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

State Demonstrations Group

March 20, 2020

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

Dear Ms. Taylor:

The Centers for Medicare & Medicaid Services (CMS) is issuing technical corrections to the Indiana section 1115 Medicaid demonstration, entitled "Healthy Indiana Plan" (HIP) (Project Number 11-W-00296/5), the amendment for serious mental illness (SMI) was approved on December 20, 2019, under the authority of section 1115(a) of the Social Security Act (the Act). CMS has issued the following technical corrections to the Special Terms and Conditions (STC), in accordance with Indiana's request:

- Removed the language "and withdrawal management services" from the expenditure authority description for inpatient treatment for individuals with serious mental illness (SMI). This treatment modality does not apply to individuals receiving short-term treatment for SMI in facilities that meet the definition of an institution of mental disease (IMD).
- Updated the budget neutrality table in Section XV STC 3 as follows (changes are italicized):

MEG	**Trend Rate**	**DY 4**	**DY 5**	**DY 6**
SMI FFS	4.6%		*$5,121.27*	*$5,356.85*
SMI Managed Care	4.6%		$1,046.32	$1,094.45

To reflect the agreed terms with the state, CMS has incorporated the technical changes into the latest version of the STCs. Please find enclosed the updated STCs.

Your project officer for this demonstration is Ms. Rachel Nichols. She is available to answer any questions concerning your section 1115 demonstration. She can be contacted at Rachel.Nichols@cms.hhs.gov.

Sincerely,

3/20/2020

X Andrea J. Casart

Signed by: Andrea J. Casart -A

Andrea J. Casart
Director
Division of Medicaid Expansion Demonstrations

Enclosure

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST

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

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

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

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

The demonstration will operate under these waiver authorities beginning February 1, 2018. The waivers will continue through December 31, 2020, unless otherwise stated.

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

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

Title XIX Waivers

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

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

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

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

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

To the extent necessary to enable Indiana to suspend eligibility for, and not make medical assistance available to, beneficiaries who fail to comply with community engagement requirements, as described in the STCs, unless the beneficiary is exempted as described in the STCs.

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

To the extent necessary to enable Indiana to make a determination of ineligibility, and terminate eligibility for, beneficiaries who are in a suspension of coverage for failure to meet the community engagement requirements described in the STCs on their redetermination date, unless the beneficiary meets the requirement or is exempted as described in the STCs during the month of redetermination.

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

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

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

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

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

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

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

7. Retroactivity **Section 1902(a)(34)**

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITIES

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

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

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

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the state for the items identified below (which would not otherwise be included as matchable expenditures under section 1903 of the Act) shall, for the period beginning February 1, 2018 through December 31, 2020, unless otherwise specified, be regarded as matchable expenditures under the state's Medicaid state plan, but are further limited by the special terms and conditions (STC) for the HIP section 1115 demonstration.

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

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

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

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

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

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

3. **Inpatient Treatment for Individuals with Serious Mental Illness.** Expenditures for Medicaid state plan services furnished to eligible individuals who are primarily receiving short-term treatment services for a serious mental illness (SMI) in facilities that meet the definition of an IMD.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

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

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

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

I. PREFACE

The following are the special terms and conditions (STC) for the Healthy Indiana Plan (HIP) section 1115(a) Medicaid demonstration (hereinafter "demonstration") to enable Indiana to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted a waiver of requirements under section 1902(a) of the Social Security Act (the Act). These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during the life of the demonstration. The demonstration will be statewide and is approved for a three-year period, from February 1, 2018 through December 31, 2020.

The STCs have been arranged into the following subject areas:

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

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

Attachment A: Developing the Evaluation Design
Attachment B: Preparing the Interim and Summative Evaluation Reports
Attachment C: Evaluation Design (reserved)
Attachment D: SUD Implementation Plan Protocol

Attachment E: SUD Monitoring Plan Protocol (reserved)
Attachment F: SUD Evaluation Design
Attachment G: SMI /SED Implementation Plan (includes Financing Plan)
Attachment H: SMI/SED Monitoring Protocol (reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

This section 1115(a) demonstration provides authority for the state to offer HIP, which provides health care coverage for adults and an account similar to a health savings account called a Personal Wellness and Responsibility (POWER) Account. Under this approval, Indiana is building on and changing its previous HIP program in multiple ways, including through POWER Account contributions determined by income tier, implementation of a tobacco user contribution surcharge, the addition of some chiropractic coverage, a change in the timing of managed care organization (MCO) selection, a non-eligibility period for failure to timely complete the redetermination process, a substance use disorder (SUD) treatment program, and required participation in community engagement.

Under HIP, beneficiaries who consistently make required monthly contributions to their POWER Account will maintain access to an enhanced benefit plan, known as "HIP Plus," which will include enhanced benefits such as dental, vision, and chiropractic coverage. HIP Plus is intended to encourage personal responsibility, improve healthy behaviors, and develop cost conscious consumer behaviors among all beneficiaries. Beneficiaries with income at or below 100 percent of the federal poverty level (FPL) who do not make monthly POWER Account contributions will be defaulted to a more limited benefit plan meeting alternative benefit plan requirements (known as "HIP Basic"). Individuals above 100 percent of the FPL who do not make the monthly contributions will be disenrolled and not able to re-enter the program for six months. The HIP Basic plan will require co-payments for all services in amounts that would be permitted in the state plan rather than the monthly POWER Account contributions required to participate in the HIP Plus plan. All beneficiaries will have the opportunity to have their POWER Account contributions reduced in subsequent years for completion of preventive services and through successfully managing their POWER accounts.

In addition, Indiana implemented community engagement requirements as a condition of eligibility for HIP beneficiaries, with exemptions for various groups, including: pregnant women, beneficiaries considered medically frail, members in active SUD treatment, and students. To remain eligible, non-exempt beneficiaries must complete a specific number of hours per week of community engagement activities, such as employment, education, job skills training, and community service for eight months in the 12-month calendar year. Beneficiaries will have their eligibility suspended in the new calendar year for failure to demonstrate compliance with the community engagement requirement during the prior calendar year. During an eligibility suspension, beneficiaries may reactivate their eligibility in the month following notification to the state that they completed a calendar month of required hours. Indiana will provide good cause exemptions in certain circumstances for beneficiaries who cannot meet requirements.

The HIP demonstration also includes a SUD program available to all Medicaid beneficiaries to ensure that a broad continuum of care is available to beneficiaries with SUD, which will help improve the quality, care, and health outcomes for Indiana Medicaid beneficiaries. In an

amendment to this demonstration dated December 20, 2019, the state also received authority under the demonstration to receive federal financial participation (FFP) for delivering high-quality, clinically appropriate treatment to beneficiaries ages 21 through 64 diagnosed with a serious mental illness (SMI) and receiving treatment while they are short-term residents in settings that meet the definition of an Institution for Mental Diseases (IMD).

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

- Moving the monthly payment obligation to a tiered structure, linked to a POWER account, will result in more efficient use of health care services, be easier for beneficiaries to understand, and increase compliance with payments;
- Implementing a community engagement requirement will lead to sustainable employment and improved health outcomes among HIP beneficiaries and former HIP beneficiaries who experience a lapse in eligibility or who transition to employer-sponsored coverage or commercial coverage;
- Charging beneficiaries an increased monthly contribution for tobacco use will discourage tobacco use and increase the utilization of tobacco cessation benefits; and
- Receiving FFP for Medicaid services rendered in an IMD for beneficiaries with an SMI and/or a SUD reduces utilization and length of stays in emergency departments and preventable readmissions to acute care hospitals and residential settings.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, and section 1557 of the Affordable Care Act.

2. **Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid program and CHIP, expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3. **Changes in Federal Law, Regulation, and Policy.** The state must, within the timeframes specified in the applicable federal law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid or CHIP program that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable as described in these STCs. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7 of this section. CMS will

notify the state 30 days in advance of the expected approval date of the amended STCs to allow the state to provide comment.

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

   a. To the extent that a change in federal law, regulation, or policy requires a change in federal financial participation (FFP) for expenditures made under this demonstration, the state shall adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration, as well as a modified allotment neutrality worksheet as necessary to comply with such change. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.

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

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

6. **Changes Subject to the Amendment Process.** If not otherwise specified in these STCs, changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, evaluation design, sources of non-federal share of funding, and budget neutrality that are specifically authorized under the demonstration project 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 FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 of this section, except as provided in STC 3 of this section.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 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 failure by the state to submit required reports and other deliverables in a timely fashion according to the deadlines specified herein. 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 applicable to amendments listed in STC 14 of this section, prior to

submission of the requested amendment;

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

c. An up-to-date CHIP allotment neutrality worksheet, if necessary;

d. A detailed description of the amendment including impact on beneficiaries, with sufficient supporting documentation and data supporting the evaluation hypotheses as detailed in the evaluation design in section XV; and

e. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.

8. **Extension of the Demonstration**. No later than twelve months prior to the expiration date of the demonstration, the Governor of the state must submit to CMS either a demonstration extension request that meets federal requirements at 42 CFR 431.412(c) or a phase out plan consistent with the requirements of STC 9 of this section.

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

a. **Notification of Suspension or Termination.** The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft plan to CMS. The state must submit the notification letter and a draft plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft 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 14 of this section, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of each public comment received, the state's response to the comment and the extent to which the state incorporated the received comment into the revised plan.

b. **Prior CMS Approval.** The state shall obtain CMS approval of the transition and phase-out plan prior to the implementation of the phase-out activities. Implementation of activities shall be no sooner than 14 calendar days after CMS approval of the plan.

c. **Transition and Phase-out Plan Requirements**. The state must include, at a minimum, in its plan the process by which it will notify affected beneficiaries, the

content of said notices (including information on the beneficiary's appeal rights, if any), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the program for the affected beneficiaries, and ensure ongoing coverage for those beneficiaries determined eligible, as well as any community outreach activities including community resources that are available.

d. **Phase-out Procedures**. The state must comply with all applicable notice requirements found in 42 CFR §431.206, §431.210, and §431.213. In addition, the state must assure all applicable appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR §431.220 and §431.221. If a demonstration participant is entitled to and requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category.

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

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

10. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six months of the demonstration's implementation, and annually thereafter, the state shall afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 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 can either use its Medical Care Advisory Committee, or another meeting that is open to the public and where an interested party can learn about the progress of the demonstration to meet the requirements of this STC. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the quarterly report associated with the quarter in which the forum was held. The state must also include the summary in its annual report.

11. Expiring Demonstration Authority. For demonstration authority that expires prior to the demonstration's expiration date, the state must submit a transition plan to CMS no later than six months prior to the applicable demonstration authority's expiration date, consistent with the following requirements:

a. **Expiration Requirements.** The state must include, at a minimum, in its demonstration expiration plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's

appeal rights, if any), the process by which the state shall conduct administrative reviews of Medicaid eligibility for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any community outreach activities.

b. **Expiration Procedures.** The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all applicable appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR, part 431 subpart E, including, sections 431.220 and 431.221. If a demonstration participant requests and is entitled to a hearing before the date of action, the state must maintain benefits as required in 42 CFR Section 431.230. In addition, the state must conduct administrative renewals for all beneficiaries in HIP in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to termination as discussed in October 1, 2010, State Health Official Letter #10- 008 and required under 42 C.F.R. 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

c. **Federal Public Notice.** CMS will conduct a 30-day federal public comment period consistent with the process outlined in 42 CFR Section 431.416 in order to solicit public input on the state's demonstration expiration plan. CMS will consider comments received during the 30-day period during its review and approval of the state's demonstration expiration plan. The state must obtain CMS approval of the demonstration expiration plan prior to the implementation of the expiration activities. Implementation of expiration activities must be no sooner than 14 days after CMS approval of the plan.

d. **Federal Financial Participation (FFP).** FFP shall be limited to normal closeout costs associated with the expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals and administrative costs of disenrolling participants.

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

13. **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.

14. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request.

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

    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.

15. **Federal Financial Participation (FFP).** No federal matching for service expenditures for this demonstration will take effect until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

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

IV. POPULATIONS AFFECTED

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

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

Table 1. Medicaid State Plan Groups Affected by the Demonstration		
Medicaid State Plan Group	**Population Description**	**Funding Stream**
New adult group under 42 CFR 435.119, including individuals who are medically frail	Individuals age 19 through 64 who are eligible in the new adult group under the state plan that is described in 1902(a)(10)(A)(i)(VIII) of the Act, including individuals who meet the definition of medically frail consistent with 42 CFR Section 440.315(f).	Title XIX
Parents & caretaker relatives eligible under 42 CFR 435.110	Parents and caretakers with income under the State's AFDC payment standard in effect as of July 16, 1996 (section 1931 parents and caretaker relatives), converted to a MAGI-equivalent amount by household size.	Title XIX
Adult Transitional Medical Assistance beneficiaries under section 1902(a)(52) and 1925 of the Act (including individuals who are medically frail)	Former Parent & Caretaker relatives eligible for a minimum of six and a maximum of 12 months of continued coverage under Transitional Medical Assistance	Title XIX
Pregnant women, age 19 and older, eligible under 42 CFR 435.116	Pregnant women with incomes up to 133 percent of FPL who are enrolled in HIP at the time they become pregnant or are determined eligible for HIP after applying for benefits.	Title XIX

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

section:

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

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

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

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

   Individuals determined presumptively eligible for HIP (Adult PE) will not have a break in coverage if they are found eligible for Medicaid through the Indiana Health Coverage Programs (IHCP) application process. Adult PE beneficiaries who do not submit a full IHCP application will have their PE benefit end on the last day of the following month after PE approval. For individuals who complete the IHCP application, Adult PE coverage will continue, at minimum, for the duration of application processing. Adult PE beneficiaries who have their IHCP application denied will be closed on the date of IHCP denial. Adult PE beneficiaries who have their IHCP application approved will move into HIP coverage the first of the month following approval of the application. Beneficiaries will have 60 days to pay any required premium payment starting from the date when fast track eligibility begins following filing of the IHCP application; this payment period will transition into HIP coverage. For example, if the member had already had 15 days to pay during PE, their payment period in HIP Basic will continue for 45 days. PE members will receive HIP Plus or HIP Basic coverage following transition to HIP per the standard processes.

   a. At state option, Indiana can reclassify presumptively eligible individuals as eligible in the new adult group for up to 3 months prior to the effective date of coverage as

outlined in STC 3 of this section. Members transitioned from Adult PE who do not make a POWER Account payment in the 60-day time frame and who have household incomes greater than 100 percent of the FPL will be terminated from HIP.

5. **Pregnant Women.** Pregnant women eligible under 42 CFR 435.116 with income under 133 percent of the FPL will be enrolled into HIP. Women who are enrolled in HIP and report a pregnancy will begin to receive state plan equivalent benefits that are equal to or more generous in all categories than the benefits provided in the HIP ABPs and all required prenatal services. Pregnant beneficiaries have no cost sharing and receive 60 days of postpartum coverage. After the completion of postpartum coverage, the beneficiaries will seamlessly transition back to the appropriate Medicaid eligibility category and will be provided an option to pay for HIP Plus benefits. Newly eligible adults who are pregnant can continue to be claimed by the state at the enhanced match until redetermination, at which time, if the beneficiary identifies as pregnant, that beneficiary must be claimed at the applicable match for pregnant women.

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

V. BENEFITS

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

Table 2. Benefit Plan Options

Eligibility Group	HIP Basic ABP	HIP Plus ABP	ABP that is the State Plan Benefit Package	State Plan benefits
Adult group, individuals with income at or below 100% of the FPL	X	X		
Adult group, individuals with income above 100% of the FPL		X		
Adult group, medically frail			X	
Section 1931 parents and caretaker relatives (including individuals who are medically frail)				X
Pregnant women				X
TMA (over 133% FPL)		X		X

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

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

VI. COMMUNITY ENGAGEMENT PROGRAM

1. General Description. Gateway to Work was launched in 2015 to promote the connection between employment and health by integrating the state's various work training and job search programs with HIP. Through the Gateway to Work initiative, for which the state does not receive federal matching funds, all eligible HIP beneficiaries who are unemployed or working less than 20 hours per week are referred to available employment, work search and job training programs to assist the member in securing gainful employment. After the referral is made via Gateway to Work, member participation in the available employment and training programs has been voluntary. Effective 2019, building upon its experience with Gateway to Work, Indiana will make participation in community engagement activities mandatory for some HIP beneficiaries as discussed below.

2. **Eligibility**. As described below, participation in the community engagement requirements specified below will be a condition of continued eligibility for all adult HIP beneficiaries who are not otherwise subject to an exemption described below in STC 3.

3. **Exempt Populations.** The following HIP beneficiaries are exempt from the community engagement requirements:
   - Students (full-time and part-time);
   - Pregnant women;
   - Beneficiaries who are a primary caregiver of a dependent child below the compulsory education age or a disabled dependent, including kinship caregivers of abused or neglected children;
   - Beneficiaries identified as medically frail under 42 CFR 440.315(f) and as defined in the ABP in the state plan (e.g. serious & complex medical conditions, chronic SUD, or disability determination);
   - Beneficiaries with temporary illness or incapacity (includes individuals on FMLA) documented by a third party;
   - Beneficiaries in active SUD treatment;
   - Beneficiaries over the age of 59;
   - Beneficiaries who are homeless;
   - Beneficiaries who were incarcerated within the last six months;
   - Beneficiaries listed at Section IV STC 2 of these STCs;
   - Beneficiaries who meet the requirements of the Temporary Assistance for Needy Families (TANF) employment initiatives, or who are exempt from having to meet those requirements;
   - Beneficiaries who are enrolled in the state's Medicaid employer premium assistance program; and
   - Persons determined eligible for a good cause exemption as described in STC 7 of this section.

Beneficiaries meeting one or more of the above listed exemptions will not be required to complete community engagement related activities during any month(s) in which the exemption applies to maintain continued eligibility. The month during which a beneficiary has an exemption will be considered a month in which that beneficiary does not have to complete the community engagement requirements.

4. **Qualifying Activities**. HIP beneficiaries may satisfy their community engagement requirements through a variety of activities, including but not limited to:
   - Employment (subsidized or unsubsidized);
   - Participation in MCO employment initiatives;
   - Job skills training;
   - Job search activities;
   - Education related to employment (e.g. classes subsidized by employer);
   - General education (e.g., high school, GED, community college, college or graduate education, etc.);
   - Accredited English as a second language education;

- Vocational education/training;
- Community work experience;
- Participation in Gateway to Work;
- Community service/public service;
- Caregiving services for a non-dependent relative or other person with a chronic, disabling health condition, including individuals receiving FMLA to provide caregiving;
- Accredited homeschooling;
- Meeting the requirements of the Supplemental Nutrition Assistance Program (SNAP) employment initiative, or being exempt from those requirements;
- Volunteer work (e.g. classroom volunteer, faith-based internship work or mission trips sponsored by a recognized religious institution, etc.); and
- Members of the Pokagon Band of Potawatomi who are participating in the tribe's comprehensive Pathways program, or any other beneficiary participating in a workforce participation program that the state has determined will promote full employment and meets the goals of Indiana's community engagement initiative.

Beneficiaries without an exemption must document their participation, in a manner consistent with 42 CFR 435.916(c) and 435.945, in any one or combination of qualifying activities described in STC 4 of this section in the number of hours described in STC 5 of this section.

5. **Hour Requirements.** Starting with the implementation date of the community engagement initiative, the community engagement requirements for all beneficiaries in the HIP demonstration will gradually increase from five (5) hours per week up to a maximum of twenty (20) hours per week as outlined in Table 3. Beneficiaries can participate in any of the qualifying activities described in STC 4 of this section and combine the hours to satisfy the weekly hours requirement. As noted in STC 7(b) of this section, if beneficiaries participate in more hours of qualifying activities than is required in a week, they can apply the extra hours to the rest of that calendar month.

Table 3. Community Engagement Participation Hours	
Hourly Requirement Phase In of the Community Engagement Initiative	**Required Participation Hours**
1-6 months	0 hours per week
7-9 months	5 hours per week
10-12 months	10 hours per week
13-18 months	15 hours per week
18+ months	20 hours per week

6. **Reasonable Modifications.** The state must provide reasonable accommodations related to meeting the community engagement requirement for beneficiaries with disabilities protected by the ADA, Section 504 of the Rehabilitation Act, and Section 1557 of the Patient Protection and Affordable Care Act, when necessary, to enable them to have an

equal opportunity to participate in and benefit from the program. The state must also provide reasonable modifications for program protections and procedures, including but not limited to assistance with demonstrating eligibility for good cause exemptions; appealing suspensions; documenting community engagement activities and other documentation requirements; understanding notices and program rules related to community engagement requirements; and other types of reasonable modifications. The reasonable modifications must include exemptions from participation where an individual is unable to participate for disability-related reasons, modification in the number of hours of participation required where an individual is unable to participate for the required number of hours, and provision of support services necessary to participate, where participation is possible with supports. In addition, the state should evaluate individuals' ability to participate and the types of reasonable modifications and supports needed.

7. **Measurement and Non-Compliance.** Beneficiaries will not be subject to a review of their community engagement hours until each December. Each December, the state will evaluate whether a beneficiary has met the community engagement hours requirement for the prior 12-month calendar year. All beneficiaries must meet the community engagement requirements for eight months per calendar year. Some beneficiaries will not have been eligible for HIP the full calendar year, and the months in which the beneficiary is not eligible will not be counted as months in which the beneficiary must meet the requirement. Months in which a beneficiary qualifies for an exemption (as described in STCs 3 and 7(a) of this section) are also not counted. Beneficiaries who are exempt for a partial year, or who participated in the program for a partial year, will still have four months per each calendar year, in which they do not have to complete the community engagement requirements or qualify for an exemption. Months for which the beneficiary has requested an appeal of/has successfully appealed the state's determination of noncompliance (according to state procedures) will also not be counted. Thus, for a person who was enrolled the full calendar year and has no exemptions or appeals, participation in community engagement activities will be required for eight out of twelve months. For a person who enrolled in September and has no exemptions or appeals, that person will not have to demonstrate participation in community engagement activities until the end of the next calendar year.

