based, non-opioid alternative treatment.
7. Created a youth drug prevention program called, *Start Talking*, which was launched in January 2014.
8. Required MCPs to implement a CSP as described in OAC rule 5160-20-01. Currently the Medicaid MCPs have approximately 3,400 members in the CSP. The OAC rule establishing CSP has been amended to specify additional lock-in criteria effective January 1, 2019. The changes are expected to increase the number of individuals enrolled in CSP.

Over the course of these guidelines and rules, the State of Ohio was able to realize a 28% reduction in solid doses of opioids prescribed from 196 million doses per quarter in Q2 2013 to 136 million Q2 2017.<sup>18</sup> For acute pain, prescriptions fell from 70 million per quarter to 51 million over that same time frame with a reduction in number of patients with any opioid falling from 1.29 million per quarter to 948,000 per quarter.

These initiatives have resulted in direct impacts on Medicaid prescribing. The Medicaid opioid claims have reached a low point of 116,348 claims in December 2017.

**Figure: Medicaid Opioid – Total Claims**

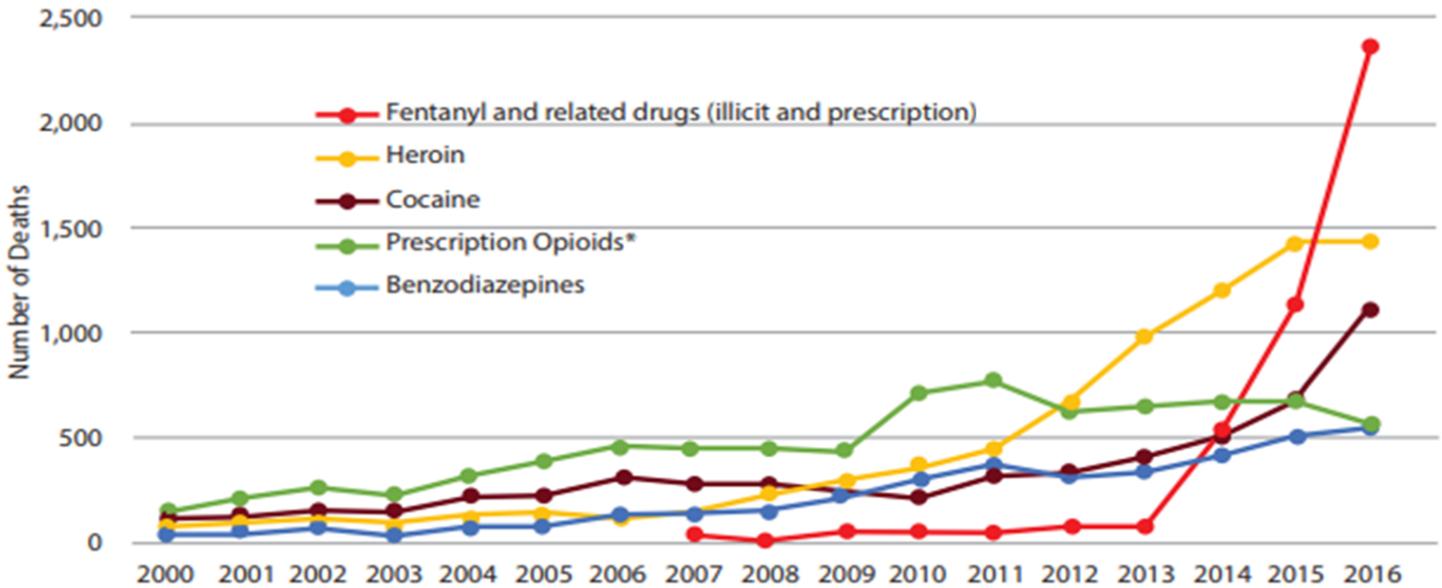


Ohio is one of the first states to realize a reduction in opioid deaths related to prescription drugs amid escalating overall deaths driven by illicit drug use. Of all unintentional drug overdose deaths, the percentage of prescription opioid-related deaths in Ohio declined for a fifth straight year in 2016 and the number of these deaths declined 15.4% from 667 in 2015 to 564 in 2016 — the fewest since 2009.<sup>19</sup> See figure below.

<sup>18</sup> OARRS data, Ohio’s Opioid Epidemic, The Medicaid Experience & Progress to Date, Agency Briefing on Opioids October 2017 SPA-5, Mary Applegate, MD, FAAP, FACP, Slide 33.

<sup>19</sup> Mortality data can be found at the following website:  
<http://publicapps.odh.ohio.gov/EDW/DataBrowser/Browse/Mortality>

**Figure 7. Number of Unintentional Drug Overdose Deaths Involving Selected Drugs, by Year, Ohio, 2000-2016**



Source: Ohio Department of Health, Bureau of Vital Statistics; analysis conducted by ODH Violence and Injury Prevention Program. Multiple drugs are usually involved in overdose deaths. Individual deaths may be reported in more than one category. Includes Ohio residents who died due to unintentional drug poisoning (underlying cause of death ICD-10 codes X40-X44). \* Excludes deaths involving fentanyl and related drugs.

Source: Ohio Department of Health  
**2016 Ohio Drug Overdose Data: General Findings**

### Medicaid Managed Care Interventions

To implement these prescribing guidelines in the Medicaid program, the Ohio Association of Health Plans convened a series of meetings to develop a comprehensive plan to address the opioid epidemic in Ohio. The most well received suggestion (or action strategy, etc.) was the high Morphine Equivalent Dosing (MED) intervention shared by one of the MCPs. MED determines a patient’s cumulative intake of any drugs in an opioid class in a 24-hour period. This involved identification of members receiving ultra-high MEDs and approaching the prescriber. The intervention included escalating letters and phone calls to the provider insisting on evidence-based practice and weaning when appropriate. There were provider consequences for non-compliance. The program has had well-documented success with a significant impact on total number of opioids prescribed.

In 2016, ODM challenged the MCP pharmacy directors to consider options specific to inappropriate opioid prescribing, aligning with internal plan efforts on the provider side of their programs. ODM FFS and the MCPs limited the number of opioid claims paid in a rolling 30 days to five, so that the sixth claim would reject for prior authorization. Both programs also tightened the allowable “early refill provisions, setting thresholds at 90%, which equated to no refills being allowed before day 27 in a 30-day month, for example.

As the MCPs agreed on these sorts of standards, there were operational considerations at the Pharmacy Benefit Manager (PBM) levels in terms of implementation. PBMs could allow the claim to pay but send a message to the pharmacy. They could deny the claim but allow the pharmacist to override after reviewing the message (and, one would hope, the patient's history and the PDMP, and maybe call one or more prescribers).

Alternatively, they could deny the claim and require prior authorization. The MCP PBMs did not achieve standardization to this degree of operational detail, but they were aligned. The PBMs for all of the MCPs and FFS utilized many other options to contain unsafe prescribing practices including using a preferred drug list, point of sale edits, step therapy, prior authorization, dispensing limits, age restrictions, prospective drug utilization review (DUR) edits like early refills, therapeutic drug duplication and drug interactions.

In 2012, ODM began coverage for MAT. While preferred MAT drugs varied by plan, as attention shifted to special populations such as the incarcerated who chose court-ordered treatment in lieu of incarceration, all of the MCPs worked together to remove barriers. As Vivitrol was the form of MAT preferred most by the judicial system, all MCPs removed prior authorization for Vivitrol, as did FFS, simplifying yet another aspect of the pharmacy program.

Ohio's BH benefit was integrated in to managed care July 1, 2018, prompting significant efforts to further remove administrative barriers to MAT utilization, ensuring the provision of MAT for individuals as well as concomitant psychosocial care. After considering the option of "gold-carding" providers, the MCPs agreed to remove all prior authorization requirements for all oral forms of short-acting buprenorphine and build a robust standardized retrospective DUR program on the back end. Some edits related to very young ages or pregnancy status may apply as the MCPs are still held to standards of patient safety. Long-acting or injectable forms of MAT (other than Vivitrol) are still subject to documentation requirements.

The MCPs also made sequential changes as the landscape of prescribing guidelines and limits evolved. In October 2017, FFS and all MCPs agreed to require prior authorization for all long-acting opioids prescribed for acute pain, supporting the state guidelines. In July 2018, all MCPs and FFS agreed to place a limit on days' supply and MED for short-acting opioids in new start patients, again stepping up to support evolving state prescribing limits by January 2018.

In 2017, alternative pain management strategies were evaluated to ensure that ODM was fully supporting strategies to minimize inappropriate prescribing of opioids. As FFS began to cover acupuncture for headache and low back pain, initially by physicians, extending to chiropractors and acupuncturists, the MCPs followed suit.

The MCPs have been active participants in many programs targeting special populations challenged with OUD consequences. The recently incarcerated were already mentioned. A Pre-Release program was developed allowing inmates to choose a Medicaid MCP in the 90 days before release, allowing for a video case conference and connectivity to needed community health services such as continuation of OUD treatment. Pregnant women are particularly affected by OUD as their infants may be

born with Neonatal Abstinence Syndrome, associated with long Neonatal Intensive Care Unit stays and child protective services (CPS) involvement. ODM has partnered with the Ohio Perinatal Quality Collaborative to develop models of care such as those described in the Maternal Opiate Medical Support program, in which the MCPs participate actively. Addressing associated social determinants of health has been particularly challenging as these are prominent issues for those with OUD, but Ohio continues to advance the field of ideal care with the support of our MCPs.

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
None	Milestone 5	

### Expanded Coverage of, and Access to, Naloxone for Overdose Reversal

#### Current and Future State:

Ohio has taken steps to prevent drug overdose deaths through the expanded availability and use of the opiate overdose reversal drug Naloxone. One of the most effective steps for expanding coverage included permitting pharmacists to dispense Naloxone without a prescription in 2015. To assist pharmacies, the State of Ohio Board of Pharmacy developed a dedicated web page, [www.pharmacy.ohio.gov/naloxone](http://www.pharmacy.ohio.gov/naloxone), which features helpful resources including a guidance document, sample protocol, and a listing of all participating pharmacies. The Pharmacy Board also offers printed, no-cost patient educational materials to any participating pharmacy. By 2017, more than 1,600 Ohio pharmacies in 87 counties offer naloxone without a prescription.

Other steps taken by the state to expand access to Naloxone include:

- Created and implemented a naloxone education and distribution program called Project DAWN (Deaths Avoided with Naloxone).
- Established an online training course for law enforcement and an educational video for the public regarding the administration of naloxone.
- Negotiated rebates with naloxone manufacturer Amphastar Pharmaceuticals, Inc., regarding rebates for public entities that purchase Amphastar naloxone.
- Funded local health department distribution to purchase naloxone for law enforcement.
- Passed a law in 2016 with a “good Samaritan” provision that provides immunity from prosecution to those who seek emergency help for the victim of an overdose.
- Issued guidance to hospitals on providing naloxone to patients upon discharge and to Emergency Medical Service organizations on providing naloxone to individuals treated for an opiate overdose.
- Passed a 2017 law allowing facilities that interact with high-risk individuals to have on-site access to naloxone including homeless shelters, halfway houses, schools and treatment centers.

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
None	Milestone 5	

## Increasing Utilization and Improving Functionality of Prescription Drug Monitoring Programs

### Current State:

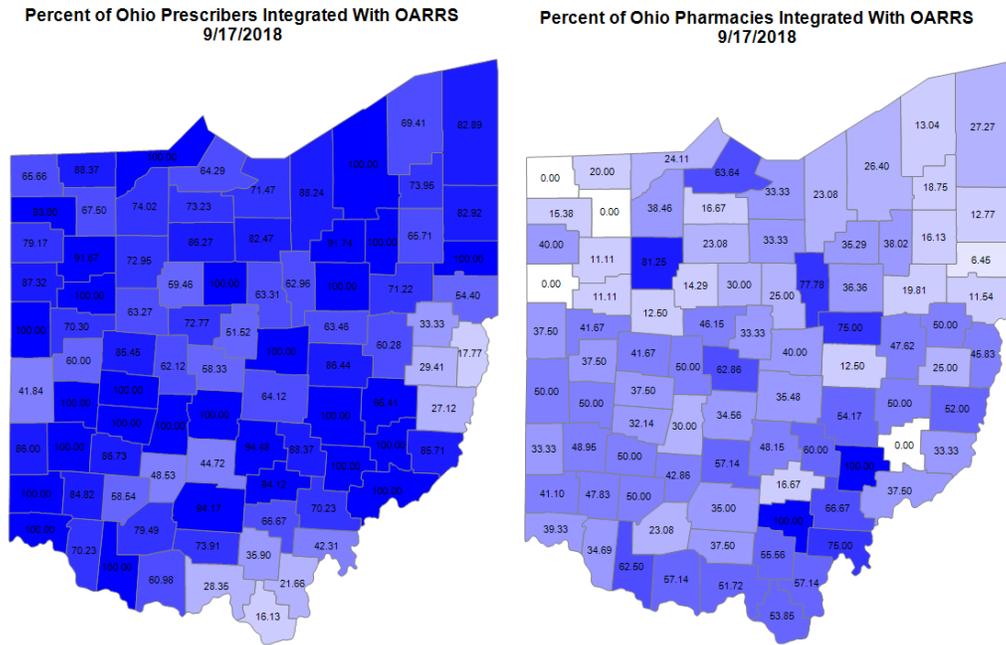
Ohio first mandated use of the OARRS, the State's PDMP by prescribers in 2011, with additional provisions added in 2013. OARRS is a tool to track the dispensing and personal furnishing of controlled prescription drugs to patients. OARRS is designed to monitor this information for suspected abuse or diversion (i.e., channeling drugs into illegal use), and can give a prescriber or pharmacist critical information regarding a patient's controlled substance prescription history. This information can help prescribers and pharmacists identify high-risk patients who would benefit from early interventions.

Since the latest mandate in 2013, the use of the OARRS has grown. In 2017, the OARRS reported a record high of 265,242 requests by prescribers and pharmacists in a single day. By comparison, the single day high in 2016 was 86,129 prescriber and pharmacist requests. In August 2018, OARRS reported an average of more than 599,000 requests per weekday — more than double the previous year's high. Notably, OARRS integration with EHRs statewide includes the following as of August 31, 2018:

- Nineteen major health systems and outpatient clinics, such as: Promedica, Mount Carmel, Mercy Health, MetroHealth, The Ohio State University Wexner Medical Center, Cleveland Clinic, Avita Health, Southwest General, University Hospital (Cleveland), Aultman, Adena, Genesis Healthcare, Kettering Health Network, Premier Health, Magruder Health, Nationwide Children's, Christ Hospital Health, Toledo Clinic Health and Licking Memorial.
- Two hundred and six independent Ohio pharmacies.
- Nine chain pharmacies, including: Discount Drug Mart (seventy-three stores), Kroger (two hundred and one stores), Giant Eagle (five stores), Costco (fourteen stores), Fruth (eleven stores), Ritzman (twenty-five stores), Acme (seventeen stores), Meijer (forty-one stores) and Walmart (174 stores).
- One hundred and forty-four physician offices.
- Fourteen hospitals.

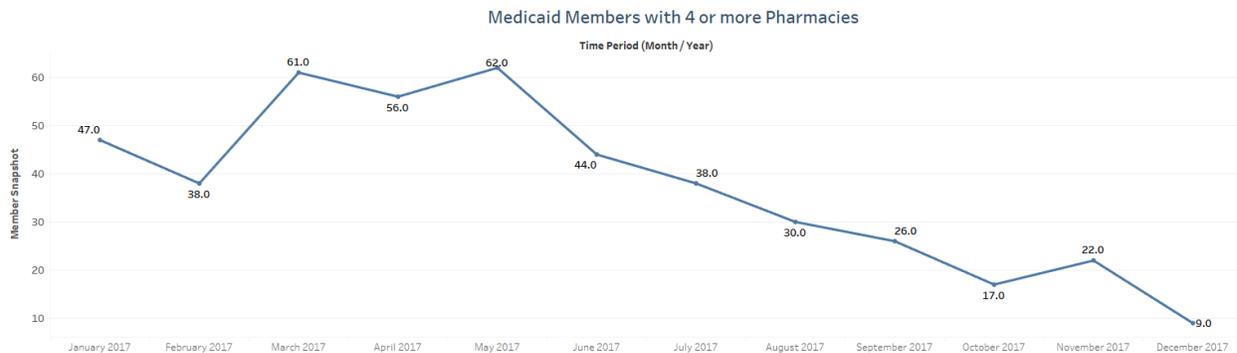
For an overall picture of the percentage of prescribers and pharmacies integrated with OARRS, see the figure below.

### Figure: Percent of Prescribers and Pharmacies integrated with OARRS



OARRS has also documented that fewer Ohioans are using multiple prescribers or pharmacies (i.e., doctor shopping). In 2017, data from OARRS found the number of individuals using more than five prescribers for prescription opiates has decreased 88% since 2011.<sup>20</sup> Similarly, the number of Medicaid members with four or more pharmacies has continuously dropped since January 2017 (see figure).

