DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop: S2-26-12
Baltimore, Maryland 21244-1850



November 19, 2026

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

Dear Director Partika:

The Centers for Medicare & Medicaid Services (CMS) is approving Ohio's request to renew its Medicaid section 1115(a) demonstration entitled, "Section 1115 Demonstration Waiver for Substance Use Disorder Treatment" (Project Number 11-W-00330/5), in accordance with section 1115(a) of the Social Security Act (the Act). This approval is effective January 1, 2027, until September 30, 2031, upon which date, unless renewed or otherwise temporarily extended, all authorities granted to operate this demonstration will expire.

CMS has determined that the Ohio Section 1115 Demonstration Waiver for Substance Use Disorder Treatment demonstration is likely to assist in promoting the objectives of the Medicaid statute by increasing access to high-quality, clinically appropriate treatment to beneficiaries with a substance use disorder (SUD) while they are short-term residents in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD). This approval is in alignment with State Medicaid Director Letter (SMDL) #17-003 RE: Strategies to Address the Opioid Epidemic.[1] and will continue the authority from the 2019 demonstration approval without any changes.

CMS's approval of this section 1115(a) demonstration is subject to the limitations specified in the attached expenditure authorities, special terms and conditions (STCs), and any supplemental attachments defining the nature, character, and extent of federal involvement in this project. The state may deviate from the Medicaid state plan requirements only to the extent those requirements have been specifically listed as waived or not applicable to expenditures under the demonstration.

Extent and Scope of the Demonstration Renewal

The demonstration renewal aims to continue providing high quality, evidence-based Opioid Use Disorder (OUD) and other SUD treatment services to short-term residents in residential treatment facilities while also improving care coordination for comorbid physical and behavioral health conditions. With this approval, the demonstration will continue current features with no changes.

[1] https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf

Budget Neutrality

This demonstration project is being renewed using CMS's current approach to determining budget neutrality as described in CMS SMDL #24-003.[2] However, CMS acknowledges that section 71118 of subchapter C of chapter 1 of subtitle B of title VII of Public Law 119-21 the Working Families Tax Cuts (WFTC) legislation adds a new subsection (g) to section 1115 of the Act with budget neutrality requirements that will apply beginning January 1, 2027 to CMS approvals of section 1115 Medicaid demonstration project applications, renewals, or amendments.[3] CMS issued SMDL #26-003[4] on June 11, 2026 to provide states with early notice regarding the changes to budget neutrality that CMS intends to propose to implement subsection 1115(g) of the Act, and expects to provide additional guidance to states on implementation of this provision.

Under SMDL #24-003, issued August 22, 2024, as a condition of demonstration approval, demonstrations must be "budget neutral," meaning the federal costs of the state's Medicaid program with the demonstration cannot exceed what the federal government's Medicaid costs likely would have been in that state absent the demonstration.[5] The demonstration renewal is projected to be budget neutral to the federal government. In practice, budget neutrality generally means that the total computable (i.e., both state and federal) costs for approved demonstration expenditures are limited to a certain amount for the demonstration approval period. This limit is called the budget neutrality expenditure limit and is based on a projection of the Medicaid expenditures that could have occurred absent the demonstration (the "without waiver" [WOW] costs). The state will be held to the budget neutrality monitoring and general financial requirements as outlined in the STCs.

Rebasing Without Waiver Baseline

Under this demonstration, for existing Medicaid Expenditure Groups (MEGs) that were implemented, CMS calculated the WOW baseline by using a weighted average of the state's historical WOW per-member-per-month (PMPM) baseline and its recent actual PMPM costs. The projected demonstration expenditures associated with each MEG in the WOW baseline have been trended forward using the President's Budget trend rate to determine the maximum expenditure authority for the new approval period. Using the President's Budget trend rate aligns the demonstration trend rate with federal budgeting principles and assumptions.

Mid-Course Correction

CMS has included a mid-course corrections STC in this demonstration approval to provide flexibility and stability for the state over the life of a demonstration. This update identifies a list of circumstances under which a state's baseline may be adjusted based on actual expenditure data to accommodate circumstances that are either out of the state's control (for example, if expensive new drugs that the state is required to cover enter the market); and/or the effect is not a condition or consequence of the demonstration (for example, unexpected costs due to a public health emergency); and/or the new expenditure (while not a new demonstration-covered service

[2] https://www.medicaid.gov/federal-policy-guidance/downloads/smd24003.pdf
[3] https://www.congress.gov/bill/119th-congress/house-bill/1/text
[4] https://www.medicaid.gov/federal-policy-guidance/downloads/smd26003.pdf
[5] https://www.medicaid.gov/medicaid/section-1115-demonstrations/budget-neutrality/index.html

or population that would require the state to propose an amendment to the demonstration) is likely to further strengthen access to care (for example, a legislated increase in provider rates). CMS also explains in the STCs what data and other information the state should submit to support a potentially approvable request for an adjustment.

Monitoring and Evaluation

Consistent with the demonstration STCs, the state submitted with the renewal application its Interim Evaluation Report (IER)[6] for the prior demonstration approval period, which was approved from October 1, 2019 through September 30, 2024, and temporarily extended through December 31, 2026. The IER covered the period from October 1, 2019 through September 30, 2023, with baseline data from January 1, 2017 through September 30, 2019. The state continued systematic monitoring during the approval period, including a mid-point assessment and annual monitoring reports. Based on the evaluation and monitoring findings, CMS determined that the state is making progress towards its demonstration goals and also identified areas for continued monitoring and improvement.

Overall, the IER findings were positive, with most metrics trending in the desired direction, although many findings were not statistically significant. Notably, interrupted time series analyses found that the demonstration was associated with a statistically significant reduction in the utilization of emergency department (ED) and inpatient psychiatric hospital settings for opioid use disorder and other SUD diagnoses. Rates of overdose deaths and opioid overdose deaths generally trended downward from 2020 through 2023. However, the IER noted a statistically significant decline in the trend for early engagement in SUD treatment after a peak in early 2020. The state noted that the decline coincided with the onset of the COVID-19 pandemic. Key informant interviews found that stakeholders generally supported the demonstration, while also providing insights into challenges in implementation. Some stakeholders noted that while provider capacity in urban settings was more than adequate, provider capacity at different levels of care in rural settings was often inadequate or had gaps. However, the expansion of telehealth was consistently cited as a positive method for expanding access to lower levels of care. Additionally, a lack of access to appropriate recovery housing was consistently identified as one of the most important barriers to SUD treatment and long-term recovery.

Recent monitoring findings generally indicate continued progress toward the demonstration goals, while also identifying areas warranting continued attention. The Annual Monitoring Report covering the period from October 1, 2024 to September 30, 2025 indicates that utilization of ED and inpatient psychiatric hospital settings for opioid use disorder and other SUD diagnoses remained stable and that the number of available SUD providers increased by three percent compared to the previous demonstration year. Other findings were more mixed. For example, the annual number of Medicaid beneficiaries with an SUD diagnosis decreased by two percent, which the state attributes to the end of the eligibility redetermination period. The number of beneficiaries receiving inpatient or residential treatment in an IMD increased by 2.5 percent, which the state interprets as reflecting increased access to IMD treatment services. The report

[6] The approved Interim Evaluation Report can be found at: https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/oh-sbstnce-dsrdr-trtmnt-cms-approved-sud-interim-evltn-rpt-03202025.pdf.

also identifies data-quality and linkage issues affecting overdose mortality reporting; the state is developing a process to address these issues by December 2026.

With this renewal of the demonstration, the state is required to continue conducting systematic monitoring and robust evaluation of the demonstration, consistent with the requirements of the STCs and applicable CMS guidance. An Annual Monitoring Report capturing key metrics and narrative updates will be due to CMS 180 days after the end of each demonstration year. The state must also conduct an independent mid-point assessment of the SUD demonstration initiatives, to identify risks and vulnerabilities and inform subsequent mitigation strategies. In addition, the state must continue evaluating the demonstration to build on the findings to date and further assess the effectiveness of the demonstration in achieving the intended outcomes for its beneficiaries and providers, as well as the state's overall Medicaid program. The state is required to develop well-crafted hypotheses and research questions for all key demonstration policy components, as described in the STCs.

Consideration of Public Comments

CMS posted the application on Medicaid.gov for a 30-day federal public comment period from April 11, 2024, through May 11, 2024. CMS received four written comments. All comments were supportive of the renewal; however, two comments also offered additional suggestions.

In addition to applauding inclusion of HIV screening as a post-intervention impact measurement in the demonstration evaluation criteria, one commenter also encouraged CMS and Ohio to add HIV Pre-Exposure Prophylaxis (PrEP) counseling and prescribing as an implementation activity. Another commenter recommended that the state establish protocols for the treatment of co-morbid health conditions during the inpatient stay, including those related to pregnancy and the postpartum period. CMS has communicated these recommendations to the state. The state shared it is reviewing available data to determine if additional information could be provided in future Annual Monitoring Reports, and CMS will continue to engage with the state through ongoing demonstration monitoring, as appropriate.

After careful review of the public comments submitted during the federal comment period and information received from the state public comment period, CMS has concluded that demonstration renewal is likely to promote the objectives of Medicaid.

Program Integrity

States are responsible for following all applicable federal law and regulations when they claim and use federal Medicaid funds and must fully comply with all applicable Medicaid statutes and regulations under a section 1115 demonstration, except where specific provisions have been expressly waived or identified as not applicable for that demonstration. This obligation includes all requirements in title XIX of the Act and implementing regulations governing provider screening and enrollment activities, pre- and post-payment review claiming, payment methodologies and rate-setting, utilization controls, and program integrity including processes to identify, investigate, and refer suspected fraud, and methods to receive complaints and identify questionable practices. States must maintain effective systems and safeguards to prevent, detect, and address any fraud, waste, or abuse (FWA) in the delivery of and payment for Medicaid services, including referrals to law enforcement when appropriate.

States should have heightened monitoring and oversight mechanisms in place featuring robust internal controls to identify and remediate all vulnerabilities (including, but not limited to, FWA and beneficiary access issues) inherent in service areas approved as part of a demonstration. At any time, CMS may request that the state provide a plan detailing the state's systems and safeguards to prevent, detect, and address any FWA relative to this demonstration. Failure to meet program integrity obligations under federal statutes and regulations or under the terms and conditions of this demonstration approval may result in compliance actions or other enforcement measures that could include requirements to develop and implement corrective action plans, withholdings, deferrals, disallowances, and termination of demonstration authority.