   Eligibility will be suspended beginning on the first day of the new calendar year for beneficiaries who did not meet required community engagement hours as stated in Table 3 for the required number of months during the prior 12-month calendar year. Unless a beneficiary reactivates eligibility (as described in STC 8 of this section), eligibility will remain suspended until the beneficiary's eligibility redetermination date. If a member is in suspended status on their redetermination date and does not meet the requirement or qualify for an exemption during the month of redetermination, their eligibility will be denied and their enrollment in the demonstration terminated, and they must reapply to regain access to Medicaid coverage, including through the demonstration. When an individual whose enrollment was terminated during redetermination reapplies, their previous noncompliance with the community engagement requirement will not be factored into the state's determination of their eligibility for reenrollment into HIP.

a. Good Cause Exemption. The recognized good cause exemptions include, but are not limited to, at a minimum, the following verified circumstances:

i. The beneficiary has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and was unable to meet the requirement for reasons related to that disability; or has an immediate family member in the home with a disability under federal disability rights laws and was unable to meet the requirement for reasons related to the disability of that family member; or the beneficiary or an immediate family member who was living in the home with the beneficiary experiences a hospitalization or serious illness;
ii. The beneficiary is a victim of domestic violence; and
iii. The state may add additional circumstances for granting exceptions, as it deems necessary.

b. Extra Hours. Beneficiaries who engage in more hours of qualifying activities than is required in a week can apply the extra hours to other weeks within that same month, but not to weeks in other months.

c. Suspension Effective Date. Suspensions for non-compliance with community engagement requirements are effective the first day of the new calendar year.

8. **Re-activation During Suspension for Non-Compliance**. During suspension for community engagement non-compliance, beneficiaries can reactivate eligibility by becoming eligible for Medicaid under an eligibility group not subject to the provisions of the community engagement requirements, by meeting an exemption (including a good cause exemption), or by completing one calendar month of required community engagement hours and submitting that information to the state. Reactivation will occur based on the specific member eligibility criteria:

a. If a beneficiary becomes eligible under another eligibility group in Medicaid, their eligibility would be reactivated with an effective date based on established state policy for that eligibility group.

b. If a beneficiary meets an exemption, their eligibility would reactivate in the concurrent month of when the state receives notification of the exemption.

c. If a beneficiary becomes pregnant, eligibility could be retroactive to a prior month per established state policy.

d. If a beneficiary completes one calendar month of required community engagement hours, they will be able to reactivate eligibility in the month following notification to the state that they have come into compliance.

9. **Community Engagement: State Assurances**. Prior to implementation of community engagement as a condition of continued eligibility, the state shall:

a. Maintain system capabilities to operationalize the suspension of eligibility, the denial of eligibility, and the lifting of suspensions of eligibility once community engagement requirements are met.

b. Maintain mechanisms to stop capitation payments to an MCO when a beneficiary's eligibility is suspended and to trigger payment once the suspension is lifted.

c. Ensure that there are processes and procedures in place to seek data from other sources, including SNAP and TANF, and systems to permit beneficiaries to efficiently report community engagement hours or obtain an exemption, in accordance with 42 CFR 435.907(a) and 435.945, and to permit Indiana to monitor compliance.

d. Ensure that there are timely and adequate beneficiary notices provided in writing, including but not limited to information about:
   i. When the community engagement requirement will commence for that specific beneficiary;
   ii. Whether a beneficiary is exempt, how the beneficiary must indicate to the state that she or he is exempt, and under what conditions the exemption would end;
   iii. The specific number of community engagement hours per week that a beneficiary is required to complete, and when and how the beneficiary must report participation;
   iv. Specific information about how participation will be assessed at the end of the calendar year;
   v. A list of specific activities that may be used to satisfy community engagement requirements;
   vi. Resources that help connect beneficiaries to opportunities for activities that would meet the community engagement requirement and the community supports that are available to assist beneficiaries in meeting community engagement requirements;
   vii. How community engagement hours will be counted and documented;
   viii. What gives rise to a suspension, what a suspension would mean for the beneficiary, and how to avoid a suspension, including how to apply for a good cause exemption and what kinds of circumstances might give rise to good cause;
   ix. How the beneficiary's eligibility will be denied and terminated on their eligibility redetermination date if their eligibility is suspended at that time for failure to comply with the community engagement requirement, unless the beneficiary meets the requirement or qualifies for an exemption during the month of redetermination;
   x. If a beneficiary's eligibility is denied and terminated at redetermination due to noncompliance with the community engagement requirement, how to appeal that decision, and how to reapply for eligibility;
   xi. If a beneficiary is not in compliance, that the beneficiary is out of compliance, and the consequences of noncompliance;
   xii. If a beneficiary has eligibility suspended, how to appeal a suspension, and how to have the suspension lifted, including the number of community engagement

hours that must be performed within a calendar month by the specific beneficiary to have the suspension lifted;

xiii. Any differences in the program requirements that individuals will need to meet in the event they transition off of SNAP or TANF but remain subject to Indiana's community engagement requirement; and

xiv. If a beneficiary has requested a good cause exemption, that the good cause exemption has been approved or denied, with an explanation of the basis for the decision and how to appeal a denial.

e. Ensure that specific activities that may be used to satisfy community engagement requirements are available during a range of times and through a variety of means (e.g. online, in person) at no cost to the beneficiary.

f. Provide full appeal rights as required under 42 CFR, Part 431, subpart E prior to suspension of eligibility or termination of eligibility, and observe all requirements for due process for beneficiaries whose eligibility will be suspended, denied, or terminated for failing to meet the community engagement requirement, including allowing beneficiaries the opportunity to raise additional issues in a hearing, including whether the beneficiary should be subject to the suspension, and provide additional documentation through the appeals process.

g. Assure that disenrollment or denial of eligibility will only occur after an individual has been screened and determined ineligible for all other bases of Medicaid eligibility and reviewed for eligibility for insurance affordability programs in accordance with 42 CFR 435.916(f).

h. Establish beneficiary protections, including assuring that HIP beneficiaries do not have to duplicate requirements to maintain access to all public assistance programs that require community engagement and employment.

i. Make good faith efforts to connect beneficiaries to existing community supports that are available to assist beneficiaries in meeting community engagement requirements, including available non-Medicaid assistance with transportation, child care, language access services and other supports; and make good faith efforts to connect beneficiaries with disabilities as defined in the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act with services and supports necessary to enable them to meet community engagement requirements.

j. Ensure the state will assess areas within the state that experience high rates of unemployment, areas with limited economies and/or educational opportunities, and areas with lack of public transportation to determine whether there should be further exemptions from community engagement requirements and/or additional mitigation strategies, so that the community engagement requirements will not be impossible or unreasonably burdensome for beneficiaries to meet.

k. Ensure that the state will assess whether people with disabilities have limited job or other opportunities for reasons related to their disabilities. If these barriers exist for people with disabilities, the state must address these barriers.

l. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable modifications related to meeting community engagement requirements.

m. Maintain a mechanism that provides reasonable modifications related to meeting the community engagement requirement to beneficiaries with disabilities as defined in the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act.

VII. HIP POWER ACCOUNTS

1. **General Description.** The POWER Account is styled like a health savings account arrangement under a consumer-directed health plan. The POWER Account will hold state and beneficiary contributions (including beneficiary contributions donated by employers or other entities). The POWER Account funds will be used to pay for the first $2,500 in claims; claims beyond the initial $2,500 will be fully covered through capitation payments or other payments made by the state. POWER Accounts may not be used to pay for beneficiary copayments. A member will have one POWER Account established per calendar year.

2. **Beneficiary and State Contributions.**

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

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

c. **Beneficiaries with income at or below 100 percent of the FPL**. Beneficiaries with income at or below l00 percent of the FPL will lose HIP Plus copayment protection (and HIP Plus benefits for those in the new adult group) if they fail to pay

their monthly contributions within the 60-day grace period. Effective the first day following the expiration of the grace period, these beneficiaries will be automatically enrolled in HIP Basic, with no gap in coverage. In HIP Basic, the beneficiary would then be responsible for paying co-payments in accordance of amounts specified in the state plan, but not monthly POWER account contributions. The minimum monthly contribution amount to access HIP Plus is one dollar per month. The beneficiary would have the option to resume making monthly POWER account contributions and enroll in HIP Plus during the annual redetermination process or upon receipt of rollover. The state may add additional times for movement from HIP Plus to HIP Basic at the state's discretion.

d. **Medically frail beneficiaries and section 1931 parents and caretaker relatives** will have the same cost sharing opportunity as described in subsection (b) or (c) above, to either make monthly POWER account contributions consistent with HIP Plus, or to transition to co-payments consistent with the HIP Basic plan. Medically frail beneficiaries above the 100 percent of the FPL who do not make monthly POWER account contributions shall have cost sharing described in STC 10(c) of this section.

e. **State Contributions.** The state will annually contribute to the POWER account for each beneficiary an amount equal to the difference between the required beneficiary contribution and $2500. The state will make an initial $1300 POWER Account contribution promptly upon the beneficiary's full enrollment with the MCO. The MCO will be responsible for reimbursing providers up to the full $2500 amount regardless of the beneficiary's current POWER Account balance, as described in STC 5 of this section. Following the conclusion of the 12-month benefit period, the MCO and state shall reconcile the POWER Account.

3. Determination of Beneficiary Contribution Amounts.

a. The household's POWER Account contributions will be calculated based upon a tiered contribution structure established by the state and described in Table 4. When added to other cost sharing incurred by the beneficiary or the beneficiary's family members, the household's out of pocket expenses shall not exceed five percent of a beneficiary's gross quarterly household income. Required beneficiary contributions will be reduced by the amounts of contributions made by third parties to the POWER Account on behalf of the beneficiary. Permissible contributions may be made by employers or other entities as indicated in STCs 8 and 9 of this section.

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

c. The state shall notify beneficiaries of POWER Account payment requirements upon eligibility determination. The state shall determine the amount of a beneficiary's monthly contribution based on the modified adjusted gross income and will notify the

beneficiary and MCO of this amount. The MCO must bill for and collect this contribution amount from beneficiaries. Monthly invoices shall include information about how to report any change in income, shall inform individuals of the consequences of nonpayment (disenrollment from all coverage, or disenrollment from HIP Plus and default into HIP Basic) and that payment of a POWER Account contribution means an individual can now only change plans for cause and how enrollment broker can help.

d. Beneficiaries enrolled in HIP Plus who are identified as tobacco users will have a tobacco user surcharge applied to their POWER Account contribution amount. This amount will be equal to a 50 percent increase in individual contribution amount. The MCO will identify tobacco users and apply the surcharge as a distinct line item separate from the regular POWER Account contribution amount in the monthly invoice. The tobacco surcharge will be waived for the first year of enrollment in order to provide the individual the opportunity to take advantage of the robust tobacco cessation benefits offered through HIP. During this 12-month period, the MCOs will be required to conduct active outreach and member education related to the tobacco cessation benefits available through HIP. If after twelve months, the member continues to be a tobacco user, a tobacco user surcharge will be applied to their POWER Account contribution amount beginning in the first month of their renewed benefit period. If a beneficiary informs the state that he or she has stopped using tobacco, the tobacco user surcharge will be removed from the following benefit year's contribution amount. The application of the tobacco user surcharge will be appealable for a beneficiary who disagrees with the application of the surcharge.

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

Table 4. POWER Account Tier Amounts

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

100% of the FPL					
Above 100% of the FPL and up to and including 133% of the FPL	$20.00	$10.00	$30.00	$10.00 & $15.00	$15.00

f. The state allows for a ten dollar ($10.00) initial fast track POWER Account payment that makes available immediate enrollment into HIP Plus effective the first date of the month in the month in which payment is received, once an individual has been determined eligible. This option is available via both fast track invoicing from the member's managed care plan and via the application. Individuals completing the application will have an option to select fast track and make a payment directly to the plan to lock in their eligibility start date to the 1st of the month of application, provided they are determined eligible. The fast track invoice option will be available only to individuals who through an initial screening process are not found to be pregnant, below age of 19, receiving Social Security Income (SSI), or potentially disabled. The initial fast track payment must be paid within 60 calendar days from the date of invoice to allow enrollment into HIP Plus (effective the first date of the month in the month in which payment is received, once the eligibility has been determined. For individuals initially screened eligible for HIP, the invoice shall be dated no later than five business days after the date of application.

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

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

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

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

4. **Grace Period/Payment Period**. Applicants and beneficiaries will have 60 days

from the date of the payment invoice to make the required monthly contribution.

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

6. **Medicaid Transitions.** For members transitioning to HIP from other Medicaid categories, including pregnant women in HIP exiting their postpartum period, individuals making such a transition will be immediately enrolled in the HIP Basic plan with a 60-day opportunity to make an initial POWER Account contribution to move to HIP Plus.

7. **Power Account Operations.** The state will continue to operate in compliance with the approved *POWER Account Contributions and Copayment Infrastructure Operational Protocol*. Any changes to the operations of the POWER Account will be amended in the protocols and submitted to CMS.

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

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

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

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

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

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

b. **Beneficiaries Eligible for the HIP Basic Plan**. Beneficiaries with income at or below 100 percent of the FPL have the opportunity to participate in the HIP Plus plan, if they make required monthly POWER account contribution. However, if such beneficiary does not pay required monthly POWER account within the grace period, they will be automatically defaulted to the HIP Basic Plan with no gap in coverage or non-eligibility period. Beneficiaries will continue to maintain a POWER account.

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

i. Medically frail beneficiaries with income above 100 percent of the FPL are required to make monthly POWER account contributions. In the event that such a beneficiary does not make a payment within the 60-day grace period the beneficiary shall --

1. Remain in their existing benefit package;
2. Be required to pay copayments as required under the HIP Basic plan; and
3. Continue to be billed for monthly POWER account contributions, however payment of contributions are not a condition of eligibility.

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

iii. Medically frail beneficiaries with income at or below 100 percent of the FPL and section 1931 parents and caregivers, may pay monthly POWER account contributions in lieu of copayments. In the event that such a beneficiary does not make a payment within the 60-day payment period, the beneficiary shall --

1. Maintain their existing benefit package; and

2. Be required to pay copayments as required under the HIP Basic.

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

i. Obtained and subsequently lost private insurance coverage;

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

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

iv. Is a victim of domestic violence;

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

vi. Is medically frail.

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

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

VIII. HIP COST-SHARING

1. Co-payments. Beneficiaries with income at or below 100 percent of the FPL, medically frail beneficiaries and section 1931 parents and caregivers who do not pay their monthly POWER account contributions within the 60-day grace period will be enrolled in HIP Basic and will be subject to co-payments. These amounts are described below in Table 5. These co-payments shall be charged consistent with Medicaid cost sharing rules at 42 CFR 447.50 – 447.56, including automated tracking of the five percent monthly or quarterly aggregate cap.

Table 5. Copayments.

HIP Basic	
Preventive Care Services (including family planning and maternity services)	$0
Outpatient Services	$4
Inpatient Services	$75
Preferred Drugs	$4
Non-Preferred Drugs	$8
HIP Basic & HIP Plus	
Non-emergent use of the ER	$8

IX. REDETERMINATION & MCO ENROLLMENT

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

2. **Failure to Complete a Redetermination.** All beneficiaries, with the exception of pregnant women or women 60 days or less postpartum, that fail to provide necessary information or documentation to complete the redetermination process will be disenrolled from HIP. Redetermination will begin 45 days prior to the expiration of a beneficiary's 12-month eligibility period. Beneficiaries failing to complete the redetermination process prior to the expiration of their 12-month eligibility period will be determined ineligible for Medicaid and disenrolled from the program unless exempted. Disenrollment from Medicaid may only occur after the state determines the beneficiary ineligible for all other bases of Medicaid eligibility and reviews him/her for eligibility for other insurance affordability programs in accordance with 42 CFR 435.916(f). Beneficiaries subject to disenrollment will be granted an additional 90-day reconsideration period to submit their redetermination paperwork to be reenrolled in HIP without submitting a new application. After the 90-day reconsideration period, individuals not exempt under STC 2(c) of this section, will be prohibited from re-enrolling in HIP for three months after the expiration of the reconsideration period, unless the individual meets a good cause exception, as described in STC 3(d) of this section.

    a. The state may not terminate eligibility if the beneficiary has provided documentation that the state has not processed yet, provided the beneficiary returned the required documentation no later than the due date on the beneficiary's redetermination notice.

b. The state may not apply the three-month non-eligibility period if the beneficiary has provided documentation that the state has not processed yet, provided the beneficiary returned the required documentation no later than the last day of the 90-day reconsideration period.

c. Any beneficiary who becomes pregnant or is determined to be medically frail during the non-eligibility period can reactivate their coverage immediately, consistent with an effective date consistent with the beneficiary's eligibility category. Beneficiaries who are pregnant, medically frail, or parents or caretakers under section 1931 of the Act are exempt from this non-eligibility period. In addition, individuals whose 90-day reconsideration period has expired, but who experience a change in circumstances which prevented completion of the redetermination process as detailed in state code, 405 IAC 10-10-13(e) are also exempt from the open enrollment period and may reapply and be assessed for eligibility taking into account the individual's notification to the state of their exemption. The exemptions in that state code are as follows:

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

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

e. The state may not terminate eligibility of any individual with a disability under the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act for failure to submit redetermination paperwork if the individual needed and was not provided with reasonable modifications necessary to complete the process

3. **Non-eligibility period for Failure to Complete Redetermination: State Assurances.** The state shall:

a. Have a renewal process, including ex parte renewals and use of pre-populated forms, consistent with all applicable Medicaid requirements, for at least twelve months prior to implementation of the demonstration.

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

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

d. Include good cause exceptions to the non-eligibility period that would allow beneficiaries to re-enroll under certain conditions without waiting three months, including but not limited to the following:
   i. Obtained and subsequently lost private insurance coverage;
   ii. Had a loss of income after disqualification due to increased income;
   iii. Took up residence in another state and later returned;
   iv. Is a victim of domestic violence;
   v. Was residing in a county subject to a disaster declaration made in accordance with IC 10-14-3-12 at the time the member was terminated for non-payment or at any time in the 60 calendar days prior to date of member termination for non-payment;
   vi. The beneficiary is hospitalized, otherwise incapacitated, or has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and as a result was unable to provide information necessary to complete the redetermination during the entire ninety redetermination or reconsideration reporting period, or is a person with a disability who was not provided with reasonable modifications needed to complete the process, or is a person with a disability and there were no reasonable modifications that would have enabled the individual to complete the process; or
   vii. A member of the beneficiary's immediate family who was living in the home with the beneficiary was institutionalized or died during the redetermination reporting period or the immediate family member has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and caretaking or other disability-related responsibilities resulted in an inability to complete redetermination.

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

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

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

g. Provide notice to beneficiaries, prior to adverse action, regarding the non-eligibility period, and explaining what this status means, including but not limited to: their

right to appeal, their right to apply for Medicaid on a basis not affected by this status, what this status means with respect to their ability to access other coverage (such as coverage in a qualified health plan through the Exchange, or access to premium tax credits through the Exchange), what they should do if their circumstances change such that they may be eligible for coverage in another Medicaid category, as well as any implications with respect to whether they have minimum essential coverage.

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

i. Provide full appeal rights prior to disenrollment and observe all requirements for due process for beneficiaries who will be disenrolled for failing to provide the necessary information to the state to complete their redeterminations to allow beneficiaries the opportunity to raise additional issues in a hearing, including whether the beneficiary should be subject to the non-eligibility period and/or provide additional documentation through the appeals process.

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

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

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

X. SUBSTANCE USE DISORDER

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

treatment services ranging from acute withdrawal management to on-going chronic care for these conditions in cost-effective settings while also improving care coordination and care for comorbid physical and mental health conditions.

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

Table 6: Indiana SUD Benefits Coverage with Expenditure Authority

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

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

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

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

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

d. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

Covered services include:

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

b. Addiction pharmacotherapy and drug screening;

c. Motivational enhancement and engagement strategies;

d. Counseling and clinical monitoring;

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

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

g. Recovery support services;

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

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

3. **SUD Implementation Plan Protocol.** The state must submit an SUD Implementation Protocol within 90 calendar days after approval of the OUD/SUD program under this demonstration. The state may not claim FFP for services provided in IMDs until CMS has approved the Implementation Protocol. Once approved, the Implementation Protocol will

be incorporated into the STCs, as Attachment D, and once incorporated, may be altered only with CMS approval. After approval of the implementation protocol, FFP will be available prospectively, not retrospectively. Failure to submit an Implementation Protocol or failure to obtain such CMS approval will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SUD program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral.

At a minimum, the SUD Implementation Protocol will describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of this SUD demonstration project:

a. **Access to Critical Levels of Care for SUDs:** Service delivery for new benefits, including residential treatment, withdrawal management, opioid treatment program and addiction recovery and management services within 12-24 months of OUD/SUD program demonstration approval;

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

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

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

e. **Standards of Care:** Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of

clinical care, and credentials of staff for residential treatment settings within 12-24 months of OUD/SUD demonstration approval;

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

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

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

i. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in STC 10 of this section; and

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

4. **SUD Monitoring Protocol.** The state must submit an SUD Monitoring Plan Protocol within 150 calendar days after approval of the OUD/SUD program under this demonstration. The SUD Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs as Attachment E. At a minimum, the SUD Monitoring Protocol will include reporting relevant to each of the program implementation areas listed in STC 3 of this section. The protocol will also describe the data collection, reporting and analytic methodologies for performance measures identified by the state and CMS for inclusion. The SUD Monitoring Protocol will specify the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section XIII of the demonstration. In addition, for each performance measure, the SUD Monitoring Protocol will identify a baseline, a target to be achieved by the end of the demonstration and an annual goal for closing the gap between baseline and target expressed as percentage points. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings. CMS will closely monitor demonstration spending on services in IMDs to ensure adherence to budget neutrality requirements.