### Figure: Medicaid Member with four or more Pharmacies



<sup>20</sup> Ohio Board of Pharmacy. [https://www.ohiopmp.gov/documents/Annual%20Report%20\(2017\)%20-%20Executive%20Summary.pdf](https://www.ohiopmp.gov/documents/Annual%20Report%20(2017)%20-%20Executive%20Summary.pdf)

The State of Ohio has leveraged opportunities described in Severely Mentally Disabled Letter 16-003 to help professionals and hospitals eligible for Medicaid EHR Incentive Payments connect to other Medicaid providers through the integration of OARRS into electronic medical records and pharmacy dispensing systems. All hospitals and pharmacies now have ability to have OARRS integrated into their EHRs and Pharmacy management systems. Nearly half of physicians now have integrated access to OARRS.<sup>21</sup> This initiative allows the State to meet the following objectives:

- Further reduce the number of individuals who doctor shop.
- Provide health care providers critical information regarding a patient's controlled substance prescription history and expand collection of other data sources to support clinical decision-making.
- Support clinician interventions for patients exhibiting high-risk behaviors.
- Assist providers in achieving the medication reconciliation meaningful use objective and measure.<sup>22</sup>
- An additional goal of this integration initiative is to provide as many avenues as possible for an authorized health care provider to access Ohio's PDMP, including integrated access through Health Information Exchanges (HIEs). In fact, Ohio's two largest HIEs — CliniSync and The Health Collaborative (HealthBridge) — have already been integrated with OARRS under this initiative. As both of the state's HIEs are integrated, there are no future plans for enhanced connectivity at this time.

### Prescription Drug Monitoring Program Functionalities

Ohio's Board of Pharmacy and OARRS system participate in the PMP Interconnect. The system allows a user to search PDMPs in 20 other states, including all of Ohio's Border States. Ohio will continue to grant access to PDMP users from other states via the Project Manager Professional (PMP) Interconnect platform. This will depend on each State's ability to share data.

Ohio is the first state in the country to pay all costs for the integration of PDMP data into EHRs and pharmacy dispensing systems. This allows for instant access to PDMP data as part of the healthcare providers workflow. County-based integration statistics are included as an attachment to this document.

Currently, there are no activities within OARRS to correlate long-term opioid use directly to clinician prescribing patterns.

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<sup>21</sup> Ohio Board of Pharmacy. [https://www.ohiopmp.gov/documents/Annual%20Report%20\(2017\)%20-%20Executive%20Summary.pdf](https://www.ohiopmp.gov/documents/Annual%20Report%20(2017)%20-%20Executive%20Summary.pdf)

<sup>22</sup> Stage 3 of Meaningful use consolidates Medication reconciliation into the Health Information Exchange Objective. The objective requires that the Eligible Professional provides a summary of the care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT. Providers must attest to all three measures and must meet the threshold for at least two measures to meet the objective.

Ohio has adopted Appriss Health's NarxCare program as its PDMP platform. NarxCare is a comprehensive platform that aggregates and analyzes prescription information from providers and pharmacies and presents visual, interactive information, as well as advanced analytic insights, complex risk scores and more to help physicians, pharmacists and care teams to provide better patient care and safety. Furthermore, NarxCare provides tools and resources that support patients' needs and connects them to treatment, if necessary. This information, insight and functionality is all accessed in clinical workflow via EHRs and pharmacy management systems, as well as through the PDMP website.

Ohio recently transitioned from the original AWARDx patient matching algorithm, to Axis, Appriss' new master patient index. Axis uses not only PDMP data, but also a number of external data sources (USPS change of address, credit headers, etc.) to inform the system as to which similar entries may be the same patient, versus which are actually two different individuals.

Unlike the previous generation of patient matching software, Axis is capable of improving its matching capabilities over time. As Board of Pharmacy staff identify instances where the matching was incorrect, Axis is able to use that information to make better matching decisions in the future.

Ohio recently implemented rules limiting the provision of initial prescriptions of opioids to treat acute pain. With limited exceptions, a prescriber is not permitted to prescribe more than a five-day supply for a minor or a seven-day supply for an adult. Additionally, the prescriptions cannot exceed 30 morphine equivalent daily dose. The rules went into effect in August 2017. The Board of Pharmacy is currently developing an enforcement plan with the State Medical Board, Nursing Board and Dental Board. In order to account of the exemptions, Ohio regulations require the inclusion of a diagnosis code on all prescriptions for controlled substances.

#### Future State:

The Board of Pharmacy will continue to onboard new EHR and pharmacy dispensing system vendors with the goal of achieving a 90% integration rate of all providers (prescribers and pharmacies). Contacting vendors and coordinating the completion of legal agreements and testing is the responsibility of OARRS Integration Project Manager in collaboration with the PDMP vendor, Appriss Health.

The Board of Pharmacy will explore the possibility of analysis to correlate long-term opioid use directly to clinician prescribing patterns in conjunction with the ODM.

NarxCare allows the Board to collect additional non-PDMP based data for inclusion in the PDMP report. The first non-PDMP data to be included will be flags in the system for those who are participating in one of Ohio's drug court programs. There are plans to include other data sources such as death after a non-fatal overdose. The Board is also working on the inclusion of naltrexone to be reported to the PDMP to identify individuals who have been treated for substance use disorder. The PDMP Administrator along with the PDMP Vendor, Appriss Health, are responsible for the development of processes

and system testing for the inclusion of additional patient data. The Ohio Supreme Court is working to compile regular data sets of drug court participants.

The Board of Pharmacy will implement an enforcement plan to minimize the risk of inappropriate overprescribing consistent with prescribing guidelines. The PDMP Administrator will be responsible for the development of a referral report to the appropriate prescriber regulatory boards. Ohio’s prescriber regulatory boards will implement education and enforcement actions against prescribers who are in violation of the rules.

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
Continue to onboard new EHR and pharmacy dispensing system vendors.	Milestone 5	Over the course of the waiver
Explore the possibility of analysis to correlate long-term opioid use directly to clinician prescribing patterns in conjunction with the ODM (action item for the Board of Pharmacy).	Milestone 5	Over the course of the waiver
Implement enhanced information in the OARRS including: OARRS flags for individuals who are participating in one of Ohio’s drug court programs; non-fatal overdose deaths, and naltrexone identification to identify individuals treated for SUD.	Milestone 5	Over the course of the waiver
Implement an enforcement plan to minimize the risk of inappropriate overprescribing consistent with prescribing guidelines.	Milestone 5	Over the course of the waiver

## Milestone 6: Improved Care Coordination and Transitions between LOCs

### CMS Specifications:

- Implementation of policies to ensure residential and inpatient facilities link individuals, especially those with OUD, with community-based services and supports following stays in these facilities.
- Additional policies to ensure coordination of care for co-occurring physical and mental health conditions.

### Current State:

ODM approaches care coordination by promoting a population health management approach as well as other reforms to create an improved system to better care for all individuals in Medicaid including those with SUD diagnoses. Specifically, ODM identifies and monitors individual patients in high risk categories, such as individuals with a BH diagnosis. Data are used to risk stratify and group individuals into population streams, one of which is BH. Strategies specific to risk levels and population streams are then

developed by ODM and contracted managed care plan partners to improve patient outcomes and quality of care. Value-based purchasing strategies further enhance the promotion of evidence-based and comprehensive care for patients with SUD.

Ohio has undertaken multiple interventions and strategies to improve coordination of care and the transition between LOCs along the continuum of care including, but not limited to, facility discharge requirements in OhioMHAS certification standards, Ohio's Comprehensive Primary Care (CPC) program, care management and transition of care requirements in MCP contracts, and targeted case management.

### **Facility discharge requirements in OhioMHAS certification standards**

OhioMHAS certification requirements at OAC 5122-29-09 require that each residential, inpatient and withdrawal management provider have an affiliation agreement with at least one provider for referral to less intensive LOC. Each provider is also required to have written policies and procedures to ensure its referral process is appropriately implemented and managed and includes:

- Referral decisions made to the appropriate LOC as determined utilizing the American Society of Addiction Medicine criteria protocols for LOC.
- Discharge plan stipulating specific recommendations and referrals for alcohol and drug addiction treatment.
- Documentation of referral and discharge must appear in the client record.

### **Comprehensive Primary Care Program**

CPC is a patient-centered medical home program, which is a team-based care delivery model led by a primary care practice (PCP) that comprehensively manages a patient's health needs. The goal is to empower practices to deliver the best care possible to their patients, both improving quality of care and lowering costs. There is an expectation that all Medicaid individuals seen by CPC practitioners will benefit from the CPC practice transformation that includes the integration of behavioral healthcare into physical health sites. Most medical costs occur outside of a PCP, but primary care practitioners can guide many decisions that impact those broader costs, improving cost efficiency and care quality.

Each CPC practice works with BH partners to coordinate care for individuals with co-occurring BH and physical health (PH) conditions. This includes coordination on SUD treatment. Joining the CPC program gives practices access to data and reports that provide actionable, timely information needed to make better decisions about outreach, care and referrals.

Each CPC practice is required to create a care plan for all high-risk patients as identified by the practice's risk stratification system. The practices must ensure follow-up after hospital discharges. To do this the CPC practice establishes relationships with all emergency departments (EDs) and hospitals from which they frequently get referrals and consistently obtains patient discharge summaries and conducts appropriate follow-up care.

The MCP plays a key role in supporting the CPC practice's with achieving optimal population-level health outcomes. MCPs have a relationship with each CPC practice and provide support as requested by the CPC practice (e.g., cross system collaboration, information sharing, addressing social determinants of health, transition of care, etc. MCPs may also choose to care manage members who are not identified by the CPC practice's high-risk stratification algorithm as further described below.

### Care Coordination in Plans

MCOPs are required to provide care management to all enrolled members. MCPs must assure care management services and supports are available to individuals when needed. Expectations for both care management programs are similar and are outlined below. The plans' care management programs incorporate: person and family centeredness; timely, proactive planned communication and action; the promotion self-care and independence; emphasis on cross continuum and system collaboration (e.g., BH) and the comprehensive consideration of physical, behavioral and social determinants of health.

In order to determine the level of care management services and supports, the plans conduct assessments of members' physical and behavioral health, social and safety needs including identification of co-occurring conditions. Based on the needs assessment, a person-centered care plan with goals, interventions and outcomes is developed in conjunction with, and support of, the managing clinician and the member. The plan's care manager and team then work to identify, address and remove barriers to care, secure resources, coordinate with providers across systems and facilitate transitions.

The plans also manage transitions of care between both PH and BH settings in order to prevent unplanned or unnecessary readmissions, emergency department visits, and/or adverse outcomes. The plans provide transition support to members attributed to CPC practices upon request. The plans are required to have a process for the following:

- Identify members who require assistance transitioning between settings.
- Develop a method for evaluating risk of readmission in order to determine the intensity of follow up required for the member after the date of discharge.
- Designate plan staff who will communicate with the discharging facility and inform the facility of the plan's designated contacts.
- Ensure timely notification and receipt of admission dates, discharge dates and clinical information is communicated between plan departments, care settings and with the primary care provider, as appropriate.
- Participate in discharge planning activity with the facility including arranging for safe discharge placement and facilitating clinical hand-offs between the discharging facility and the plan.
- Obtain a copy of the discharge/transition plan.
- Arrange for services specified in the discharge/transition plan.
- Conduct timely follow up with the member and the member's primary provider to ensure post discharge services have been provided.

When a plan is contacted by an inpatient facility with a request to participate in discharge planning, plans ensure a safe discharge placement and services are arranged for the member.

### Targeted Case Management

Ohio has historically offered SUD targeted case management to individuals in Medicaid receiving alcohol or SUD treatment services from a certified or licensed treatment program. SUD case management includes four components: assessment/reassessment, development and revision of an individualized care plan, referral and monitoring and follow up activities. The goal of SUD case management is to determine the need for any medical, educational, social or other services as the individual transitions to the community and to address those needs on an on-going basis to ensure the success of the individual in the community.

### Future State:

To develop a coordinated statewide strategy to address the opioid epidemic, other substance use disorders, and serious mental illness, the state has been facilitating regular stakeholder meetings with behavioral health providers for well over a year. These efforts have culminated in the development of possible care coordination models that are designed to improve care through intensive care coordination for individuals with substance use disorders (SUD) or serious mental illness (SMI). Initial efforts focused upon individuals with SUD/ODU/SPMI with any of the following conditions:

- a primary psychiatric diagnosis, or
- a primary or secondary diagnosis of OUD/SUD, including individuals who had received Medication Assisted Treatment for any substance use disorder; or
- individuals admitted to residential or inpatient facilities for diagnoses that included SUD or SMI.

With the recent change in administration at the state level, and Ohio's subsequent request for approval of an 1115 Substance Use Disorder Waiver Demonstration, ODM and OhioMHAS have decided to use the flexibility extended to state agencies within the context of the 1115 Waiver Demonstration to re-evaluate care coordination strategies and develop tailored care coordination model(s) specifically for individuals with substance use disorders, including Opioid Use Disorder.

Accordingly, in order to make improvements to the current policies that support this milestone, the state will conduct a review of SUD service utilization pre and post the 01/01/2018 implementation of the redesign of Ohio's behavioral health benefit package of services provided by agencies certified by OhioMHAS and hospital outpatient facilities that also furnish these behavioral health services. This analysis will provide an inventory of SUD treatment services provided, patterns of treatment including retention in care, and the current system capacity available at all ASAM levels of care including variations in treatment available in urban and rural locations. Most importantly the inventory will identify specific populations accessing treatment, including children, adults, and those with co-morbid conditions. Using this inventory, the state will develop care coordination models to address deficits and challenges in providing consistent

SUD/ODU treatment for the identified populations.

Summary of Actions Needed	Milestone	Timeline Post Waiver Approval
Review data and conduct analysis of individuals with SUD	Milestone 6	12 to 24 months
Based upon data analysis develop care coordination model(s) specific to identified populations	Milestone 6	12 to 24 months
Implement care coordination for identified populations	Milestone 6	12 to 24 months

## Section II. Implementation Administration

Contact information for Implementation Plan Point of Contact:

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### **Section III. Relevant Documents**

#### **Attachment A. SUD Health Information Technology Plan**

##### **SUD Demonstration Milestone 5.0, Specification 3: Implementation of Strategies to Increase Utilization and Improve Functionality of PDMP**

The specific milestones to be achieved by developing and implementing an SUD Health Information Technology (IT) Plan include:

- Enhancing the health IT functionality to support PDMP interoperability.
- Enhancing and/or supporting clinicians in their usage of the state's PDMP.

The state should provide CMS with an analysis of the current status of its health IT infrastructure/"ecosystem" to assess its readiness to support PDMP interoperability. Once completed, the analysis will serve as the basis for the health IT functionalities to be addressed over the course of the demonstration — or the assurance described above.

The SUD Health IT Plan should detail the current and planned future state for each functionality/capability/support — and specific actions and a timeline to be completed over the course of the demonstration — to address needed enhancements. In addition to completing the summary table below, the state may provide additional information for each Health IT/PDMP milestone criteria to further describe its plan.

**Table: State Health IT/PDMP Assessment and Plan**

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>Implementation of comprehensive treatment and prevention strategies to address Opioid Abuse and OUD, that is:</p> <ul style="list-style-type: none"> <li>• Enhance the state’s health IT functionality to support its PDMP.</li> <li>• Enhance and/or support clinicians in their usage of the state’s PDMP.</li> </ul>	<p>Provide an overview of current PDMP capabilities, health IT functionalities to support the PDMP, and supports to enhance clinicians’ use of the state’s health IT functionality to achieve the goals of the PDMP.</p>	<p>Provide an overview of plans for enhancing the state’s PDMP, related enhancements to its health IT functionalities, and related enhancements to support clinicians’ use of the health IT functionality to achieve the goals of the PDMP.</p>	<p>Specify a list of action items needed to be completed to meet the HIT/PDMP milestones identified in the first column. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item.</p>
<b>PDMP Functionalities</b>			
<p>Enhanced interstate data sharing in order to better track patient specific prescription data.</p>	<p>Ohio’s PDMP participates in PMP Interconnect. The system allows a user to search PDMPs in 20 other states, including all of Ohio’s border states.</p>	<p>Ohio will continue to grant access to PDMP users from other states via the PMP Interconnect platform. This will depend on each state’s ability to share data.</p>	<p>As data sharing is dependent on other states (including necessary changes to state law), there are no milestones that can be listed.</p>
<p>Enhanced “ease of use” for prescribers, other state and federal stakeholders.</p>	<p>Ohio is the first state in the country to pay all costs for the integration of PDMP data into EHRs and pharmacy dispensing systems. This allows for instant access to PDMP data as part of the healthcare providers workflow. County-based integration statistics are included as an attachment to this document.</p>	<p>The Board of Pharmacy will continue to onboard new EHR and pharmacy dispensing system vendors with the goal of achieving a 90% integration rate of all providers (prescribers and pharmacies).</p>	<p>Contacting vendors and coordinating the completion of legal agreements and testing is the responsibility of OARRS Integration Project Manager in collaboration with the PDMP vendor, Apriss Health. As of June 17, 2019, 56.5% of pharmacies have completed integration As of June 17,2019, 86.8% of prescribers have completed integration. (See Attachment C: Integration Maps for Pharmacies and Prescribers)</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Enhanced connectivity between the state’s PDMP and any statewide, regional or local HIE.	Ohio’s two HIEs are now fully integrated with the state’s PDMP.	As both of the state’s HIEs are integrated, there are no future plans for enhanced connectivity at this time.	N/A
Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns <sup>23</sup> (see also “Use of PDMP” #2 below).	Currently, there are no activities to correlate long-term opioid use directly to clinician prescribing patterns.	The Board of Pharmacy will explore the possibility of engaging in this type of analysis in conjunction with the ODM through the hiring of a data analyst.	ODM hired a data analyst in January of 2019. For this milestone criteria two tasks have been developed. A description of the tasks and progress made to date on them can be found in Attachment D.
<b>Current and Future PDMP Query Capabilities</b>			
Facilitate the state’s ability to properly match patients receiving opioid prescriptions with patients in the PDMP (i.e., the state’s master patient index strategy with regard to PDMP query).	Ohio’s PDMP vendor, Appriss Health, recently deployed an enhanced patient record matching solution, known as ApprissID. ApprissID incorporates advanced machine learning and consolidated algorithms to create a smart system capable of providing unmatched patient record matching results. The new solution is dynamic, allowing new IDs to be connected, deleted and evolve in real-time. More information regarding ApprissID can be found here: <a href="https://hitconsultant.net/2019/05/15/appriss-machine-learning-powered-patient-matching-solution/#.XNxwNExFyUm">https://hitconsultant.net/2019/05/15/appriss-machine-learning-powered-patient-matching-solution/#.XNxwNExFyUm</a>	Ohio’s PDMP director will provide regular feedback on patient matching to Appriss Health to improve the overall functionality of the system.	