Other Information

CMS's approval of this renewal is conditioned upon compliance with the enclosed set of expenditure authorities and STCs defining the nature, character and extent of anticipated federal involvement in the demonstration. The award is subject to CMS receiving written acceptance of this award within 30 days of the date of this approval letter. Your project officer for this demonstration is Laura Gray, who is available to answer any questions concerning your section 1115 demonstration and her contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
Email: Laura.Gray@cms.hhs.gov

If you have questions regarding this approval, please contact Sarah Aker, Acting Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Sincerely,

[redacted]

Dan Brillman
Deputy Administrator, CMS
Director, Center for Medicaid and CHIP Services

Enclosure

cc: Keri Rosenbloom, State Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: 11-W00330/5

TITLE: Ohio Section 1115 Demonstration Waiver for Substance Use Disorder Treatment

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 January 1, 2027 through September 30, 2031, 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.

Title XIX Expenditure Authority:

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

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

NUMBER: 11-W00330/5

TITLE: Ohio Section 1115 Demonstration Waiver for Substance Use Disorder Treatment

AWARDEE: Ohio Department of Medicaid

1. PREFACE

The following are the Special Terms and Conditions (STCs) for the "Ohio 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 authority 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 populations affected by the demonstration are effective from January 1, 2027 through September 30, 2031, unless otherwise specified.

The STCs have been arranged into the following subject areas:

1	Preface
2	Program Description and Objectives
3	General Program Requirements
4	Eligibility and Enrollment
5	Substance Use Disorder (SUD) Program and Benefits
6	Cost Sharing
7	Delivery System
8	Monitoring and Reporting Requirements
9	Evaluation of the Demonstration
10	General Financial Requirements
11	Monitoring Budget Neutrality for the Demonstration
12	Schedule of Deliverables for the Demonstration Period

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

Attachment A	SUD Implementation Plan
Attachment B	SUD Evaluation Design (Reserved)

2. PROGRAM DESCRIPTION AND OBJECTIVES

In this demonstration, the state will maintain and enhance access to opioid use disorder (OUD) and other substance use disorder (SUD) services and continue delivery system improvements for these services 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 SUD while they are short-term residents in residential and inpatient treatment settings that qualify as an IMD. It will also support state efforts to enhance provider capacity, improve the availability of Medication Assisted Treatment (MAT) and improve access to a continuum of SUD evidence-based services at varied levels of intensity, including withdrawal management services.

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

1	Increase rates of identification, initiation, and engagement in treatment for SUD
2	Increase adherence to and retention in treatment
3	Reduce overdose deaths, particularly those due to opioids
4	Reduce 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
6	Improve access to care for physical health conditions among beneficiaries with SUD

3. GENERAL PROGRAM REQUIREMENTS

3.1. **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).

3.2. **Compliance with Medicaid and Children's 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 expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3.3. **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 3.7. 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.

3.4. **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 3.7 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.

3.5. **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.

3.6. **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 3.7 below, except as provided in STC 3.3.

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 3.12. 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 monitoring reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

3.8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor 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 a phase-out plan consistent with the requirements of STC 3.9.

3.9. **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 3.12, 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 redeterminations 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 redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 435.916(d)(1). For individuals determined ineligible for Medicaid and CHIP, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e). The state must comply with all applicable advance notice requirements and fair hearing rights described at 42 CFR part 431, subpart E. 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.

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.

3.10. **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.

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

3.12. **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 3.7 or extension, are proposed by the state.

3.13. **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.

3.14. **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.

3.15. **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).

4. ELIGIBILITY AND ENROLLMENT

4.1. **Eligibility Groups Affected by the Demonstration.** Under the demonstration, there is no change to Medicaid eligibility and the standards and methodologies for eligibility remain set forth under the state plan.

5. SUBSTANCE USE DISORDER (SUD) PROGRAM AND BENEFITS

5.1. **SUD Program Benefits.** The demonstration benefit package for Medicaid beneficiaries will include SUD treatment services, including services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state is eligible to receive FFP for Medicaid beneficiaries who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including SUD services, that would otherwise be matchable if the beneficiary were not residing in an IMD. The state will aim for a statewide average length of stay of 30 days or less in residential treatment settings, to be monitored pursuant to STC 8.5 below, to ensure short-term residential stays.

Under this demonstration, beneficiaries will have access to high quality, evidence-based SUD treatment services across a comprehensive continuum of care, ranging from residential and inpatient treatment to ongoing care for these conditions in cost-effective community-based settings.

5.2. **SUD Implementation Plan.** The state's SUD implementation plan, initially approved for the period October 1, 2019 through December 31, 2026, remains in effect for the approval period from January 1, 2027 through September 30, 2031, and is affixed to the STCs as Attachment A. Any future modifications to the approved Implementation Plan will require CMS approval. Failure to progress in meeting the milestones agreed upon by the state and CMS will result in a funding deferral as described in STC 8.1. The approved SUD Implementation Plan describes the strategic approach and a 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:

a. Access to Critical Levels of Care for OUD and other SUDs**.** Coverage of SUD treatment services across a comprehensive continuum of care including: outpatient; intensive outpatient; medication assisted treatment (medication as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state); intensive levels of care in residential and inpatient settings; and medically supervised withdrawal management;

b. Use of Evidence-based SUD-specific Patient Placement Criteria**.**

1. Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines;

2. Utilization Management. 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;

c. Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities.

1. Implementation of residential treatment provider qualifications. 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, 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;

2. 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;

3. Availability of MAT. Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site;

d. Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for SUD/OUD. 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;

e. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/OUD.

1. Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse;

2. Expand coverage of and access to naloxone for overdose reversal;

3. Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;

f. 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;

g. SUD Health IT Plan. Implementation of a Substance Use Disorder Health Information Technology Plan which describes technology that will support the aims of the demonstration. Further information which describes milestones and metrics are detailed in STC 5.3 or Attachment A.

5.3. **SUD Health Information Technology Plan ("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 Health IT Plan, to be included as a section of the associated SUD Implementation Plan (see STC 5.2[g]), to develop infrastructure and capabilities consistent with the requirements outlined in each demonstration-type.

The Health IT Plan should describe how technology can support outcomes through care coordination; linkages to public health and prescription drug monitoring programs; establish data and reporting structures to monitor outcomes and support data driven interventions. Such technology should, per 42 CFR 433.112(b), use open interfaces and exposed application programming interfaces and ensure alignment with, and incorporation of, standards adopted by the Assistant Secretary for Technology/ Office of the National Coordinator for Health IT (ASTP/ONC) in accordance with 42 CFR part 170, subpart B.

The state's Health IT Plan, initially approved for the period from October 1, 2019 through December 31, 2026, remains in effect for the approval period from January 1, 2027 through September 30, 2031 and is affixed to the STCs as Attachment A.

a. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines–and report on its progress to CMS within its Annual Report (see STC 8.5).

b. As applicable, the state should advance the HHS adopted standards in 45 CFR 170 Subpart B 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.[1]

c. 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 to acquire, upgrade, or implement health IT that can be supported by standards referenced in 45 CFR 170 Subpart B, the state should use the federally recognized standards.

[1] Where the plan involves health IT that is acquired, upgraded, or implemented by health care providers that have been eligible for CMS incentives to adopt health IT certified under the ONC Health IT Certification Program, states should advance the use of certified health IT, as applicable. Certified health IT incorporates the standards in 45 CFR 170 Subpart B.

d. Where there are opportunities at the state- and provider-level to leverage federal funds to acquire, upgrade, or implement health IT that cannot be supported associated with a standard not already referenced in 45 CFR 170 Subpart B, the state should seek to use other non-proprietary standards and implementation specifications developed by consensus-based standards development organizations. This may include standards identified in the ASTP/ ONC Interoperability Standards Advisory (ISA).[2]

e. Specific components of the Health IT Plan include:

1. The Health IT Plan must describe the state's alignment with Section 5042 of the SUPPORT Act requiring Medicaid providers to query a Qualified Prescription Drug Monitoring Program (PDMP).[3]
2. The Health IT Plan must address how the state's Qualified PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[3] States should favor procurement strategies that incorporate Qualified PDMP data into electronic health records as discrete data without added interface costs to Medicaid providers, leveraging existing federal investments in open interfaces and exposed application program interfaces.
3. The Health IT Plan will describe how technology will support substance use disorder prevention and treatment outcomes described by the demonstration.

5.4. **Unallowable Expenditures Under the SUD Expenditure Authority.** The state may not receive FFP for room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(s) of the Act.

6. COST SHARING

6.1. **Cost Sharing.** Cost sharing imposed upon individuals enrolled in the demonstration is consistent with the provisions of the approved Medicaid state plan.

7. DELIVERY SYSTEM

7.1. **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.

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[2] https://www.healthit.gov/isp/

[3] 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.

8. MONITORING AND REPORTING REQUIREMENTS

8.1. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the demonstration 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) 30 calendar 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) 30 calendar 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. The extension request must explain the reason why the required deliverable was not submitted, the steps the state has taken to address such issue, and the state's anticipated date of submission. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided. CMS may agree to a corrective action plan as an interim step before applying the deferral, if a corrective action plan is proposed in the state's written extension request.

c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) that meets 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 for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables

will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

8.2. **Deferral of Federal Financial Participation 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 Annual Monitoring Report. Once CMS determines the state has not made adequate progress, up to $5,000,000 will be deferred in the next calendar year and each calendar year thereafter until CMS has determined sufficient progress has been made.

8.3. **Submission of Post-Approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs, unless CMS and the state mutually agree to another timeline.

8.4. **Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional section 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 section 1115 demonstration, 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.

8.5. **Monitoring Reports**. The state must submit one Annual Monitoring Report each demonstration year (DY) that is due no later than 180 calendar days following the end of the DY. The state must submit a revised Annual Monitoring Report within 60 calendar days after receipt of CMS's comments, if any. CMS might increase the frequency of monitoring reporting if CMS determines that doing so would be appropriate. CMS will make on-going determinations about reporting frequency under the demonstration by assessing the risk that the state might materially fail to comply with the terms of the approved demonstration during its implementation and/or the risk that the state might implement the demonstration in a manner unlikely to achieve the statutory purposes of Medicaid. See 42 CFR 431.420(d)(1)-(2).

The Annual Monitoring Report 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 Annual Monitoring Report must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve and must be provided in a structured manner that supports federal tracking and analysis.

a. **Operational Updates**. Per 42 CFR 431.428, the Annual Monitoring Report must document any policy or administrative difficulties in operating the demonstration. The Annual Monitoring Report must provide sufficient information to document key operational and other challenges, underlying causes of challenges, and 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 Annual 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 the state's progress towards meeting the demonstration's goals and any applicable milestones. Per 42 CFR 431.428, the Annual Monitoring Report must document the impact of the demonstration on beneficiaries' outcomes of care, quality and overall cost of care, and access to care, as applicable. This should also include the results of beneficiary satisfaction or experience of care surveys, if conducted, as well as grievances and appeals. The Annual Monitoring Report must provide detailed information about deviations from CMS's applicable metrics technical specifications, relevant methodology, plans for phasing in metrics, and data or reporting issues for applicable metrics, in alignment with CMS guidance and technical assistance.