5. **Mid-Point Assessment.** The state must conduct an independent mid-point assessment between DYs 5 and 6 of the demonstration. The assessor must collaborate with key stakeholders, including representatives of MCOs, SUD treatment providers, beneficiaries, and other key partners in the design, planning and conducting of the mid-

point assessment. The assessment will include an examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Protocol, and toward closing the gap between baseline and target each year in performance measures as approved in the SUD Monitoring Protocol. The assessment will also include a determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date, and a determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and about the risk of possibly missing those milestones and performance targets. The mid-point assessment will also provide a status update of budget neutrality requirements. For each milestone or measure target at medium to high risk of not being met, the assessor will provide for consideration by the state, recommendations for adjustments in the state's implementation plan or to pertinent factors that the state can influence that will support improvement. The assessor will provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. A copy of the report will be provided to CMS. CMS will be briefed on the report.

For milestones and measure targets at medium to high risk of not being achieved, the state will submit to CMS modifications to the SUD Implementation and SUD Monitoring Protocols for ameliorating these risks subject to CMS approval.

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

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

8. **SUD Evaluation.** The SUD Evaluation will be subject to the same terms as the overall demonstration evaluation, as listed in in the General Reporting Requirements and Evaluation of the Demonstration of the STCs.

9. **SUD Evaluation Design.** The state must submit, for CMS comment and approval, an updated Evaluation Design with implementation timeline, no later than 180 days after the effective date of these STCs. Failure to submit an acceptable and timely evaluation design along with any required monitoring, expenditure, or other evaluation reporting will subject the state to a $5 million deferral. The state must use an independent evaluator to design the evaluation.

a. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within 60 days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Quarterly Reports and Annual Reports, including any required Rapid Cycle Assessments specified in these STCs.

b. **Evaluation Questions and Hypotheses.** The state must follow the general evaluation questions and hypotheses requirements as specified in Section XVI STC 5. In addition, hypotheses for the SUD program should include an assessment of the objectives of the SUD component of this section 1115 demonstration, to include (but is not limited to): initiation and compliance with treatment, utilization of health services (emergency department and inpatient hospital settings), and a reduction in key outcomes such as deaths due to overdose.

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

a. The SUD Health IT section of the Implementation Protocol will include implementation milestones and dates for achieving them (see Attachment D).

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

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

d. The SUD Health IT Plan will address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[2] This will also include plans to include PDMP interoperability with a statewide, regional or local Health

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

[2] *Ibid*.

Information Exchange. Additionally, the SUD Health IT Plan will describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.

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

f. The SUD Health IT Plan will describe how the activities described in (a) through (e) above will: (a) support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns[3] and (b) ensure that Medicaid does not inappropriately pay for opioids–and that states implement effective controls to minimize the risk.

g. In developing the Health IT Plan, states shall use the following resources.
    i. States may use resources at Health IT.Gov (https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/) in "Section 4: Opioid Epidemic and Health IT."

    ii. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.

    iii. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP plans and, more generally, to meet the goals of the demonstration.

h. The state will include in its Monitoring Protocol (see STC 4 of this section) an approach to monitoring its SUD Health IT Plan which will include performance metrics provided by CMS or State defined metrics to be approved in advance by CMS.

i. The state will 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

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

CMS in in an addendum to its Annual Reports (see Section XIII STC 6).

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

i. Wherever it is appropriate, the state must require that contractors providing services paid for by funds authorized under this demonstration shall adopt the standards, referenced in 45 CFR Part 170.

ii. Wherever services paid for by funds authorized by this demonstration are not addressed by 45 CFR Part 170 but are addressed by the ISA, the state should require that contractors providing such services adopt the appropriate ISA standards.

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

a. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.

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

c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) 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 the final Interim Evaluation Report 60 days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.

e. The Interim Evaluation Report must comply with Attachment B of these STCs.

12. **SUD Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.
    a. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within 60 days of receiving comments from CMS on the draft.
    b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 days of approval by CMS.

XI. SERIOUS MENTAL ILLNESS

1. **SMI Program Benefits.** Under this demonstration, beneficiaries will have access to high quality, evidence-based mental health treatment services. These services will range in intensity from short-term acute care in settings that qualify as an IMD to ongoing chronic care for such conditions in cost-effective community-based settings. The state must achieve a statewide average length of stay of no more than 30 days in inpatient treatment settings, to be monitored pursuant to the SMI/SED Monitoring Plan as outlined in STCs 3 of this section.

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

Table 7. SMI Benefits Coverage

Benefit	Type	Medicaid Authority	Expenditure Authority
Crisis Stabilization Services	SMI/SED	State plan (Individual services covered)	N/A
Outpatient services	SMI/SED	State plan (Individual services covered)	N/A
Intensive outpatient treatment (IOT) services	SMI/SED	State plan (Individual services covered)	N/A
Inpatient (acute) services	SMI	State plan (Individual services covered)	Services provided to individuals in IMDs
Medicaid Rehabilitation Option (MRO)	SMI/SED	State plan (Individual services covered)	N/A
Adult Mental Health Habilitation	SMI	State plan (Individual services covered)	N/A
Children's Mental Health Wraparounds	SMI/SED	State plan (Individual services covered)	N/A

Table 7. SMI Benefits Coverage			
Benefit	**Type**	**Medicaid Authority**	**Expenditure Authority**
Behavioral & Primary Healthcare Coordination	SMI	State plan (Individual services covered)	N/A

2. SMI/SED Implementation Plan.

a. The state must submit the SMI/SED Implementation Plan within 90 calendar days after approval of the demonstration for CMS review and comment. The state must submit the revised SMI/SED Implementation Plan within sixty (60) calendar days after receipt of CMS's comments. The state may not claim FFP for services provided in IMDs to beneficiaries with a primary diagnosis of SMI/SED under the SMI/SED IMD expenditure authority until CMS has approved the SMI/SED Implementation Plan and the SMI/SED Financing Plan described in STC 2(e) of this section. After approval of the applicable implementation plans required by these STCs, FFP will be available prospectively, not retrospectively.

b. Once approved, the SMI/SED Implementation Plan will be incorporated into the STCs as Attachment G, and once incorporated, may be altered only with CMS approval. Failure to submit an SMI/SED Implementation Plan will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SMI/SED program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral as described in section X STC7.

c. At a minimum, the SMI/SED Implementation Plan must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:

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

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

accrediting organization whose psychiatric hospital accreditation program or acute hospital accreditation program has been approved by CMS.

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

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

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

individuals directly and by contacting the community-based provider they were referred to;

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

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

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

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

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

d. **SMI/SED Health IT Plan.** Implementation of the milestones and metrics as detailed in Attachment H.

e. **SMI/SED Financing Plan.** As part of the SMI/SED implementation plan referred to in STC2 of this section, the state must submit, within 90 calendar days after approval of the demonstration, a financing plan that will be approved by CMS. Once approved, the SMI/SED Financing Plan will be incorporated into the STCs as part of the SMI/SED

Implementation Plan in Attachment G and, once incorporated, may only be altered with CMS approval. Failure to submit an SMI/SED Financing Plan will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SMI/SED program under this demonstration. Components of the financing plan must include:

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

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

   a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 2 of this section reporting relevant information to the state's SMI/SED financing plan described in Attachment G, and reporting relevant information to the state's Health IT plans described in STC 2(d) of this section;
   b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section XIII of the demonstration; and
   c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

4. **Evaluation.** The SMI/SED Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections XIII (General Reporting Requirements) and XVI (Evaluation of the Demonstration) of these STCs.

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

6. **SMI/SED Mid-Point Assessment.** The state must conduct an independent mid-point assessment by December 31, 2022. In the design, planning and conduction of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of managed care organizations (MCO), SMI/SED providers, beneficiaries, and other key partners.

   The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 days after December 31, 2022. The state must brief CMS on the report.

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

   Elements of the mid-point assessment include:

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

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

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

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

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

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

8. **Updated SMI Deliverable.** Within 60 days of approval, the state must submit an updated current assessment of mental health services that includes the geographical break-down of the availability of all services following the CMS template, to replace the existing assessment. The state submitted a current assessment of mental health services as part of its amendment application and used the draft template available at the time. Since the state's amendment submission, CMS has published an updated template on Medicaid.gov that states are to follow that Indiana did not have access to so CMS is providing Indiana 60 additional days to submit the updated template.

XII. DELIVERY SYSTEM

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

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

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

    a. **Special Health Care Needs**. Beneficiaries with special health care needs

must have direct access to a specialist, as appropriate for the individual's health care condition, as specified in 42 CFR 438.208(c)(4).

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

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

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

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

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

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

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

6. Beneficiary's Right to Change MCOs.

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

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

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

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

   i. Receiving poor quality care;

   ii. Failure of the Insurer to provide covered services;

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

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

   v. Significant language or cultural barriers;

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

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

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

   ix. Other circumstances determined by FSSA or its designee to constitute poor quality of health care coverage

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

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

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

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

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

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

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

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

XIII. GENERAL REPORTING REQUIREMENTS

1. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in the amount of $5,000,000 (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. Specifically:

a. Thirty (30) days after the deliverable was due, CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverables.

b. For each deliverable, the state may submit a written request for an extension to submit the required deliverable. Extension requests that extend beyond the fiscal quarter in which the deliverable was due must include a Corrective Action Plan (CAP).
   i. CMS may decline the extension request.
   ii. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided.
   iii. If the state's request for an extension includes a CAP, CMS may agree to or further negotiate the CAP as an interim step before applying the deferral.

c. The deferral would be issued against the next quarterly expenditure report following the written deferral notification.

d. When the state submits the overdue deliverable(s) that are accepted by CMS, the deferral(s) will be released.

e. As the purpose of a section 1115 demonstration is to test new methods of operation or services, and timely and complete submission of required deliverables is necessary for effective testing, a state's failure to submit all required deliverables may preclude a state from renewing a demonstration or obtaining a new demonstration.

f. CMS will consider with the state an alternative set of operational steps for implementing the intended deferral to align the process with the state's existing deferral process, for example which quarter the deferral applies to, and how the deferral is released.

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

3. **General Financial Requirements.** The state must comply with all general financial requirements under Title XIX outlined in Section XIV of these STCs.

4. **Reporting Requirements Related to Budget Neutrality.** The state shall comply with all reporting requirements for monitoring budget neutrality set forth in Section XV of these STCs.

5. **Periodic Monitoring Calls.** CMS will convene periodic conference calls with the state. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration; including planning for future changes in the program or intent to further

the HIP demonstration beyond December 31, 2020. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration. The state and CMS will jointly develop the agenda for the calls.

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

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

    b. Performance Metrics – Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

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

Administrative costs should be reported separately.

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

7. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents 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) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 1 of this section.

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

   a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;

   b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to are provided; and

   c. Submit the monitoring reports and evaluation reports to the appropriate system as directed by CMS.

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

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

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

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

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

comments.

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

10. CMS Review of the Protocols. Once reviewed by CMS, the Evaluation Design will become Attachment C of the STCs and will be binding upon the state. The state may request changes to protocols, which will be effective prospectively. Changes may be subject to an amendment to the STCs in accordance with Section III STC 7, depending upon the nature of the proposed change. A delay in submitting such protocols could subject the state to penalties described in STC 1 of this section.

XIV. GENERAL FINANCIAL REQUIREMENTS

1. Quarterly Expenditure Reports. The state must report quarterly expenditures associated with the populations affected by this demonstration on the Form CMS-64.

2. Reporting Expenditures under the Demonstration. The following describes the reporting of expenditures:

a. **Tracking Expenditures**. In order to track expenditures under this demonstration, Indiana must report demonstration expenditures through the MBES and state Children's Health Insurance Program Budget and Expenditure System (CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the state Medicaid Manual. All demonstration expenditures claimed under the authority of title XIX of the Act must be reported each quarter on separate Forms CMS-64.9 Waiver and/or 64.9P Waiver, identified by the demonstration project number assigned by CMS, including the project number extension, which indicates the DY in which services were rendered or for which capitation payments were made. For this purpose, DY 1 is defined as the year beginning February 1, 2015, and ending December 31, 2015; subsequent DYs are defined accordingly. All title XIX service expenditures that are not demonstration expenditures and are not part of any other title XIX waiver program should be reported on Forms CMS-64.9 Base/64.9P Base.

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

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

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

matching, they are not to be reported on the CMS-64.).

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

c. **Cost Settlements.** For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (Form CMS-64.9P Waiver) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any cost settlements not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the state Medicaid Manual.

d. **Use of Waiver Forms**. Forms CMS-64.9 Waiver and/or 64.9P must be submitted each quarter (when applicable) to report title XIX expenditures for individuals enrolled in the demonstration. The expressions in quotation marks are the waiver names to be used to designate these waiver forms in the MBES/CBES system.

i. "SUD/IMD" Expenditures
ii. "SMI FFS" Expenditures
iii. "SMI Managed Care" Expenditures

e. **Pharmacy Rebates.** The state may propose a methodology for assigning a portion of pharmacy rebates to the demonstration, in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of the demonstration population, and which reasonably identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must also be approved in advance by the Regional Office. The portion of pharmacy rebates assigned to the demonstration using the approved methodology will be reported on the appropriate Forms CMS-64.9 Waiver for the demonstration, and not on any other CMS-64.9 form (to avoid double-counting). Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.

f. **Administrative Costs.** The following provisions govern reporting of administrative costs during the demonstration.

i. Administrative costs attributable to the demonstration must be reported under waiver name "HIP."

ii. Administrative costs not related to the demonstration should be reported on the appropriate CMS-64.10 Base or 64.10P Base, or another waiver schedule as appropriate.

g. **Claiming Period.** All claims for expenditures (including any cost settlements) must be made within 2 years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) must be made within 2 years after the conclusion or termination of the demonstration. During the latter 2-year period, the state must continue to identify separately on the CMS-64 waiver forms the net expenditures related to dates of service during the operation of the section 1115 demonstration, in order to account for these expenditures properly to determine budget neutrality.

3. **Standard Medicaid Funding Process.** The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable demonstration expenditures (total computable and federal share) and separately report these expenditures by quarter for each federal fiscal year on the Form CMS-37 for both the Medical Assistance Payments (MAP) and State and Local Administration Costs (ADM). CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS will reconcile expenditures reported on the Form CMS-64 quarterly with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

4. **Extent of FFP for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole as outlined below:

   a. Administrative costs, including those associated with the administration of the demonstration.

   b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved state plan.

   c. Medical Assistance expenditures made under section 1115 demonstration authority, including those made in conjunction with the demonstration, cost sharing, pharmacy rebates, and all other types of third party liability or CMS payment adjustments.

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

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

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

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

d. Under all circumstances, health care providers must retain 100 percent of the HIP reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business (such as payments related to taxes (including health care provider-related taxes), fees, and business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments) are not considered returning and/or redirecting a Medicaid payment.

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

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

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

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

c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for payments under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such tax revenue (state or local) used to fund the non-federal share of demonstration expenditures. The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.

d. The state may use intergovernmental transfers to the extent that such funds are

derived from state or local tax revenues and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of Title XIX payments.

e. Under all circumstances, health care providers must retain 100 percent of the HIP reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business (such as payments related to taxes (including health care provider-related taxes), fees, and business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments) are not considered returning and/or redirecting a Medicaid payment.

7. **Monitoring the Demonstration.** The state shall provide CMS with information to effectively monitor the demonstration, upon request, in a reasonable timeframe.

XV. BUDGET NEUTRALITY DETERMINATION

1. **Limit on Title XIX Funding.** The state shall be subject to a limit on the amount of federal title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration. The limit will be determined by using a per capita cost method. The budget neutrality expenditure targets are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. Actual expenditures subject to the budget neutrality expenditure limit shall be reported by the state using the procedures described in Section XIV STC 2(d). The data supplied by the state to CMS to set the annual limits is subject to review and audit, and, if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

2. **Risk.** Indiana shall be at risk for the per capita cost (as determined by the method described below in this section) for Medicaid eligibles but not for the number of demonstration eligibles in each of the groups. By providing FFP for HIP enrollees in these eligibility groups, Indiana shall not be at risk for changing economic conditions that impact enrollment levels. However, by placing Indiana at risk for the per capita costs for HIP enrollees, CMS assures that the federal demonstration expenditures do not exceed the level of expenditures that would have occurred had there been no demonstration.

3. **Budget Neutrality Annual Expenditure Limits.** For each DY, annual limits are calculated. As part of the SUD and SMI initiatives, the state may receive FFP for the continuum of services specified in Tables 6 and 7 to treat OUD and other SUDs that are provided to Medicaid beneficiaries in an IMD. These are

state plan services that would be eligible for reimbursement if not for the IMD exclusion. Therefore, they are being treated as hypothetical. The state may only claim FFP via demonstration authority for the services listed in Tables 6 and 7 that will be provided in an IMD. However, the state will not be allowed to obtain budget neutrality "savings" from these services. Therefore, a separate expenditure cap is established for SUD and SMI services.

a. The SUD and SMI MEGs listed in the table below are included in SUD budget neutrality test.

b. SUD and SMI expenditures caps are calculated by multiplying the projected PMPM for each SUD MEG, each DY, by the number of actual eligible SUD and SMI member months for the same MEG/DY—and summing the products together across all DYs. The federal share of the SUD expenditure cap is obtained by multiplying those caps by the Composite Federal Share (see STC 4 of this section).

c. SUD and SMI budget neutrality test is a comparison between the federal share of SUD expenditure cap and total FFP reported by the state for the SUD and SMI MEGs.

Eligibility Group	Trend Rate	DY 4	DY5	DY 6
SUD	4.9%	$6,834.71	$7,169.61	$7,520.92
SMI FFS	4.6%		$5,121.27	$5,356.85
SMI Managed Care	4.6%		$1,046.32	$1,094.45

d. The budget neutrality cap is calculated by taking the PMPM cost projection for the above group in each DY, times the number of eligible member months for that group and DY, and adding the products together across groups and DYs. The federal share of the budget neutrality cap is obtained by multiplying total computable budget neutrality cap by the federal share.
e. The state will not be allowed to obtain budget neutrality "savings" from the SUD and SMI MEGs.

4. **Composite 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 three-year approval period, as reported on the form listed in Section XIV STC 2(d) by total computable demonstration expenditures for the same period as reported on the same forms. Should the demonstration be terminated prior to the end of the three-year approval period, the Composite Federal Share will be determined based on actual expenditures for the period in which the demonstration was active. For the purpose of

interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be used.

5. **Future Adjustments to the Budget Neutrality Expenditure Limit.** CMS reserves the rights to adjust the budget neutrality expenditure limit to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statues, or policy interpretations implemented through letter, memoranda, or regulations with respect to the provision of services covered under HIP.

6. **Enforcement of Budget Neutrality.** CMS shall enforce budget neutrality over the life of the demonstration rather than on an annual basis, by combining the annual limits calculated following this STC into lifetime limits for the demonstration. The budget neutrality test for the demonstration extension will incorporate net savings from the immediately prior demonstration period of February 1, 2015 through January 31, 2018, but not from any earlier approval period.

7. **Budget Neutrality Savings Phase-Down**. Beginning with the demonstration period that begins on February 1, 2018, the net variance between the without-waiver and actual with-waiver costs will be reduced. The reduced variance, calculated as a percentage of the total variance, is used in place of the total variance to determine overall budget neutrality of the demonstration. The formula for calculating the reduced variance is, reduced variance equals total variance times applicable percentage. The percentages are determined based on how long Medicaid populations have been enrolled in managed care subject to the demonstration. In the case of Indiana, the managed care program will retain 25 percent of the total variance as future savings for the demonstration. Should the state request an extension of its demonstration beyond December 31, 2020, the state must provide actual managed care capitation rate data for enrollees. Budget neutrality will be adjusted again to reflect revised PMPMs based on this data.

8. **Exceeding Budget Neutrality.** If at the end of the demonstration period the cumulative budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the budget neutrality agreement, an evaluation of this provision will be based on the time elapsed through the termination date.

9. **Impermissible DSH, Taxes or Donations.** The CMS reserves the right to adjust the budget neutrality expenditure limit in order to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statutes, or with policy interpretations implemented through letters, memoranda, or regulations. CMS reserves the right to make adjustments to the budget neutrality expenditure limit if CMS determines that any health care-related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is in violation of the provider donation and health care related tax provisions of Section 1903(w) of the Act. Adjustments to the budget neutrality agreement will reflect the phase-out of impermissible provider payments by law or regulation, where applicable.

XVI. EVALUATION

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

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

3. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with attachments A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than (180 days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state may choose to use the expertise of the independent party in the development of the draft Evaluation Design.

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

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

Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

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

    a. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.

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

    c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) 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 the final Interim Evaluation Report 60 days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.

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

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

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

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

8. **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, and/or the summative evaluation.

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

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

Attachment A – Developing the Evaluation Design

Introduction

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

Expectations for Evaluation Designs

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

The format for the Evaluation Design is as follows:

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

Submission Timelines

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

Required Core Components of All Evaluation Designs

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

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

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

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

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

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

5) Describe the population groups impacted by the demonstration.