<sup>23</sup> Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: <http://dx.doi.org/10.15585/mmwr.mm6610a1>.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<b>Use of PDMP – Supporting Clinicians with Changing Office Workflows/Business Processes</b>			
<p>Develop enhanced provider workflow/business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance to address the issues, which follow.</p>	<p>Ohio is the first state in the country to pay all costs for the integration of PDMP data into EHRs and pharmacy dispensing systems. This allows for instant access to PDMP data as part of the healthcare providers workflow. County-based integration statistics are included as an attachment to this document.</p>	<p>The Board of Pharmacy will continue to onboard new EHR and pharmacy dispensing system vendors with the goal of achieving a 90% integration rate of all providers (prescribers and pharmacies).</p>	<p>Contacting vendors and coordinating the completion of legal agreements and testing is the responsibility of OARRS Integration Project Manager in collaboration with the PDMP vendor, Appriss Health. See Attachment C for percentage of the integration rate for prescribers and pharmacies.</p>
<p>Develop enhanced supports for clinician review of the patients' history of controlled substance prescriptions provided through the PDMP — prior to the issuance of an opioid prescription.</p>	<p>Ohio has adopted Appriss Health's NarxCare program as its PDMP platform. NarxCare is a comprehensive platform that aggregates and analyzes prescription information from providers and pharmacies and presents visual, interactive information, as well as advanced analytic insights, complex risk scores and more to help physicians, pharmacists and care teams to provide better patient care and safety. Furthermore, NarxCare provides tools and resources that support patients' needs and connects them to treatment, if necessary. This information, insight and functionality is all accessed in clinical workflow via EHRs and pharmacy management systems, as well as through the PDMP website.</p>	<p>NarxCare allows the Board to collect additional non-PDMP based data for inclusion in the PDMP report. The first non-PDMP data to be included will be flags in the system for those who are participating in one of Ohio's drug court programs. There are plans to include other data sources such as non-fatal overdose deaths. The Board is also working on the inclusion of naltrexone to be reported to the PDMP to identify individuals who have been treated for SUD.</p>	<p>The PDMP Administrator along with the PDMP Vendor, Appriss Health, are responsible for the development of processes and system testing for the inclusion of additional patient data. The Ohio Supreme Court is working to compile regular data sets of drug court participants.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<b>Master Patient Index/Identity Management</b>			
<p>Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery.</p>	<p>Ohio recently transitioned from the original AWARxE patient matching algorithm, to Axis, Aprriss' new master patient index. Axis uses not only PDMP data, but also a number of external data sources (USPS change of address, credit headers, etc.) to inform the system as to which similar entries may be the same patient, versus which are actual two different individuals.</p>	<p>Unlike the previous generation of patient matching software, Axis is capable of improving its matching capabilities over time. As Board of Pharmacy staff identify instances where the matching was incorrect, Axis is able to use that information to make better matching decisions in the future.</p>	<p>The Board of Pharmacy PDMP staff will continue to monitor the Axis system to ensure that appropriate matches are being made. As incorrect matches are identified, they will be corrected so that the system can continue to improve on its abilities to accurately match patients.</p>
<b>Overall Objective for Enhancing PDMP Functionality and Interoperability</b>			
<p>Leverage the above functionalities/capabilities/supports (in concert with any other state health IT, TA or workflow effort) to implement effective controls to minimize the risk of inappropriate opioid overprescribing — and to ensure that Medicaid does not inappropriately pay for opioids.</p>	<p>Ohio recently implemented rules limiting the provision of initial prescriptions of opioids to treat acute pain. With limited exceptions, a prescriber is not permitted to prescribe more than a five-day supply for a minor or a seven-day supply for an adult. Additionally, the prescriptions cannot exceed 30 morphine equivalent daily dose. The rules went into effect in August 2017. The Board of Pharmacy is currently developing an enforcement plan with the State Medical Board, Nursing Board and Dental Board. In order to account of the exemptions, Ohio regulations require the inclusion of a diagnosis code on all prescriptions for controlled substances.</p>	<p>The Board of Pharmacy will implement an enforcement plan to minimize the risk of inappropriate overprescribing.</p>	<p>The PDMP Administrator will be responsible for the development of a referral report to the appropriate prescriber regulatory boards. Ohio's prescriber regulatory boards will implement education and enforcement actions against prescribers who are in violation of the rules.</p>

Ohio SUD 1115 Demonstration Implementation Plan

Ohio's point of contact for the SUD Health IT Plan.

Name and Title: Matthew Williams, Data Systems Administrator

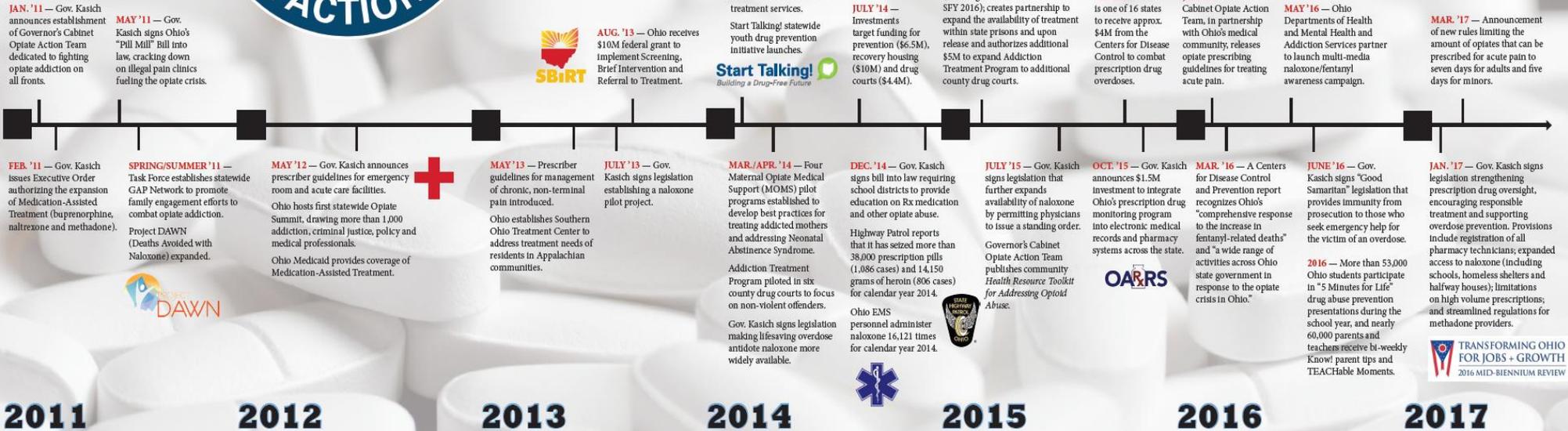
Telephone Number: 614-752-2411

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Attachment B. GCOAT Timeline



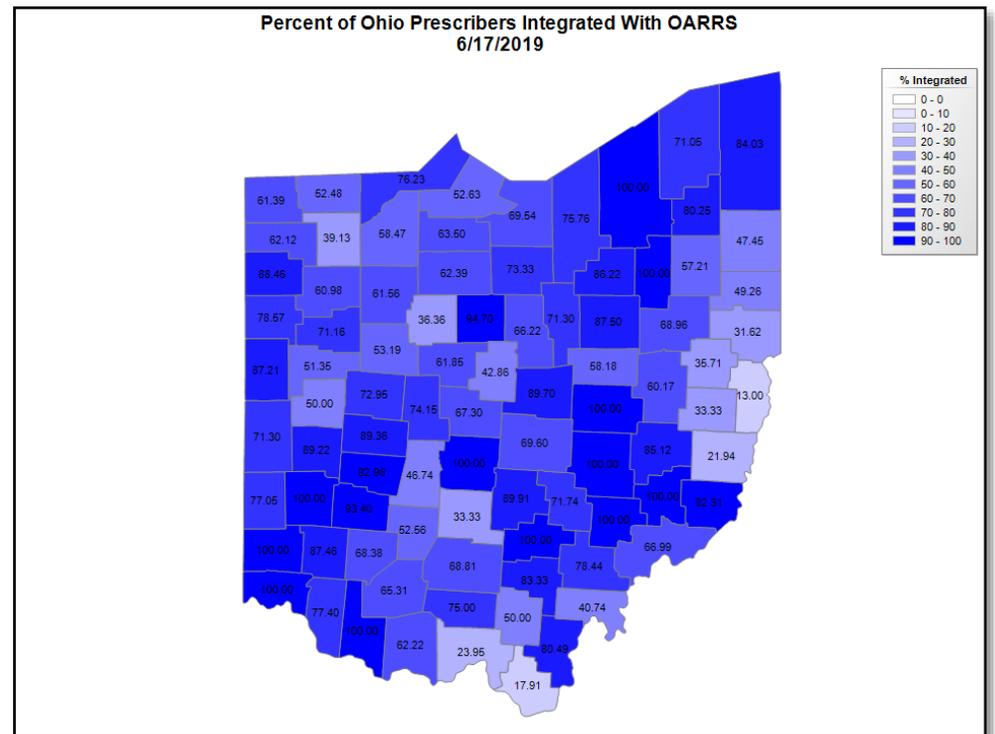
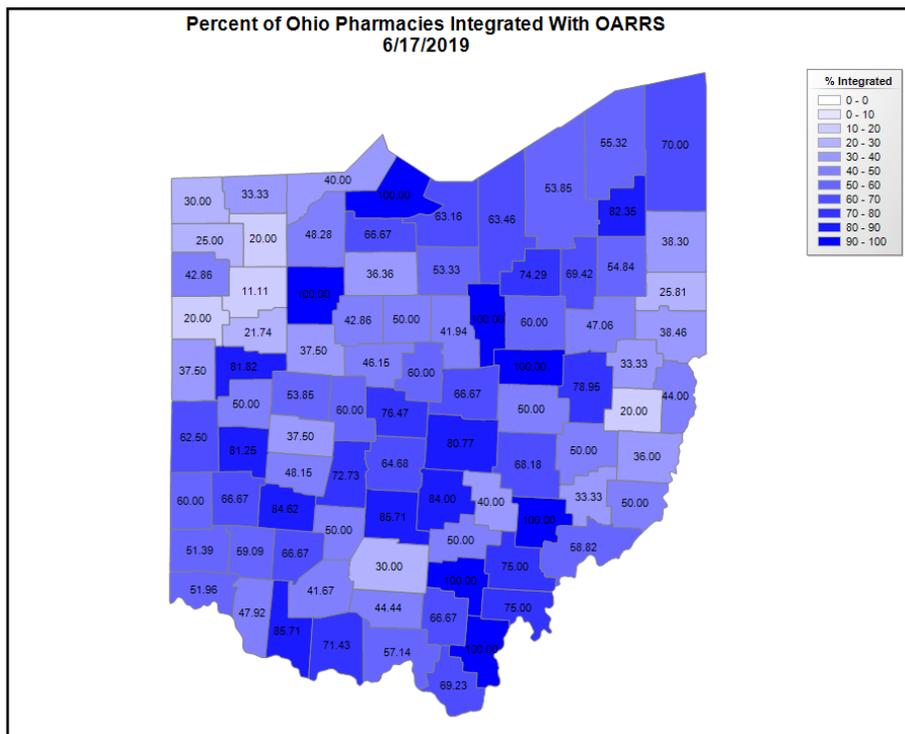
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**Attachment C: Integration Maps**  
Pharmacies and Prescribers

Total No. of Pharmacies	Total No. of Pharmacies Integrated	Percent Integrated
2551	1441	56.487

Total No. of Prescribers	Total No. of Prescribers Integrated	Percent Integrated
51,467*	44,668	86.789



## **Attachment D: Development of the Opioid-related measures**

The GRC analyst started in January 2019 and the work is still on-going. The major milestone has been: Development of the Opioid-related measure methodologies and baseline rates for the CICIP program as of June 2019 (Task 1). Task two work has not yet started. A description of each task is below.

1. Assisting with the development, coding and analysis of quality metrics for the Care Innovation and Community Improvement Program (CICIP). CICIP was developed to increase alignment of quality improvement strategies and goals between the State, Managed Care Organizations (MCO), and both public and nonprofit hospital agencies. The four agencies are large Medicaid safety-net and academic medical centers. The CICIP goal aligns with the Ohio Department of Medicaid (ODM) goal: Improve healthcare for Medicaid beneficiaries at risk of or with an opioid or other substance abuse disorder. The CICIP payment arrangement creates incentives for participating agencies to perform quality improvement program tasks, optimize care, and improve prescribing practices, resulting in less illicit drug use, more opioid addiction prevention, timely access to treatment and recovery support, and appropriate responses to crisis situations.
2. Working with staff at the Board of Pharmacy and the Ohio Department of Medicaid to develop predictive models related to opioid use disorder, including but not limited to CICIP quality metrics, health care utilization such as emergency department (ED) visits, and overdose events. One of the goals will be to develop a modeling framework for identifying high-risk individuals for possible interventions prior to adverse events.

**Attachment E**

# **APPROVED EVALUATION DESIGN**



**Section 1115 Substance Use Disorder Demonstration  
Evaluation Design  
October 23, 2020**

Governor Mike DeWine | Lt. Governor Jon Husted | Director Maureen Corcoran

**[medicaid.ohio.gov](https://www.medicaid.ohio.gov)**

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## 1. General Background Information

Ohio's Substance Use Disorder (SUD) Section 1115 Demonstration Waiver, approved by the Centers for Medicare and Medicaid Services (CMS) on September 24, 2019, encompasses a five-year period, which began October 1, 2019, and will end September 30, 2024.

As described in the implementation plan, the number of individuals enrolled in Ohio Medicaid with an SUD diagnoses continues to grow. The largest increase (23%) occurred between 2014 and 2015, with Ohio's Medicaid eligibility expansion reflecting a large unmet treatment need among that newly eligible population. Since Medicaid expansion, the rate of SUD diagnoses has continued to increase by 8% in 2015-2016 and 4% in 2016-2017. As of 2018, approximately 9% of the non-dually eligible adult population (18-64) had a primary SUD diagnosis. Opioid overdose deaths have also increased in the state from 1,914 in 2012 to 4,293 in 2017.<sup>1</sup>

Recent behavioral health system changes in Ohio expanded access to evidence-based practices, increased provider capacity to render medication assisted treatment (MAT), strengthened efforts to integrate behavioral and physical health care and expanded services to individuals diagnosed with mental illness and SUDs. Beginning in 2011, Ohio mandated use of the prescription drug monitoring program (PDMP) to monitor dispensing of controlled prescription drugs for suspected abuse or diversion. Since 2012, Ohio implemented five sets of opiate prescribing guidelines to address the easiest sources of uncoordinated prescription medications, such as prescriptions obtained via hospital emergency departments. Since 2015, Ohio took important steps to extend access to the opiate overdose reversal drug, Naloxone, by permitting pharmacists to dispense the drug without a prescription.

In January 2018, Ohio implemented broad policy changes to modernize Medicaid behavioral health benefits. This initiative, called Behavioral Health Redesign, revised Ohio's Medicaid behavioral health benefit to align with national coding and health care billing standards. Changes included:

- Adding coverage for primary care billing codes rendered by community behavioral health agencies;
- Expanding the service array for mental health and SUD treatment services;
- Requiring that SUD treatment services align with the American Society of Addiction Medicine (ASAM) levels of care;
- Establishing a unique benefit package for opiate treatment programs (OTP) offering MAT; and
- Adding new evidence-based behavioral health services for adults and youth with high intensity treatment needs.