   The state and CMS will work collaboratively to finalize the list of metrics to be reported on in the Annual Monitoring Report. The demonstration's monitoring metrics must cover categories to include, but not be limited to, eligibility, utilization of services, quality of care and health outcomes, and grievances and appeals. The state must report these metrics for all demonstration populations. Demonstration monitoring reporting does not duplicate or replace reporting requirements for other authorities, such as Home and Community Based Services and Managed Care authorities.

   In addition, the state is expected to report monitoring metrics for the following demonstration initiative(s), as described below and per applicable CMS guidance:

   1. For the SUD component(s), the state's monitoring must cover metrics in alignment with CMS guidance and the demonstration's milestones as outlined in the SUD State Medicaid Director Letter (SMDL) dated November 1, 2017 (SMD #17–003).

   The reporting of these monitoring metrics may also be stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, or geography) and by demonstration component, as appropriate. Subpopulation reporting can support identifying any gaps in quality of care and health outcomes, and help track whether the demonstration's initiatives help improve outcomes for the state's Medicaid population.

c. **Evaluation Activities and Interim Findings.** Per 42 CFR 431.428, the Annual Monitoring Report 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.

8.6. **SUD Mid-Point Assessment.** The state must contract with an independent entity (herein referred to as the Independent Assessor) to conduct an Independent Mid-Point Assessment and submit to CMS by September 30, 2029. This timeline will allow for the Mid-Point Assessment to capture approximately the first two and a half years of program data, accounting for data run-out and data completeness. In addition, if applicable, the state should use the prior approval period experiences as context, and conduct the Mid-Point Assessment in light of the data from any such prior approval period(s). In the design, planning and execution of the Mid-Point Assessment, the state must require that the Independent Assessor consult with key stakeholders such as, representatives of MCOs, health care providers, beneficiaries, community groups, and other key partners.

a. The state must require that the assessor provide a Mid-Point Assessment to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations, and any recommendations. If requested, the state must brief CMS on the Mid-Point Assessment. The state must submit a revised Mid-Point Assessment within 60 calendar days after receipt of CMS's comments, if any.

Elements of the Mid-Point Assessment include:

1. An examination of progress toward meeting each milestone and timeframe approved in the Implementation Plan. ;
2. A determination of factors that affected achievement on the milestones and performance metric gap closures to date;
3. 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;
4. For milestones or targets identified by the Independent Assessor as at medium to high risk of not being met, recommendations for adjustments in the state's Implementation Plan or to pertinent factors that the state can influence that will support improvement.

8.7. **Corrective Action Plan Related Monitoring.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS might withdraw an authority, as described in STC 3.10, if metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals

and desired directionality, and the state has not implemented corrective action, and the circumstances described in STC 3.10 are met. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

8.8. **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 Close-Out Report must comply with the most current guidance from CMS.

b. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim or Summative Evaluation Reports stipulated in STCs 9.7 and 9.8, respectively.

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

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

e. A revised Close-Out Report is due to CMS no later than 30 calendar days after receipt of CMS' comments.

f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 8.1.

8.9. **Monitoring Calls**. CMS will convene, no less frequently than quarterly, monitoring calls with the state.

a. The purpose of these calls is to discuss ongoing demonstration operations and implementation which align with the state's demonstration monitoring reports, including (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, eligibility and access, and progress on evaluation activities.

b. These calls will follow the structure of and focus on the topics in the Annual Monitoring Report.

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

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

8.10. **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six 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 30 calendar 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 Monitoring Report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the public comments in the Annual Monitoring Report associated with the year in which the forum was held.

9. EVALUATION OF THE DEMONSTRATION

9.1. **Cooperation with Federal Evaluators and Learning Collaborative.** As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents 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 shall include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they shall make such data available for the federal evaluation as is required under 42 CFR 431.420(f). This may also include the state's participation—including representation from the state's contractors, independent evaluators, and organizations associated with the demonstration operations, as applicable—in a federal learning collaborative aimed at cross state technical assistance, and identification of lessons learned and best practices for demonstration measurement, data development, implementation, monitoring, and 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 8.1.

9.2. **Independent Evaluator.** The state must use an independent entity (herein referred to as the Independent Evaluator) 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 Independent Evaluator must sign an agreement to conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

9.3. **Evaluation Design.** The state must submit, for CMS comment and approval, an Evaluation Design with implementation timeline no later than 180 calendar days after the approval of the demonstration. The Evaluation Design must be developed in accordance with the STCs and any applicable CMS evaluation guidance and technical assistance for the demonstration's policy components. The Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations.

The state is strongly encouraged to use the expertise of the Independent Evaluator in the development of the Evaluation design. The Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STC 9.7 and 9.8.

For any amendment to the demonstration, the state will be required to update the approved Evaluation Design to accommodate the amendment component, unless otherwise agreed upon by the state and CMS. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS's approval of the demonstration amendment. The amendment components of the Evaluation Design must also be reflected in the state's Interim and Summative Evaluation Reports, described below.

9.4. **Evaluation Design Approval and Updates.** The state must submit a revised Evaluation Design within 60 calendar days after receipt of CMS' comments, if any. Upon CMS approval of the Evaluation Design, the document will be posted to Medicaid.gov. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within 30 calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation progress in each Annual Monitoring Report. Once CMS approves the Evaluation Design, if the state wishes to make changes, and the changes are substantial in scope, the state must submit a revised Evaluation Design to CMS for approval; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in an Annual Monitoring Report.

9.5. **Evaluation Questions and Hypotheses.** Consistent with the STCs, and applicable CMS guidance, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding of the demonstration's impact and its effectiveness in achieving the demonstration's goals.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study outcomes, such as eligibility and various measures of access, utilization, costs, and health outcomes, as appropriate and in alignment with applicable CMS evaluation guidance and technical assistance for the demonstration policy components. The evaluation is expected to use applicable demonstration monitoring and other data on the provision of and beneficiary utilization of demonstration and other applicable services. Proposed measures should be selected from nationally recognized sources and national measures sets, where possible. Measures sets could include the Consumer Assessment of Health Care Providers and Systems (CAHPS); the Medicaid and CHIP Core Sets of Health Care Quality measures, commonly referred to as the Child and Adult Core Sets, the Behavioral Risk Factor Surveillance System (BRFSS) surveyor measures endorsed by National Quality Forum (NQF).

The state must develop robust evaluation questions and hypotheses related to each demonstration initiative, and per applicable CMS guidance. Specifically:

a. Hypotheses for the SUD component of the demonstration must align with the goals of the program, including increasing rates of identification and initiation of and engagement in treatment as well as adherence to and retention in treatment, reducing overdose deaths, reducing utilization of emergency departments and inpatient hospitalizations as well as readmissions to the same or higher levels of care, and improving access to care for physical health conditions.

As part of its evaluation efforts, the state must also conduct an overall demonstration cost assessment to include, but not be limited to, administrative costs of demonstration implementation and operation and Medicaid health services expenditures. In addition, the state must use findings from hypothesis tests aligned with other demonstration goals and cost analyses to assess the demonstration's effects on the fiscal sustainability of the state's Medicaid program.

CMS underscores the importance of the state undertaking a well-designed beneficiary survey or interviews to assess, for instance, beneficiary understanding of the demonstration policy components and beneficiary experiences with access to and quality of care. To better understand whether implementation of certain key demonstration policies happened as envisioned during the demonstration design process and whether specific factors acted as facilitators of—and barriers to—implementation, the state is strongly encouraged to undertake a robust process/implementation evaluation. The implementation evaluation can inform the state's crafting and selection of testable hypotheses and research questions for the demonstration's outcome and impact evaluations and provide context for interpreting the findings.

Finally, the state may collect data to support analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, or geography). Such stratified data analyses can provide a fuller understanding of gaps in access to and quality of care and health outcomes, as well as help inform how the demonstration's various policies support improving outcomes.

9.6. **Evaluation Budget.** A budget for the evaluations must be provided with the 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 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.

9.7. **Interim Evaluation Report.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). The draft Interim Evaluation Report must be developed in alignment with the approved Evaluation Design, and in accordance with the requirements outlined in these STCs and applicable CMS guidance.

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

b. For demonstration authority or any component within the demonstration that expires prior to the overall demonstration's expiration date, and depending on the timeline of the expiration/phase-out, the Interim Evaluation Report must include an evaluation of the authority, to be collaboratively determined by CMS and the state.

c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. When applying for an extension of the demonstration, the Interim Evaluation Report should be posted to the state's website with the application for public comment. If the state does not request an extension for the demonstration, the Interim Evaluation Report is due one year prior to the end of the demonstration. For demonstration phase-outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

d. The state must submit a revised Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report, if any.

e. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website within 30 calendar days.

9.8. **Summative Evaluation Report.** The state must submit the 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 draft Summative Evaluation Report must be developed in alignment with the approved Evaluation Design, and in accordance with the requirements outlined in these STCs and applicable CMS guidance. .

a. The state must submit a revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft Summative Evaluation Report, if any.

b. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within 30 calendar days.

9.9. **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 an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

9.10. **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, or the Summative Evaluation Report.

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

9.12. **Additional Publications and Presentations.** For a period of 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 30 calendar 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.

10. GENERAL FINANCIAL REQUIREMENTS

10.1. **Allowable Expenditures.** This demonstration project is approved for authorized demonstration expenditures applicable to services rendered and for costs incurred during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.

10.2. **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.

10.3. **Sources of Non-Federal Share.** As a condition of demonstration approval, the state certifies that its funds that make up the non-federal share are obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that federal funds provided under this section 1115 demonstration must not be used as the non-federal share required under any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of

any underlying source of non-federal share or associate funding mechanisms, and all all sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable implementing regulations. CMS reserves the right to deny FFP in expenditures for which it determines that the sources of non-federal share are impermissible.

a. If requested, the state must submit for CMS review and approval documentation of any sources of non-federal share that would be used to support payments under the demonstration.

b. If CMS determines that any funding sources are not consistent with applicable federal statuses or regulations, the state must address CMS's concerns within the time frames allotted by CMS.

c. Without limitation, CMS may request information about the non-federal share sources for any amendments that CMS determines may financially impact the demonstration.