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

1) Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf

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

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

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

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

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

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

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

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

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

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

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

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

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

Research question 2a	-Measure 1 -Measure 2	-Sample, e.g., PPS administrators	-Key informants	Qualitative analysis of interview material

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

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

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

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

F. Attachments

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

B. Evaluation Budget. A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and

analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

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

Attachment B: Preparing the Interim and Summative Evaluation Reports

Introduction

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

Expectations for Evaluation Reports

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

Intent of this Attachment

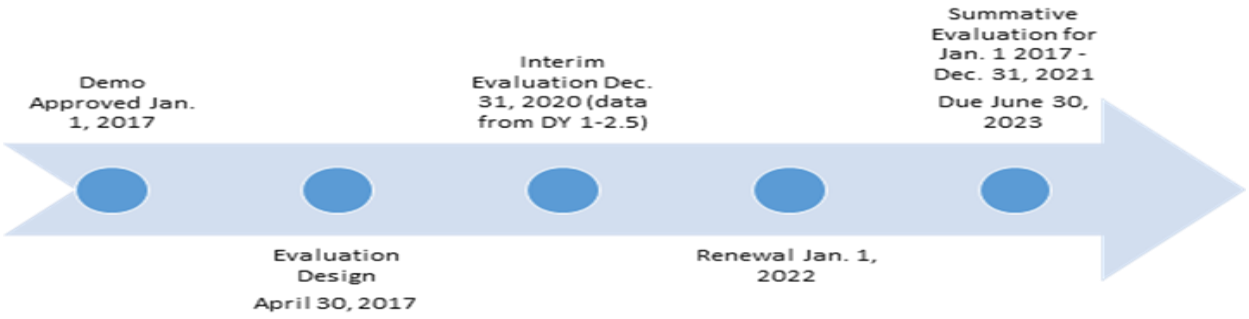
Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified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

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

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

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

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



Required Core Components of Interim and Summative Evaluation Reports

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

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

B. General Background Information about the Demonstration – In this section, the state should include basic information about the demonstration, such as:
i. The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.

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

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

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

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

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

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

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

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

E. Methodological Limitations

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

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

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

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

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

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

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

1. What lessons were learned as a result of the demonstration?

2. What would you recommend to other states which may be interested in implementing a similar approach?

J. Attachment

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

State of Indiana
1115 SUD Waiver
Implementation Plan

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

Healthy Indiana Plan
Effective: February 1, 2018 through December 31, 2020
Amendment approved: December 20, 2019

Contents

Introduction

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

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

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

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

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

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

Access to Critical Levels of Care for SUD Treatment

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

[1] INDIANA STATE DEPARTMENT OF HEALTH, INDIANA:SPECIAL EMPHASIS REPORT, DRUG OVERDOSE DEATHS, 1999-2013 (2016), available at http://www.in.gov/isdh/files/2016_SER_Drug_Deaths_Indiana.pdf.
[2] Based on ICD-10 claims analysis for claims with a date a service between January 1 and December 31, 2016. Excludes tobacco use disorder.

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

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

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

Level of Care: OTS (Opioid Treatment Services)

Summary of Actions Needed:

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

Current State:

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

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

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

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

Future State:

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

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

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

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

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

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

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

Level of Care: 0.5 (Early Intervention)

Summary of Actions Needed:

- None anticipated

Current State:

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

Future State:

No changes are expected at this ASAM level of care.

Level of Care: 1.0 (Outpatient Services)

Summary of Actions Needed:

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

Current State:

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

Office-Based Treatment

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

Community-Based Treatment

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

Services billable through MRO include the following:

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

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

Future State:

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

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

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

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

Level of Care: 2.1 (Intensive Outpatient Services)

Summary of Actions Needed:

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

Current State:

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

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

For providers billing on a UB-04 claim form:

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

For providers billing on a CMS-1500 claim form:

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

Future State:

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

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

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

Level of care: 2.5 (Partial Hospitalization)

Summary of Actions Needed:

- None anticipated

Current State:

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

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

Future State:

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

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

Summary of Action Items:

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

Current State:

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

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

Future State:

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

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

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

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

Drug Testing	Encounter	80101	$19.03

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

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

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

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

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

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

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

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

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

Summary of Action Items:

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

Current State:

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

Future State:

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

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

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

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

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

Sub Support Service – Addiction Recovery Management Services

Summary of Action Items:

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

Current State:

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

Future State:

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

- Peer Recovery Support
- Recovery-Focused Case Management

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

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

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

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

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

Sub Support Service – Supportive Housing Services

Summary of Action Items:

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

Current State:

Indiana Medicaid currently provides no coverage for supportive housing services.

Future State:

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

- Transitioning Services

  - Identification of resources to help cover the security deposit, moving costs, environmental modifications, and other one-time expenses
  - Tenant screening and housing assessment to identify individual's preferences and barriers related to successful tenancy
  - Assistance with housing application or housing search process
  - Assistance with arranging for and supporting details of the move
  - Development of a housing support crisis plan
- Sustaining Services
  - Early identification and intervention for behaviors that may jeopardize housing
  - Education and training on the roles, rights, and responsibilities of a tenant and landlord
  - Coaching on key relationships with landlords and property managers
  - Assistance with resolving disputes with landlords
  - Assistance with housing recertification process
  - Training in being a good tenant and lease compliance

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

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

Withdrawal Management Services (Inpatient Detoxification)

Summary of Action Items:

- Conversation with MCEs regarding authorization criteria

Current State

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

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

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

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

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

Future State:

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

Use of Evidenced-Based SUD-Specific Patient Placement Criteria

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

Patient Assessment

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

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

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

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

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

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

Utilization Management

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sufficient Provider Capacity at Critical Levels of Care

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

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

Addiction Treatment Services Provider (Regular)

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

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

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

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

Addiction Treatment Services Provider (Outpatient)

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

Provider Enrollment

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

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

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

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

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

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

Overall Provider Strategy

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

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

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

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

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

Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse

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

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

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

Enforcement Recommendations:

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

Treatment Recommendations:

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

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

Gold Card Program

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

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

Buprenorphine Prior Authorization Criteria

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

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

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

Indiana Attorney General's Prescription Drug Abuse Prevention Task Force

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

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

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

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

Prescribing Guidelines

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

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

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

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

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

Expanded Access to Naloxone

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

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

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

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

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

Prescription Drug Monitoring Program

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

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

Improved Care Coordination and Transitions Between Levels of Care

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

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

member. This information sharing must include primary and secondary diagnoses, findings from assessments, medication prescribed, psychotherapy prescribed, and other relevant information.

- Each MCE is required to send a behavioral health profile to a member's primary medical provider (PMP) on a quarterly basis. Information about substance use treatment may only be released only with a member's consent, per *42 CFR Part 2* standards.

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

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

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

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

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

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

Abbreviations

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

Opioid use disorders= OUDs

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

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

Guideline Summary:

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

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

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

Treatment for opioid use disorders shall be comprehensive and include:

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

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

Introduction:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Introduction:

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

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

(i) Opioid maintenance treatment options:

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

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

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

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

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

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

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

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

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

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

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

(ii) Detoxification:

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

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

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

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

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

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

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

(iv) Relapse prevention:

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

Naltrexone (ASAM guidelines [1]):

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 3. Switching between medications that treat OUDs

Introduction:

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

(Excerpted from ASAM guidelines [1]):

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

(1) Patient experiences intolerable methadone side effects.

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

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

(II) Switching from methadone to buprenorphine:

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

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

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

(III) Switching from Methadone to Naltrexone

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

(IV) Switching from Buprenorphine to Naltrexone

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

(V) Switching to Methadone

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

Section 4. Counseling and Ancillary services for OBOT providers

Introduction:

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

Excerpted from APA Guidelines [2]:

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

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

"1. Cognitive-behavioral therapies

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

2. Behavioral therapies

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

3. *Psychodynamic and interpersonal therapies*

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

4. *Family therapies*

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

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

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

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

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

Introduction:

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

Excerpted from ASAM guidelines [1]:

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

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

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

(3) Positive changes in the psychosocial environment.

(4) Evidence of additional psychosocial supports.

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

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

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

(1) Minimal Prescriber Requirements for Buprenorphine Prescribing

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

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

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

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

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

(3) Requirements for INSPECT reviews when prescribing opioids

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

Section 7. Addressing benzodiazepine use

Introduction:

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

Excerpted from Management of Benzodiazepines in Medication-Assisted Treatment

[44]:

"Generally:

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

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

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

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

6. If a person presenting for MAT will not allow a clinician to coordinate care, he or she [is not] appropriate for methadone and/or buprenorphine

Section 8. Managing Relapse

Introduction:

Relapse is an anticipated event in the process of recovery. . Nonetheless, there are practices that prescribers can adopt that are more likely to promote recovery than others. Best practices to address relapse are detailed here.

Excerpted from APA guidelines [2]:

“Because individuals with substance use disorders are often ambivalent about giving up their substance use, it can be useful to monitor their attitudes about participating in treatment and adhering to specific recommendations. These patients often deny or minimize the negative consequences attributable to their substance use; this tendency is often erroneously interpreted by clinicians and significant others as evidence of dishonesty. Even patients entering treatment with high motivation to achieve abstinence will struggle with the reemergence of craving for a substance or preoccupation with thoughts about attaining or using a substance. Moreover, social influences (e.g., substance- using family or friends), economic influences (e.g., unemployment), medical conditions (e.g., chronic pain, fatigue), and psychological influences (e.g., hopelessness, despair) may make an individual more vulnerable to a relapse episode even when he or she adheres to prescribed treatment. For these reasons, it can be helpful for clinicians and patients to anticipate the possibility that the patient may return to substance use and to agree on a corrective

plan of action should this occur. If the patient is willing, it can be helpful to involve significant others in preventing the patient's relapse and prepare significant others to manage relapses should they occur.

Supporting patients in their efforts to reduce or abstain from substance use positively reinforces their progress. Overt recognition of patient efforts and successes helps to motivate patients to remain in treatment despite setbacks. Clinicians can optimize patient engagement and retention in treatment through the use of motivational enhancement strategies [45, 46] and by encouraging patients to actively partake in self-help strategies. Monitoring programs, such as EAPs and impaired-physician programs [47-49], can sometimes help patients adhere to treatment.

Early in treatment a clinician may educate patients about cue-, stress-, and substance-induced relapse triggers [50, 51]. Patients benefit from being educated in a supportive manner about relapse risk situations, thoughts, or emotions; they must learn to recognize these as triggers for relapse and learn to manage unavoidable triggers without resorting to substance-using behaviors. Participation in AA or similar self-help group meetings can also support patients' sobriety and help them avoid relapse. Many other strategies can also help prevent relapse. Social skills training is targeted at improving individual responsibility within family relationships, work related interactions, and social relationships. During the early recovery phase, it can be helpful to encourage patients to seek new experiences and roles consistent with a substance-free existence (e.g., greater involvement in vocational, social, or religious activities) and to discourage them from instituting major life changes that might increase the risk of relapse. Facilitating treatment of co-occurring psychiatric and medical conditions that significantly interact with substance relapse is a long- term intervention for maintaining sobriety [52-54]. Therapeutic strategies to prevent relapse have been well studied and include teaching individuals to anticipate and avoid substance-related cues (e.g., assessing individual capacity to avoid relapse in the presence of substance-using peers), training individuals how to monitor their affective or cognitive states associated with increased craving and substance use, behavioral contingency contracting, training individuals in cue extinction and relaxation therapies to reduce the potency of substance-related stimuli and modulate craving intensity, and supporting patients in the development of coping skills and lifestyle changes that support sobriety [55, 56]. Behavioral techniques that enhance the availability and perceived value of social reinforcement as an alternative to substance use or reward for remaining abstinent have also been used [57]. If relapse does occur, individuals should be praised for even limited success and encouraged to continue in or resume treatment. Clinicians may help patients analyze relapses as well as periods of sobriety from a functional and behavioral standpoint and use what is learned to adjust the treatment plan to fit the individual's present needs. For chronically relapsing substance users, medication therapies may be necessary adjuncts to treatment."

Section 9. Obtaining informed consent concerning all available opioid use disorder treatment options, including risks and benefits of each option.

Introduction:

The informed consent process should ensure that each patient voluntarily chooses their treatment and that relevant facts concerning the use of the medications (including non-opioid medication treatment options) are clearly and adequately explained, such as follows :

Opioids are drugs that stimulate mu-receptors in the brain to produce a wide range of effects including pain relief, sedation, euphoria, addiction, and, with high enough doses, death. Opioids include heroin, morphine, methadone, oxycodone, hydrocodone, buprenorphine, tramadol and others. An opioid use disorder (i.e. addiction) is diagnosed when opioids are used in a compulsive, uncontrolled way producing negative physical, mental and social consequences. Treatment options for opioid addictions are compared below.

Behavioral Interventions: Behavioral interventions are recommended to accompany any addiction treatment.

Benefits and advantages

- Capable of addressing a host of contexts associated with addiction (e.g., depression or pain)
- No medication costs or side effects, except in the case of adolescents, where groups have been shown to worsen prognosis

Risks and downsides

- The long-term chance of quitting opioids is low without taking medication like those listed below.
- Group therapies involve some compromise of confidentiality and can be time consuming.

Methadone: Methadone is an opioid dispensed by a government regulated Opiate Treatment Provider (OTP).

Benefits and advantages

- Scientifically proven to reduce withdrawal, illicit opioid relapse, psychiatric, legal, medical, social and financial consequences of opioid addiction.
- Clients are monitored closely for progress.

Risks and downsides

- Requires ongoing use of opioids
- Requires daily, often early morning visits to the OTP in the first months.
- OTPs typically focus on only opioid addiction and do not treat other co-occurring addictions and mental illnesses.
- OTP/Methadone treatment is generally not covered by public/private insurance. Only 13 OTP clinics and the Veteran's Administration in Indiana--so may need to drive long distances.
- Methadone can cause serious side effects with high doses, or when mixed with alcohol, benzodiazepines, barbiturates or certain muscle relaxants; Can cause irregular heartbeat, cessation of breathing and death.
- Stopping methadone, as with any opioid, causes opioid withdrawal sickness. Accidental ingestion by children can be fatal.

Buprenorphine (Suboxone, Subutex, Zubsolv, Bunavail): Buprenorphine is an opioid prescribed by an OTP or a doctor with a special prescribing certification. It has many of the same benefits and risks as methadone. However there are several key differences listed as follows.

Benefits and advantages

- Buprenorphine treatment (outside of an OTP) typically requires fewer treatment appointments than methadone to receive medication.
- Buprenorphine treatment is more often covered by public and private insurance. Risk of lethal over dose is much less than with methadone or other opioids.
- Babies born to mothers maintained on Buprenorphine have less risk of experiencing NAS.

Risks and downsides

- May not work as well as methadone in certain patients with severe opioid addiction. Lack of highly structured treatment programming with buprenorphine does not serve some people well.

Naltrexone (Revia, Vivitrol): Naltrexone is a prescription drug that blocks the effects of opioids in the brain. Naltrexone comes as a pill that is taken one or two times a day or as a shot given by a nurse once a month. You can not take opioids for about two weeks before starting naltrexone. Naltrexone is also used to treat alcohol addiction.

Benefits and advantages

- Does not require the use of an opioid to facilitate recovery Increases adherence to psycho-social treatment.
- Significantly reduces cravings for opioids.

- Will not result in respiratory depression if taken in excess Covered by most insurance plans.
- Treats alcohol addiction too.

Risks and downsides

- Naltrexone may cause opioid withdrawal symptoms if started before someone has detoxed from opioids.
- Can cause serious liver problems, although this is more likely when taking high doses of the oral form. Opioid pain medications will not work as well when taking naltrexone. The injection can cause some discomfort, rarely could become infected. Individuals can still overdose on opioids, while taking naltrexone.
- Should not be started during pregnancy.

This information has been reviewed with the client, by the signing physician. Signature of

Client: date:

Signature of

Physician: date:

Section 10. Drug Testing

Introduction:

Testing biological samples for the presence of drugs of abuse is an essential part of the treatment of OUDs. Best practices of drug screening are detailed here.

Excerpted from APA[2]:

"Urine drug testing, or other reliable biological tests for the presence of drugs, during the initial evaluation and frequently throughout treatment, is highly recommended. Results from some studies have indicated that more intensive monitoring of substance use may increase recovery rates from a substance use disorder…There are a variety of toxicology tests available, some with greater and lesser reliability and validity. Urine testing is useful for detecting substance use over the preceding 5-day period for common substances of abuse (cocaine, opiates, cannabis, amphetamines, benzodiazepines, and PCP); however, certain opioids (buprenorphine, oxycodone, hydrocodone, and fentanyl) cannot be detected with routine methods and require special assays. [It is important to screen for the metabolites of the prescribed opioid agonist (e.g. norbuprenorphine), to ensure compliance with the treatment. Point of care testing (e.g., urine testing) is needed to make rapid clinical decisions, supplemented by "send out," confirmatory

laboratory values.] The person who is interpreting these labs should be very familiar with the methodology and the reliability.

There is little research on the optimal frequency of testing, [however, random drug testing is optimal.]….The frequency of drug testing will be determined by a number of factors, including the stability of the patient, the type of treatment, the treatment setting, and the half-life of drugs in the matrix being tested. Patients will likely require more testing early in treatment or during periods of relapse. Patients participating in office based treatment with buprenorphine may be tested at each office visit.

Opioids are detectable in the urine for 1–3 days after use. A negative urine test combined with no history of withdrawal may indicate a lack of physical dependence.

However, a negative urine test does not rule out opioid use, disorder, or physical dependence. Urine testing is also helpful to identify

(1) Use of other psychoactive substances.

(2) If a patient tests positive for an illegal drug…or a controlled substance that the patient is not taking as part of the treatment plan, then the provider needs to review the treatment plan and consider changes with the goal of opioid abstinence."

Section 11. Pregnant Women with OUDs

Introduction:

Pregnant women have unique needs and require treatment customized to their situation. Best practices for their treatment are highlighted here.

(Excerpted from ASAM guidelines [1]

"(1) The first priority in "treating" pregnant women for opioid use disorder should be to identify emergent or urgent medical conditions that require immediate referral for clinical evaluation.

(2) A medical examination and psychosocial assessment is recommended when evaluating pregnant women for opioid use disorder.

(3) Obstetricians and gynecologists should be alert to signs and symptoms of opioid use disorder. Pregnant women with opioid use disorder are more likely to seek prenatal care late in pregnancy, miss appointments, experience poor weight gain, or exhibit signs of withdrawal or intoxication.

(4) [As with all patients with OUDs,] psychosocial treatment is [strongly] recommended in the treatment of pregnant women with opioid use disorder.

(5) Counseling and testing for HIV should be provided in accordance with state law. Tests for hepatitis B and C and liver function are also suggested. Hepatitis A and B vaccination is recommended for those whose hepatitis serology is negative.

(6) Urine drug testing may be used to detect or confirm suspected opioid and other drug use with informed consent from the mother, realizing that there may be adverse legal and social consequences of her use. State laws differ on reporting substance use during pregnancy. Laws that penalize women for use and for obtaining treatment serve to prevent women from obtaining prenatal care and worsen outcomes.

(7) Pregnant women who are physically dependent on opioids should receive treatment using methadone or buprenorphine mono-product rather than withdrawal management or abstinence.

(8) Care for pregnant women with opioid use disorder should be co-managed by an obstetrician and an addiction specialist physician. Release of information forms need to be completed to ensure communication among healthcare providers.

(9) Treatment with [buprenorphine or] methadone [(within a licensed Opioid Treatment Program)] should be initiated as early as possible during pregnancy.

(10) Hospitalization during initiation of methadone and treatment with buprenorphine may be advisable due to the potential for adverse events, especially in the third trimester.

(14) Clinicians should be aware that the pharmacokinetics of [buprenorphine] are affected by pregnancy….Increased or split doses may be needed as pregnancy progresses. After child birth, doses may need to be adjusted.

(15) Buprenorphine monoproduct is a reasonable and recommended alternative to methadone for pregnant women. Whereas there is evidence of safety, there is insufficient evidence to recommend the combination buprenorphine/ naloxone formulation.

(16) If a woman becomes pregnant while she is receiving naltrexone, it is appropriate to discontinue the medication if the patient and doctor agree that the risk of relapse is low. If the patient is highly concerned about relapse and wishes to continue naltrexone, she should be informed about the risks of staying on naltrexone and provide her consent for ongoing treatment. If the patient wishes to discontinue naltrexone, but then reports relapse to opioid use, it may be appropriate to consider treatment with methadone or treatment with buprenorphine.

(17) Naloxone is not recommended for use in pregnant women with opioid use disorder except in situations of life-threatening overdose.

(18) Mothers receiving methadone and buprenorphine monoproduct for the treatment of opioid use disorders should be encouraged to breastfeed.

(19) [Naltrexone may be appropriate for a mother after delivery who is capable of detoxification and at risk of relapse.]

Methadone Versus Buprenorphine

The discussion and decision for medication should be reviewed with the patient and documented in her chart. For women who are pregnant or breastfeeding, opioid agonist treatment with methadone or buprenorphine is seen as the most appropriate treatment, taking into consideration effects on the fetus, neonatal abstinence syndrome, and impacts on perinatal care and parenting of young children. Methadone is the accepted standard of care for use during pregnancy; however, buprenorphine monoproduct is a reasonable alternative and also has some advantages over methadone. Infants born to mothers treated with buprenorphine had shorter hospital stays (10 vs. 17.5 days), had shorter treatment durations for neonatal abstinence syndrome (NAS) (4.1 vs. 9.9 days), and required a lower cumulative dose of morphine (1.1 vs. 10.4 mg) compared to infants born to mothers on treatment with methadone.

Combination Buprenorphine/Naloxone

There is some evidence suggesting that buprenorphine/ naloxone is equivalent in safety and efficacy to the monoproduct for pregnant women…At present, however, this evidence is insufficient to recommend the combination buprenorphine/naloxone formulation in this population."