Since January 1, 2019, working in partnership with the State's managed care plans (MCPs), Ohio eliminated prior authorization in most instances for MAT for opioid use disorder. Beginning January 1, 2020, the state began implementation of a unified preferred drug list that insured consistency in coverage across fee-for-service (FFS) and the MCPs.

The approved SUD 1115 demonstration waiver gives Ohio the opportunity to continue progress with additional flexibility and tools to counter the state's elevated levels of SUD, including opi-

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<sup>1</sup><http://publicapps.odh.ohio.gov/EDW/DataBrowser/Browse/Mortality>

oid use disorder (OUD). The waiver authorizes Ohio to implement programmatic changes that address the waiver milestones established by CMS, which will impact all Medicaid beneficiaries with a SUD.

Ohio Medicaid currently covers all the ASAM levels of care and administers treatment services based on the ASAM Patient Placement Criteria. Through this demonstration, Ohio will take additional steps to ensure providers utilize SUD-specific, multi-dimensional assessment tools, permitting patients to receive the appropriate level of care (LOC) that reflects evidence-based clinical treatment guidelines. The Medicaid Behavioral Health Provider Manual, managed care provider agreement, and/or Ohio Administrative Code (OAC) will be modified to establish provider responsibilities for screening, assessment and treatment plan review. ODM will conduct reviews of provider and plan utilization management (UM) processes, while using findings to improve UM and prior authorization approaches as the waiver demonstration evolves.

Ohio will also revise licensure requirements, policies, and managed care contracts. This will allow for services to be aligned with national standards and evidence-based practices. All service definitions, eligibility criteria, and program requirements and provider qualifications will be aligned with ASAM in the published Medicaid provider manual. Residential program standards will be updated to include more detail about particular types of services, hours of clinical care, and credentials of staff for residential treatment settings. Educational efforts and licensure standards will be revised to assure that all residential organizations offer MAT onsite or through coordination with offsite providers.

In order to improve access to each critical LOC, Ohio will assess availability of treatment providers focusing on geographic distribution and anticipated penetration rates. The results will be utilized to update MCP access standards for the Behavioral Health State Plan services including all ASAM LOC and MAT.

Ohio will improve the utilization and functionality of the existing prescription drug monitoring system. Planned improvements include: (1) expanding the state's health IT functionality to improve utilization; (2) enhance available information that can inform treatment and referral (e.g., identify individuals with prior history of non-fatal overdose); (3) conduct analyses to demonstrate the impact of clinician prescribing patterns on long-term opioid use; and (4) implement an enforcement plan to minimize inappropriate overprescribing. Finally, the state will seek to improve care coordination and transitions between LOCs gathering data to identify opportunities for improvement and support the development of a new care coordination model.

To determine the impact of this demonstration Ohio has arranged for an independent evaluation to be conducted throughout the waiver time period. The proposed evaluation described in this document includes quantitative and qualitative methods to measure the impact of key waiver provisions on Medicaid enrolled adults and youth with SUD.

The demonstration period is October 1, 2019, through September 30, 2024. An interim evaluation will be completed by September 30, 2023, and a draft summative evaluation report will be submitted to CMS within 18 months after the end of the demonstration. The evaluation period ends on March 30, 2026.

## 1.1 Evaluation Overview and Process

As described previously, Ohio's SUD Waiver demonstration was designed to address the six major goals and six milestones established by CMS. These include:

### Milestones:

1. Access to critical LOCs for OUD and other SUDs.
2. Use of ASAM placement criteria.
3. Use of ASAM program standards for residential provider qualifications.
4. Provider capacity of SUD treatment including MAT.
5. Implementation of OUD comprehensive treatment and prevention strategies.
6. Improved care coordination and transition between LOCs.

### Goals:

1. Increased rates of identification, initiation, and engagement in treatment.
2. Increased adherence to and retention in treatment for OUD and other SUDs.
3. Reductions in overdose deaths, particularly those due to opioids.
4. Reduced utilization of emergency departments (EDs) and inpatient (IP) hospital settings for OUD and other SUD 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 LOC where readmissions is preventable or medically inappropriate for OUD and other SUD.
6. Improved access to care for physical health conditions among beneficiaries with OUD or other SUDs.

ODM worked with an independent evaluator to clarify the relationships between the key provisions of Ohio's demonstration and the desired outcomes that aligned with the six goals established by CMS. Within the framework of a driver diagram, goal 3, reduction of overdose deaths, was viewed as the primary purpose of Ohio's demonstration, while other goals were viewed as primary drivers of reduction in overdose death. Goals 1, 2, 4, 5, and 6 were subsumed in three categories of primary drivers. Primary Driver 1, reduction in hospital-based SUD service use and treatment readmissions, aligned with goals 4 and 5. Primary Driver 2, increased adherence to and retention in treatment, corresponds to goal 2. Primary Driver 3 combines goal 1, initiation and engagement in treatment, and goal 6, access to physical health care, under the umbrella of health care quality. A driver diagram was developed to depict the hypothesized relationships between the desired outcomes of the demonstration and the factors that are expected to drive improvement (see Figure 1). A description of the hypothesized relationship between provisions of the demonstration, primary and secondary drivers, and the purpose of the demonstration are described in Section 2.

### Purpose:

1. Reductions in overdose deaths, particularly those due to opioids.

### Primary Drivers:

1. Reduce hospital-based SUD service use and treatment readmissions.
2. Increase adherence to and retention in treatment.
3. Improve quality of care.

**Secondary Drivers:**

1. Improve access to care.
2. Improve utilization of care.
3. Improve coordination and management of care.

## 2. Evaluation Questions and Hypotheses

The following section of the evaluation reflects the CMS-issued guidance for the evaluation of SUD demonstration waivers.<sup>2</sup> It includes a driver diagram describing key features of Ohio's demonstration and associated demonstration milestones and drivers established by CMS. It also describes the evaluation questions and hypotheses that assess the strength of those associations.

### 2.1 Driver Diagram

The driver diagram displayed in Figure 1 serves as the basis for this evaluation proposal. The driver diagram depicts the expected relationships between the demonstration's chief purpose, which is to reduce drug overdose deaths, and key drivers that contribute to reducing overdose deaths either directly or indirectly. The demonstration's purpose and primary drivers align with the six goals established by CMS for the SUD 1115 Waiver. The logic of the driver diagram suggests that drug overdose deaths (goal 3) will be reduced by implementing interventions to:

1. Reduce the need for preventable hospital-based care (goal 4) and readmissions (goal 5),
2. Improve treatment adherence (goal 2), including continuity of pharmacotherapy, and
3. Improve the quality of care through evidence-based treatment engagement (goal 1), and the integration of behavioral health and primary care (goal 6).

The primary drivers are dependent on three secondary drivers in the model: (1) access to care; (2) service utilization; and (3) care coordination and oversight. These secondary drivers represent the immediate outcomes of specific programmatic changes that Ohio will implement in response to the SUD 1115 Waiver. As depicted in the model:

1. Access to care will be improved through programmatic elements focused on coverage for all critical levels of care (LOC) (milestone 1), developing provider networks and certification of new provider types, and incorporating access standards in managed care contracts (milestone 4);
2. Utilization will be improved through new residential treatment (RT) program standards that require access to MAT in RT settings (milestone 3), and new care coordination approaches to assure patients are engaged in appropriate LOCs (milestone 6); and
3. Care coordination and oversight will be achieved through use of evidence-based patient placement criteria and utilization management approach to assure that services meet the appropriate level of need (milestone 2), expanded access and use of Ohio's prescription drug management program (PDMP) to prevent high-risk prescribing (milestone 5), as well as coordination of services to improve transitions between LOCs (milestone 6).

The proposed evaluation design follows the logic of this driver diagram. Each secondary driver is expected to exert influence on all three primary drivers, and all primary drivers are expected to impact drug overdose deaths. Thus, the primary drivers are grouped together with a dotted line. It is hypothesized that the planned programmatic changes will have a direct and immediate impact on secondary drivers. These hypotheses will be tested by assessing the causal impact of

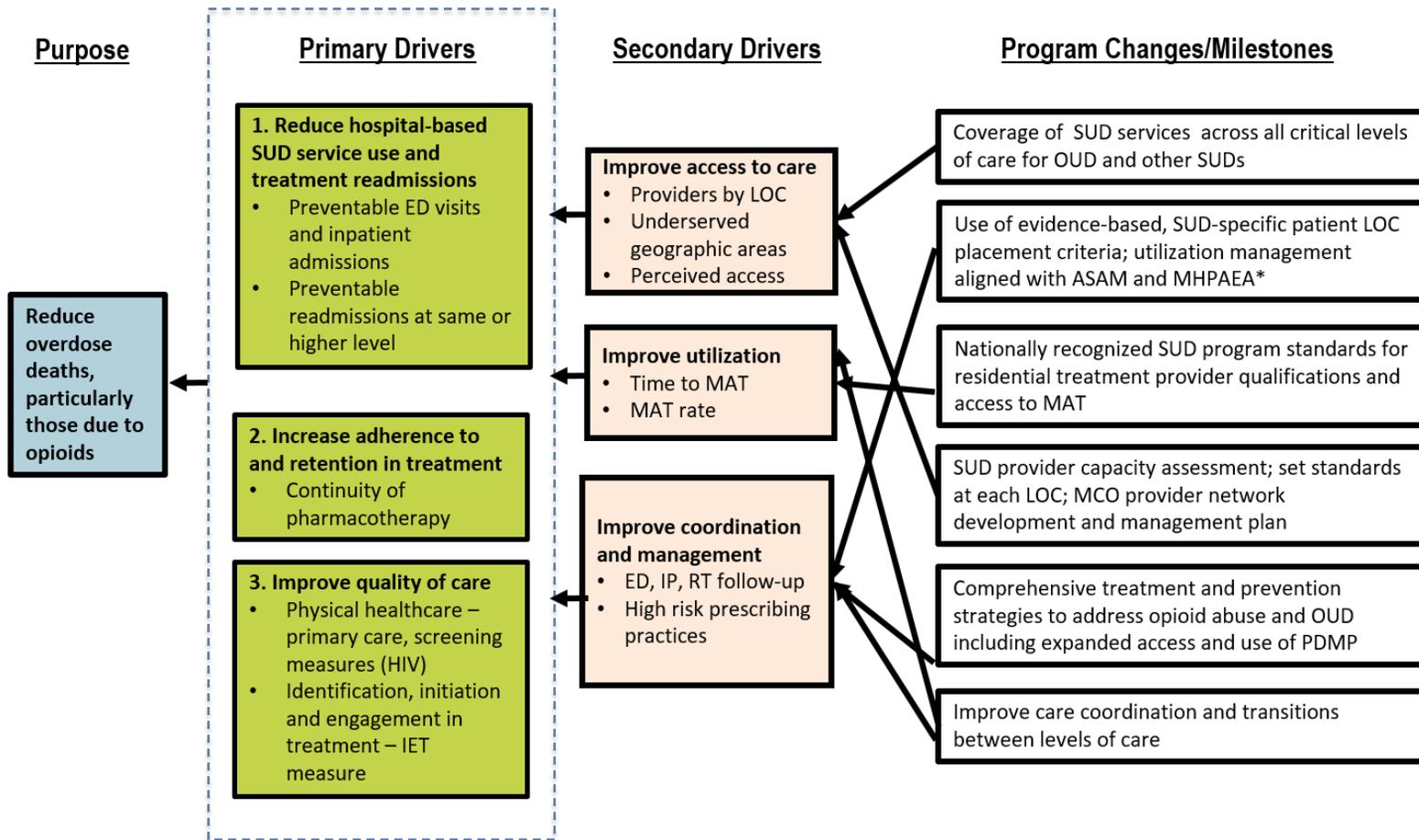
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<sup>2</sup>Centers for Medicare and Medicaid Services. Substance Use Disorder Section 1115 Demonstration Evaluation Design- Technical Assistance. March 6, 2019. Available at: <https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html>.

interventions on secondary drivers, including access to care, utilization patterns, and coordination and management.

The evaluation will also address the effects of the SUD demonstration waiver on drug overdose deaths and outcomes identified as primary drivers of drug overdose death, including hospital ED and inpatient admissions, readmissions, continuity of pharmacotherapy, physical health screening and utilization and treatment engagement.

**Figure 1: Driver Diagram**



\*Mental Health Parity And Addiction Equity Act

## 2.2 Questions and Hypotheses

The following questions and hypotheses will be examined and tested as part of the evaluation:

**Q1** Does the demonstration increase access to SUD treatment services?

*H1.a* The demonstration will increase the ratio of SUD providers to beneficiaries enrolled in Medicaid and qualified to deliver SUD services.

*H1.b* The demonstration will increase the ratio of providers to beneficiaries at each of the levels of care.

*H1.c* The demonstration will increase the ratio of providers to beneficiaries in geographic areas that are underserved at baseline.

**Q2** Does the demonstration increase utilization of SUD treatment by enrollees with SUD?

*H2.a* The demonstration will reduce the time between initial diagnosis and treatment.

*H2.b* The demonstration will increase the rate of MAT usage.

**Q3** Does the demonstration improve coordination and management of care?

*H3.a* The demonstration will increase the proportion of IP stays which have a timely follow-up visit with a corresponding primary diagnosis of SUD.

*H3.b* The demonstration will increase the proportion of RT visits which have a timely follow-up visit with a corresponding primary diagnosis of SUD.

*H3.c* The demonstration will increase the proportion of ED visits which have a timely follow-up visit with a corresponding primary diagnosis of SUD.

*H3.d* The demonstration will decrease high-risk prescribing practices (i.e., high dose, multiple prescribers and pharmacies, concurrent use of benzodiazepines).

**Q4** Does the demonstration reduce the utilization of ED and IP hospital settings for OUD and other SUD treatment?

*H4.a* The demonstration will decrease the rate of ED and IP visits within the beneficiary population for SUD.

*H4.b* The demonstration will decrease the rate of readmissions to ED and IP settings.

**Q5** Does the demonstration improve adherence to SUD treatment?

*H5.a* The demonstration will increase continuity of pharmaceutical care.

**Q6** Do beneficiaries receiving SUD services experience an improved quality of care?

*H6.a* The demonstration will increase the percentage of beneficiaries with SUD who receive screening and care for co-morbid conditions.

*H6.b* The demonstration will increase early engagement in SUD treatment.

**Q7** Does the demonstration reduce rates of opioid-related overdose deaths?

*H7.a* The demonstration will decrease the rate of overdose deaths, including those due to opioids.

**Q8** How do costs related to the demonstration waiver change throughout the pre- and post-demonstration periods?

*H8.a* The demonstration will decrease or have no effect on total costs. The demonstration will increase SUD-IMD, SUD-other, and Non-SUD costs, but decrease IP, non-ED outpatient, ED outpatient, pharmacy and long-term care costs.

## 3. Methodology

### 3.1 Evaluation Methodology

This section describes the mixed methods strategy that will be used for the evaluation, including both quantitative and qualitative methods. Below are summaries of the quantitative and qualitative methods followed by Table 1 which lists specific measures, data sources, analytic approaches, and their relationship to specific evaluation questions and hypotheses. This is accompanied by a narrative description of the analytic approaches in Section 3.2 to provide additional detail. The target and comparison populations, evaluation period, data sources, and analytic methods are described in greater detail.

#### Quantitative Methods

A majority of measures will be quantitative and derived from Medicaid administrative data (claims/encounters, eligibility, and provider information). The use of Medicaid administrative data allows measures to not only be tracked prospectively but also calculated historically to measure trends. The primary causal analysis method of use is an interrupted time series (ITS). Medicaid administrative data are ideal for this method because measures can be constructed over repeated time periods and calculated historically, in many cases, allowing pre-intervention trends to be properly estimated. In addition, descriptive analysis such as demographic or geographic stratification of measures will add context to the results of the formal hypothesis tests where applicable. After careful consideration, Ohio has not been able to identify a feasible in-state or out-of-state comparison population to provide a counterfactual for causal inference. The topic of comparison populations is discussed in Section 3.3.

#### Qualitative Methods

Qualitative data will be gathered at two points during the demonstration from focus groups of people with a SUD insured by Medicaid. The goal of the focus groups is to gather consumer perspectives regarding the outcomes of Ohio's implementation strategy and better understand the lived experiences of individuals receiving treatment. The first set of focus groups will be conducted as part of the Midpoint Assessment required by CMS and scheduled between February and April 2021. While this timeframe begins 16 months after the demonstration start date, most of the demonstration interventions will not be fully implemented at that time. Therefore, the focus group participants may be able to identify barriers to access and recovery that could be addressed over the course of the demonstration. The second set of focus groups will take place near the end of the demonstration (approximately October through November 2024). The focus group questions will concentrate on perceptions regarding changes in access to care, coordination between LOCs, integration of primary care, and key factors that support recovery. Focus group participants will be engaged through RT facilities and/or community behavioral health providers. Facilities and providers will be asked to recruit consumers who received treatment in the previous six months. This target population is well suited since it is likely to include individuals who are subject to changes in services that are an important element of the demonstration. Individuals with recent experience in residential treatment facilities and community behavioral health are likely to understand the barriers to access at various LOCs within the behavioral health (BH) system.