10.4. **State Certification of Funding Conditions.** As a condition of demonstration approval, the state certifies that the following conditions for non-federal share financing of demonstration expenditures have been met:

a. If units of state or local government, including health care providers that are units of state or local government, supply any funds used as non-federal share for expenditures under the demonstration, the state must certify that state or local monies have been expended as the non-federal share of funds under the demonstration in accordance with section 1903(w) of the Act and applicable implementing regulations.

b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the non-federal share of expenditures under the demonstration, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, by which the state identifies those costs eligible for purposes of certifying public expenditures. The certifying unit of government that incurs costs authorized under the demonstration must certify to the state the amount of public funds allowable under 42 CFR 433.51 it has expended. The federal financial participation paid to match CPEs may not be used as the non-federal share to obtain additional federal funds, except as authorized by federal law, consistent with 42 CFR 433.51(c).

c. The state may use intergovernmental transfers (IGT) to the extent that the transferred funds are public funds within the meaning of 42 CFR 433.51 and are transferred by units of government within the state. Any transfers from units of government to support the non-federal share of expenditures under the demonstration must be made in an amount not to exceed the non-federal share of the expenditures under the demonstration.

d. Under all circumstances, health care providers must retain 100 percent of their payments for or in connection with furnishing covered services to beneficiaries. Moreover, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments, or third parties to return and/or redirect to the state any portion of the Medicaid payments in a manner inconsistent with the requirements in Section 1903(w) of the Act and its implementing regulations. 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.

   The State Medicaid Director or his/her designee certifies that all state and/or local funds used as the state's share of the allowable expenditures reported on the CMS-64 for this demonstration were in accordance with all applicable federal requirements and did not lead to the duplication of any other federal funds.

10.5. **Financial Integrity for Managed Care Delivery Systems.** As a condition of demonstration approval, the state attests to the following, as applicable:

a. All risk-based managed care organization, prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) payments, comply with the requirements on payments in 42 CFR 438.

b. For non-risk-based PIHPs and PAHPs, arrangements comply with the upper payment limits specified in 42 CFR 447.362, and if payments exceed the cost of services, the state will recoup the excess and return the federal share of the excess to CMS.

10.6. **Requirements for Health Care-Related Taxes and Provider Donations.** As a condition of demonstration approval, the state attests to the following, as applicable:

a. Except as provided in paragraph (c) of this STC, all health care-related taxes as defined by Section 1903(w)(3)(A) of the Act and 42 CFR 433.55 are broad-based as defined by Section 1903(w)(3)(B) of the Act and 42 CFR 433.68(c).

b. Except as provided in paragraph (c) of this STC, all health care-related taxes are uniform as defined by Section 1903(w)(3)(C) of the Act and 42 CFR 433.68(d).

c. If the health care-related tax is either not broad-based or not uniform, the state has applied for and received a waiver of the broad-based and/or uniformity requirements as specified by 1903(w)(3)(E)(i) of the Act and 42 CFR 433.72.

d. The tax does not contain a hold harmless arrangement as described by Section 1903(w)(4) of the Act and 42 CFR 433.68(f).

e. All provider-related donations as defined by 42 CFR 433.52 are bona fide as defined by Section 1903(w)(2)(B) of the Social Security Act, 42 CFR 433.66, and 42 CFR 433.54.

10.7. **State Monitoring of Non-federal Share.** If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS regarding payments under the demonstration no later than 60 days after demonstration approval. This deliverable is subject to the deferral as described in STC 8.1. This report must include:

a. A detailed description of and a copy of (as applicable) any agreement, written or otherwise agreed upon, regarding any arrangement among the providers including those with counties, the state, or other entities relating to each locality tax or payments received that are funded by the locality tax;

b. Number of providers in each locality of the taxing entities for each locality tax;

c. Whether or not all providers in the locality will be paying the assessment for each locality tax;

d. The assessment rate that the providers will be paying for each locality tax;

e. Whether any providers that pay the assessment will not be receiving payments funded by the assessment;

f. Number of providers that receive at least the total assessment back in the form of Medicaid payments for each locality tax;

g. The monitoring plan for the taxing arrangement to ensure that the tax complies with section 1903(w)(4) of the Act and 42 CFR 433.68(f); and

h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under section 1903(w) of the Act.

10.8. **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 following demonstration expenditures, subject to the budget neutrality expenditure limits described in section 11:

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.

10.9. **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.

10.10. **Medicaid Expenditure Groups.** Medicaid Expenditure Groups (MEG) 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 Master MEG Chart table provides a master list of MEGs defined for this demonstration.

Table 1: Master MEG Chart

MEG	Which BN Test Applies?	WOW Per Capita	WOW Aggregate	WW	Brief Description
Managed Care IMD Services	Hypo	X		X	All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to individuals who receive services via managed care
FFS IMD Services	Hypo	X		X	All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to individuals who receive services via FFS

BN – budget neutrality; MEG – Medicaid expenditure group; WOW – without waiver; WW – with waiver

10.11. **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), or line 7. 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. 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 MEG Charts and in the STCs in section 12, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

e. **Member Months.** Using the Budget Neutrality Monitoring Tool, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting 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 2: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
Managed Care IMD Services	All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to individuals who receive services via managed care	Refer to STC #5.4 Unallowable Expenditures	Follow CMS-64.9 Base Category of Service Definitions	Date of service	MAP	Y	10/1/19	9/30/31
FFS IMD Services	All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to individuals who receive services via FFS	Refer to STC #5.4 Unallowable Expenditures	Follow CMS-64.9 Base Category of Service Definitions	Date of service	MAP	Y	10/1/ 19	9/30/31
ADM	Report all additional administrative costs that are directly attributable to the demonstration and are not described elsewhere and are not subject to budget neutrality		Follow standard CMS 64.10 Category of Service Definitions	Date of payment	ADM	N	10/1/19	9/30/31

ADM – administration; DY – demonstration year; MAP – medical assistance payments; MEG – Medicaid expenditure group

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

Table 3: Demonstration Years

Demonstration Year 9	January 1, 2027 to September 30, 2027	9 months
Demonstration Year 10	October 1, 2027 to September 30, 2028	12 months

Demonstration Year 11	October 1, 2028 to September 30, 2029	12 months
Demonstration Year 12	October 1, 2029 to September 30, 2030	12 months
Demonstration Year 13	October 1, 2030 to September 30, 2031	12 months

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

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

b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

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

audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

10.15. **Budget Neutrality Mid-Course Correction Adjustment Request.** No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

a. **Contents of Request and Process**. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 10.15.c. If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. After acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 3.7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

b. **Types of Allowable Changes.** Adjustments will be made only for actual costs as reported in expenditure data. CMS will not approve mid-demonstration adjustments for anticipated factors not yet reflected in such expenditure data. Examples of the types of mid-course adjustments that CMS might approve include the following:

1. Provider rate increases that are anticipated to further strengthen access to care;
2. CMS or state technical errors in the original budget neutrality formulation applied retrospectively, including, but not limited to the following: mathematical errors, such as not aging data correctly; or unintended omission of certain applicable costs of services for individual MEGs;
3. Changes in federal statute or regulations, not directly associated with Medicaid, which impact expenditures;
4. State legislated or regulatory change to Medicaid that significantly affects the costs of medical assistance;
5. When not already accounted for under Emergency Medicaid 1115 demonstrations, cost impacts from public health emergencies;
6. High-cost innovative medical treatments that states are required to cover; or,

7. Corrections to coverage/service estimates where there is no prior state experience (e.g., SUD) or small populations where expenditures may vary widely.

c. **Budget Neutrality Update.** The state must submit an updated budget neutrality analysis with its adjustment request, which includes the following elements:

1. Projected without waiver and with waiver expenditures, estimated member months, and annual limits for each DY through the end of the approval period; and,

2. Description of the rationale for the mid-course correction, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

11. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

11.1. **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 consists of 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.

11.2. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 1, Master MEG Chart and Table 2, MEG Detail of Expenditure and Member Month Reporting. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions; however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

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

FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

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

11.5. **Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), or when a WOW spending baseline for certain WW expenditures is difficult to estimate due to variable and volatile cost data resulting in anomalous trend rates, CMS considers these expenditures to be "hypothetical," such that the expenditures are treated as if the state could have received FFP for them absent the demonstration. 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 expenditures on those services. When evaluating budget neutrality, however, 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 separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as part of this demonstration approval. If the state's WW hypothetical spending exceeds the Hypothetical Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration or to refund the FFP to CMS.

11.6. **Hypothetical Budget Neutrality Test 1: SUD IMD.** 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.

Table 4: Hypothetical Budget Neutrality Test 1

MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 9	DY 10	DY 11	DY 12	DY 13

Managed Care IMD Services	PC	Both	4.9%	$1,685.95	$1,758.02	$1,844.16	$1,934.52	$2,029.31
FFS IMD Services	PC	Both	4.9%	$5,868.41	$6,119.26	$6,419.10	$6,733.64	$7,063.59

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

11.8. **Budget Neutrality Monitoring Tool and Reporting Requirements**. Per 42 CFR 431.428, the state must document the financial performance of the demonstration. The state must provide quarterly budget neutrality status updates that meet all 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), using the Budget Neutrality Monitoring Tool provided through the Demonstration Evaluation & Management Oversight System (DEMOS). The tool incorporates the "Schedule C Report" for comparing the demonstration's actual expenditures to the budget neutrality expenditure limits described in the Monitoring Budget Neutrality for the Demonstration section. The quarterly budget neutrality status updates are due no later than 60 calendar days following the end of each demonstration quarter, while the fourth-quarter information is due no later than 90 calendar days following the end of the DY. These monitoring reports are subject to the deferral as described in STC 8.1. CMS will provide technical assistance, upon request.[4]

11.9. **Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from 1/1/2027 to 9/30/2031. If at the end of the demonstration approval period the Hypothetical Budget Neutrality Test(s) has been exceeded, the excess federal funds will be returned to CMS. If the Demonstration is

[4] Per 42 CFR 431.420(a)(2), 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 states agree to use the tool as a condition of demonstration approval.

terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.

11.10. **Corrective Action Plan.** 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.