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Attachment E: SUD Monitoring Plan Protocol
[To be incorporated after CMS approval]

Attachment F: SUD Evaluation Design

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

FINAL DRAFT
MARCH 21, 2019

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SECTION I: GENERAL BACKGROUND INFORMATION

I.A Introduction

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

- Nearly six times as many Hoosiers died from drug overdoses in 2014 as did in 2000, and the number of heroin overdose deaths increased by nearly 25 times between 2000 and 2014.[1]
- In 2014, Indiana had the 16th highest drug overdose death rate in the nation, which represented a statistically significant increase in the rate from 2013.[2]
- Since 2009, more Hoosiers have lost their lives due to a drug overdose than in automobile accidents on state highways.[3]
- The State's Medicaid population has been particularly impacted by the crisis: nearly 100,000 individuals were treated for a diagnosis of substance use disorder in 2016.[4]

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

On February 1, 2018, Indiana also received approval of its SUD Implementation Protocol as required by special terms and conditions (STC) X.10 of the state's section 1115 Health Indiana Plan (HIP) demonstration. As set forth in the Implementation Plan, Indiana is aligning the six goals for the SUD waiver component with the milestones outlined by CMS as follows:[5]

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

To accomplish these six goals, Indiana Medicaid is focusing on the three following areas[6]:

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

In support of these focus areas, Indiana Medicaid and CMS identified six key milestones, as described in their approved Implementation and Monitoring Plan, which include:[7].

1. Access to critical levels of care for SUD treatment;
2. Use of evidence-based SUD-specific patient placement criteria; prior-authorization, providers, payers; matching need to capacity
3. Use of nationally recognized SUD-specific program standards to set provider qualifications for residential treatment facilities;
4. Sufficient provider capacity at critical levels of care, including medication assisted treatment for opioid use disorder (OUD);
5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD; and
6. Improved care coordination and transition between levels of care.

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I.B Indiana Medicaid's Six Milestones

A detailed description of activities related to each milestone are

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

treatment

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

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

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

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

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

4. Sufficient provider capacity at critical levels of care

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

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

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

findings and actionable recommendations:

  - 17 recommendations in total;
  - 3 recommendations related to enforcement; and
  - 14 recommendations related to treatment, including pursuit of a Medicaid 1115 Demonstration Waiver for individuals with SUD.

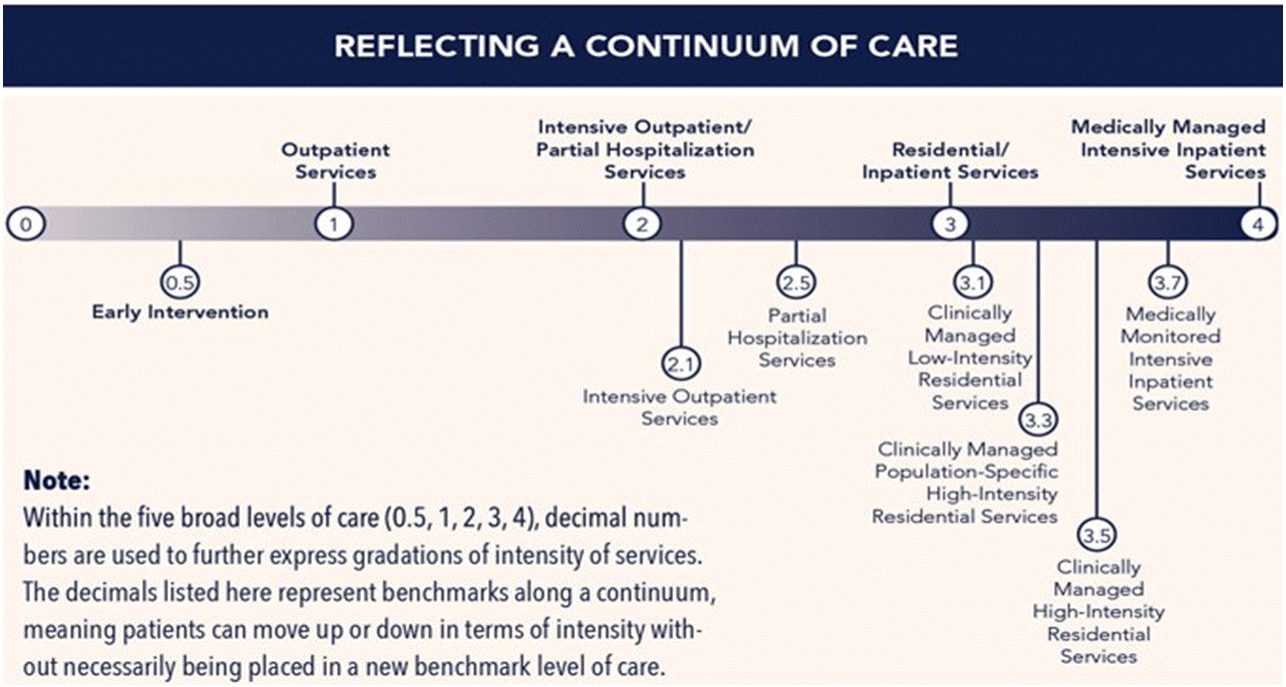
- Gold Card Program
  - Implemented late 2015.
  - Program allows qualified Medicaid prescribers to be exempt from prior authorization document submission requirements when prescribing buprenorphine and buprenorphine/naloxone.
- Buprenorphine Prior Authorization Criteria
  - Established specific prior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

6. Improved care coordination and transitions between levels of care

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

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

Figure 1. ASAM Levels Reflect a Continuum of Care[8]



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

Figure 2. Current and Proposed Coverage for Indiana Medicaid, and Implementation Timeline, by ASAM level of care[9]

ASAM Level of Care	Service Title	Description	Curre nt Coverage	Future Coverage	Implementation Timeline
OTP	Opioid Treatment Program	Pharmacological and non-pharmacological treatment in an office-based setting (methadone)	Currently covered for all (as of September 2017)	Continued oversight of new policy	December 31, 2018
0.5	Early Intervention	Services for individuals who are at risk of developing substance-related disorders	Currently covered for all	No change expected	
1	Outpatient Services	Outpatient treatment (usually less than 9 hours a week), including counseling, evaluations, and interventions	Currently covered for all	No change expected	
2.1	Intensive Outpatient Services	9-19 hours of structured programming per week (counseling and education about addiction-related and mental health programs)	Currently MRO-only	Will be covered for all individuals	December 31, 2018
2.5	Partial Hospitalization	20 or more hours of clinically intensive programming per week	Covered for all	No change expected	
3.1	Clinically Managed Low- Intensity Residential	24-hour supportive living environment; at least 5 hours of low-intensity treatment per week	No coverage	Bundled daily rate for residential treatment	March 1, 2018
3.5	Clinically Managed High- Intensity Residential	24-hour living environment, more high-intensity treatment (level 3.7 without intensive medical and nursing component)	No coverage	Bundled daily rate for residential treatment	March 1, 2018
3.7	Medically Monitored Intensive Inpatient	24-hour professionally directed evaluation, observation, medical monitoring, and addiction treatment in an inpatient setting	Covered for all (based on medical necessity)	Align authorization criteria with ASAM	Fall 2018
4	Medically Managed Intensive Inpatient	24-hour inpatient treatment requiring the full resources of an acute care or psychiatric hospital	Covered for all (based on medical necessity)	Align authorization criteria with ASAM	Fall 2018
Sub-Support	Addiction Recovery Management Services	Services to help people overcome personal and environmental obstacles to recovery, assist the newly recovering person into the recovering community, and serve as a personal guide and mentor toward the achievement of goals	No coverage	Covered for all individuals	December 31, 2018
Sub-Support	Supportive Housing Services	Services for individuals who are transitioning or sustaining housing.	No coverage	Explore options for coverage	Begin in 2018

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

Figure 3. Indiana SUD Waiver Implementation Activities and Timeline[10]

Waiver Goal	Activitie s	Imple mentation Time line
Improve access to critical levels of care for SUD treatment	Pursue Indiana Administrative Code (IAC) change for coverage and reimbursement of OTPs	Will be filed by December 31, 2018
	Pursue IAC amendments to Mental Health Services Rule for outpatient services	Will be filed by December 31, 2018
	Pursue IAC and SPA amendments to move IOT coverage from MRO to State Plan	IAC will be filed by December 31, 2018. SPA amendment filed by June 30, 2018.
	Pursue amendment to 1915(b)(4) waiver	Will be filed by June 30, 2018
	Make necessary systems changes to CoreMMIS related to IOT coverage change	Will be completed by June 30, 2018
	Develop provider communication over new IOT benefits	Contingent upon approval of SPA (formal notification will be delivered at least 30 days prior to launch)
	Make necessary system changes to CoreMMIS to enroll residential addiction facilities and to reimburse for residential treatment	Will be completed by March 1, 2018
	Develop provider communication over new residential treatment facility benefits	Ongoing as part of roll-out; formal communication will be released with at least 30
	Determine final action and necessary system changes to CoreMMIS to allow reimbursement for inpatient SUD stays on a per diem basis	Fall 2018
	Develop provider communication over changes in reimbursement structure	Ongoing as part of roll-out; formal communication will be released with at least 30 days-notice ahead of launch
	Make necessary system changes to allow reimbursement for Addiction Recovery Management	Spring 2018
	Pursue State Plan Amendment (SPA) to add coverage and reimbursement of services. Coverage of services will begin upon approval of SPA	Spring 2018
	Pursue IAC changes to add coverage of Addiction Recovery Management Services	Will be filed by December 31, 2018
	Develop provider communication over new addiction recovery management benefits	Ongoing as part of roll-out; formal communication will be released with at least 30 days-notice ahead of launch
Use of evidence-based SUD-specific patient placement criteria	Provider education on ASAM Criteria	Ongoing throughout 2018
	Development of standard prior authorization SUD treatment form	Will be completed by July 1, 2018
	Review contracts and pursue amendments where necessary	Will be filed by July 1, 2018
	Review CANS/ANSA for alignment with ASAM Criteria	Will be completed by December 31, 2018
Use of nationally recognized SUD-specific program standards for residential treatment	Finalize process for provisional ASAM designation	Will be completed by December 31, 2017
	Insert permanent certification language in Indiana Administrative Code	Will be filed by December 31, 2018
Sufficient provider capacity at critical levels of care	Create new provider specialty for residential addictions facilities	Will be completed by March 1, 2018
	Data reporting by provider specialty and ASAM level of care	Will be completed by March 31, 2018
	Assessment of ASAM providers and services	Will be completed by December 31, 2018
Implementation of comprehensive treatment and prevention strategies to address opioid abuse	Consider options for emergency responder reimbursement of naloxone	Will be completed in early 2018

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

SECTION II: EVALUATION QUESTIONS AND HYPOTHESES

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

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

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

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

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

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

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

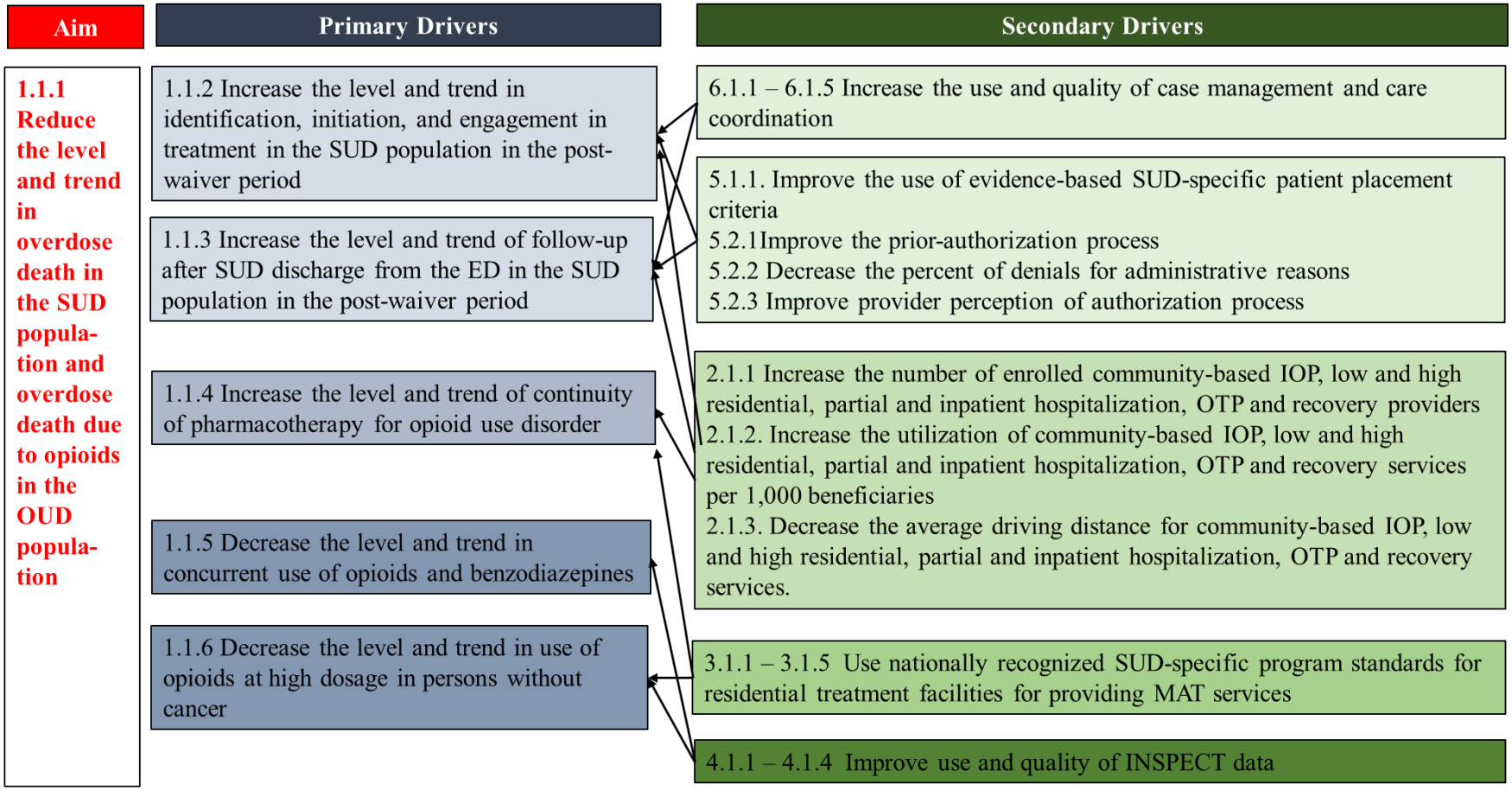
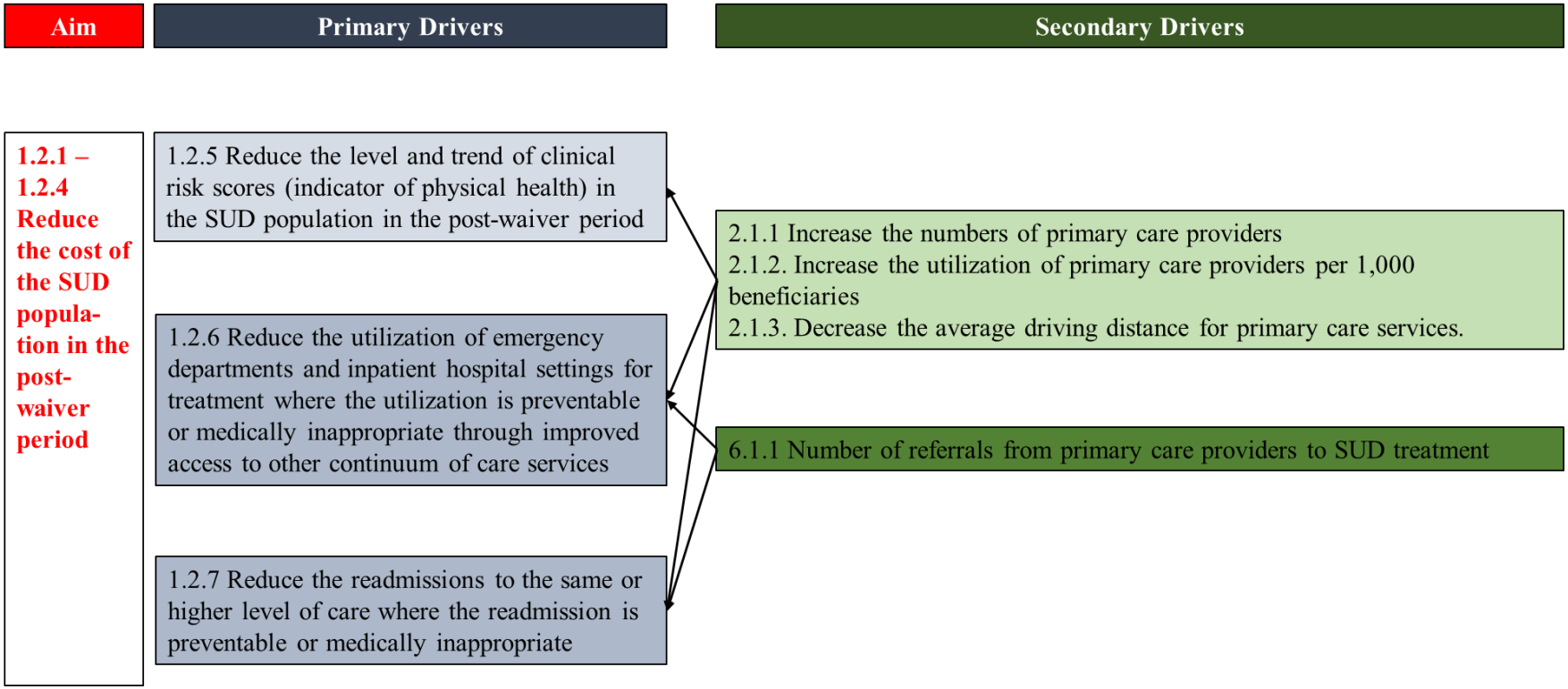


Figure 5. Driver Diagram 1.2 Target Health Outcome: Reductions in Per Capita Cost



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

Aims and Primary Drivers

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

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

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

include: H 1.1 Key health outcomes improve in the SUD population in the post-

waiver period.

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

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

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

post waiver period?

Secondary Drivers

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

The hypotheses and research questions specific to the secondary drivers

include: H 2.1 Access to care improved in the SUD population in the

post-waiver period.

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

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

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

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

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

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

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

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

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

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

- Q 6.1.1 Does the proportion of beneficiaries receiving ASAM designation who had a claim in that ASAM level within the next two consecutive months following the month of ASAM assignment increase over time?
- Q 6.1.2 Does the proportion of beneficiaries with a SUD diagnosis who are receiving care coordination increase over time?
- Q 6.1. 3 Do Indiana's MCEs facilitate more active engagement in the case/care management process between behavioral health/substance abuse providers and primary care/other physical health providers for their patients with a SUD diagnosis?

SECTION III: METHODOLOGY

III.A Evaluation Design

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

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

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

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

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

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

Figure 6. Summary of Six Methods by Hypotheses

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

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

Italics indicate the method will be used "as needed"

III.B Target and Comparison Populations

Target Population

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

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

- ASAM Levels: 2.1; 3.1; 3.5; 4; OTP; RS. It is possible that outcomes may differ among the SUD population based on their access to services. B&A will examine the outcomes by those accessing a particular level of care for differences in health outcomes or cost in the post-waiver period compared to the pre-wavier period.

- Risk Scores: Similarly, outcomes may differ among the SUD population for some types of clinically similar groups compared to others. Therefore, B&A will examine outcomes by categorized groups of clinically similar beneficiaries based on the 3M™ Clinical Risk Groups (CRG) to examine whether there are differences in health outcomes or cost among clinically similar groups of SUD beneficiaries.

- ASAM 2.1 Intensive Outpatient Services: coverage is expanding beyond the community-based treatment or Medicaid Rehabilitation Option (MRO); those previously receiving IOP via the MRO option therefore, may not be impacted as much as others not previously eligible for MRO.

- Opioid Use Disorder (OUD): It is likely that those beneficiaries with OUD, compared to those with other types of SUD, may have different health outcomes and access a different mix of services. Therefore, it is possible that the waiver impacts these populations differently and those beneficiaries will be identified and examined as a sub-population. B&A will use the specification for OUD described in the CMS-approved Monitoring Plan.

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

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

Comparison Groups

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

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

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

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

III.C Evaluation Period

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

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

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

III.D Evaluation Measures

The measures included in the evaluation plan directly relate to the aims, primary and secondary drivers described in Section II. The measures fall into three primary domains: quality, access and financial. All the measures in Indiana's existing Monitoring Plan are included as well as additional measures including average driving distance, potentially preventable emergency department visits and hospital readmissions.

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

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

Figure 7. List of Measures by Domain

Quality

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

Access

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

Financial

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

III.E Data Sources

As described in section III.A, Evaluation Design, B&A will use existing secondary data sources as well as collect primary data. The evaluation design relies most heavily on the use of Indiana Medicaid administrative data, i.e., enrollment, claims and encounter data. Supplemental administrative data, such as prior approval denials and authorizations, will also be incorporated. Primary data will be limited and include data created by surveys, desk review and facilitated interview instruments. A brief description of these data and their strengths and weaknesses are below.

Indiana Medicaid Administrative Data

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

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

Additional data from the MCEs and the State will be collected on prior authorizations, denials, denial reason codes as well as data on care coordination activities. There could be some data validity or quality issues with these sources as they are not as rigorously collected as claims and encounters data. That being said, we will use a standard quality review and data cleaning protocol in order to validate these data, as well as provide detailed specifications and reporting tools to the MCEs and the state to minimize potential for differences in reporting of the requested ad-hoc data.