A total of 10-15 focus groups will be conducted in a mix of residential and community behavioral health provider settings located in both urban and rural areas, serving youth and adults. To

ensure focus groups reflect a diversity of perspectives, participant recruitment will focus on geographic, gender, age, racial, and ethnic diversity. Treatment facilities and other providers will be recruited from each of the three Ohio Medicaid Assessment Survey county types, metro, non-metro, and non-metro Appalachian to ensure geographic diversity. Treatment providers will be recruited with assistance from the Ohio SUD 1115 Stakeholder Advisory Committee, whose members were selected to represent diverse perspectives from recovery advocates, treatment providers, prescribers, and recovery housing. Focus group facilitators will work with participating treatment facilities and providers to recruit participants for gender, age, race, and ethnic diversity. Additional detail on the qualitative focus groups can be found in Section 3.7.

In addition to the qualitative information gathered as part of the focus group, the evaluation will seek to give a broad view of how Ohio's behavioral health treatment system changes during the demonstration period. This might include information on provider changes, such as adding or discontinuing the delivery of certain services, and different ways that consumers access services during the course of the demonstration. This information will help contextualize the quantitative results.

**Table 1: Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches**

Driver	Measure Description [period]	Steward	Numerator	Denominator	Data Source	Analytic Approach
<b>Q1 Does the demonstration increase access to SUD treatment services?</b>						
<i>H1.a The demonstration will increase the ratio of SUD providers to beneficiaries enrolled in Medicaid and qualified to deliver SUD services.</i>						
Secondary Driver: <i>(Improve access to care)</i>	SUD provider availability ratio [quarterly]		The number of providers who were enrolled in Medicaid and delivered SUD services during the measurement period	Number of beneficiaries with an SUD diagnosis during the measurement period	Medicaid administrative data	Interrupted time series, descriptive statistics
	SUD provider availability ratio – MAT [quarterly]		The number of providers who were enrolled in Medicaid and provided MAT (buprenorphine, methadone, or naltrexone)	Number of beneficiaries with an OUD diagnosis during the measurement period	Medicaid administrative data	Interrupted time series, descriptive statistics
<i>H1.b The demonstration will increase the ratio of providers to beneficiaries at each of the levels of care.</i>						
Secondary Driver: <i>(Improve access to care)</i>	SUD provider availability ratio by level of care [quarterly]		The number of providers who were enrolled in Medicaid and delivered SUD services during the measurement period by category (appropriate sublevels of 1, 2, and 3)	Number of beneficiaries with an SUD diagnosis during the measurement period	Medicaid administrative data	Interrupted time series, descriptive statistics
<i>H1.c The demonstration will increase the ratio of providers to beneficiaries in geographic areas that are underserved at baseline.</i>						
Secondary Driver: <i>(Improve access to care)</i>	SUD provider availability ratio within underserved areas [quarterly]		The number of providers who were enrolled in Medicaid and delivered SUD services during the measurement period in select counties determined to be underserved based on the number, percentage, and ratio of provider to beneficiaries.	Number of beneficiaries with an SUD diagnosis during the measurement period within selected counties	Medicaid administrative data and ODM Provider Address Database	Interrupted time series, descriptive statistics
<b>Q2 Does the demonstration increase utilization of SUD treatment by enrollees with SUD?</b>						
<i>H2.a The demonstration will reduce the time between initial diagnosis and treatment.</i>						
Secondary Drivers: <i>(Improve utilization)</i>	Initiation of SUD Treatment [quarterly]	Based on MM** 15	Number of beneficiaries who initiated treatment through an IP SUD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or MAT within 14 days of diagnosis	Number of beneficiaries with a new episode of SUD abuse or dependence	Medicaid administrative data	Interrupted time series

MM\*\* Same Measure as Monitoring Metric

**Table 1: Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches**

Driver	Measure Description [period]	Steward	Numerator	Denominator	Data Source	Analytic Approach
<b>H2.b</b> The demonstration will increase the MAT usage rate.						
Secondary Drivers: <i>(Improve utilization)</i>	MAT usage [quarterly]	Based on MM12**; MODRN	The number of beneficiaries who have a claim for MAT during the measurement period.	The number of beneficiaries with an OUD diagnosis during the measurement period.	Medicaid administrative data	Interrupted time series
	RT stays with MAT [quarterly]		The number of RT stays with MAT administered or prescribed during the stay or 15 days before the start or after the end of the stay	RT stays during the measurement period	Medicaid administrative data	Interrupted time series
<b>Q3</b> Does the demonstration improve coordination and management of care?						
<b>H3.a</b> The demonstration will increase the proportion of IP visits which have a timely follow-up visit with a corresponding primary diagnosis of SUD.						
Secondary Driver: <i>(Improve care coordination/ management)</i>	IP follow-up [quarterly]	Based on MM 17**; adjusted measurement period	Number of IP visits for beneficiaries who have a principal diagnosis of SUD abuse or dependence and who had a follow-up visit with a corresponding principal diagnosis for SUD within 30 days.	Number of IP visits for beneficiaries who have a principal diagnosis of SUD abuse or dependence.	Medicaid administrative data	Interrupted time series
<b>H3.b</b> The demonstration will increase the proportion of RT visits which have a timely follow-up visit with a corresponding primary diagnosis of SUD.						
Secondary Driver: <i>(Improve care coordination/ management)</i>	RT follow-up [quarterly]	Based on MM 17**; adjusted measurement period	Number of visits for beneficiaries who have a principal diagnosis of SUD abuse or dependence and who had a follow-up visit with a corresponding principal diagnosis for SUD within 30 days.	Number of RT visits for beneficiaries who have a principal diagnosis of SUD abuse or dependence.	Medicaid administrative data	Interrupted time series
<b>H3.c</b> The demonstration will increase the proportion of ED visits which have a timely follow-up visit with a corresponding primary diagnosis of SUD.						
Secondary Driver: <i>(Improve care coordination/ management)</i>	ED follow-up [quarterly]	MM 17**; adjusted measurement period	Number of ED visits for beneficiaries who have a principal diagnosis of SUD abuse or dependence and who had a follow-up visit with a corresponding principal diagnosis for SUD within 30 days.	Number of ED visits for beneficiaries who have a principal diagnosis of SUD abuse or dependence.	Medicaid administrative data	Interrupted time series

MM\*\* Same Measure as Monitoring Metric

**Table 1: Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches**

Driver	Measure Description [period]	Steward	Numerator	Denominator	Data Source	Analytic Approach
<i>H3.d</i> The demonstration will decrease high-risk prescribing practices.						
Secondary Driver: <i>(Improve care coordination and oversight)</i>	Use of opioids from multiple providers in persons without cancer [quarterly]	Based on MM 19**; adjusted requirement and measurement period	The number of beneficiaries without cancer who received prescriptions for opioids from four or more prescribers or four or more pharmacies	Beneficiaries without cancer/1000	Medicaid administrative data	Interrupted time series
	Use of opioids at high dosage in persons without cancer [quarterly]	Based on MM 20**; adjusted measurement period and no multiple provider requirement	The number of beneficiaries without cancer who received prescriptions for opioids at high dosage, $\geq$ 120 morphine milligram equivalents	Beneficiaries without cancer/1000	Medicaid administrative data	Interrupted time series
<b>Q4</b> Does the demonstration reduce the utilization of ED and IP hospital settings for OUD and other SUD treatment?						
<i>H4.a</i> The demonstration will decrease the rate of ED and IP visits within the beneficiary population for SUD.						
Primary Driver: <i>(Reduce hospital-based SUD service use and treatment readmissions)</i>	Emergency department utilization for SUD [quarterly]	MM** 23	The number of ED visits for SUD during the measurement period	Beneficiaries with a SUD enrolled in Medicaid during the measurement period	Medicaid administrative data	Interrupted time series
	IP stays for SUD [quarterly]	MM** 24	The number of IP discharges related to a SUD stay during the measurement period	Beneficiaries with a SUD enrolled in Medicaid during the measurement period	Medicaid administrative data	Interrupted time series

MM\*\* Same Measure as Monitoring Metric

**Table 1: Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches**

Driver	Measure Description [period]	Steward	Numerator	Denominator	Data Source	Analytic Approach
<i>H4.b</i> The demonstration will decrease the rate of readmissions to ED and IP settings.						
Primary Driver: <i>(Reduce hospital-based SUD service use and treatment readmissions)</i>	The 30-day all-cause IP admission rate following a RT stay among beneficiaries with SUD [quarterly]	MM** 25; adjusted index locations and measurement period	The count of 30-day IP admissions: at least one acute admission for any diagnosis within 30 days of the index discharge date	Index RT	Medicaid administrative data	Interrupted time series
	The 30-day all-cause ED visit rate following a RT stay among beneficiaries with SUD [quarterly]	MM** 25; adjusted index locations and measurement period	The count of ED visits within 30-days of the index date: at least one acute visit for any diagnosis within 30 days of the index discharge date	Index RT	Medicaid administrative data	Interrupted time series
	The 30-day all-cause visit rate to an ED following an ED visit among beneficiaries with SUD [quarterly]	Based on MM** 23/25; adjusted measurement period	The count of ED visits within 30-days of the index date: at least one acute visit for any diagnosis within 30 days of the index discharge date	Index ED Visits	Medicaid administrative data	Interrupted time series
<b>Q5</b> Does the demonstration improve adherence to SUD treatment?						
<i>H5.a</i> The demonstration will increase continuity of pharmaceutical care.						
Primary Driver: <i>(Increased adherence to and retention in treatment)</i>	Continuity of pharmacotherapy for opioid use disorder [quarterly]	MM 22*, adjusted measurement period, MODRN	Number of participants who have at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than seven days	Individuals who had a diagnosis of OUD and at least one claim for an OUD medication	Medicaid administrative data	Interrupted time series

MM\*\* Same Measure as Monitoring Metric

**Table 1: Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches**

Driver	Measure Description [period]	Steward	Numerator	Denominator	Data Source	Analytic Approach
<b>Q6</b> Do beneficiaries receiving SUD services experience an improved quality of care?						
<i>H6.a</i> The demonstration will increase the percentage of beneficiaries with SUD who receive screening and care for co-morbid conditions.						
Primary Driver: <i>(Improve quality of care)</i>	Access to preventive/ ambulatory health services for adult Medicaid beneficiaries with SUD [quarterly]	MM** 32; adjusted measurement period	Number of beneficiaries with SUD who had an ambulatory or preventive care visit during past 12 months	Number of beneficiaries with SUD during the measurement period.	Medicaid administrative data	Interrupted time series
	Screening for HIV/HCV/HBV [quarterly]	MODRN	Number of beneficiaries with SUD who were screened for HIV/HCV/HBV during past 12 months	Number of beneficiaries with SUD during the measurement period	Medicaid administrative data	Interrupted time series
<i>H6.b</i> The demonstration will increase early engagement in SUD treatment.						
Primary Driver <i>(Improve quality of care)</i>	Initiation and engagement of alcohol and other drug abuse or dependence treatment [quarterly]	MM** 15; adjusted measurement period	Number of beneficiaries who initiated treatment and who had two or more additional SUD services or MAT within 34 days of the initiation visit	Number of beneficiaries with a new episode of alcohol or other drug abuse or dependence	Medicaid administrative data	Interrupted time series
<b>Q7</b> Does the demonstration reduce rates of opioid-related overdose deaths?						
<i>H7.a</i> The demonstration will decrease the rate of overdose deaths, including those due to opioids.						
Purpose: <i>(Reductions in overdose deaths particularly those due to opioids)</i>	Rate of overdose deaths [quarterly]	MM* 27	Number of overdose deaths	Number of beneficiaries/1000	Medicaid and ODH administrative data	Interrupted time series, descriptive statistics
	Rate of overdose deaths due to opioids [quarterly]	MM* 27	Number of overdose deaths due to opioids	Number of beneficiaries/1000	Medicaid and ODH administrative data	Interrupted time series, descriptive statistics

MM\*\* Same Measure as Monitoring Metric

**Table 1: Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches**

Driver	Measure Description [period]	Steward	Numerator	Denominator	Data Source	Analytic Approach
<b>Q8</b> How do costs related to the demonstration waiver change throughout the pre- and post-demonstration periods?						
<i>H8.a</i> The demonstration will decrease or have no effect on total costs. The demonstration will increase SUD-IMD, SUD-other, and Non-SUD costs, but decrease IP, non-ED outpatient, ED outpatient, pharmacy and long-term care costs.						
	Total costs [quarterly]		Total costs from fee-for-service and encounter claims, including inpatient, outpatient, professional medical, pharmacy, dental, and long-term care	Total member-months	Medicaid administrative data	Beneficiary-level interrupted time series model
	Total federal costs [quarterly]		Total Medicaid costs * federal Medicaid percentage	Total member-months	Medicaid administrative data	Beneficiary-level interrupted time series model
	SUD-IMD costs [quarterly]		IMD costs	Total member-months	Medicaid administrative data	Beneficiary-level interrupted time series model
	SUD-other costs [quarterly]		Costs with SUD diagnosis and/or SUD-related code (procedure, revenue, POS, provider type)	Total member-months	Medicaid administrative data	Beneficiary-level interrupted time series model
	Non-SUD costs [quarterly]		Costs without SUD diagnosis and without SUD-related code (procedure, revenue, POS, provider type)	Total member-months	Medicaid administrative data	Beneficiary-level interrupted time series model
	Outpatient costs - non ED [quarterly]		Costs associated with outpatient and professional medical and dental, non ED claims	Total member-months	Medicaid administrative data	Beneficiary-level interrupted time series model
	Outpatient costs - ED [quarterly]		Costs associated with ED claims that do not result in an inpatient admission	Total member-months	Medicaid administrative data	Beneficiary-level interrupted time series model
	Inpatient costs [quarterly]		Costs associated with inpatient claims	Total member-months	Medicaid administrative data	Beneficiary-level interrupted time series model
	Pharmacy costs [quarterly]		Costs associated with pharmacy claims	Total member-months	Medicaid administrative data	Beneficiary-level interrupted time series model

MM\*\* Same Measure as Monitoring Metric

**Table 1: Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches**

Driver	Measure Description [period]	Steward	Numerator	Denominator	Data Source	Analytic Approach
	Long-term care costs [quarterly]		Costs associated with long-term care claims	Total member-months	Medicaid administrative data	Beneficiary-level interrupted time series model

MM\*\* Same Measure as Monitoring Metric

### 3.2 Descriptions of Analytic Approaches by Hypothesis

*Hypothesis H1.a* states that the demonstration will increase the ratio of qualified SUD providers to beneficiaries. To test this hypothesis, the ratio of providers to beneficiaries will be calculated and tracked quarterly and an ITS model will be applied to test for statistically significant changes in the trajectory of the measures over time. Providers and their locations will be identified using the methodology described in Section 3.6.

The approach of standardizing the number of providers by the number of beneficiaries with an SUD or OUD diagnosis rather than the total number of beneficiaries was chosen because it better reflects the relative population need. Descriptive statistics also will be calculated to assess changes in the distribution of MAT providers by MAT type (buprenorphine, methadone, or naltrexone), and to better understand the geographic distribution of providers and beneficiaries by calculating the provider-beneficiary ratio within each county.

*Hypothesis H1.b* considers whether the demonstration will produce an increase in the ratio of providers to beneficiaries at each LOC. This hypothesis will be tested by applying an ITS model to examine changes in the ratio of providers to beneficiaries at each ASAM LOC and applying descriptive statistics to examine the geographic distribution of providers by county.

*Hypothesis H1.c* examines access to care in areas that are underserved. Access will be defined in terms of the ratio of providers and beneficiaries in a given county. Preliminary analyses suggest that there is wide variation in provider-to-beneficiary ratios across the state. Underserved counties will be defined as those counties that have a combination of a large number and percentage of beneficiaries with OUD and a small provider access ratio. Ratios of providers-to-beneficiaries will be tracked over time in these counties to assess improvement over time and indicate a reduction in access gaps. Additional descriptive statistics mapping provider locations will be used to add context to the analysis.

*Hypothesis H2.a* considers timely utilization of treatment after diagnosis. The impact of the demonstration on timely utilization will be tested using an ITS analysis with the outcome based on a modified version of monitoring metric 15 (initiation and engagement of alcohol and other drug abuse or dependence treatment). The measurement periods will be reduced to quarters instead of the annual measurement period specified in the monitoring metric.

*Hypothesis H2.b* expects that access to all ASAM levels of care and MAT will improve the MAT utilization rate over the course of the demonstration. This hypothesis will be tested using an ITS model applied to identify improvement over time in MAT usage rates among beneficiaries with OUD and beneficiaries in RT for OUD.

As part of the demonstration's goal of improving coordination and management of care, *Hypotheses H3.a, H3.b, and H3.c* consider the demonstration's effect on timely follow-up care after an IP or RT stay or ED visit. These hypotheses will be tested using ITS models with the outcome measures based on monitoring metric 17. *Hypothesis H3.d* relates to the demonstration's effect on high-risk prescribing practices. Two measures based on monitoring metrics 19 and 20 will be calculated quarterly and used as the outcomes in ITS models to test whether there are reductions in the proportion of beneficiaries who are prescribed opioids at high dosages ( $\geq 120$  morphine milligram equivalent [MME]) and the proportion of beneficiaries with opioids from four or more prescribers or pharmacies in the past year.