Table 5: Budget Neutrality Test Corrective Action Plan Calculation

Demonstration Year	Cumulative Target Definition	Percentage
DY 7	Cumulative budget neutrality limit plus:	2.0 percent
DY 7 through DY 8	Cumulative budget neutrality limit plus:	1.5 percent
DY 7 through DY 9	Cumulative budget neutrality limit plus:	1.0 percent
DY 7 through DY 10	Cumulative budget neutrality limit plus:	0.5 percent
DY 7 through DY 11	Cumulative budget neutrality limit plus:	0.0 percent

12. SCHEDULE OF STATE DELIVERABLES FOR THE DEMONSTRATION

Table 6: Schedule of State Deliverables for the Demonstration

Deliverable	Timeline	STC Reference
State acceptance of demonstration STCs and Expenditure Authorities	30 calendar days after demonstration approval	Approval letter
Evaluation Design	No later than 180 calendar days after approval of the demonstration. Revised no later than 60 days after receipt of CMS comments.	STC 9.3
Mid-Point Assessment	No later than 60 calendar days after September 30, 2029. Revised no later than 60 days after receipt of CMS comments.	STC 8.7
Interim Evaluation Report	One year prior to the end of the demonstration period, or when the extension application is submitted, whichever is sooner. Revised no later than 60 calendar days after receipt of CMS comments.	STC 9.7
Summative Evaluation Report	No later than 18 months after the end of the demonstration period. Revised no later than 60 calendar days after receipt of CMS comments.	STC 9.8
Quarterly Budget Neutrality Monitoring Report	60 calendar days after the end of each quarter except the 4th quarter which is due 90 days after the end of each DY.	STC 8.6
CMS-64 Quarterly Medicaid Expenditure Report	30 calendar days after the end of each quarter	STC 10.2
Annual Monitoring Report	No later than 180 calendar days after the end of each demonstration year.	STC 8.5



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.[1] 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

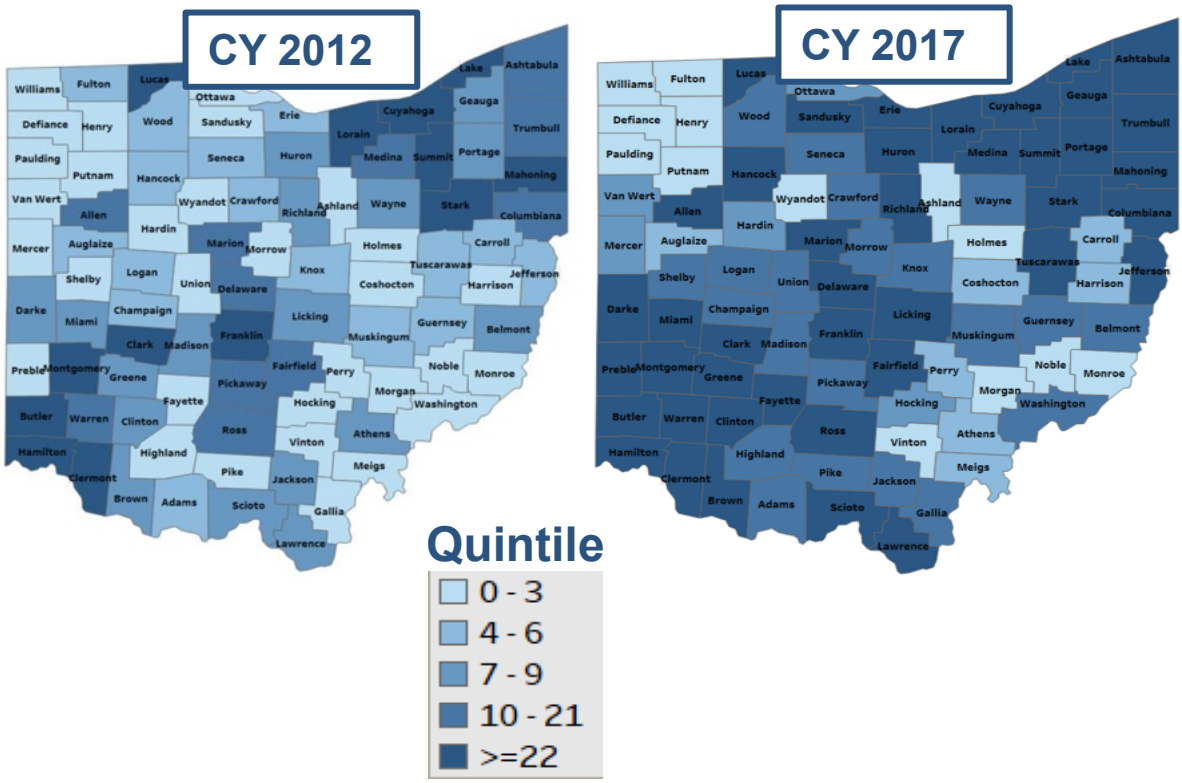
Ohio has remained especially vigilant in tracking and fighting opioid use disorders and deaths from opioid overdoses. Opioids deaths in Ohio rose from 1,914 in 2012 to 4,050 in 2016.[2] See Figure 1 for maps outlining the growth in number of unintentional opioid drug-related deaths in Ohio counties between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

[1] 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

[2] Mortality data can be found at the following website: http://publicapps.odh.ohio.gov/EDW/DataBrowser/Browse/Mortality

[3] "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.[4]

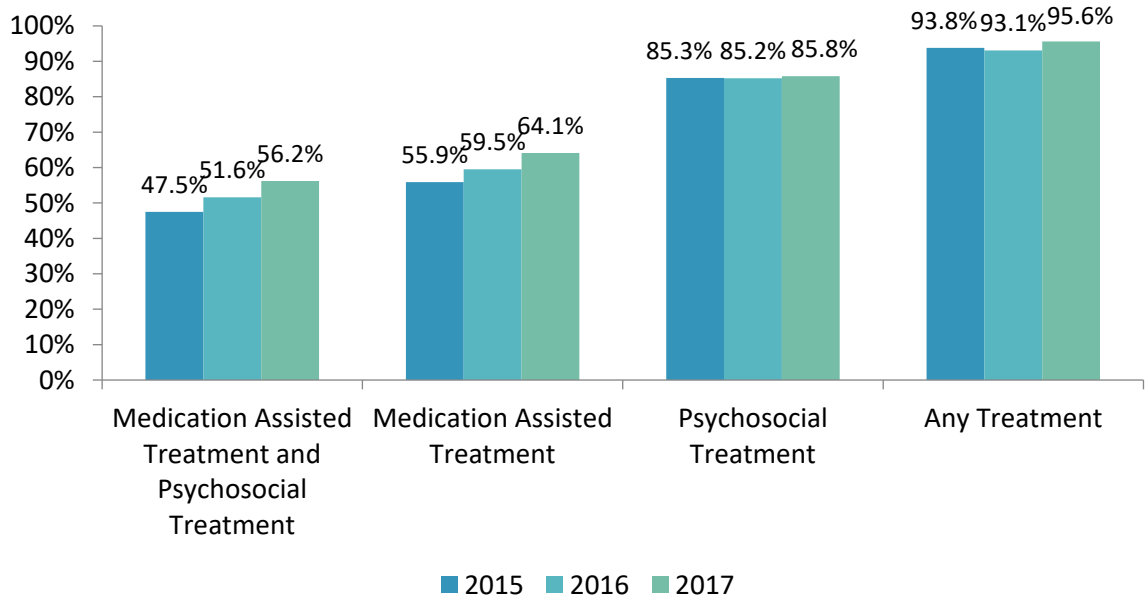
As of August 2018, Ohio averaged about three million individuals enrolled in Medicaid a month. The number of Medicaid individuals with SUD diagnoses continues to grow. The largest increase in the number of Medicaid individuals with SUD occurred between 2014 and 2015 with the implementation of the Medicaid 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

[4] 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.[5]. 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



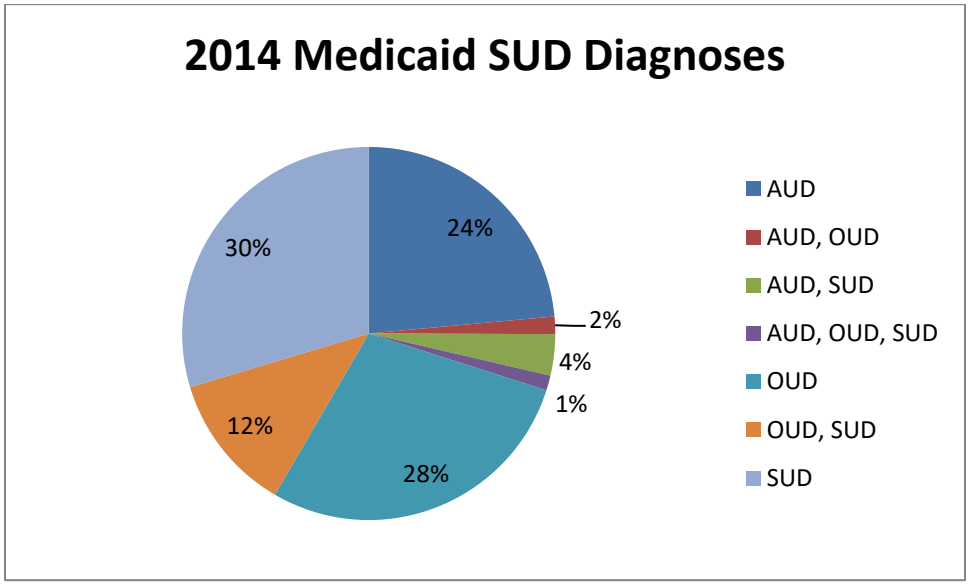
Source: Medicaid Administrative Data

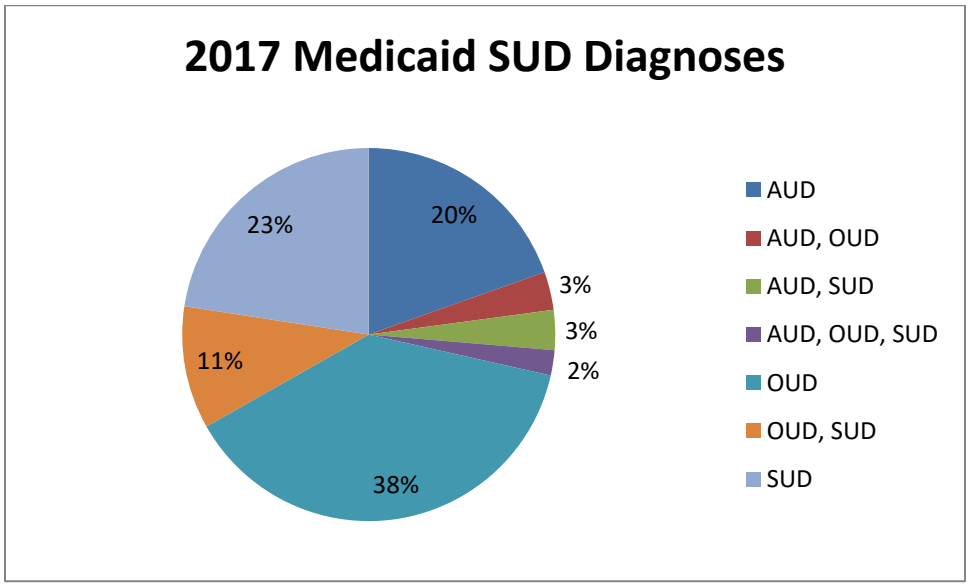
Billing codes used to define MAT and psychosocial treatment are in the Methodological Report

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.