Survey and Facilitated Interview Data

N-SSATS

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

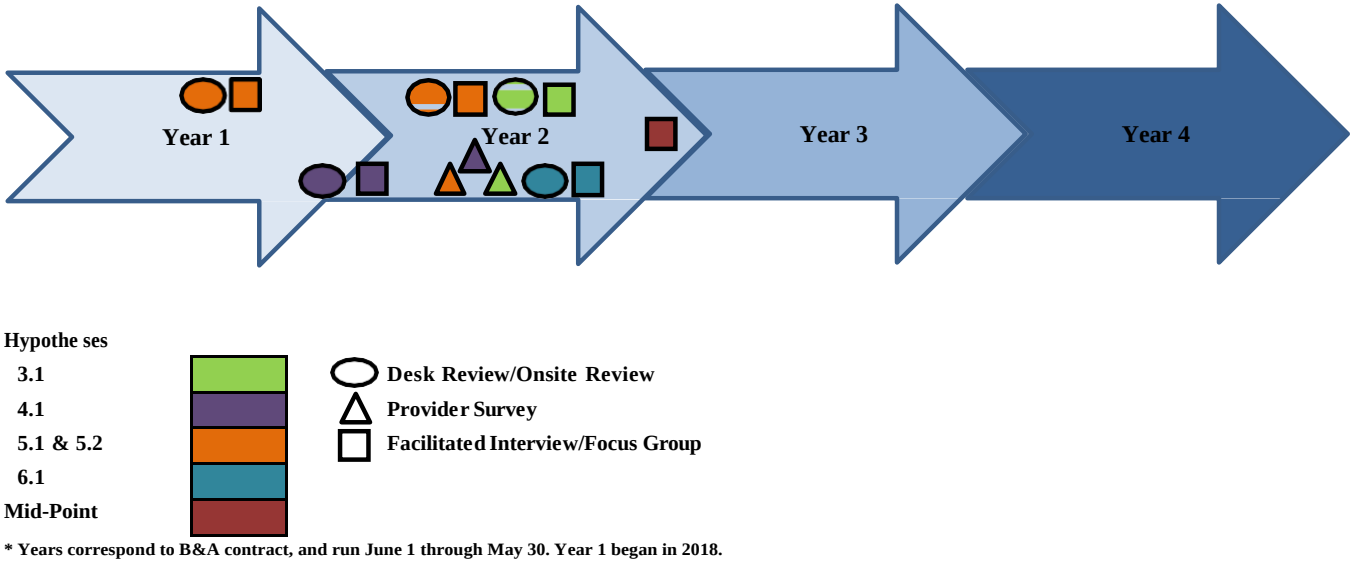
B&A will construct standardized instruments in order to create primary data. The instruments will be provided to CMS for their feedback in advance of fielding. The instruments will be created after doing preliminary desk reviews and analysis, and therefore, are not included in the evaluation plan. It is anticipated that once the survey instruments are approved by CMS, they will be fielded for one month before initial results would be tabulated. Where focused interviews are used to collect data, B&A will hold a sufficient number of sessions to collect the required data in accordance with the research question and CMS deliverable. Figure 8 contains the proposed primary data collection activities by source, year, and hypotheses. Figure 9 demonstrates the proposed primary data collection timeline by type, year, and hypotheses.

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

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

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

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



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

III.F Analytic Methods

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

Method 1: Interrupted Time Series (ITS)

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

An ITS analysis relies on a continuous sequence of observations on a population taken at equal intervals over time in which an underlying trend is "interrupted" by an intervention. In this evaluation, the waiver is the intervention and it occurs at a known point in time. The trend in the post-waiver is compared against the expected trend in the absence of the intervention.

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

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

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

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

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

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

[16] Wagner AK , Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther 2002;27:299-309.

[17] James Lopez Bernal, Steven Cummins, Antonio Gasparrini; Interrupted time series regression for the evaluation of public health interventions: a tutorial, International Journal of Epidemiology, Volume 46, Issue 1, 1 February 2017, Pages 348–355, https://doi.org/10.1093/ije/dyw098

[18] James Lopez Bernal, Steven Cummins, Antonio Gasparrini; Interrupted time series regression for the evaluation

of public health interventions: a tutorial, International Journal of Epidemiology, Volume 46, Issue 1, 1 February 2017, Pages 348–355, https://doi.org/10.1093/ije/dyw098

ITS Descriptive Statistics

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

To identify underlying trends, seasonal patterns and outliers, scatter plots of each measure will be created and examined. Moreover, each outcome will undergo bivariate comparisons; a Pearson correlation coefficient will be produced for each measure compared to the others as well as each measure in the pre- and post- periods.

Regression Analysis

Wagner et al. described the single segmented regression equation as[19]:

$$\hat{Y}_t = \beta_0 + \beta_1 * \text{time}_t + \beta_2 * \text{intervention}_t + \beta_3 * \text{time\_after\_intervention}_t + e_t$$

Where: Y_t is the outcome

time indicates the number of months or quarters from the start of the series

intervention is a dummy variable taking the values 0 in the pre-intervention segment and 1 in the post-intervention segment

time_after_intervention is 0 in the pre-intervention segment and counts the

β_0 estimates the base level of the outcome at the beginning of the series

β_1 estimates the base trend, i.e. the change in outcome in the pre-intervention segment

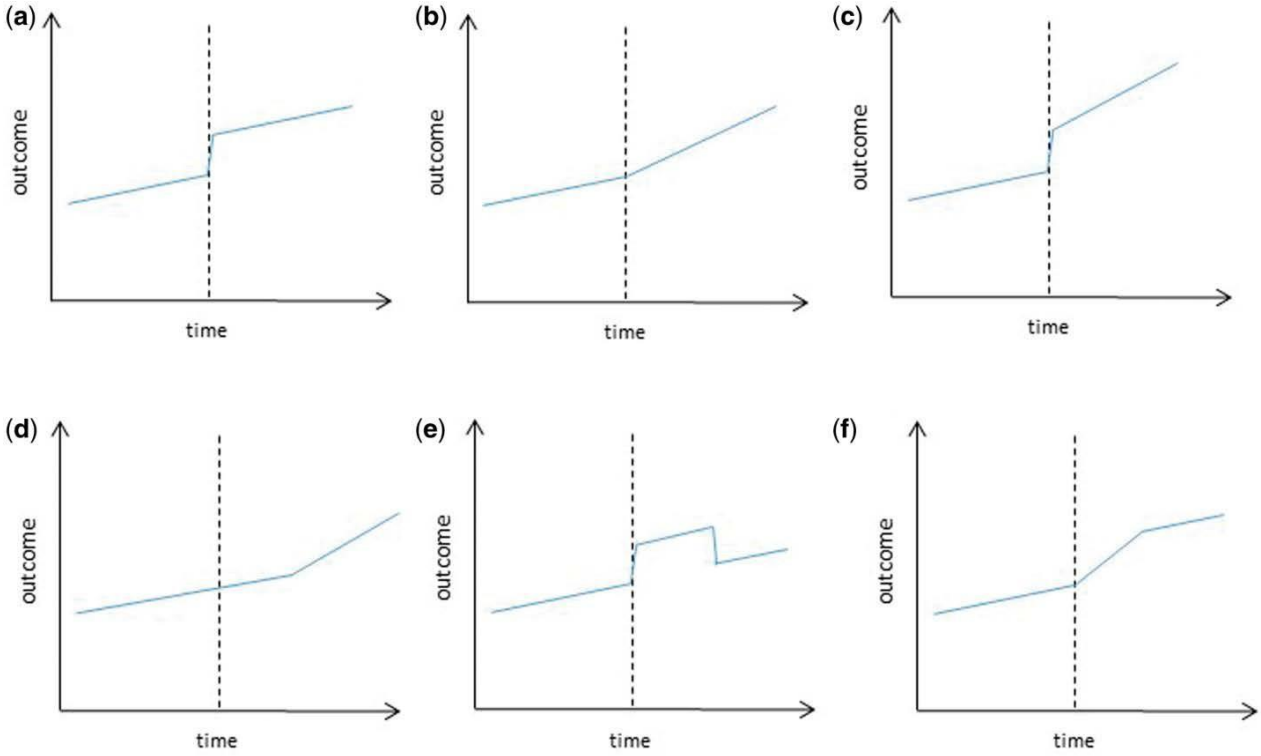
β_2 estimates the change in level from the pre- to post-intervention segment

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

Visualization and interpretation will be done as depicted in the Figure 10. Each outcome will be assessed for one of the following types of relationships in the pre- and post- wavier period: (a) Level change; (b) Slope change; (c) Level and slope change; (d) Slope change following a lag; (e) Temporary level change;
(f) Temporary slope change leading to a level change.

[19] Wagner AK , Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther 2002;27:299-309.

Figure 10. Illustration of Potential ITS Relationships[20]



Seasonality and Autocorrelation

One strength of the ITS approach is that it is less sensitive to typical confounding variables which remain fairly constant such as population age or socio-economic status as these changes relatively slowly over time. However, ITS may be sensitive to seasonality. To account for seasonality in the data, the same time period, measured in months or quarters, will be used in the pre- and post-waiver period. Should it be necessary, a dummy variable can be added to the model to account for the month or quarter of each observation thereby controlling for the seasonal impact.

An assumption of linear regression is that errors are independent. When errors are not independent, as is often the case for time series data, alternative methods may be warranted. To test for the independence, B&A will review a residual time series plot and/or autocorrelation plots of the residuals. In addition, a Durbin-Watson test will be constructed to detect the presence of autocorrelation. If the Durbin-Watson test statistic value is well below 1.0 or well above 3.0, there is an indication of serial correlation. If autocorrelation is detected, an autoregressive regression model, like the Cochrane-Orcutt model, will be used in lieu of simple linear regression.

Other assumptions of linear regression are that data are linear and that there is constant variance in the errors versus time. Heteroscedasticity will be diagnosed by examining a plot of residuals verses predicted values. If the points are not symmetrically distributed around a horizontal line, with roughly constant variance, then the data may be nonlinear and transformation of the

dependent variable may be warranted. Heteroscedasticity often arises in time series models due to the effects of inflation and/or real compound growth. Some combination of logging and/or deflating may be necessary to stabilize the variance in this case.

For these reasons and in accordance with CMS technical guidance specific to models with cost-based outcomes, B&A will use log costs rather than untransformed costs, as costs are often not normally distributed. For example, many person-months may have zero healthcare spending and other months very large values. To address these issues, B&A will use a two-part model that includes zero costs (logit model) and non-zero costs (generalized linear model).

Controls and Stratification

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

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

Method #2: Descriptive Statistics

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

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

Method #3: Provider Surveys (PS)

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

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

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

Method #4: Onsite Reviews (OR)

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

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

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

In some cases, the onsite reviews will employ a sampling approach whereby a limited number of

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

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

Method #5: Desk Reviews (DR)

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

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

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

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

III.G Other Additions

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

1.1 Key health outcomes improve in the SUD population in the post-waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
1.1.1. Does the level and trend of overdose deaths and overdose due to opioids decrease among the SUD population in the post-waiver period?	• Overdose Deaths • *Opioid Overdoes Deaths* Description The number of overdose deaths per 1,000 Medicaid beneficiaries *Description* *The number of opioid overdose deaths per 1,000 Medicaid beneficiaries* Computed Monthly or Quarterly **if denominator is <100 at this level, compute annual and use for descriptive analysis only*	Numerator 1. Members who died of overdose in month or quarter. Denominator Number of beneficiaries eligible in month or quarter/1000 Age 18 years and older *Numerator* *1. Members who died of overdose due to opioid in month or quarter.* *Denominator* *Number of beneficiaries eligible in month or quarter/1000* *Age* *18 years and older*	OMPP Enterprise Data Warehouse (EDW) Vital Statistics/Indiana State Department of Health (ISDH)	• Interrupted Time Series o Examine whether statistically significant differences exist in the rates of change in overdose deaths in the pre- and post-intervention periods. Pre-intervention Timeframe Monthly or Quarterly CY2015-CY2017 Post-intervention Timeframe Monthly or Quarterly CY2018-CY2020* **refreshed every six months until after six months following run-out.* Stratification Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use

1.1 Key health outcomes improve in the SUD population in the post-waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
1.1.2 Does the level and trend of initiation and engagement in treatment increase in the SUD population in the post waiver period?	• Initiation and Engagement of Alcohol and Other Drug (AOD) Dependence Treatment Description Number of Indiana Medicaid members who have initiated treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter, or partial hospitalization within 14 days of a diagnosis (or two or more additional services within 30 days of the visit). Computed Monthly or Quarterly **if denominator is <100 at this level, compute annual and use for descriptive analysis only*	Numerator 1. Members who initiated treatment within 14 days of the diagnosis 2. Members who initiated treatment and who had two or more additional services with a diagnosis within 30 days of the initiation visit Denominator Individuals who were diagnosed with alcohol or drug dependency during a visit within the previous rolling 11 months Age 18 years and older	OMPP Enterprise Data Warehouse (EDW) NCQA	• Interrupted Time Series o Examine whether statistically significant differences exist in the rates of change in initiation and engagement in the pre- and post- intervention periods. Pre-intervention Timeframe Monthly or Quarterly CY2015-CY2017 Post-intervention Timeframe Monthly or Quarterly CY2018-CY2020* **refreshed every six months until after six months following run-out.* Stratification Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use

1.1 Key health outcomes improve in the SUD population in the post-waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
1.1.3 Does the level and trend of follow-up after discharge from the ED for SUD increase among the SUD population in the post waiver period?	• Follow-Up After Discharge from the Emergency Department for Alcohol or Other Drug (AOD) Dependence Description The percentage of ED visits for members 18 years of age and older with a primary diagnosis of alcohol and other drug (AOD) dependence, who had an outpatient visit, an intensive outpatient encounter, or a partial hospitalization for AOD. Computed Monthly or Quarterly **if denominator is <100 at this level, compute annual and use for descriptive analysis only*	Numerator 1. Members who had a follow-up visit to an ED visit with a SUD indicator within 7 days of discharge within the previous rolling 12 months. 2. Members who had a follow-up visit to and ED visit with a SUD indicator within 30 days of Discharge within the previous rolling 12 months. Denominator Individuals with an ED visit (with SUD indicator) within the previous rolling 12 months Age 18 years and older	OMPP Enterprise Data Warehouse (EDW) NCQA	• Interrupted Time Series ○ Examine whether statistically significant differences exist in the rates of change in follow up after discharge in the pre- and post- intervention periods. Pre-intervention Timeframe Monthly or Quarterly CY2015-CY2017 Post-intervention Timeframe Monthly or Quarterly CY2018-CY2020* **refreshed every six months until after six months following run-out.* Stratification Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use

1.1 Key health outcomes improve in the SUD population in the post-waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
1.1.4 Does the level and trend in continuity of pharmacotherapy for opioid use disorder increase among the OUD population in the post waiver period?	• Continuity of Pharmacotherapy for Opioid Use Disorder Description The percentage of adults (18 through 64) with pharmacotherapy for opioid use disorder who have at least 180 days of continuous treatment. Computed Monthly or Quarterly **if denominator is <100 at this level, compute annual and use for descriptive analysis only*	Numerator Individuals who have had at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than seven days Denominator Individuals with a diagnosis of opioid use disorder and at least one claim for opioid use disorder medication in the previous rolling 12 months. Age 18 – 64 years and older	OMPP Enterprise Data Warehouse (EDW) RAND	• Interrupted Time Series o Examine whether statistically significant differences exist in the rates of change of continuity of pharmacotherapy for opioid use disorder in the pre- and post-intervention periods. Pre-intervention Timeframe Monthly or Quarterly CY2015-CY2017 Post-intervention Timeframe Monthly or Quarterly CY2018-CY2020* **refreshed every six months until after six months following run-out.* Stratification Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use

1.1 Key health outcomes improve in the SUD population in the post-waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
1.1.5 Does the level and trend in concurrent use of opioids and benzodiazepines decrease in the OUD population in the post waiver period?	• Concurrent Use of Opioids and Benzodiazepines Description The percentage of beneficiaries 18 years and older with concurrent use of prescription opioids and benzodiazepines. Computed Quarterly **if denominator is <100 at this level, compute annual and use for descriptive analysis only*	Numerator The number of individuals with: 1. 2 or more prescription claims for any benzodiazepine filled on two or more separate days; AND 2. Concurrent use of opioids and benzodiazepines for 30 or more cumulative days Denominator Any member with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days supply is >= 15 Age 18 years and older	OMPP Enterprise Data Warehouse (EDW) PQA/CMT –Measure 903	• Interrupted Time Series o Examine whether statistically significant differences exist in the rates of change of concurrent opioid and benzodiazepines in the pre- and post- intervention periods. Pre-intervention Timeframe Quarterly CY2015-CY2017 Post-intervention Timeframe Quarterly CY2018-CY2020* **refreshed every six months until after six months following run-out.* Stratification Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP

1.1 Key health outcomes improve in the SUD population in the post-waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
1.1.6 Does the level and trend in the rate of use of opioids at high dosage in persons without cancer decrease in the post waiver period?	• Use of Opioids at High Dosage in Persons Without Cancer Description The proportion (out of 1,000) of beneficiaries without cancer receiving a daily dosage of opioids greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer with and without a SUD diagnosis. Computed Quarterly **if denominator is <100 at this level, compute annual and use for descriptive analysis only*	Numerator Any member in the denominator with greater than 120 MME for >= 90 days in the quarter. Denominator Any member with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days supply is >= 15 in the quarter. Age Ages 18 years and older	OMPP Enterprise Data Warehouse (EDW) PQA, CMT-884	• Interrupted Time Series o Examine whether statistically significant differences exist in the rates of change of the use of opioids at a high dosage in the pre- and post- intervention periods. Pre-intervention Timeframe Quarterly CY2015-CY2017 Post-intervention Timeframe Quarterly CY2018-CY2020* **refreshed every six months until after six months following run-out.* Stratification Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP

1.2 Costs of care decreases in the SUD population in the post waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**

1.2.1. Does the level and trend in overall spending for the SUD population decrease in the post waiver period?	• Total Spending
	  ○ Estimated State and Federal Share
	• Per Capita Spending
	  ○ Estimated State and Federal Share
	
	<u>Description</u>
	Total spending and per capita total spending broken down by estimated federal and state share using an average FMAP for the study period.
	
	Computed Quarterly
	**if denominator is <100 at this level, compute annual and use for descriptive analysis only*
		<u>Numerator</u>
		All paid claims based on service date for any beneficiary with SUD indicator in month or quarter. Excludes crossovers.
		
		<u>Denominator (Per Capita)</u>
		Number of enrolled beneficiaries in month or quarter
		
		<u>Age</u>
		All ages
			OMPP Enterprise Data Warehouse (EDW)
			
			B&A
				• Interrupted Time Series
				  ○ Examine whether statistically significant differences exist in the rates of change of total and per capita spending in the pre- and post- intervention periods.
				
				<u>Pre-intervention Timeframe</u>
				Monthly or Quarterly CY2015-CY2017
				
				<u>Post-intervention Timeframe</u>
				Monthly or Quarterly CY2018-CY2020*
				**refreshed every six months until after six months following run-out.*
				
				<u>Stratification</u>
				Demographics and Geography
				Clinical Risk Group (CRG)
				Previous MRO Use
				MCE and OMPP
				Opioid Use
				ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]

1.2 Costs of care decreases in the SUD population in the post waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
1.2.2 Does the level and trend in SUD service spending for the SUD population increase in the post waiver period?	• Any SUD Spending • SUD Spending in IMDs • Per Capita Any SUD Spending • Per Capita SUD Spending in IMDs <u>Description</u> Any SUD and IMD spending in total and per capita. Computed Monthly or Quarterly **if denominator is <100 at this level, compute annual and use for descriptive analysis only*	<u>Numerator</u> All SUD and IMD paid claims based on service date for any beneficiary with SUD indicator in month or quarter. Excludes crossovers. <u>Denominator (Per Capita)</u> Number of enrolled individuals in month or quarter. <u>Age</u> All ages	OMPP Enterprise Data Warehouse (EDW) B&A	• Interrupted Time Series o Examine whether statistically significant differences exist in the rates of change of total SUD and SUD per capita spending in the pre- and post- intervention periods. <u>Pre-intervention Timeframe</u> Monthly or Quarterly CY2015-CY2017 <u>Post-intervention Timeframe</u> Monthly or Quarterly CY2018-CY2020* **refreshed every six months until after six months following run-out.* <u>Stratification</u> Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]

1.2 Costs of care decreases in the SUD population in the post waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**

1.2.3. Does the level and trend in non-SUD service spending for the SUD population decrease in the post waiver period?	• Any non-SUD Spending
	• Per Capita non-SUD Spending
	  ○ Non-emergency Outpatient
	  ○ Emergency Department Outpatient
	  ○ Inpatient
	  ○ Pharmacy
	  ○ Long Term Care
	  ○ Professional Services: Primary versus Specialty
	  ○ Other
	
	Description
	Any non-SUD spending in total and per capita. Broken down by key categories of services.
	
	Computed Monthly or Quarterly
	**if denominator is <100 at this level, compute annual and use for descriptive analysis only*
		Numerator
		All non-SUD paid claims based on service date for any beneficiary with SUD indicator in month or quarter. Excludes crossovers.
		
		Denominator (Per Capita)
		Number of enrolled individuals in month or quarter.
		
		Age
		All ages
			OMPP Enterprise Data Warehouse (EDW)
			
			B&A
				• Interrupted Time Series
				  ○ Examine whether statistically significant differences exist in the rates of change of total SUD and SUD per capita spending in the pre- and post- intervention periods.
				