*Hypothesis H4.a* assesses changes in ED and IP utilization for SUD by applying ITS models to monitoring metrics 23 and 24. Similarly, the analysis for *Hypothesis H4.b* considers the rate of readmission to an ED following an ED visit, and the rate of admission to ED and IP settings following a RT stay. Monitoring metric 23 will be used to capture ED readmissions and an adapted version of monitoring metric 25 will be used to capture ED visits and IP stays following RT. An ITS model will be used to test for significant changes in the trajectories of these metrics over the course of the demonstration.

Adherence to treatment can support individuals in their pursuit of recovery and reduce risk of overdose. *Hypothesis H5.a* states that the demonstration will increase continuity of pharmaceutical care. The 180-day continuity of pharmacotherapy measure, based on monitoring metric 22, with an adjusted measurement period, will be used for this analysis.

*Hypothesis H6.a* assesses improvement in quality of care for beneficiaries receiving SUD services. The demonstration is expected to be associated with increases in the percentage of beneficiaries with SUD receiving primary care and screening for co-morbid conditions. ITS models will be used to assess changes in several measures over the course of the demonstration. The first is the proportion of beneficiaries with SUD who had an ambulatory or preventive care visit in the past year. This measure is based on monitoring metric 32 with an adjusted measurement period. The other measures assess proportions of beneficiaries receiving HIV, HCV, and HBV screening during the past year. These measures will be calculated quarterly with a rolling annual lookback period. *Hypothesis H6.b* assesses early engagement in SUD treatment. An ITS model will be used to test for changes over time in the proportion of beneficiaries who had two or more additional SUD services or MAT within 34 days of treatment initiation, based on monitoring metric 15.

*Hypothesis H7.a* addresses the fundamental goal of the demonstration to decrease the rate of drug overdose deaths, particularly those due to opioids. An ITS model will test for changes in drug overdoses and opioid overdoses over time as a result of the demonstration. In addition, descriptive statistics will show the breakdown of opioid overdose deaths by type (e.g. fentanyl, heroin).

Evaluation question **Q8** considers changes in the cost of services that are due to program changes implemented in the demonstration. To estimate the effect of the demonstration on per-beneficiary cost, an interrupted time series model will be constructed for each outcome of interest. These models will be different from previous ITS analyses in that the modelled outcomes will be at the beneficiary level instead of the summary level. See Section 3.7 for additional details on the modelling methodology.

In addition to the analytic approaches, descriptive comparisons may be conducted with a group of states that are implementing SUD 1115 Waiver demonstration projects and participating in a distributed research network as described in Section 3.8. These comparisons may be used to evaluate unique elements of Ohio's implementation plan compared to those of other states. Descriptive comparisons may also be conducted to compare the impact of the waiver on demographic subpopulations of interest. See Section 3.8 for a full description.

### **3.3 Target and Comparison Populations**

The demonstration will impact services for Medicaid enrollees of any age with a SUD. Adolescence is recognized as an important period of prevention and early intervention. However, ado-

lescents differ substantially in terms of the prevalence of SUD and aspects of treatment that are the focus of this evaluation. Therefore, the evaluation will focus on the target population of individuals ages 18 through 64 during a given measurement period. Adolescents, ages 12 through 17, will be considered as an additional population of interest for descriptive analysis for relevant measures given data availability. Beneficiaries who are dually enrolled in Medicaid and Medicare will be excluded from all analyses because it is not possible to observe all of their health care in Medicaid claims and encounters. Additional inclusion criteria for specific construct measures such as SUD/OD diagnosis and/or continuous enrollment are described in Table 1.

In considering possible comparison populations, note that the interventions are state- and system-wide, and therefore apply to all Medicaid beneficiaries. Also, there is no readily available source of service data from persons who are not enrolled in Medicaid. Consequently, there are no opportunities to gather data from a comparison group of Ohio Medicaid enrollees not subject to interventions, or a comparison group of Ohioans who are not enrolled in Medicaid.

Several national data sources were considered to provide a state-level comparison group. However, because many states already have an 1115 SUD Waiver demonstration, or have submitted an application for a waiver to CMS, there are few remaining states to serve as candidates for a valid counterfactual comparison to Ohio. Summary measures for the states with similar characteristics to Ohio indicate that states without a waiver have much lower opioid-involved overdose death rates (Table 2). Therefore, these states make a poor counterfactual comparison to Ohio's experience with the opioid crisis. Furthermore, these states (Connecticut, New York, and South Carolina) may choose to apply for an SUD 1115 waiver in the coming years.

Since Ohio has limited options for a valid comparison group, the evaluation will utilize statistical methods that compare the outcomes across time. These methods compare pre- and post-intervention outcomes in a time series controlling for pre-intervention trends. The majority of the proposed evaluation outcomes are derived from Medicaid administrative data and are ideal candidates for a time series modelling approach, because they can be calculated over repeated intervals and gathered retrospectively for a period prior to implementation of the demonstration interventions.

**Table 2: Opioid-involved overdose deaths and prescriptions for selected states**

<b>1115 SUD Waiver States</b>	<b>Opioid-Involved Overdose Deaths/100,000 persons (2017)</b>	<b>Opioid Prescriptions/100 persons (2017)</b>
West Virginia	49.6	81.3
Ohio	39.2	63.5
New Hampshire	34.0	52.8
Maryland	32.2	51.7
Massachusetts	28.2	40.1
Kentucky	27.9	86.8
Michigan	21.2	74.0
Wisconsin	16.9	52.6
<b>Non-SUD Waiver States</b>	<b>Opioid-Involved Overdose Deaths/100,000 persons (2017)</b>	<b>Opioid Prescriptions/100 persons (2017)</b>
Maine <sup>3</sup>	29.9	55.7
Connecticut	27.7	48
Missouri <sup>4</sup>	16.5	71.8
New York	16.1	37.8
South Carolina	15.5	79.3

### 3.4 Evaluation Period

The demonstration waiver period began October 2019, and will continue for 5 years. Based on the state’s implementation plan<sup>5</sup>, the majority of the actions related to the milestones will take place within the first 12-24 months of the waiver time period (October 2020-October 2021) with a few actions that already have taken place. Evaluators will use data starting with January 2018, or earlier to model the outcome trends in the pre-demonstration period. January 2018 is significant because it marks the implementation of Ohio’s behavioral health system redesign which included significant changes in Medicaid behavioral health benefits and billing codes.

January 1, 2018, was the earliest that certain relevant Medicaid claims codes were used. Since many of the outcome measures are dependent on Medicaid benefits structure, the start date for those measures will be set at Q1 2018. Those outcome measures unlikely to be affected by behavioral health system redesign will be measured starting in Q1 2017. As specified in Table 3, Q4 2021 will be treated as the start of the post-implementation period for ITS models because

<sup>3</sup>On November 26, 2019, MaineCare submitted a 1115 demonstration waiver application to CMS with the goal of improving the SUD service delivery system. If approved, this waiver would allow for additional federal funding for RT or IP SUD treatment for MaineCare-enrolled adults and would provide state flexibility to pilot four services focused on MaineCare-enrolled parents with SUD who are involved with or at-risk of involvement with Child Protective Services.

<sup>4</sup>In August 2018, the state of Missouri requested authority to amend the demonstration to include a substance use treatment benefit. The amendment request was approved with an implementation date of February 1, 2019, to cover outpatient substance use services in the primary care home, including pharmacotherapy, for SUD treatment of Gateway enrollees. Sources: MACPAC Report – States with approved or pending 1115 SUD waivers (as of July 2019), NIDA report (opioid summaries by state, 2017) <https://www.macpac.gov/subtopic/section-1115-waivers-for-substance-use-disorder-treatment/>, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state>

<sup>5</sup><https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/oh/oh-substance-use-disorder-treatment-pa.pdf>

that is when the majority of actions related to the milestones will be completed. As a result, 15 quarters of data will be available in the models' pre-implementation period and 13 quarters will be available for the models' post-implementation period. See Figure 6 for a visual reference to important policy time points.

**Table 3: Summary of ITS Measures and Time Periods**

<b>Hypothesis</b>	<b>Measure</b>	<b>Earliest Data Point</b>	<b>Start of Post-Implementation Period for ITS Model</b>
<i>H1.a</i>	SUD provider availability ratio [quarterly]	Q1 2018	Q4 2021
<i>H1.a</i>	SUD provider availability ratio – MAT [quarterly]	Q1 2017	Q4 2021
<i>H1.b</i>	SUD provider availability ratio by Level of Care [quarterly]	Q1 2018	Q4 2021
<i>H1.c</i>	SUD provider availability ratio within Underserved Areas [quarterly]	Q1 2018	Q4 2021
<i>H2.a</i>	Initiation of SUD Treatment [quarterly]	Q1 2018	Q4 2021
<i>H2.b</i>	MAT Usage [quarterly]	Q1 2017	Q4 2021
<i>H2.b</i>	RT Treatment Stays with MAT [quarterly]	Q1 2018	Q4 2021
<i>H3.a</i>	IP Follow-Up [quarterly]	Q1 2018	Q4 2021
<i>H3.b</i>	RT Follow-Up [quarterly]	Q1 2018	Q4 2021
<i>H3.c</i>	ED Follow-Up [quarterly]	Q1 2018	Q4 2021
<i>H3.d</i>	Use of Opioids from Multiple Providers in Persons Without Cancer [quarterly]	Q1 2017	Q4 2021
<i>H3.d</i>	Use of Opioids at High Dosage in Persons Without Cancer [quarterly]	Q1 2017	Q4 2021
<i>H4.a</i>	Emergency Department Visits for SUD-Related Diagnoses and Specifically for OUD [quarterly]	Q1 2017	Q4 2021
<i>H4.a</i>	IP Admissions for SUD, and Specifically OUD [quarterly]	Q1 2017	Q4 2021
<i>H4.b</i>	The 30-day All-Cause IP Admission Rate Following a RT Stay Among Beneficiaries with SUD [quarterly]	Q1 2018	Q4 2021
<i>H4.b</i>	The 30-day All-Cause ED Admission Rate Following a RT Stay Among Beneficiaries with SUD [quarterly]	Q1 2018	Q4 2021
<i>H4.b</i>	30-day Readmission Rate to an ED Following ED Visit for an SUD-Related Diagnosis, and Specifically for OUD [quarterly]	Q1 2018	Q4 2021
<i>H5.a</i>	Continuity of Pharmacotherapy for Opioid Use Disorder [quarterly]	Q1 2017	Q4 2021
<i>H6.a</i>	Access to Preventive/ Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD [quarterly]	Q1 2018	Q4 2021
<i>H6.a</i>	Screening for HIV/HCV/HBV [quarterly]	Q1 2018	Q4 2021

**Table 3: Summary of ITS Measures and Time Periods**

Hypothesis	Measure	Earliest Data Point	Start of Post-Implementation Period for ITS Model
<i>H6.b</i>	Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment [quarterly]	Q1 2018	Q4 2021
<i>H7.a</i>	Rate of Overdose Deaths [quarterly]	Q1 2018	Q4 2021
<i>H7.a</i>	Rate of Overdose Deaths Due to Opioids [quarterly]	Q1 2018	Q4 2021
<i>H8.a</i>	Total Costs Per-Beneficiary [quarterly]	Q1 2018	Q4 2021
<i>H8.a</i>	Total Federal Costs Per-Beneficiary [quarterly]	Q1 2018	Q4 2021
<i>H8.a</i>	SUD-IMD Costs Per-Beneficiary [quarterly]	Q1 2018	Q4 2021
<i>H8.a</i>	SUD-other Costs Per-Beneficiary [quarterly]	Q1 2018	Q4 2021
<i>H8.a</i>	Non-SUD Costs Per-Beneficiary [quarterly]	Q1 2018	Q4 2021
<i>H8.a</i>	Outpatient non-ED Costs Per-Beneficiary [quarterly]	Q1 2018	Q4 2021
<i>H8.a</i>	Outpatient ED Costs Per-Beneficiary [quarterly]	Q1 2018	Q4 2021
<i>H8.a</i>	Inpatient Costs Per-Beneficiary [quarterly]	Q1 2018	Q4 2021
<i>H8.a</i>	Pharmacy costs - ED Costs Per-Beneficiary [quarterly]	Q1 2018	Q4 2021
<i>H8.a</i>	Long-term care costs - ED Costs Per-Beneficiary [quarterly]	Q1 2018	Q4 2021

### 3.5 Data Sources

This section provides additional detail on the data sources to be used in the evaluation. See Table 1 for additional specificity on hypotheses, measures and their associated data sources. The primary data source for the evaluation will be Medicaid administrative data as supplied to the Ohio Colleges of Medicine Government Resource Center (GRC) by the Ohio Department of Medicaid (ODM). Medical claims and encounter data for professional medical, outpatient facility, inpatient facility, and pharmacy will be used to assess service utilization. Eligibility and enrollment records will be used to determine eligibility and continuous enrollment criteria. Provider records from Medicaid administrative data, programmatic data, and additional information from ODM’s provider capacity scan will be used to assess provider capacity and access. This data will be used to construct a majority of the proposed measures.

All quantitative data in the evaluation will be drawn from Medicaid administrative data. Cleaning of Medicaid administrative data primarily occurs through eligibility verification and claim adjudication processes. Eligibility verification occurs regularly at Ohio Medicaid to determine whether individuals are eligible for Medicaid benefits and the appropriate category of eligibility. The claims adjudication process validates submitted claims against Medicaid coverage policies. When multiple claims have been submitted by a provider for the same service(s), only the most recent version of the claim is retained for the evaluation. Due to the lag in submitting claims, the evaluation team will pull claims on a six-month delay (e.g., claims for services rendered in January 2020 will be analyzed in July 2020). The evaluation team will validate measure results through comparison to other Ohio SUD treatment data work, including but not limited to the

MODRN OUD project and other SUD work conducted by GRC on behalf of the Ohio Department of Medicaid and Ohio Department of Mental Health and Addiction Services.

In order to answer evaluation question **Q7** about the number of overdose deaths, Vital Statistics death records from the Ohio Department of Health (ODH) will be linked to Medicaid administrative data to determine Medicaid beneficiary status. The Vital Statistics–Medicaid record linkage methods will be based on prior established methods as approved by ODM.

To add context to the quantitative findings, 10-15 beneficiary focus groups will be conducted at two post-implementation time points with enrolled members who have received SUD treatment services. Residential treatment facilities and community behavior health providers will be asked to assist with recruitment of participants and host focus groups. Topics addressed may include perceptions regarding changes in access to care, coordination of transitions between levels of care, and integration of primary care. Questions will be aligned with topics from the Consumer Assessment of Healthcare Providers and Systems (CAHPS)<sup>6</sup> survey series where possible.

### **3.6 Identifying Providers**

Medicaid claims include various provider identification numbers for billing, rendering (for medical), attending (for hospital outpatient and inpatient), and prescribing (for pharmacy) providers. Rendering providers can then be linked to a practice address file to determine the location. All three pieces of location information are often needed to get a full picture of all individual practitioners and practice locations. Billing providers will provide additional context, but as the primary identifier of providers for the ratio measures in Table 1, the rendering providers will be used. In addition, for MAT providers, the prescribing provider will be used for pharmacy claims and the rendering provider will be used for outpatient and professional claims.

ODM's administrative data on provider locations will be used to help geolocate providers for use in geographic-based measures. Evaluators also will consider using an alternative source of provider addresses such as the National Plan and Provider Enumeration System (NPPES) National Provider Identifier (NPI) Registry file. ODM researchers are developing a provider capacity scan that may be utilized to improve the accuracy of analyses that require provider location. Such methods will be considered for the evaluation if they can be applied consistently across time and the impact of the interventions are not confounded by changes in methodology.

### **3.7 Analytic Methods**

The following section describes the proposed analytic methods for evaluation of the hypotheses and evaluation questions. These include descriptive statistics, a summary-level Interrupted Time Series (ITS), a beneficiary-level ITS, and qualitative focus groups. Additional information regarding descriptive analysis that falls outside of the formal hypotheses yet adds to the general context of the evaluation is found in Section 3.8.

#### **Descriptive Statistics**

As appropriate, descriptive statistics for metrics will be shown along with more formal statistical models. Depending on the particular metric, this could include information on sample size,

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<sup>6</sup><https://www.ahrq.gov/cahps/index.html>

trends in the metric over time and/or maps of the metric by county. These analyses will be used to give additional context and information to the evaluation of research questions.

### Summary-Level Interrupted Time Series (ITS)

The majority of analysis will be conducted with a summary-level interrupted time series, meaning that unit of analysis is the summary measure (e.g. a ratio or percentage) at a given time period rather than individual's outcome at the given time period. Assume an outcome of interest  $Y$ , across  $t = 0, \dots, m$  time periods. Let  $Y_t$  represent the outcome at time  $t$ ,  $T$  represent the time elapsed, and  $W_t$  represent an indicator variable specifying whether or not time  $t$  is part of the post-intervention period. Then the standard ITS regression model is given by:

$$Y_t = \beta_0 + \beta_1 T + \Delta_1 W_t + \Delta_2 W_t T + \epsilon_t, \quad (1)$$

where  $\beta_0, \beta_1$  represent the pre-intervention intercept and slope respectively, and  $\Delta_1, \Delta_2$ , the represent the change in the intercept and slope respectively during the post-intervention period. The variable  $\epsilon_t$  represents random error in the time series at time  $t$ . The coefficients  $\Delta_1$  and  $\Delta_2$  are the causal parameters of the interest in the model.