[5] This finding is based on diagnosed opioid use disorder, which is likely to be an underestimate of the actual prevalence of opioid use disorder.

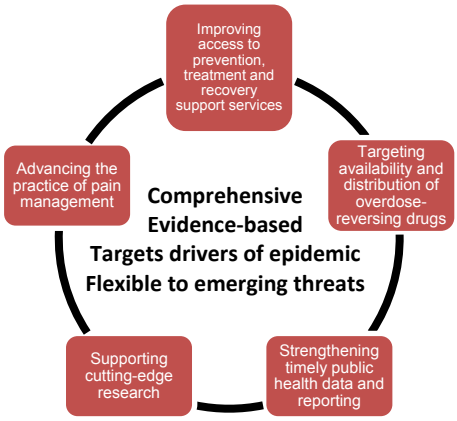
Tables: The type of SUD diagnosis for the Medicaid population





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.[6] 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 ASAM Level 1	Early Intervention Outpatient Services	Both Both	State Plan Authority items 13 c and 13 d. 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

[6] 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.[7] 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.

[7]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.[8] 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

[8] 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.[9] 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:[10]

- 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

[10] 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: [11]

- 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

[11] 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.[12] 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:

[12] 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.[13]

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.

[13] 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.

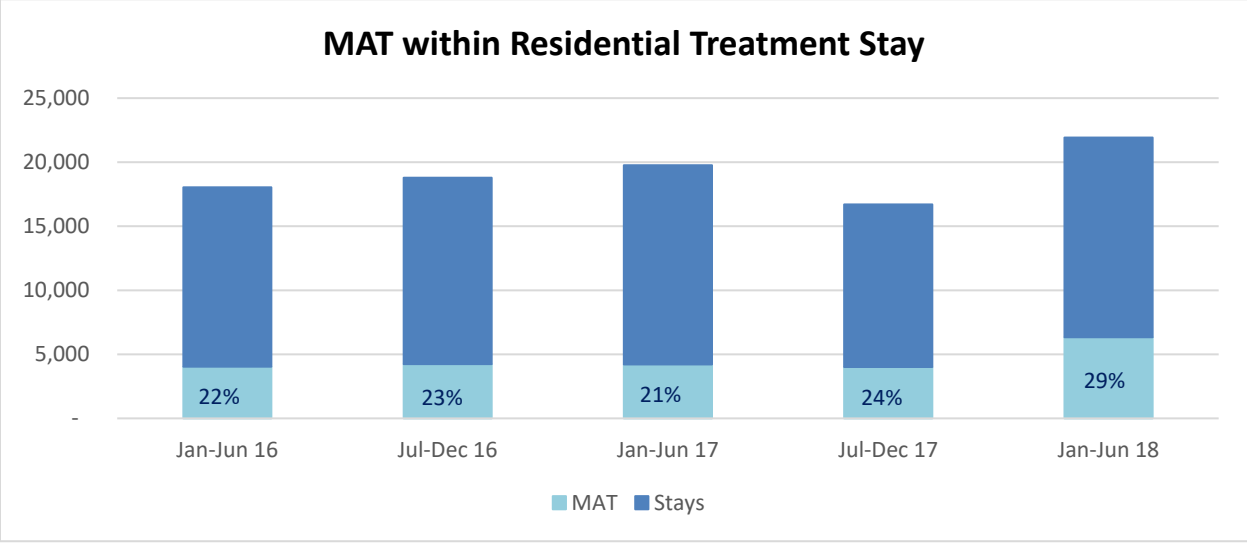
In addition, ODM intends to procure a single, statewide vendor to perform SUD treatment provider management including a qualification and verification function to assure statewide standards are met. It is intended that this will achieve a single, reliable provider registry. This new provider enrollment 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

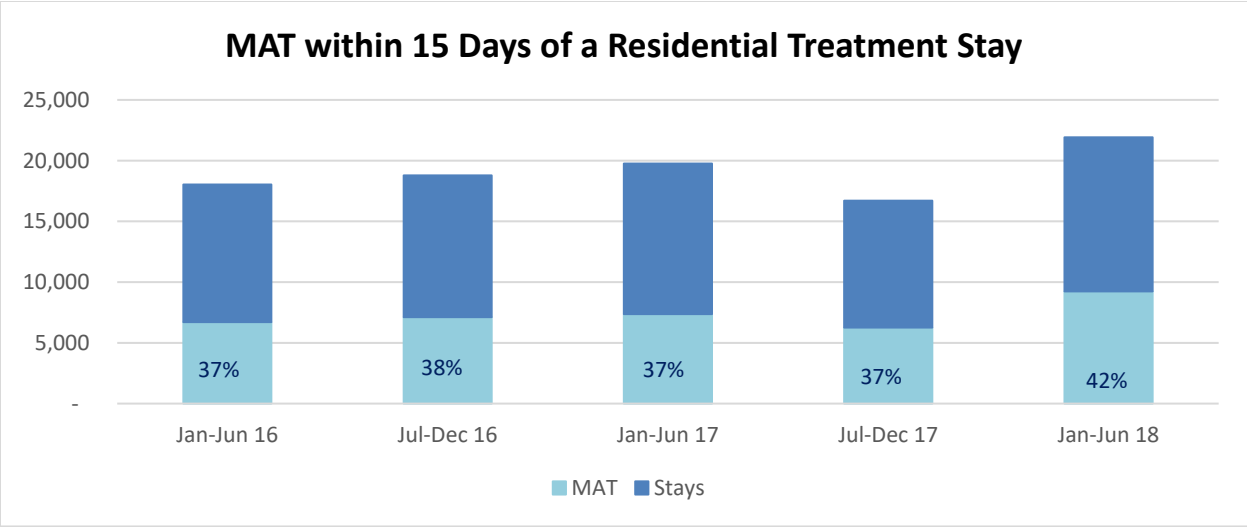
Implementation of requirement that residential treatment facilities offer MAT on-site or facilitate access off-site

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
Total	**102,542**	**41,637**	**144,179**

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:[14]

- 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

[14] 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."[15] The MCOPs are also required to demonstrate an adequate provider network "sufficient in number, mix, and geographic distribution" to ensure access to BH services.[16] 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

[15] Section 2.7.10 of the three-way contract
[16] Section 2.6.1.1 of the three-way contract

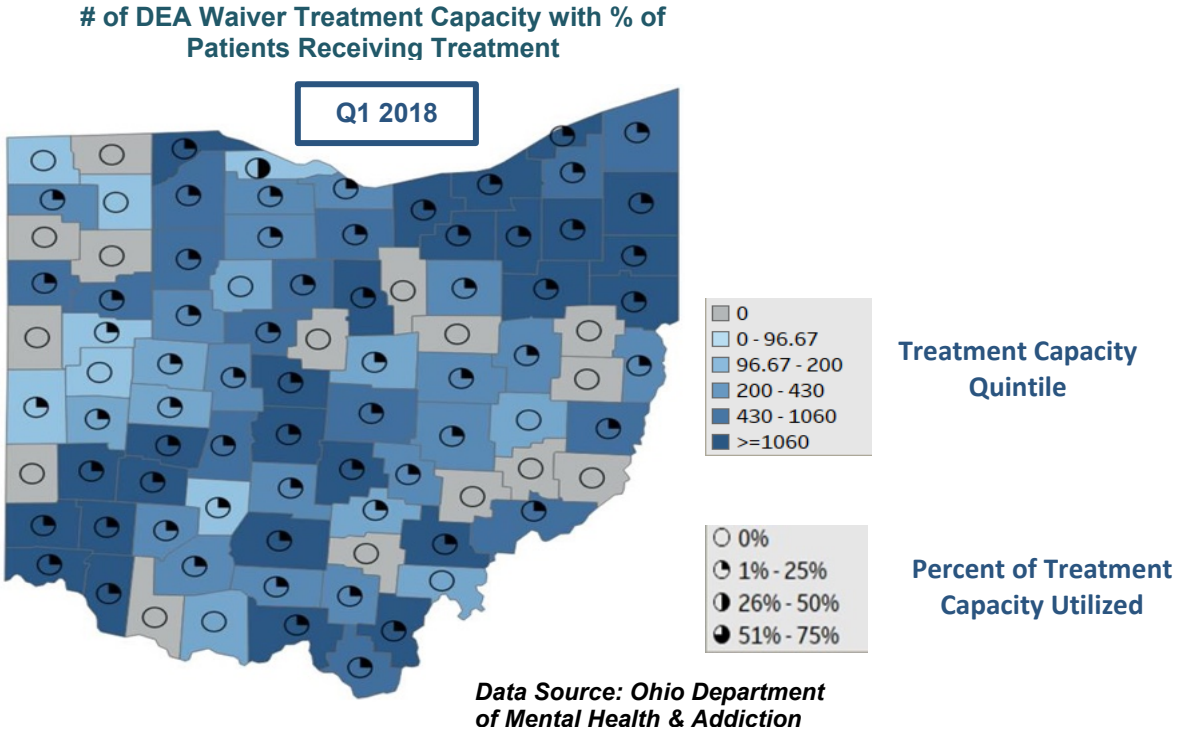
Region	OMHAS SUD Provider Agencies
Northwest	6
Southwest	8
West Central	6

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%

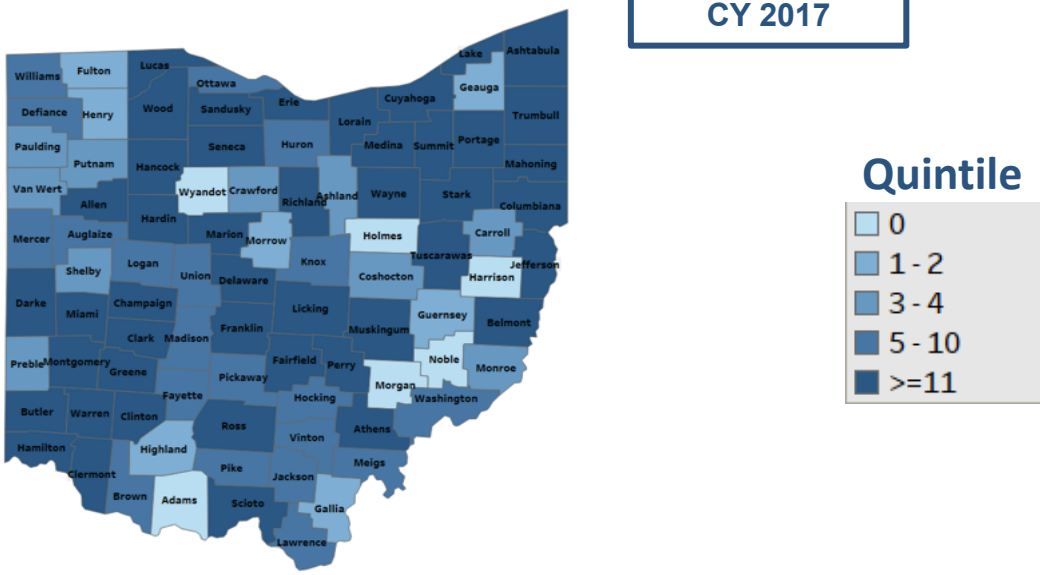
The State also monitors MAT providers. The State trends the number of providers with Drug Enforcement Agency (DEA) waivers as well as the capacity of those providers. Monitoring also includes the number of providers prescribing Vivitrol. See figures below:



Data Source: Ohio Department of Mental Health & Addiction

Number of Providers Prescribing 1 or more Vivitrol

CY 2017



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[17] 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.