				Pre-intervention Timeframe
				Monthly or Quarterly CY2015-CY2017
				
				Post-intervention Timeframe
				Monthly or Quarterly CY2018-CY2020*
				**refreshed every six months until after six months following run-out.*
				
				Stratification
				Demographics and Geography
				Clinical Risk Group (CRG)
				Previous MRO Use
				MCE and OMPP
				Opioid Use
				ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]

1.2 Costs of care decreases in the SUD population in the post waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
1.2.4. Does the level and trend in the percentage of SUD facilities who report they accept Medicaid as a payer increase in the post waiver period?	• Proportion of SUD Providers Who Report Accepting Medicaid *If Quarterly reporting not available, this measure will be reported annually and use for descriptive analysis only*	Indiana SUD providers who respond to N-SSATS survey.	National Survey of Substance Abuse Treatment Services (N-SSATS)	• Interrupted Time Series/*Descriptive* o Examine whether statistically significant differences exist in the rates of change of total SUD and SUD per capita spending in the pre- and post- intervention periods. Pre-intervention Timeframe Quarterly or Annually CY2015-CY2017 Post-intervention Timeframe Quarterly or Annually CY2018-CY2020* **refreshed every six months until after six months following run-out.* <u>Stratification</u> N/A

1.2 Costs of care decreases in the SUD population in the post waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
1.2.5. Does the level and trend in average CRG risk scores decrease among the SUD population in the post-waiver period?	• Average Clinical Risk Group (CRG) Score Description The average CRG score for Medicaid beneficiaries with a SUD diagnosis in the month or quarter. Computed Monthly or Quarterly **if denominator is <100 at this level, compute annual and use for descriptive analysis only*	Numerator Total CRG risk score for members with SUD in month or quarter. Denominator Members with SUD in month or quarter. Age 18 – 64 years and older	OMPP Enterprise Data Warehouse (EDW) 3M/B&A	• Interrupted Time Series o Examine whether statistically significant differences exist in the level and trend in average CRG risk score in the pre- and post- intervention periods. Pre-intervention Timeframe Monthly or Quarterly CY2015-CY2017 Post-intervention Timeframe Monthly or Quarterly CY2018-CY2020* **refreshed every six months until after six months following run-out.* Stratification Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]

1.2 Costs of care decreases in the SUD population in the post waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
1.2.6 Does the level and trend in acute utilization for SUD, potentially preventable emergency department or potentially preventable hospital readmissions decrease in the SUD population in the post waiver period?	• PPVs and PPRs Description Rate of potentially preventable emergency department visits (PPVs) and hospital readmissions (PPRs) among Indiana Medicaid members with SUD. • ED, Admission and Readmission per member month Description The total number of emergency department visits, hospital admissions and readmissions for SUD diagnosis in the reporting month (per 1,000 enrolled Medicaid members) in previous three months (separate count for each month). Computed Quarterly **if denominator is <100 at this level, compute annual and use for descriptive analysis only*	Numerator Number of potentially preventable visits and/or readmissions Denominator Individuals who were diagnosed with alcohol or drug dependency during the calendar year. Age 18 – 64 years and older Numerator Number of ED visits, hospital admissions, and readmissions with SUD diagnosis. Denominator Enrolled Medicaid members/1000 Age 18 – 64 years and older	OMPP Enterprise Data Warehouse (EDW) 3M PPV and PPR Software B&A	• Interrupted Time Series o Examine whether statistically significant differences exist in the rates of change in acute utilization in the pre- and post-intervention periods. Pre-intervention Timeframe Quarterly CY2015-CY2017 Post-intervention Timeframe Quarterly CY2018-CY2020* **refreshed every six months until after six months following run-out.* Stratification Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]

2.1 Access to care improved in the SUD population in the post-waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
2.1.1. Does the level and trend in the number of SUD and primary care providers and the number of providers per capita in the SUD population increase in the post waiver period for each ASAM level of care?	• Count of ASAM-specific Medicaid enrolled providers • Number of ASAM-specific Medicaid enrolled providers per 1,000 SUD population Computed Quarterly	Numerator Number of providers enrolled as of last day of quarter. Denominator Individuals with SUD as of the last day of the quarter. Age 18 and older	OMPP Enterprise Data Warehouse (EDW)	• Descriptive Statistics o Examine trends in counts of Medicaid-enrolled providers by ASAM level and per capita in the SUD population, MCE and region. Pre-intervention Timeframe Quarterly CY2015-CY2017 Post-intervention Timeframe Quarterly CY2018-CY2020* **refreshed every six months until after six months following run-out.* Stratification Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]
	• Count of ASAM-specific statewide self-reported provider (N-SSATS)	Indiana SUD providers who respond to N-SSATS survey.	National Survey of Substance Abuse Treatment Services (N-SSATS)	• Descriptive Statistics o Examine changes in statewide trends in

2.1 Access to care improved in the SUD population in the post-waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
2.1.2 Does the utilization per 1,000 of SUD services and primary care in the SUD population increase in the post waiver period for each ASAM level of care? Computed Quarterly	• Utilization of ASAM-specific services per 1,000 • Utilization of primary care services per 1,000	Numerator Number of unique SUD and primary care services as of last day of quarter. Denominator Individuals with SUD as of the last day of the quarter. Age 18 and older	OMPP Enterprise Data Warehouse (EDW)	• Descriptive Statistics o Examine trends in utilization of services per 1,000 SUD population by ASAM level, MCE and region. Pre-intervention Timeframe Quarterly CY2015-CY2017 Post-intervention Timeframe Quarterly CY2018-CY2020* **refreshed every six months until after six months following run-out.* Stratification Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [3.1; 3.1; 3.5; 4; OTP; RS]

2.1 Access to care improved in the SUD population in the post-waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
2.1.3. Does the average driving distance for SUD services and primary care decrease in the SUD population in the post waiver period for each ASAM level of care?	• Average driving distance for ASAM-specific services • Average driving distance for primary care Computed Quarterly	Numerator Number of unique SUD and primary care services as of last day of quarter. Denominator Individuals with SUD as of the last day of the quarter. Age 18 and older	OMPP Enterprise Data Warehouse (EDW) B&A	• Descriptive Statistics o Examine trends in the average driving distance to SUD and primary care services by ASAM level, MCE and region. Pre-intervention Timeframe Quarterly CY2015-CY2017 Post-intervention Timeframe Quarterly CY2018-CY2020* **refreshed every six months until after six months following run-out.* Stratification Demographics and Geography Clinical Risk Group (CRG) Previous MRO Use MCE and OMPP Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]

3.1 Implementing residential treatment facility provider certification requirements based on ASAM level 3.1 and 3.5 criteria will improve provision of care.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
3.1.1. Does provider certification shift from resident and facility-based criteria to treatment-based certification criteria using ASAM level of care over the length of the waiver?	• Document process to phase in and adopt certification criteria based on ASAM level of care • Number of providers pre-waiver • Number of providers certified • Number of providers denied certification and why	OMPP and DMHA certification policies and procedures. MCEs credentialing policies and procedures	Desk Review of OMPP, DMHA, MCE	• Descriptive Statistics o Examine results of process review and measures and develop trend over waiver
3.1.2. Does the ability to measure utilization by ASAM facility level will improve program monitoring?	• Document that ASAM level captured in EDW • Document reports created to track by ASAM level of care and by which metrics • Document use of reports through waiver period to monitor	OMPP and DMHA reporting measures MCEs reporting measures	Desk Review of OMPP, DMHA, MCE	• Descriptive Statistics o Examine results of process review and measures and develop trend over waiver

3.1 Implementing residential treatment facility provider certification requirements based on ASAM level 3.1 and 3.5 criteria will improve provision of care.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
3.1.3. Does provider awareness and use of ASAM Patient Placement Criteria increase over the length of the waiver?	• Document knowledge of criteria • Number of providers using criteria	Residential services providers	Provider Focus Study or Provider Survey* *subject to CMS approval	• Cross-sectional, online, census provider survey. o Examine results of provider focus study or online provider survey and measures and develop trend over waiver
3.1.4. Do providers offer medication-assisted treatment (MAT)?	• Document process to phase in and adopt MAT. • Number of providers pre-waiver • Number of providers offering MAT onsite. • Number of providers offering access to MAT at an affiliated location	Residential services provider	Provider Survey* or Onsite *subject to CMS approval	• Cross-sectional, online, census provider survey. o Examine results of provider focus study or online provider survey and measures and develop trend over waiver

3.1 Implementing residential treatment facility provider certification requirements based on ASAM level 3.1 and 3.5 criteria will improve provision of care.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
3.1.5. Do residential facilities not currently enrolled in Indiana Medicaid have the opportunity to meet standards for enrollment leading to increased enrollment of residential addictions facilities?	• Document process to outreach to unenrolled providers to make them aware of the new enrollment opportunities. • Number of known providers who were not enrolled pre-waiver • Number of providers that enrolled during the waiver period • Number of providers denied enrollment and why	OMPP and DMHA certification policies and procedures. MCEs credentialing policies and procedures	Desk Reviews of OMPP, DMHA, MCE	• Descriptive Statistics o Examine results of process review and measures and develop trend over waiver

4.1 The quality and use of INSPECT data will improve in the post waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
4.1.1. Were changes to INSPECT made according to the Implementation Plan?	• Number of Changes Implemented as Expected • Number of Changes Implemented, but with less than a year delay • Number of Changes Not Implemented or delayed >1 year	INSPECT	Desk Review of admin documentation and interview notes	• Desk review of administrative documentation between proposed and actual implementation dates • As needed, conduct supplemental facilitated interviews with OMPP staff, fiscal agent staff, and/or INSPECT users
4.1.2. Did changes to INSPECT result in meaningful reporting capabilities?	• Perceptions of Usefulness of INSPECT Reporting Capabilities • Estimated Frequency of Use • Recommended Improvements	INSPECT	Facilitated Interviews	• Review findings of facilitated interviews with IPLA and Indiana Board of Pharmacy staff. • As needed, conduct supplemental facilitated OMPP interviews with broader group of stakeholders including INSPECT users.
4.1.3. Has the number of prescribers using INSPECT increased over time?	• Number of prescribers using INSPECT	All providers using inspect	INSPECT	• Descriptive Statistics o Review trends in use number of prescribers using INSPECT over time.
4.1.4. Has the volume of inquiries into the INSPECT database increased over time?	• Number of queries against INSPECT	All providers using inspect	INSPECT	• Descriptive Statistics o Review trends in use of querying of INSPECT over time.

5.1 The Child and Adolescent Needs and Strengths (CANS) and Adult Needs and Strengths Assessment (ANSA) tools are being used to place beneficiaries in ASAM levels of care.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
5.1.1. Are clinical criteria for authorization review for services delivered to beneficiaries with SUD being applied consistently across Indiana's Health Coverage Programs (Hoosier Healthwise, Healthy Indiana Plan, Hoosier Care Connect, and Traditional Medicaid)?	• Average turnaround time for authorization decisions • For denied authorizations, the percentage of denials based on application of medical necessity criteria • For denied authorizations, the percentage of denials in which the specific reason/criteria were cited to the requesting provider	MCE and FFS	Onsite Review of MCE and FFS Documentation and System B&A	• Develop standardized data request to the MCEs/OMPP to analyze all authorization records related to SUD services • Develop standardized tool with which to evaluate a sample of authorization records related to SUD services in the field at each MCE and at OMPP • In person interviews with the MCE/OMPP (or its contractor) staff who review authorization requests for SUD services to assess their capacity and training

5.2 Prior authorization (PA) requirements do not negatively impact access to residential or inpatient services (ASAM 3.1, 3.5 and 4.0).				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
5.2.1. Are the rates of prior authorizations (PAs) submitted and PA requests that are denied in the SUD population, controlling for volume, relatively consistent by MCE and over time?	• Number of Prior Authorizations (PA) for ASAM 3.1, 3.5 and 4.0 • Number of PA Denials for ASAM 3.1, 3.5 and 4.0 • Rate of Approved and Denied SUD Authorizations for ASAM 3.1, 3.5 and 4.0	Numerator The total number of prior approved and denied authorizations for ASAM 3.1, 3.5 and 4.0 in a calendar year. Denominator Total number of authorizations for ASAM 3.1, 3.5 and 4.0 in a calendar year. Age All ages	OMPP Enterprise Data Warehouse (EDW)/OMPP Data B&A	• Descriptive Statistics o Examine trends in the rate of prior authorizations and denials among stratified populations, over time and by region and MCE.
5.2.2. Are prior authorization denials predominately for reasons directly related to not meeting clinical criteria as opposed to administrative reasons such as lack of information submitted?	• Frequency of Denial Reasons Codes for ASAM 3.1, 3.5 and 4.0 • Percent of Total Denials for ASAM 3.1, 3.5 and 4.0	Numerator Count of denials with each reason for denial for ASAM 3.1, 3.5 and 4.0 in a calendar year. Denominator Total number of denials for ASAM 3.1, 3.5 and 4.0 in a calendar year. Age All ages	OMPP Enterprise Data Warehouse (EDW)/OMPP Data B&A	• Descriptive Statistics o Examine the frequency of denial codes among stratified populations over time and by region and MCE.

5.2 Prior authorization (PA) requirements do not negatively impact access to residential or inpatient services (ASAM 3.1, 3.5 and 4.0).				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
5.2.3. Is provider administrative burden associated with PA requests cited as a perceived barrier to access to care?	• Rate of participation in the FSSA Gold Card program (status to reduce burden on authorization requests) • Provider satisfaction rates with the Gold Card application process	Residential and inpatient service providers.	Online Survey	• Cross-sectional, census provider of survey. o Examine rate of growth among participating providers in the Gold Card program o Examine results of point in time survey of provider perceptions

6.1 Care coordination and transitions between ASAM levels of care will increase in the post-waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
6.1.1. Does the proportion of beneficiaries receiving ASAM designation who had a claim in that ASAM level within the next two consecutive months following the month of ASAM assignment increase over time?	• Rate of beneficiaries who received ASAM service within two months following screening and ASAM designation	Numerator Number of beneficiaries who received an ASAM in a given calendar year and received a service within two months within that ASAM level. Denominator Number of beneficiaries who received each ASAM designation in a calendar year. Age All ages	OMPP Enterprise Data Warehouse (EDW) B&A	• Descriptive Statistics o Examine changes in statewide, regional and payer trends in proportion of beneficiaries with an ASAM designation receiving that level of care within the two following months.

6.1 Care coordination and transitions between ASAM levels of care will increase in the post-waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
6.1.2. Does the proportion of beneficiaries with a SUD diagnosis who are receiving care coordination increase over time?	• Number of beneficiaries receiving care coordination • Proportion of SUD population receiving care coordination • Percent of all SUD providers reporting using case management (N-SSATS)	Numerator Number of beneficiaries who received care coordination in a calendar year. Denominator Number of beneficiaries with SUD in a calendar year. Age All ages Numerator Number of providers reporting offering case management services. Denominator Number of SUD providers who responded to the survey.	OMPP Enterprise Data Warehouse (EDW) B&A N-SSATS	• Descriptive Statistics o Examine the absolute number of beneficiaries receiving care by MCE over time o Examine the proportion of the SUD population receiving care by ASAM and MCE over time. o Compare Medicaid trends to those reported in all-payer survey. o Stratify SUD and OUD populations if feasible.

6.1 Care coordination and transitions between ASAM levels of care will increase in the post-waiver period.				
Research Question	**Evaluation Measure(s)**	**Study Population**	**Data Sources and Measure Steward**	**Analytic Methods**
6.1.3. Do Indiana's MCEs facilitate more active engagement in the case/care management process between behavioral health/substance abuse providers and primary care/other physical health providers for their patients with a SUD diagnosis?	• Number of care plan meetings between the MCE, primary care and BH/SA providers for patients with a SUD diagnosis • Number of protocols in place for coordination between providers (required by OMPP contract) • Number of referrals from primary care providers for treatment for SUD members • Number of behavioral health provider notifications to the MCE (required by contract)	MCE and OMPP	Onsite Review of MCE and FFS Documentation and Systems	• Descriptive Statistics o Examine trends in reports of count of care plan meetings documented o Examine trends in behavioral health provider reports submitted per SUD member per year o Examine trends in referrals from primary care providers for treatment for SUD

SECTION IV: METHODOLOGICAL LIMITATIONS

There are inherent limitations to both the study design and its specific application to the SUD waiver evaluation. That being said, the proposed design is feasible, and is a rational explanatory framework for evaluating the impact of the SUD waiver on the SUD population. Moreover, to fill gaps left by the limitations of this study design, a limited number of provider surveys, onsite reviews, desk reviews, and facilitated interviews/focus groups are proposed to provide a more holistic and comprehensive evaluation.

Another limitation is the length of time of the evaluation period. It is not expected that a two-year evaluation period, assuming year one is the benchmark period, would be sufficient time to observe changes in all measures of interest. In some cases, the time period may be insufficient to observe descriptive or statically significant differences in outcomes in the SUD population. Therefore, it is expected that not all outcomes included in the study will show a demonstrable change descriptively, although we do expect some process measures to show a change during this time frame.

Moreover, with any study focused on the SUD population and potentially rare outcome measures, such as overdose rates, insufficient statistical power to detect a difference is a concern. For any observational studies, especially if the exposures and the outcomes being assessed are rare, it is difficult to find statistically significant results. It is not unexpected, therefore, that many of the outcome measure sample sizes will be too small to observe statistically significant results.

Related to the issues mentioned above, many of the outcome measures are multi-dimensional and influenced by social determinants of health. While changes under the waiver related to access to care may be one dimension of various outcomes of interest, and may contribute to improvements, it may be difficult to achieve statistically significant findings in the absence of data on other contributing dimensions, like social determinants of health such as housing, employment, and previous incarcerations.

Section V, Special Considerations, will summarize the unique challenges in this study, reemphasizing the need for a mix-methods approach.

SECTION V: SPECIAL METHODOLOGICAL CONSIDERATIONS

Given that the waiver is new, and there are no identified implementation delays, or any other outstanding concerns, the proposed Evaluation Design Plan provides more than adequate rigor in the observational study design, especially when considering the range of supplemental evaluation methods proposed for inclusion. As described in detail in Section IV, Methodological Limitations, the study mitigates known limitations to the extent feasible drawing upon the range of options to fill gaps in the observational study design. Moreover, this Evaluation Design Plan is consistent with, and expands upon, CMS approved 1115 demonstration waiver SUD evaluation plans available on the CMS State Waivers List.[21]

Another special consideration is in the case of residential treatment in IMDs. While the waiver change is stated as "no coverage" to "coverage for all", B&A identified that IMD residential services may have been provided in the pre-waiver period, but these would be funded by100% state funds as opposed to matched federal dollars. Therefore, it is unclear whether a detectable change will be seen related to IMDs specifically, or whether change is created by the availability of new funds to be invested in other waiver services. This nuance will be considered when evaluating the results.

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

ATTACHMENT A: INDEPENDENT EVALUATOR

Process

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

Vendor Qualifications

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

Assuring Independence

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

ATTACHMENT B: EVALUATION BUDGET

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

Figure 1. Cost Proposal Summary

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

Total Bid Amount	$ 1,196,190.00		Blended Hourly Rate	$ 198.01

Figure 2. Proposed Staffing Costs and Hours Allocation

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

ATTACHMENT C: TIMELINE AND MILESTONES

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

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

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

Figure 1. Proposed Timeline and Milestones

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

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

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

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

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

Attachment G: SMI/SED Implementation Plan

Section 1115 SMI/SED Demonstration Implementation Plan

Overview: The implementation plan documents the state's approach to implementing SMI/SED demonstrations. It also helps establish what information the state will report in its quarterly and annual monitoring reports. The implementation plan does not usurp or replace standard CMS approval processes, such as advance planning documents, verification plans, or state plan amendments.

This template only covers SMI/SED demonstrations. The template has three sections. Section 1 is the uniform title page. Section 2 contains implementation questions that states should answer. The questions are organized around six SMI/SED reporting topics:

1. Milestone 1: Ensuring Quality of Care in Psychiatric Hospitals and Residential Settings
2. Milestone 2: Improving Care Coordination and Transitioning to Community-Based Care
3. Milestone 3: Increasing Access to Continuum of Care, Including Crisis Stabilization Services
4. Milestone 4: Earlier Identification and Engagement in Treatment, Including Through Increased Integration
5. Financing Plan
6. Health IT Plan

State may submit additional supporting documents in Section 3.

Implementation Plan Instructions: This implementation plan should contain information detailing state strategies for meeting the specific expectations for each of the milestones included in the State Medicaid Director Letter (SMDL) on "Opportunities to Design Innovative Service Delivery Systems for Adults with [SMI] or Children with [SED]" over the course of the demonstration. Specifically, this implementation plan should:

1. Include summaries of how the state already meets any expectation/specific activities related to each milestone and any actions needed to be completed by the state to meet all of the expectations for each milestone, including the persons or entities responsible for completing these actions; and
2. Describe the timelines and activities the state will undertake to achieve the milestones.

The tables below are intended to help states organize the information needed to demonstrate they are addressing the milestones described in the SMDL. States are encouraged to consider the evidence-based models of care and best practice activities described in the first part of the SMDL in developing their demonstrations.

The state may not claim FFP for services provided to Medicaid beneficiaries residing in IMDs, including residential treatment facilities, until CMS has approved a state's implementation plan.

Memorandum of Understanding: The state Medicaid agency should enter into a Memorandum of Understanding (MOU) or another formal agreement with its State Mental Health Authority, if one does not already exist, to delineate how these agencies will work with together to design, deliver, and monitor services for beneficiaries with SMI or SED. This MOU should be included

as an attachment to this Implementation Plan.

State Response: **In accordance with Indiana's approved Medicaid State Plan, the Office of the Secretary of the Family and Social Services Administration (FSSA) is the single state agency. The Division of Mental Health and Addiction (DMHA) is within the FSSA; therefore, no MOU is applicable to this waiver request.**

State Point of Contact: Please provide the contact information for the state's point of contact for the implementation plan.

Name and Title:	Amy Owens Federal Relations Lead, Indiana Medicaid
Telephone Number:	317-233-7007
Email Address:	Amy.Owens@fssa.IN.gov

1. Title page for the state's SMI/SED demonstration or SMI/SED components of the broader demonstration

The state should complete this transmittal title page as a cover page when submitting its implementation plan.

State	*Indiana*
Demonstration name	*Healthy Indiana Plan –* *Project Number 11-W-00296/5*
Approval date	*TBD – Amendment submitted* *August 30, 2019*
Approval period	*January 1, 2020 – December 31, 2020*
Implementation date	*January 1, 2020*

2. Required implementation information, by SMI/SED milestone

Answer the following questions about implementation of the state's SMI/SED demonstration. States should respond to each prompt listed in the tables. Note any actions that involve coordination or input from other organizations (government or non-government entities). Place "NA" in the summary cell if a prompt does not pertain to the state's demonstration. Answers are meant to provide details beyond the information provided in the state's special terms and conditions. Answers should be concise, but provide enough information to fully answer the question.