There may be specific outcomes of interest to examine changes in three time periods rather than two. In this case, additional parameters for the change in intercept and slope in the third time period would also be estimated giving the model the following form:

$$Y_t = \beta_0 + \beta_1 T + \Delta_1 W_{1t} + \Delta_2 W_{1t} T + \Delta_3 W_{2t} + \Delta_4 W_{2t} T + \epsilon_t, \quad (2)$$

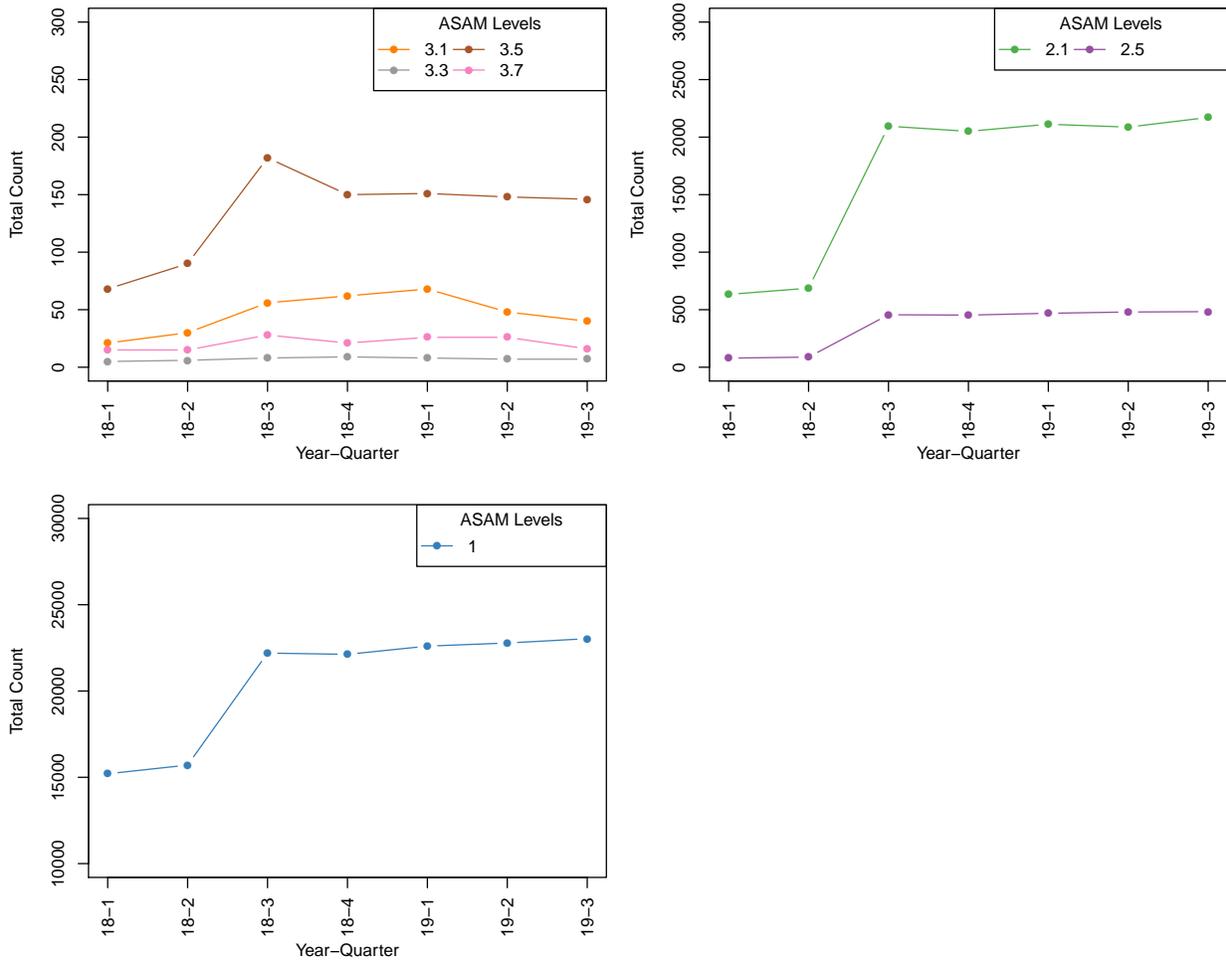
where  $W_{1t}$  and  $W_{2t}$  are indicators of the second and third time periods (post-intervention) respectively. The coefficients  $\Delta_1$  and  $\Delta_2$  represent the changes in the second time period relative to the first (pre-intervention) and  $\Delta_3$  and  $\Delta_4$  represent the changes in the third time period relative to the first.

One important consideration in time series models is autocorrelation, meaning the outcome at a point in time is correlated with its past values. Auto-correlation can violate the linear regression model's assumption that errors are independent over time. In order to account for autocorrelation, a correction to the standard errors such as the Newey-West estimator<sup>7</sup> is planned.

Figure 2 provides an example of the data that will be utilized in an interrupted time series model. It shows unique counts of rendering providers who were listed on at least one final paid inpatient, outpatient, or professional claim during the measurement period. For the time series model, the provider counts would be standardized by the number of OUD beneficiaries, and data would be extended into the future attempting to detect outcome shifts or changes in outcome slope.

<sup>7</sup>Newey, W. K., & West, K. D. (1986). A simple, positive semi-definite, heteroskedasticity and autocorrelation consistent covariance matrix.

**Figure 2: Provider Totals by ASAM level by Service Quarter**



### Beneficiary-Level Interrupted Time Series (ITS)

As recommended in the CMS technical assistance, a beneficiary-level interrupted time series model will be used to model outcomes related to evaluation question **Q8**, concerning per-beneficiary quarterly cost data (capitation and claim cost). The unit of analysis in the model are individuals rather than aggregate measures. The beneficiary-level approach will allow for the model to control for individual-level demographics (e.g. age, race, gender) and potentially clinical characteristics (e.g. comorbidities, delivery system). Including these covariates should not only increase the predictiveness of the model itself, but also will help account for any changes in the underlying population over time that could affect costs.

Let  $Y$  be some outcome of interest. Then  $Y_{it}$ , the outcome for individual  $i$  at time  $t$  will be explicitly modelled. As advised in the CMS technical assistance, a few different modelling functional forms will be considered including log-transformed linear models and a zero-inflated (two-part) generalized linear models such as a zero-inflated Poisson or zero-inflated negative binomial. Zero-inflated models attempt to better capture zeros in the data by first modelling if the

outcome is zero or greater than zero. Then, conditional on the outcome being greater than zero, a secondary model is used to estimate the outcome. The two model parts can, but do not need to, utilize the same set of predictor variables. Because multiple observations per beneficiary will be used, the outcomes will be correlated with one another. In order to take into account this within-beneficiary dependence, a GEE (Generalized Estimating Equations) version, and a random effects model of the model forms will be considered. GEE models take into account within-person dependence through a parameterized and estimated working correlation matrix. Random effects models take into account within-person dependence by assuming a person-level random effect that is constant over time.

In addition to parameters for time, post-implementation time periods, and an interaction thereof, fixed-effects for age, gender, race, and possibly calendar month will be included to control for changes in demographics over time and seasonal effects. A separate model will be fit for each cost outcome: total, total federal, SUD-IMD, SUD-other, non-SUD, outpatient non-ED, outpatient ED, IP, pharmacy, and long-term care costs.

### **Hypothesis Testing**

Formal statistical tests will be conducted on model parameters that represent the change in the metric over time in order to determine statistically significant changes in trends. For summary-level ITS models this includes the parameters that represent the change in the intercept and slope respectively from pre- to post-intervention time periods. For beneficiary-level ITS models, this includes parameters for indicators of the post-implementation time periods and those of interactions of the post-implementation time periods with time. Depending on the specific model, a t-test (linear model) or Wald test (generalized linear or GEE model) will be used to test for non-zero parameter values. Descriptive statistics or exploratory analysis will focus on estimation and uncertainty quantification (confidence intervals) rather than statistical significance. In interpreting results, additional context and descriptive analysis will be considered in order to give a full picture of the findings.

### **Qualitative Focus Groups**

Qualitative methods of data collection, including semi-structured interviews and focus groups, will be a unique component of the evaluation given their ability to answer the “how” and “why” questions. Beneficiary focus groups will be conducted at each of two post-implementation time points. Ten to fifteen focus groups will be conducted, targeting seven or more participants per group, with enrolled members who have received SUD treatment services. Residential treatment facilities and community behavior health providers will be asked to host focus groups and assist with recruitment of participants.

Prior to each focus group, participants will complete a brief questionnaire on subjects like age, gender, race/ethnicity, city of residence, occupation (if any), major health concerns, and household composition. A member of the evaluation team will collect each questionnaire and label the seat location of each respondent (see Figure 3 below). During the focus group, the note taker will operate the audio-recorder and document SUD-associated major themes generated by the participants. The note taker will also highlight brief excerpts of compelling quotes and indicate the speaker by seat number and the time on the recording. For example, “Having Medicaid coverage...has changed my life.” Time: 34:14.<sup>8</sup> This procedure will enable evaluators to

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<sup>8</sup>See page 43 of 2018 Ohio Medicaid Group VIII Assessment <https://medicaid.ohio.gov/Portals/0/Resources/>

**Figure 3: Focus Group Seating Arrangement**



more easily find and transcribe compelling quotes from the audio-recording and link the quote to de-identified characteristics of the speaker (e.g., “A 45-year-old daycare worker in Hocking County”).

Both the note taker and the facilitator will document the “mood” or feel for how the discussion is proceeding, a respondent’s reactions, and the potential need to pause or otherwise sustain a supportive environment for all respondents. Given the sensitivity of focus group topics, the evaluation team will be responsive to the respondent’s reactions to establish and sustain a comfortable environment. For qualitative semi-structured interviews and focus groups, the evaluator will develop an informed consent process guided by federal regulations detailed in 45 CFR 46.116, approved by the Institutional Review Board of the Ohio State University, and reviewed by ODM.

Focus group recordings will be transcribed by a third party. Transcripts will be reviewed by focus group facilitators for quality assurance. Transcripts will then be loaded into computer-assisted qualitative data analysis software to aide in the management of transcripts, coding, and emergent themes. Grounded theory will underpin the analyses conducted of these interviews with regard to access to care, coordination of care, and medication assisted therapy. Codes pertaining to the hypotheses described in Table 1 will be developed prior to the qualitative interviews, and evaluators also will inductively develop codes based on the data during review as concepts emerge. Subsequent discussion of the codes by evaluators will determine the salient themes present in the findings.

### **3.8 Additional Descriptive Analysis**

#### **Time and Distance Standards Analysis**

Another marker of provider capacity is the time and distance that consumers need to travel from their residence to their provider. ODM requires Medicaid managed care plans to maintain certain minimum time and distance standards as part of their provider agreement.<sup>9</sup> Based on these standards and subject to availability, descriptive analysis will be completed in order to help describe changes in provider capacity. ODM’s provider data along with beneficiaries address data from administrative records will be used in this analysis. This analysis will help provide additional context to the evaluation results.

Reports/Annual/Group-VIII-Final-Report.pdf

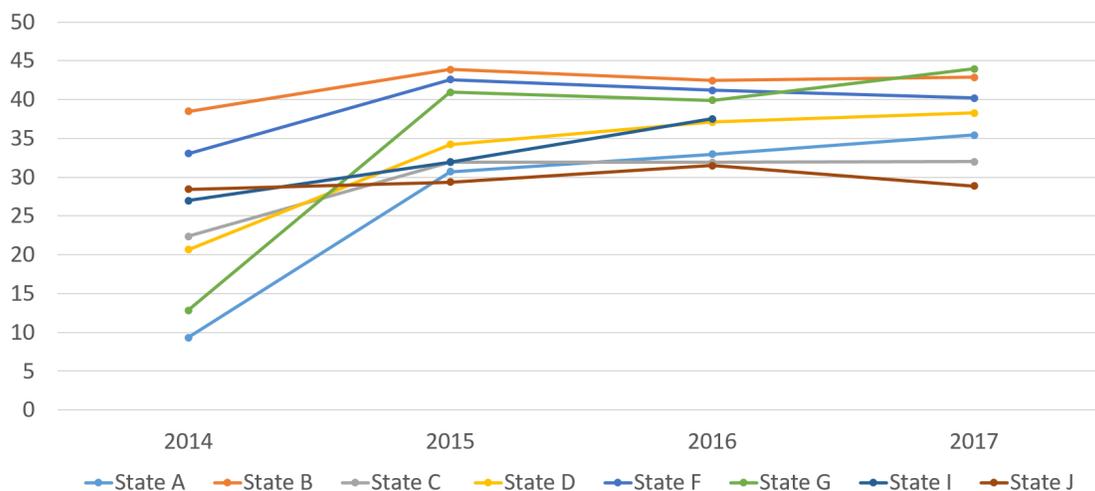
<sup>9</sup>[https://medicaid.ohio.gov/Portals/0/Providers/ProviderTypes/Managed%20Care/Provider%20Agreements/01\\_2020\\_MMC\\_Final\\_Rates.pdf](https://medicaid.ohio.gov/Portals/0/Providers/ProviderTypes/Managed%20Care/Provider%20Agreements/01_2020_MMC_Final_Rates.pdf)

## MODRN State Comparisons

Ohio is part of a multi-state opioid-focused research network that provides an opportunity to contrast results of Ohio's SUD waiver to those of other states. The Medicaid Outcomes Distributive Research Network (MODRN), facilitated by AcademyHealth, is a collaborative effort to analyze data across multiple states to facilitate learning among Medicaid agencies. Academic institutions in 11 states (Delaware, Kentucky, Maryland, Michigan, North Carolina, Ohio, Pennsylvania, Tennessee, Virginia, West Virginia and Wisconsin) began working with their Medicaid state partners in 2014 to establish a set of common quality metrics for opioid use disorder treatment and outcomes. The majority of states in the MODRN collaborative have SUD waivers approved or pending, making them poor choices for a counterfactual comparison group. Instead, data from these other states will be used to describe how Ohio's outcomes change over the course of the waiver in reference to other states. See Figure 4 for a MODRN data example. Possible MODRN measures that may be informative are:

- Measure 1: Initiation and Engagement in Treatment (annual percent);
- Measure 3 Annual Rate of MAT among Enrollees with OUD (rate per 1,000 member months);
- Measure 4: Continuity of Pharmacotherapy  $\geq$  180 days (annual percent);
- Measure 12: Opioid Fills at High Dose (rate per 1,000 enrollees without cancer);
- Measure 13: Multiple Opioid Prescribers or Providers (rate per 1,000 enrollees); and
- Measure 14: Concurrent Use of Benzodiazepines with MAT (annual percent).

**Figure 4: Initiation in treatment rate per 1,000 enrollees with an OUD diagnosis, 2014-2017, MODRN collaborative**



## Subpopulations

Evaluators may conduct descriptive analyses to assess the impact of the demonstration on Ohio's priority subpopulations identified by gender, race, and age subgroups. ODM is working in collaboration with other state agencies to address the needs of vulnerable populations who are involved in multiple systems of care. Examples include adolescents, multi-system youth (MSY) and their families, enrollees involved in the criminal justice system, individuals with chronic physi-

cal and/or mental health conditions, and women in the post-partum period who are at risk of morbidity and mortality. Ohio proposes to explore the waiver's impact on these subpopulations, given data availability, even though it is not a requirement of the demonstration evaluation.

## 4. Methodological Limitations

There are several major methodological limitations of the evaluation design that reduce the ability to draw causal arguments about the effect of the demonstration. Each is outlined below with discussion on how it will be addressed or considered in the evaluation.

First, there are minimal opportunities for a valid comparison group for the evaluation. While it would be ideal to draw comparison to a “control” population that was not subject to the policy changes within Ohio, it is not feasible due to the state-wide implementation of the demonstration and the lack of available non-Medicaid claims data. Data from other states exist through national surveys and summary data reports, but there are only a few states that are not participating the SUD waiver. Among these states, no candidates were found to be comparable to Ohio’s opioid overdose rates. Further, it is not known whether these states will apply for the waiver in the future. Therefore, the interrupted time series (ITS) approach is the best option available for measures of Ohio administrative Medicaid data. Though it doesn’t utilize an external comparison group, ITS remains a rigorous strategy to estimate the impact of a population-level health intervention that is implemented at a clearly-defined point in time.<sup>10</sup>

Another major methodological limitation is the impact of COVID-19 pandemic and resulting impact on services, behavioral health needs, and Medicaid enrollment. Emergency rules were enacted to temporarily extend the definition of telehealth to additional behavioral health services and communication modalities (e.g., telephone). Federal OTP requirements were relaxed to increase at-home administration of Methadone. There have been temporary interruptions in services as providers implemented safety measures. There also has been a reduction in demand due to fear of exposure and the closure of referral sources. Though the extent and length of this disruption is unknown, the primary and secondary drivers of overdose death will likely be affected. For example, access to care, treatment utilization, and coordination of care are likely to decrease temporarily, as consumers were concerned about seeking care and getting exposed, and providers had to develop telemedicine capacity. In the long run, this may have a negative impact on some of CMS’s goals for the demonstration, including overdose and preventable hospitalizations.