[17] 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
Effective Date	**April 2012**	**October 2013**	**January 2016**	**August 2017**	**October 2018**
Specific Goals	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
Prescribing Limitations	• No more than 3 day supply • No recurrent refills for chronic conditions • No long-acting opioids • Connect to usual source of chronic care	• At ≥ 80 mg MED "press pause" • Caution with co-prescribing of benzodiazepines • Mandatory written agreement • Prescribe Naloxone • Mandatory OARRS checks and monitoring	• Discuss pain management expectations • First consider non-pharmacologic and non-opioid therapies • Limit pills per script • No Long-acting opioids • 2 week check point	• 7 day supply for adults • 5 day supply for youth • 30 MED average	• At ≥ 50 MED, "press pause" • Informed consent • Screen for OUD • At ≥80 MED, subspecialty consultation • At 120MED, pain medicine specialist

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:

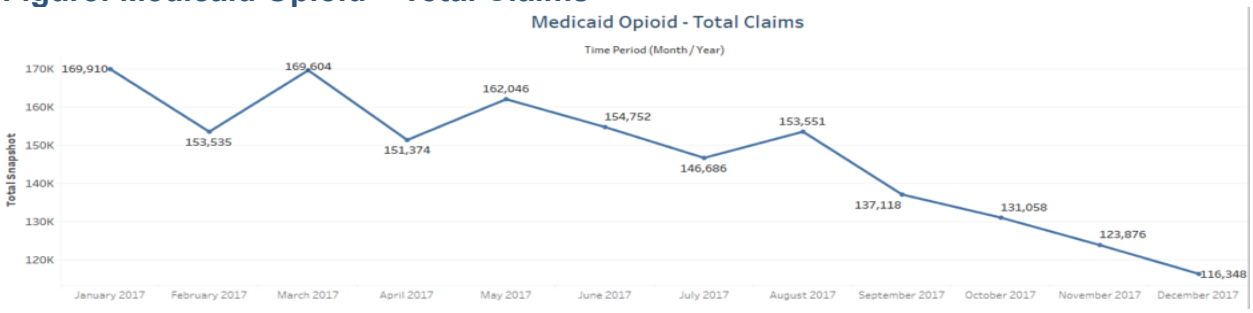
1. Closed "pill mills" in 2012.
2. Eliminated the authority of physicians to telephone in prescriptions for Schedule II drugs such as hydrocodone (Vicodin®).
3. Reduced the number of patients starting their first opioid.
4. Required Medicaid MCPs put edits in place within their pharmacy programs to support 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.[18] 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.

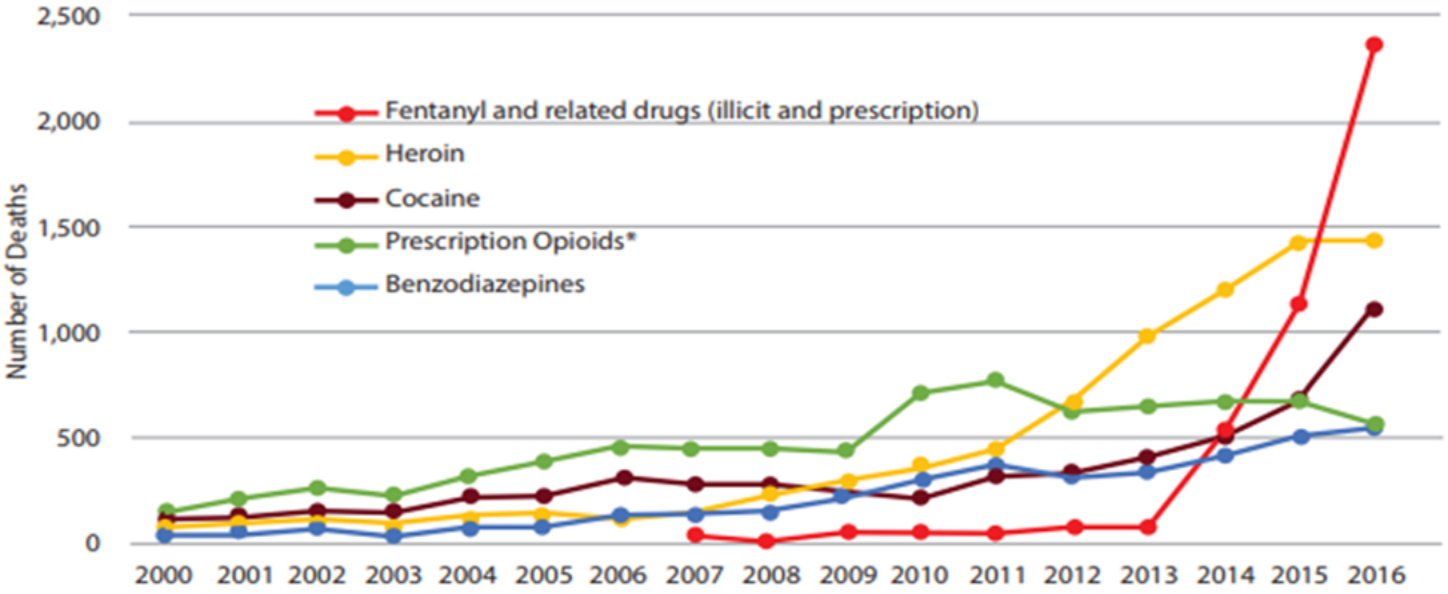
Figure: Medicaid Opioid – Total Claims



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.[19] See figure below.

[18] 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.
[19] 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, 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:

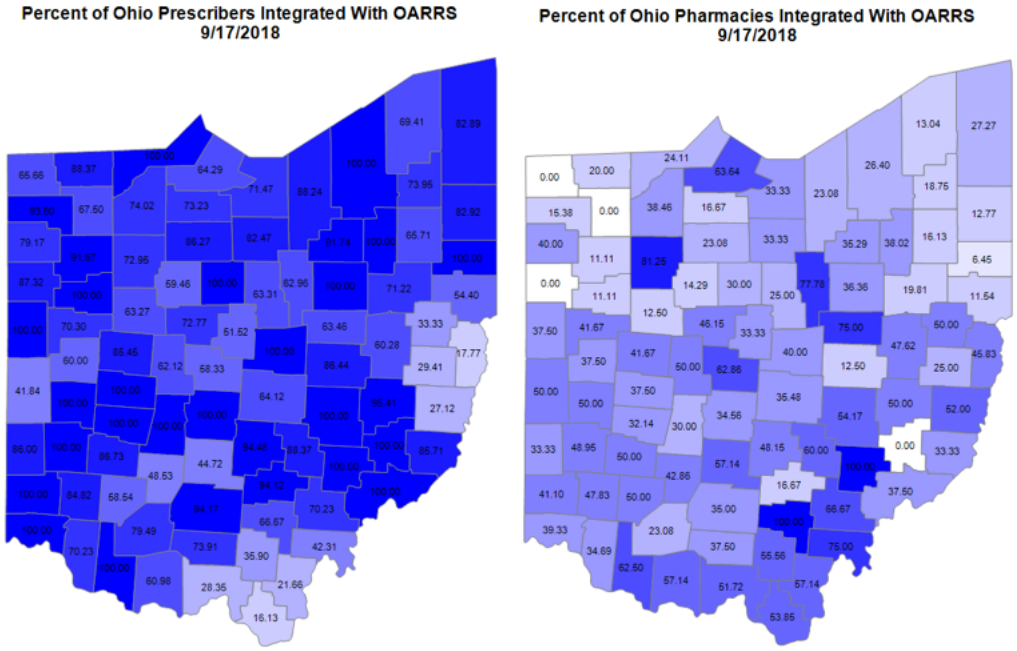
Ohio first mandated use of the OARRS, the State's PDMP by prescribers in 2011, with additional provisions added in 2013. OARRS is a tool to track the dispensing and personal furnishing of controlled prescription drugs to patients. OARRS is designed to monitor this information for suspected abuse or diversion (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.

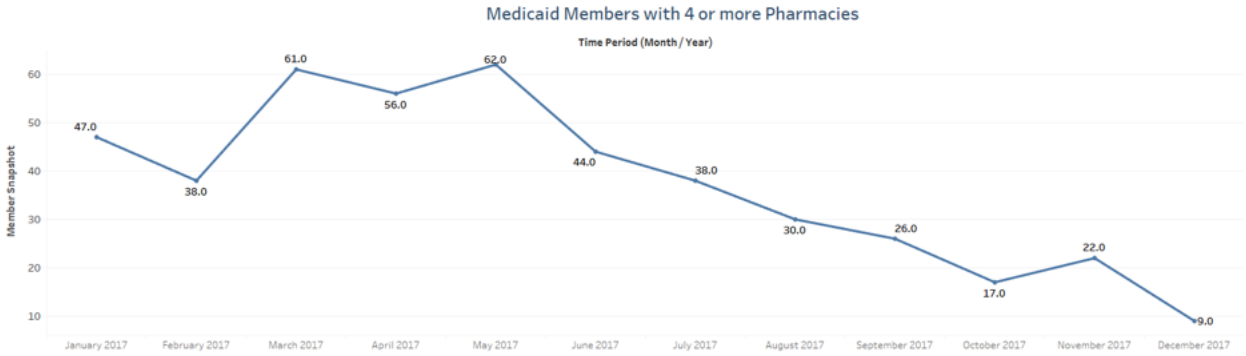
For an overall picture of the percentage of prescribers and pharmacies integrated with OARRS, see the figure below.

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.[20] 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



[20] Ohio Board of Pharmacy. 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.[21] 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.[22]
- 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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[21] Ohio Board of Pharmacy. https://www.ohiopmp.gov/documents/Annual%20Report%20(2017)%20-%20Executive%20Summary.pdf

[22] 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 AWARxE 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/OUD/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/OUD 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:

Behavioral Health Policy

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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
Implementation of comprehensive treatment and prevention strategies to address Opioid Abuse and OUD, that is: • Enhance the state's health IT functionality to support its PDMP. • Enhance and/or support clinicians in their usage of the state's PDMP.	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.	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.	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.
PDMP Functionalities			
Enhanced interstate data sharing in order to better track patient specific prescription data.	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.	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.	As data sharing is dependent on other states (including necessary changes to state law), there are no milestones that can be listed.
Enhanced "ease of use" for prescribers, other state and federal stakeholders.	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.	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. 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)

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[23] (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.
Current and Future PDMP Query Capabilities			
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: https://hitconsultant.net/2019/05/15/appriss-machine-learning-powered-patient-matching-solution/#.XNxwNExFyUm	Ohio's PDMP director will provide regular feedback on patient matching to Appriss Health to improve the overall functionality of the system.	

[23] 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.

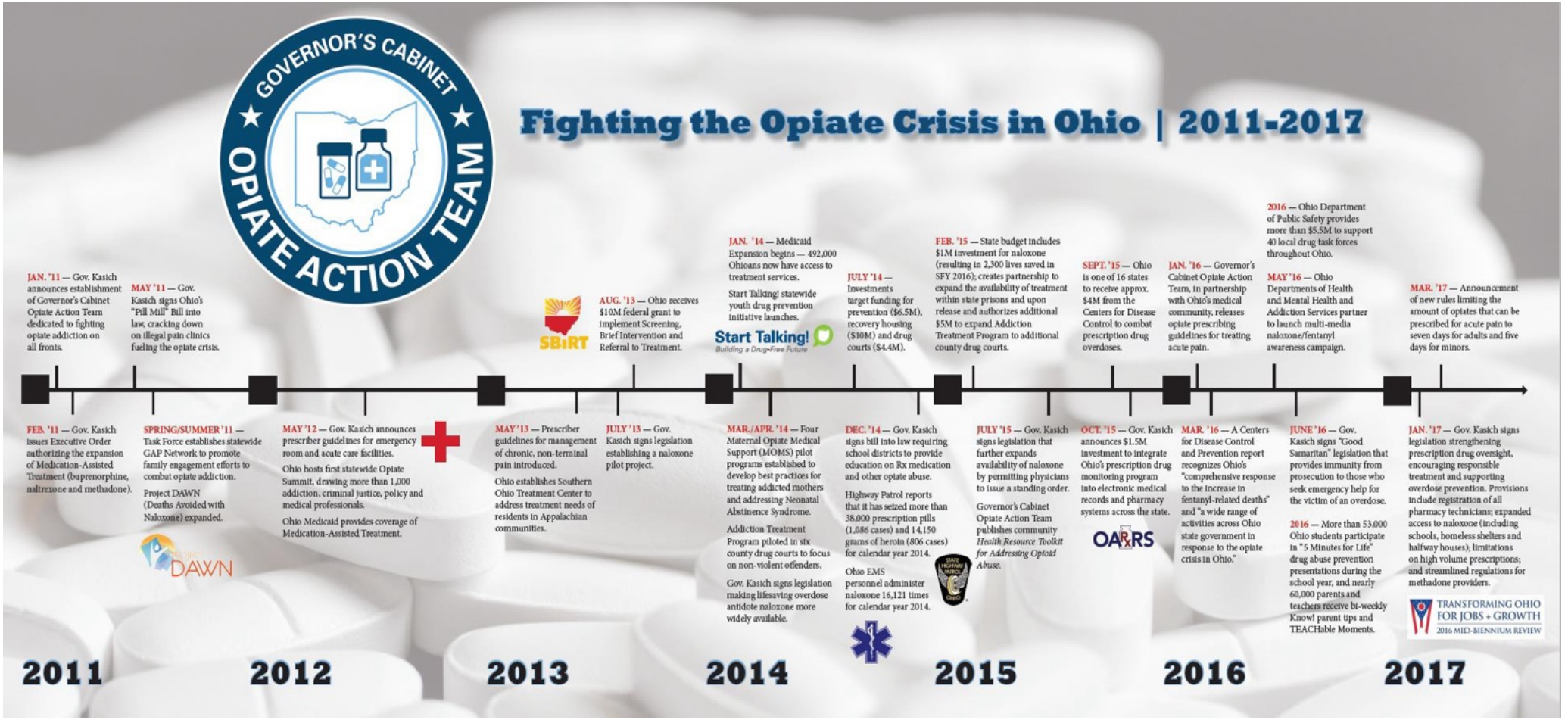
Milestone Criteria	Current State	Future State	Summary of Actions Needed
Use of PDMP – Supporting Clinicians with Changing Office Workflows/Business Processes			
Develop enhanced provider workflow/business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance to address the issues, which follow.	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.	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. See Attachment C for percentage of the integration rate for prescribers and pharmacies.
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.	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.	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.	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.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Master Patient Index/Identity Management			
Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery.	Ohio recently transitioned from the original AWARxE 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 actual 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.	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.
Overall Objective for Enhancing PDMP Functionality and Interoperability			
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.	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.	The Board of Pharmacy will implement an enforcement plan to minimize the risk of inappropriate overprescribing.	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.

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

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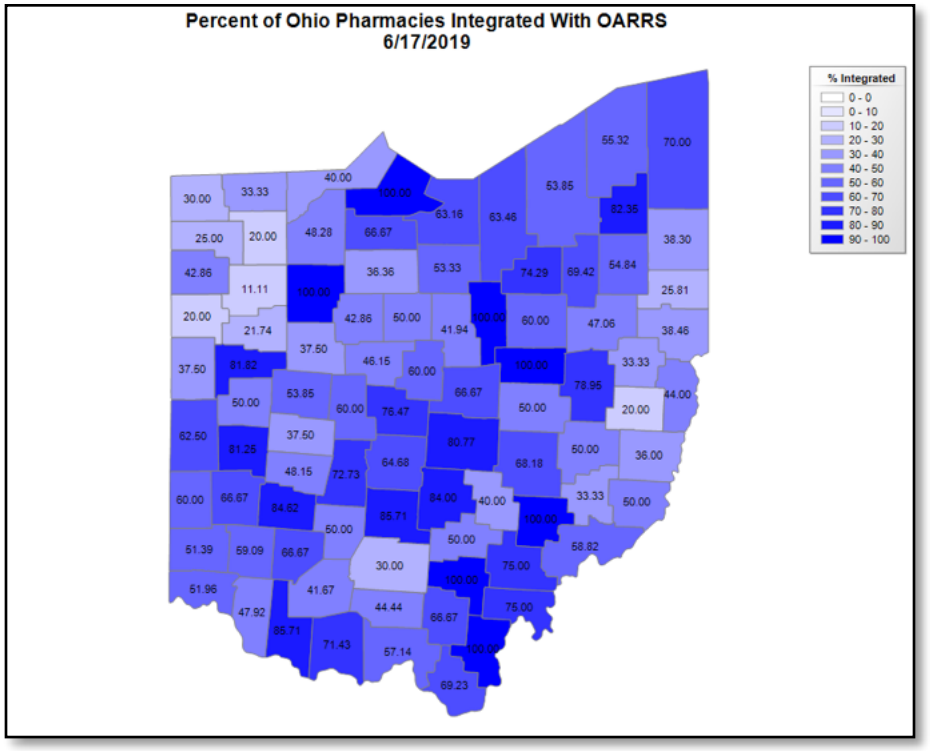
Attachment B. GCOAT Timeline



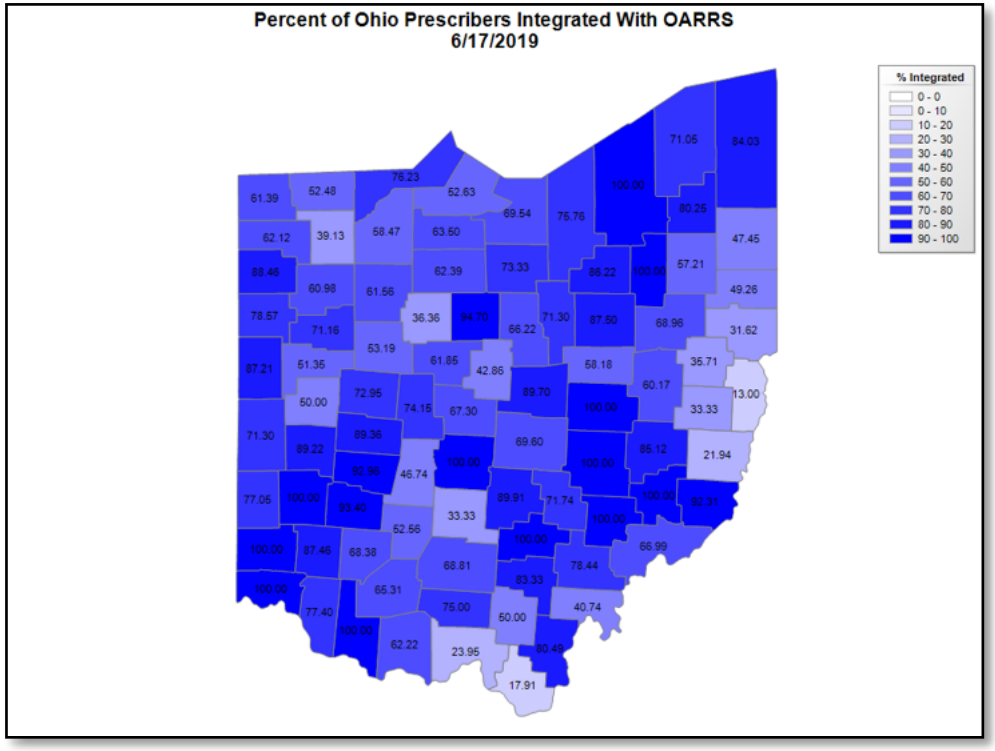
Attachment C: Integration Maps

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 B

SUD Evaluation Design (Reserved)