It is also expected that there could be a surge of new Medicaid enrollees requiring SUD treatment due to increased stress related to this virus and the loss of employee sponsored health insurance coverage. As the emergency provisions expire and the virus eventually diminishes, the SUD treatment utilization and Medicaid coverage may return to levels observed before the pandemic. Information about policy changes and their impact will be gathered from ODM and the stakeholder advisory committee over time to assess the length and depth of pandemic’s impact on the behavioral health system and individuals with SUD. The evaluation findings will be interpreted in the larger context of the pandemic and its effects and as appropriate, methodology will be adjusted to better take into account the effects of the pandemic. For example, baseline and comparison time frames may be adjusted to isolate the impact of the demonstration from the impact of COVID.

Beyond COVID-19, Ohio has already implemented numerous program and policy changes to address the opioid crisis. It may be challenging to isolate the effects of previous program and policy changes from those of the demonstration, particularly if additional policy changes take

<sup>10</sup>Bernal, J. L., Cummins, S., & Gasparrini, A. (2017). Interrupted time series regression for the evaluation of public health interventions: a tutorial. *International journal of epidemiology*, 46(1), 348-355.

place concurrent to the demonstration. As a result, evaluation findings will be considered in the context of the larger policy and economic environment. Major policy changes outside of the waiver during the demonstration period that could affect the evaluation outcomes will be noted and discussed.

It is possible that characteristics of the population (e.g. the age distribution) will change over time either as a result of the demonstration itself, or because of outside factors such as loss of employee-sponsored insurance in an economic crisis. A change to the population characteristics also could affect the outcome measures. If there are meaningful changes to population characteristics over time, a propensity score weighting methodology will be utilized to adjust for changes in the population characteristics to better estimate the effect of the demonstration itself, rather than demographic changes.

In addition, identifying providers and locating their practice address from claims, billing, and other administrative data is challenging because services are provided both by sites and individuals. Several of the proposed evaluation measures dealing with access to care rely on counting and possibly geolocating providers. As a result, a consistent methodology for identifying and locating practices must be applied over time so that increases in access to care can be attributed to the intervention itself rather than changes in accuracy of the provider identification methodology. As best possible, a consistent methodology will be used and any changes in the methodology over time will be noted in the evaluation.

Lastly, because there are many hypotheses, measures, and models that will be formally tested as part of the evaluation, it is important to keep in mind issues of statistical significance and multiple comparisons when interpreting results. To minimize the risk of erroneous inference, only pre-specified hypotheses will be tested and stricter significance thresholds may be considered. Conclusions will not be based solely on a p-value threshold in keeping with statistical best practices.<sup>11</sup> Any descriptive statistics or exploratory analysis will focus on estimation and uncertainty quantification (confidence intervals) rather than hypothesis testing.

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<sup>11</sup>Ronald L. Wasserstein & Nicole A. Lazar (2016) The ASA Statement on p-Values: Context, Process, and Purpose, *The American Statistician*, 70:2, 129-133, DOI: <https://doi.org/10.1080/00031305.2016.1154108>

## 5. Attachments

### 5.1 Independent Evaluator

The 1115 SUD demonstration will be evaluated by an independent party. The Ohio Colleges of Medicine Government Resource Center (GRC) will conduct the evaluation. This entity is separate from ODM and has extensive experience evaluating Medicaid programs, including Ohio's State Innovation Model grant, and a legislatively mandated evaluation of Ohio's Group VIII population in 2016. GRC partners with public universities in Ohio to leverage methodological and subject matter expertise.

GRC will maintain communication with ODM staff throughout the evaluation period to better understand policy and program implementation, and to obtain ODM's assistance with access to administrative data. GRC will make independent decisions about the evaluation itself, including methodology, analytical strategy, analysis of evaluation data, and presentation of results.

GRC agrees that no agency, employment, joint venture, or partnership has been or will be created between ODM and GRC. GRC further agrees that as an independent entity, it assumes all responsibility for any federal, state, municipal or other tax liabilities along with workers compensation, unemployment compensation, and insurance premiums that may accrue as a result of funds received pursuant to this work. GRC agrees that it is an independent entity for all purposes including, but not limited to, the application of the Fair Labor Standards Act, the Social Security Act, the Federal Unemployment Tax Act, the Federal Insurance Contribution Act, provisions of the Internal Revenue Code, Ohio tax law, Workers Compensation law, and Unemployment Insurance law.



February 7, 2020

I, Aimee Nielsen-Link, Director Health Sciences Office, Office of Sponsored Programs, warrant that: 1) I am an official authorized to bind the entity; and 2) to the best of my knowledge and belief, actual and potential organizational conflicts of interest have been identified, and disclosed to our institution's COI Administrator as of August 30, 2019.

I certify that The Ohio State University's Financial Conflicts of Interest policy complies with the requirements of the Department of Health and Human Services and 42 CFR Part 50 Subpart F. The full policy can be found at: <http://orc.osu.edu/files/Policy-on-Faculty-Financial-Conflict-of-Interest.pdf>

The Section 1115 Substance Use Disorder demonstration will be evaluated by an independent evaluator. The Ohio Colleges of Medicine Government Resource Center (GRC) will conduct the evaluation. This entity is separate from the Ohio Department of Medicaid (ODM) and has extensive experience evaluating Medicaid programs, including Ohio's State Innovation Model grant and a legislatively-mandated evaluation of Ohio's Medicaid expansion population in 2016. GRC partners with many public universities in Ohio to leverage methodological and subject matter expertise.

GRC will maintain communication with Ohio Department of Medicaid staff throughout the evaluation period in order to better understand policy and program implementation and to obtain ODM's assistance with access to administrative data, although GRC will make independent decisions about the evaluation itself, including methodology, analytical strategy, analysis of evaluation data, and presentation of results.

The Ohio State University agrees on behalf of GRC that no agency, employment, joint venture, or partnership has been or will be created between ODM and GRC. GRC further agrees that as an independent entity, it assumes all responsibility for any federal, state, municipal or other tax liabilities along with workers compensation, unemployment compensation and insurance premiums that may accrue as a result of funds received pursuant to this work. GRC agrees that it is an independent entity for all purposes including, but not limited to, the application of the Fair Labor Standards Act, the Social Security Act, the Federal Unemployment Tax Act, the Federal Insurance Contribution Act, provisions of the Internal Revenue Code, Ohio tax law, Workers Compensation law, and Unemployment Insurance law.

[REDACTED]

Aimee Nielsen-Link, Director, Health Sciences Office, Office of Sponsored Programs

## 5.2 Evaluation Budget

**Table 4: Evaluation Budget for State Fiscal Years (SFY) 2020-2026**

	SFY 2020	SFY 2021	SFY 2022	SFY 2023	SFY 2024	SFY 2025	SFY 2026
Estimated independent evaluator staff costs*	\$159,816	\$241,592	\$224,212	\$262,743	\$310,100	\$294,759	\$228,525
Estimated other direct costs**	\$50,000	\$50,000	\$50,000	\$50,000	\$125,747	\$50,000	\$50,000
Estimated administrative costs***	\$20,982	\$29,159	\$27,421	\$31,274	\$43,585	\$34,476	\$27,853
<b>Total Estimated Cost</b>	<b>\$230,798</b>	<b>\$320,751</b>	<b>\$301,633</b>	<b>\$344,017</b>	<b>\$479,43</b>	<b>\$379,235</b>	<b>\$306,378</b>

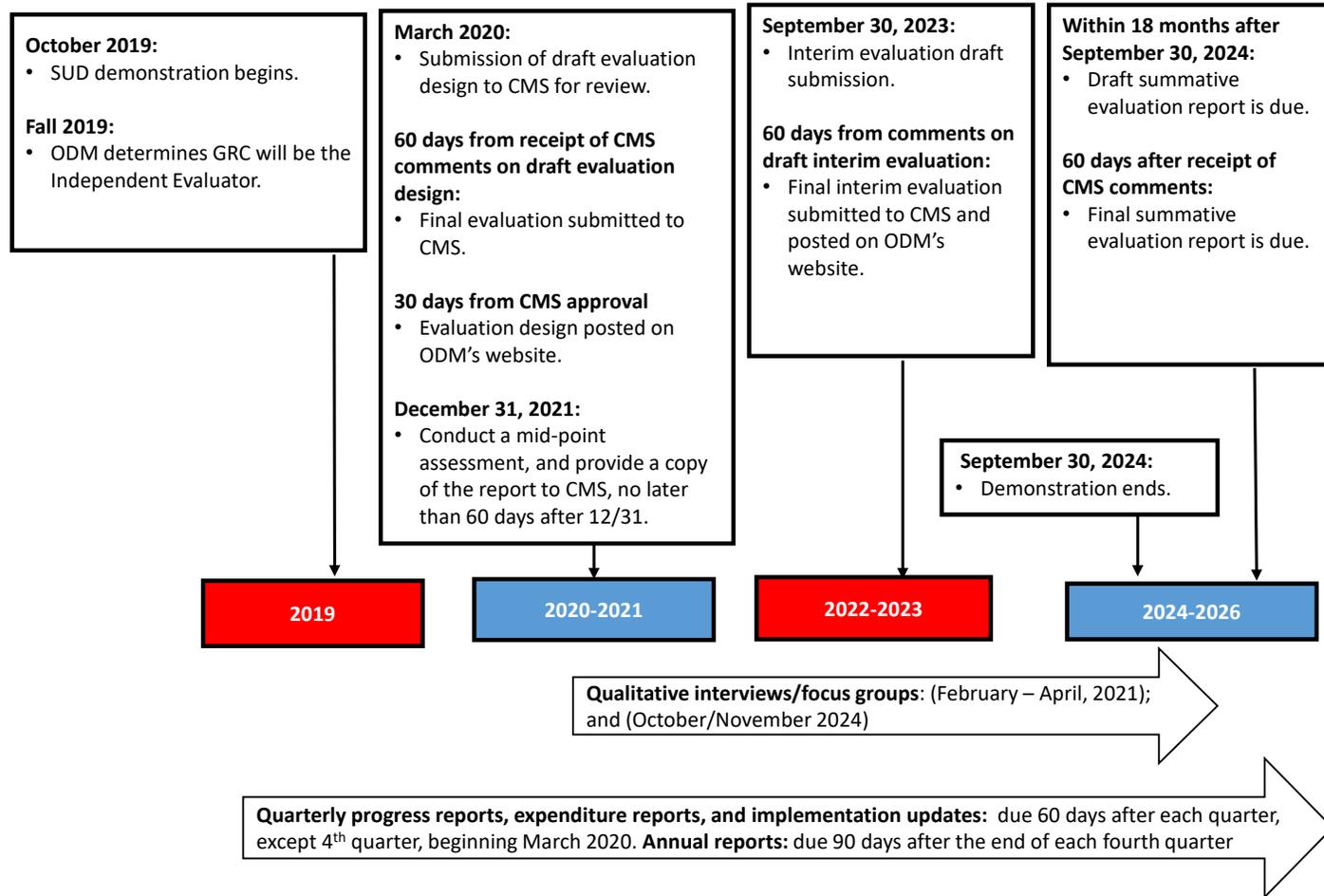
\*Independent evaluator staffing costs

\*\*Subcontractors will complete measurement development, qualitative data collection and cleaning, quantitative data cleaning, analyses, and report generation

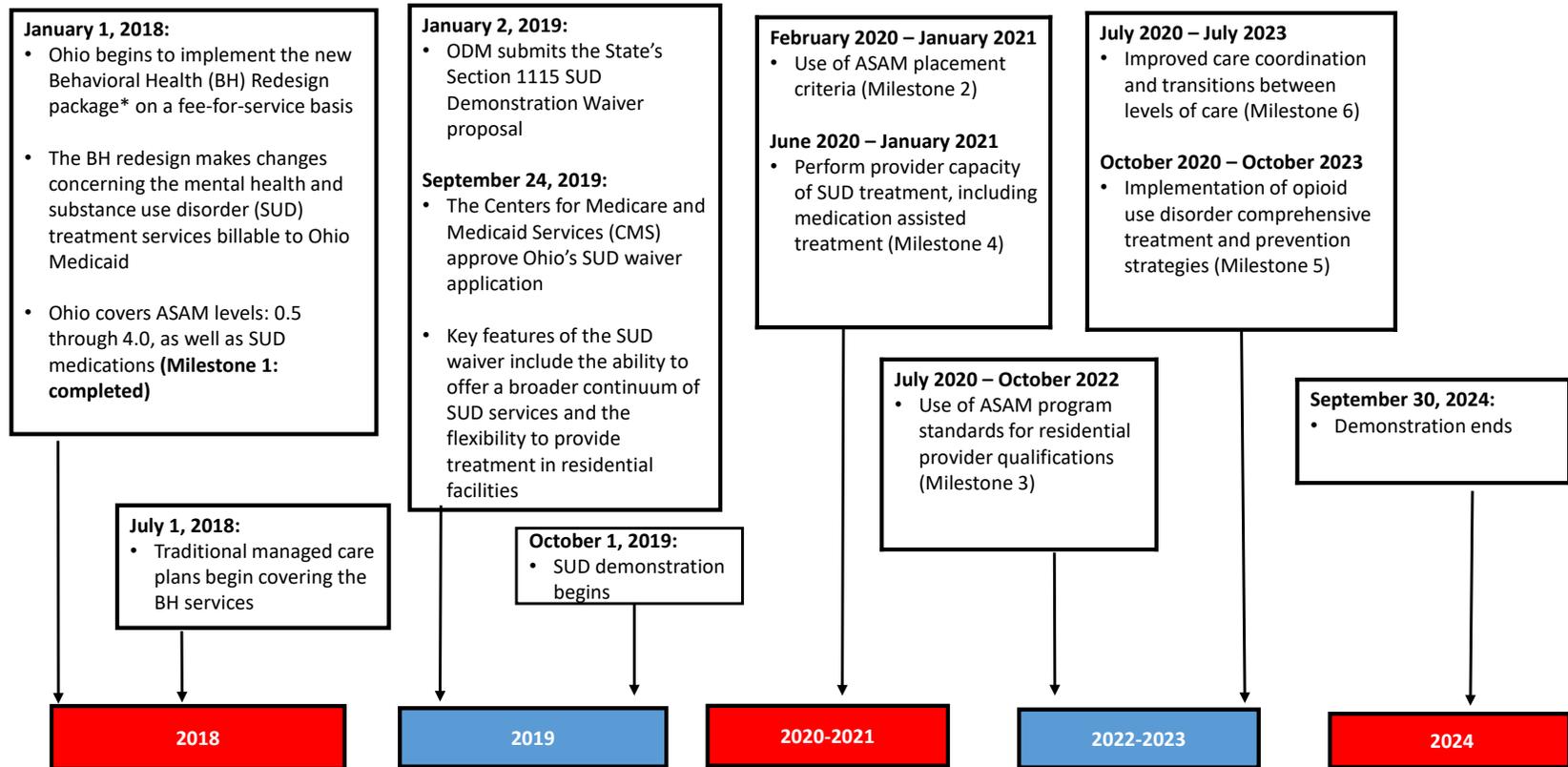
\*\*\*Facilities and Administrative costs

### 5.3 Timeline and Major Milestones

**Figure 5: Evaluation Timeline and Major Milestones**



**Figure 6: Timeline of Ohio Policy Changes**



\*The new BH benefit package was offered to outpatient hospitals beginning August 1, 2017

## 6. Appendix

### 6.1 Common Acronym List

**Table 5: Common Acronym List**

Acronym	Full Name
ASAM	American Society of Addiction Medicine
BH	Behavioral Health
BHCC	Behavioral Health Care Coordination
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
COI	Conflict of Interest
ED	Emergency Department
GEE	Generalized Estimating Equations
GRC	Government Resource Center
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IET	Initiation and Engagement of Alcohol and other Drug Dependence Treatment
IMD	Institutions for Mental Disease
IP	Inpatient
ITS	Interrupted Time Series
LOC	Level of Care
MACPAC	Medicaid and Children's Health Insurance Program Payment and Access Commission
MAT	Medication Assisted Treatment
MHPAEA	Mental Health Parity and Addiction Equity Act
MM	Monitoring Metric
MME	Morphine Milligram Equivalent
MODRN	Medicaid Outcomes Distributive Research Network
MSY	Multi-System Youth
NPI	National Provider Identifier
NPPES	National Plan & Provider Enumeration System
ODM	Ohio Department of Medicaid
ODU	Opioid Use Disorder
PDMP	Prescription Drug Monitoring Program
RT	Residential Treatment
SFY	State Fiscal Year
SUD	Substance Use Disorder
UM	Utilization Management