This template only includes SMI/SED policies.

Prompts	Summary
SMI/SED. Topic_1. Milestone 1: Ensuring Quality of Care in Psychiatric Hospitals and Residential Settings	
To ensure that beneficiaries receive high quality care in hospitals and residential settings, it is important to establish and maintain appropriate standards for these treatment settings through licensure and accreditation, monitoring and oversight processes, and program integrity requirements and processes. Individuals with SMI often have co-morbid physical health conditions and substance use disorders (SUDs) and should be screened and receive treatment for commonly co-occurring conditions particularly while residing in a treatment setting. Commonly co-occurring conditions can be very serious, including hypertension, diabetes, and substance use disorders, and can also interfere with effective treatment for their mental health condition. They should also be screened for suicidal risk. *To meet this milestone, state Medicaid programs should take the following actions to ensure good quality of care in psychiatric hospitals and residential treatment settings.*	
Ensuring Quality of Care in Psychiatric Hospitals and Residential Treatment Settings	
Assurance that participating hospitals and residential settings are licensed or otherwise authorized by the state primarily to provide mental health treatment; and that residential treatment facilities are accredited by a nationally recognized accreditation entity prior to participating in Medicaid	*Current Status:* In accordance with Indiana Administrative Code (440 IAC 1.5), all free-standing psychiatric hospitals must be licensed as a private mental health institution (PMHI)[4] by the Indiana Division of Mental Health and Addiction (DMHA). PMHI licensure must be renewed annually. Additionally, all entities must be accredited by an agency approved by DMHA, which currently include the following: • National Committee for Quality Assurance (NCQA) • CARF – The Rehabilitation Accreditation Commission • Joint Commission on Accreditation of Healthcare Organizations (JCAHO) The following general components are required for licensure: • A governing board

[4] Defined as an inpatient hospital setting, including inpatient and outpatient services provided in that setting, for the treatment and care of individuals with psychiatric disorders or chronic addictive disorders, or both, that is physically, organizationally, and programmatically independent of any hospital or health facility licensed by the Indiana State Department of Health.

Prompts	Summary
	• Medical or professional staff organization • A quality assessment and improvement program • Dietetic service • Infection control program • Medical record services • Nursing service • Physical plan, maintenance and environmental services • Intake and treatment services • Discharge planning services • Pharmacy services • A plan for special procedures An entity seeking a license as a PMHI must file an application with DMHA which includes, at minimum: • A description of the organizational structure and mission of the applicant • The location of all operational sites of the applicant • The consumer population to be served and program focus • A list of governing board members and executive staff • A copy of the applicant's procedures to ensure protection of consumer rights and confidentiality • Written evidence of an onsite review and inspection by the Indiana Department of Health and Department of Homeland Security Division of Fire and Building Safety and the correction of any deficiencies identified • Proof of accreditation including site survey recommendations from the accrediting agency and the applicant's response to such recommendations To maintain licensure, a PMHI must meet the following conditions: • Maintain accreditation from a DMHA approved accrediting agency • Maintain compliance with required health, building, fire and safety codes as prescribed by federal, state and local law • Have written policies and enforce these policies to support and protect the fundamental human, civil, constitutional and statutory rights of each consumer • Comply with requirements for providing, posting and documenting consumer statement of rights under Indiana Code 12-27 • Respond to complaints from the consumer service line in a timely manner

Prompts	Summary
	Future Status: Continued operation of current requirements.
	Summary of Actions Needed: N/A –milestone requirements already met.
Oversight process (including unannounced visits) to ensure participating hospital and residential settings meet state's licensing or certification and accreditation requirements	*Current Status:* DMHA currently conducts annual unannounced site visits of each PMHI. Site visits are conducted using a checklist which crosswalks with all licensure requirements.
	Future Status: Continued operation of current requirements.
	Summary of Actions Needed: N/A –milestone requirements already met.
Utilization review process to ensure beneficiaries have access to the appropriate levels and types of care and to provide oversight on lengths of stay	*Current Status:* In accordance with 405 IAC 5-3-13, all inpatient psychiatric, substance abuse and rehabilitation admissions require prior authorization to ensure the appropriate level of care. Medical necessity reviews are completed by Indiana's managed care organizations (MCOs) and the State's fee-for-service prior authorization (PA) entity, based on the individual's enrollment. The PA entity utilizes Milliman Care Guidelines and OMPP reviews the MCO's UM practices. As described in the Indiana Medicaid Medical Policy Manual, acute psychiatric inpatient admissions are available for enrollees with a sudden onset of a psychiatric condition manifesting itself by acute symptoms of such severity that the absence of immediate medical attention could reasonably be expected to result in one or more of the following: • Danger to the individual • Danger to others • Death of the individual Reimbursement is available for inpatient care only when the need for admission has been certified. Emergency and nonemergency admissions require telephonic precertification review. The precertification review must be followed by a written certification of need through completion of State Form 44697 – Certification of the Need for Inpatient Psychiatric Hospital Services (1261A form) along with a written plan of care. This form documents the enrollee's: • Psychiatric and medical evaluation • Functional capacity • Prognoses • Recommendations

Prompts	Summary
	• Certification by an interdisciplinary team that based upon physical, mental and social evaluations the individual requires inpatient psychiatric treatment and available alternative community resources do not meet the patient's mental health care needs All requests for PA are reviewed on a case-by-case basis. The MCO or PA entity reviews each State Form 44697 to determine whether the requested acute inpatient services meet medical necessity. Reimbursement is denied for any days the facility cannot justify a need for inpatient care. If the provider fails to complete a telephone PA precertification, reimbursement will be denied from the admission to the actual date of notification. Additionally, in accordance with 440 IAC 1.5-3-9, all PMHIs must have policies and procedures that govern the intake and assessment process to determine eligibility for services. Each admitted Medicaid enrollee must have a preliminary treatment plan formulated within 60 hours of admission on the basis of the intake assessment at admission, which must specify the services necessary to meet the consumer's needs and contain discharge or release criteria and the discharge plan. Further, progress notes must be entered daily and the consumer's treatment plan must be reviewed at least every seven days.
	Future Status: OMPP will develop a report to monitor average length of stay (ALOS) for all Medicaid programs. All reporting will follow CMS monitoring guidance. Additionally, OMPP will review timeline requirements for submission of the 1261A form.
	Summary of Actions Needed: The Quality and Outcomes section of OMPP, in coordination with the evaluation vendor and MCOs, will develop reporting specifications to implement monitoring for implementation. OMPP will make necessary updates to the provider manuals to reflect any changes by Q2 of 2020. Providers were notified of program changes via bulletin on November 26, 2019.
Compliance with program integrity requirements and state compliance assurance process	*Current Status:* In order to receive reimbursement under Medicaid, participating psychiatric hospitals must be enrolled to participate in Indiana Medicaid. Provider enrollment processes fully comply with 42 CFR Part 455 Subparts B&E. As MCOs have been reimbursing IMDs as an in lieu of service and are only permitted to contract with Indiana Medicaid screened and enrolled providers, the State is currently screening and revalidating this provider type.
	Future Status: Continued operation of current requirements.
	Summary of Actions Needed: N/A –milestone requirements already met.

Prompts	Summary
State requirement that psychiatric hospitals and residential settings screen beneficiaries for co-morbid physical health conditions, SUDs, and suicidal ideation, and facilitate access to treatment for those conditions	*Current Status:* Indiana Administrative Code (440 IAC 1.5-3-9) details a series of required policies and procedures for intake and assessment processes. This includes, but is not limited to completion of the following assessments: • Physical examination by a licensed physician, advance practice nurse or physician's assistant • Emotional, behavioral, social and legal assessment Compliance with these requirements, including screening for SUD, is reviewed during annual site reviews conducted by the DMHA.
	Future Status: Compliance will continue to be monitored via the annual unannounced site visits of hospitals as part of their recertification.
	Summary of Actions Needed: N/A –milestone requirements already met.
Other state requirements/policies to ensure good quality of care in inpatient and residential treatment settings.	*Current Status:* DMHA conducts the Mental Health Statistical Improvement Project Survey for Adults and Youth (MHSIP), an annual consumer satisfaction surveys for all individuals who have been served by DMHA contracted providers. In addition, the MCOs conduct annual consumer assessment of healthcare providers and systems (CAHPS) surveys which provide insight into the consumer experience with their healthcare providers. Findings from these surveys are utilized in quality assurance and improvement activities as needed.
	Future Status: Continued operation of current consumer satisfaction surveys.
	Summary of Actions Needed: N/A –milestone requirements already met.
SMI/SED. Topic_2. Milestone 2: Improving Care Coordination and Transitioning to Community-Based Care	
Understanding the services needed to transition to and be successful in community-based mental health care requires partnerships between hospitals, residential providers, and community-based care providers. To meet this milestone, state Medicaid programs, must focus on improving care coordination and transitions to community-based care by taking the following actions.	
Improving Care Coordination and Transitions to Community-based Care	
Actions to ensure psychiatric hospitals and residential settings carry out intensive pre-discharge planning, and include community-based providers in care transitions.	*Current Status:* Indiana Administrative Code (440 IAC 1.5-3-10) outlines minimum requirements for discharge planning. Hospitals are required to initiate discharge planning at admission that includes the following: • Facilitates the provision of follow-up care. • Transfers or refers consumers, along with necessary medical information and records, to appropriate facilities, agencies, or outpatient services for follow-up or ancillary care. Required minimum information to be transferred includes: o Medical history o Current medications o Available social, psychological and educational services o Nutritional needs o Outpatient service needs

Prompts	Summary
	○ Follow-up care needs Additionally, in accordance with the Indiana Medicaid Medical Policy Manual, all plans of care must document a post-discharge plan and a plan for coordination of inpatient services with partial discharge plans, including appropriate services in the member's community to ensure continuity of care when the patient returns to his or her family and community upon discharge. Community mental health centers (CMHCs) are required, as codified in Indiana Administrative Code (440 IAC 9-2-4), to be involved in the planning of treatment for and the discharge of consumers during the time a consumer is in inpatient care, to maintain continuity of care. Additionally, MCOs are contractually required to provide case management services for any member discharged from an inpatient psychiatric or substance abuse hospitalization for no fewer than 90 calendar days following discharge. MCO contracts also require case managers to contact members during an inpatient hospitalization, or immediately upon receiving notification of a member's inpatient behavioral health hospitalization and must schedule an outpatient follow-up appointment to occur no later than seven calendar days following the inpatient behavioral health hospitalization discharge. If a member misses an outpatient follow-up or continuing treatment, the MCO is contractually required to ensure that a behavioral health care provider or the MCO's behavioral health case manager contacts that member within three business days of notification of the missed appointment.
	Future Status: Continued operation of current requirements.
	Summary of Actions Needed: N/A –milestone requirements already met.
2.b Actions to ensure psychiatric hospitals and residential settings assess beneficiaries' housing situations and coordinate with housing services providers when needed and available.	*Current Status:* MCOs are contractually required to provide case management services for any member at risk for or discharged from an inpatient psychiatric or substance abuse hospitalization. Case managers must contact members during an inpatient hospitalization and as a component of case management, must make every effort to assist members in navigating community resources and linking members with community-based services such as Connect2Help211, food pantries, housing and housing supports, legal, employment and disaster services. Additionally, CMHCs are required, in accordance with IAC 440 IAC 9-2-10, as a component of case management, to provide advocacy and referral including helping individuals access entitlement and other services, such as Medicaid, housing, food stamps, educational services, recovery groups, and vocational services.

Prompts	Summary
	Future Status: Indiana Medicaid Provider Manual will be updated to explicitly require psychiatric hospitals have protocols in place to assess for housing insecurity as part of the social work assessment and discharge planning processes and to refer to appropriate resources. Compliance will be monitored via the annual unannounced site visits of hospitals as part of their recertification. Post-discharge follow-up will continue to be provided by MCOs and providers eligible to deliver case management services.
	Summary of Actions Needed: Provider Manual will be updated by OMPP by Q2 2020. The State issued provider communication materials detailing the requirements on November 26, 2019.
2.c State requirement to ensure psychiatric hospitals and residential settings contact beneficiaries and community-based providers through most effective means possible, e.g., email, text, or phone call within 72 hours post discharge	*Current Status:* MCOs currently undertake the primary responsibility for assuring enrollees access follow-up care post-discharge. They are contractually required to schedule an outpatient follow-up appointment to occur no later than seven calendar days following an inpatient behavioral health hospitalization discharge. If a member misses an outpatient follow-up appointment, the MCO must ensure that a behavioral health provider or the MCO's case manager contacts that member within three business days of notification of the missed appointment. Additionally, Indiana Medicaid provides coverage for bridge appointments, which are follow-up appointments after inpatient hospitalization for behavioral health issues, when no outpatient appointment is available within seven days of discharge. The goal of the bridge appointment is to provide proper discharge planning while establishing a connection between the member and the outpatient treatment provider. During the bridge appointment, the provider ensures, at minimum, the following: • The member understands the medication treatment regimen as prescribed. • The member has ongoing outpatient care. • The family understands the discharge instructions for the member. • Barriers to continuing care are addressed. • Any additional questions from the member or family are answered.
	Future Status: Indiana Medicaid Provider Manual will be updated to explicitly require psychiatric hospitals have protocols in place to ensure contact is made by the treatment setting with each discharged beneficiary within 72 hours of discharge and follow-up care is accessed. Compliance will be monitored via the annual unannounced site visits of hospitals as part of their recertification.
	Summary of Actions Needed: Provider Manual will be updated by OMPP by Q2 2020. A provider bulletin detailing these requirements was published on November 26, 2019.
2.d Strategies to prevent or decrease lengths of stay in EDs	*Current Status:* MCOs are required to identify high utilizers of ED services and ensure members are coordinated and participating in the appropriate disease management or care management services. Any member with ED utilizations at least three standard deviations from the mean are referred to care coordination.

Prompts	Summary
among beneficiaries with SMI or SED prior to admission	*Future Status:* OMPP, in collaboration with its Provider Relations contractor, will monitor provider network capacity on an annual basis and identify underserved areas for targeted provider recruitment. Additionally, DMHA plans to pilot two Crisis Stabilization Units (CSU) in the northern and southern parts of the state. The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units. FSSA's OMPP, DMHA, and Division of Disability and Rehabilitative Services (DDRS) are partnering with the Department of Child Services (DCS) and Juvenile Justice agencies to explore piloting mobile response stabilization services (MRSS). MRSS would provide community-based crisis intervention including short term follow-up and support for the youth and family to prevent reescalation, emergency department utilization and/or inpatient admission.
	Summary of Actions Needed: OMPP will annually identify geographic shortage areas and Provider Enrollment will conduct targeted outreach to non-Medicaid enrolled providers in those areas. The CSU is proposed for implementation in SFY2020. The timeline for a potential MRSS is currently under review.
2.e Other State requirements/policies to improve care coordination and connections to community-based care	*Current Status:* Please refer to previous sections.
	Future Status: N/A
	Summary of Actions Needed: N/A
SMI/SED. Topic_3. Milestone 3: Increasing Access to Continuum of Care, Including Crisis Stabilization Services	
Adults with SMI and children with SED need access to a continuum of care as these conditions are often episodic and the severity of symptoms can vary over time. Increased availability of crisis stabilization programs can help to divert Medicaid beneficiaries from unnecessary visits to EDs and admissions to inpatient facilities as well as criminal justice involvement. On-going treatment in outpatient settings can help address less acute symptoms and help beneficiaries with SMI or SED thrive in their communities. Strategies are also needed to help connect individuals who need inpatient or residential treatment with that level of care as soon as possible. To meet this milestone, state Medicaid programs should focus on improving access to a continuum of care by taking the following actions.	
Access to Continuum of Care Including Crisis Stabilization	
3.a The state's strategy to conduct annual assessments of the availability of mental health providers including psychiatrists, other practitioners, outpatient, community mental health	*Current Status:* Indiana provides a comprehensive statewide service array inclusive of: • Outpatient behavioral health services currently delivered by providers across the State, as delineated in the attached Mental Health Services Availability Assessment Template. • Medicaid rehabilitation option (MRO) delivered by the State's 24 CMHCs. All 92 counties in Indiana have at least one CMHC delivering care in the geographical area and most counties in the state, other than very rural ones, have more than one CMHC offering services within a county.

Prompts	Summary
centers, intensive outpatient/partial hospitalization, residential, inpatient, crisis stabilization services, and FQHCs offering mental health services across the state, updating the initial assessment of the availability of mental health services submitted with the state's demonstration application. The content of annual assessments should be reported in the state's annual demonstration monitoring reports. These reports should include which providers have waitlists and what are average wait times to get an appointment	• Three §1915(i) programs serving individuals with behavioral health needs. • Expanded SUD services in accordance with the State's approved SUD waiver. • Partial hospitalization programs which are time-limited medical services intended to provide a transition from inpatient psychiatric hospitalization to community-based care or, in some cases, substitute for an inpatient admission. Indiana Administrative Code and DMHA contracts require CMHCs to provide a defined continuum of care directly, or through subcontract which includes: • Individualized treatment planning to increase patient coping skills and symptom management • 24/7 crisis intervention • Case management to fulfill individual patient needs, including assertive case management • Outpatient services, including intensive outpatient services, substance abuse services, counseling and treatment • Acute stabilization, including detoxification services • Residential services • Day treatment • Family support services • Medication evaluation and monitoring • Services to prevent unnecessary and inappropriate treatment and hospitalization and the deprivation of a person's liberty Further, House Enrolled Act 1175, passed in the 2019 legislative session, will expand access to behavioral health providers for Medicaid enrollees. Under this law, licensed clinical social workers, licensed mental health counselors, licensed clinical addiction counselors and licensed marriage and family therapists will be eligible providers for the supervision of a plan of treatment for a patient's outpatient mental health or substance abuse treatment services. Prior to this legislation, midlevel behavioral health practitioners were not eligible to independently enroll in Indiana Medicaid and were required to bill under the supervision of an HSPP or psychiatrist. Additionally, effective July 1, 2019, in accordance with the CMS approval of SPA TN 18-012, Indiana Medicaid expanded crisis intervention services, intensive outpatient program services and peer recovery services to all Indiana Medicaid programs; these services were previously limited to the MRO option. This change will expand the available provider base from the Indiana's CMHCs to all Medicaid enrolled providers meeting the applicable criteria.

Prompts	Summary
	OMPP and DMHA continually assess access and availability of behavioral health services. For example, in accordance with the State's approved §1915(b)(4) waivers for MRO services and §1915(i) programs, FSSA utilizes information gathered from analysis of Indiana's MMIS, site reviews, and recipient reports and complaints to evaluate the need to expand provider agencies and/or provide training and/or corrective actions to assist provider agencies in increasing efficiencies for timely access to services. When "timely access" is identified as a provider agency issue, the State uses a request for corrective action and provides technical assistance and training in order to assist the agency in correcting the issue. If the issue is not remediated satisfactorily, further sanctions are applied, up to and including decertification of the agency as an MRO or §1915(i) provider. Further, OMPP's Provider Relations contractor identifies underserved areas by calculating the ratio of providers to members by county. Recruiting efforts are intensified in counties that are identified as not meeting HRSA provider-to-member ratio standards. Utilizing the results of this analysis, the Provider Relations team outreaches to behavioral health providers not currently Medicaid enrolled. Provider Relations employs the following strategy to reach out to potential providers: ● Analyze the provider-to-population report to prioritize the geographic areas to be targeted. ● Analyze NPI reports to determine which specialties are underrepresented in the selected geographic region. ● Collaborate with residency programs to educate graduating classes about the benefits of providing services to the Medicaid population and encourage enrollment in Medicaid when residents graduate. ● Contact providers by telephone or via on-site visit. During the contact, Provider Relations will: ○ Invite the provider to consider Medicaid enrollment. ○ Explain the benefits of Medicaid enrollment. ○ Educate the provider regarding any misconceptions about Medicaid. ○ Mitigate the provider's objections. ○ Offer to make an on-site visit to discuss enrollment and help the provider complete the online enrollment application, if applicable. ○ Ascertain the reasons the provider chooses not to enroll, if applicable. Additionally, MCOs are contractually required to meet network adequacy standards for behavioral health providers in accordance with 42 CFR §438.68. Corrective action is implemented when standards are not met.

Prompts	Summary
	Future Status: OMPP will continue to monitor provider network capacity on an annual basis. Additionally, DMHA plans to pilot two Crisis Stabilization Units (CSU) in the northern and southern parts of the state. The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units. FSSA's OMPP, DMHA, and Division of Disability and Rehabilitative Services (DDRS) are partnering with the Department of Child Services (DCS) and Juvenile Justice agencies to explore piloting mobile response stabilization services (MRSS). MRSS would provide community-based crisis intervention including short term follow-up and support for the youth and family to prevent reescalation, emergency department utilization and/or inpatient admission.
	Summary of Actions Needed: OMPP will annually identify geographic shortage areas and Provider Enrollment will conduct targeted outreach to non-Medicaid enrolled providers in those areas. The CSU is proposed for implementation in SFY2020. The timeline for MRSS is currently under review.
3.b Financing plan	*Current Status:* Please refer to Financing Plan below.
	Future Status: Please refer to Financing Plan below.
	Summary of Actions Needed: Please refer to Financing Plan below.
3.c Strategies to improve state tracking of availability of inpatient and crisis stabilization beds	*Current Status:* In March 2018, FSSA implemented a new tool to help Hoosiers seeking treatment for SUD immediately connect with available inpatient or residential treatment services. This new tool is made possible by a partnership between the State, OpenBeds, a software platform that manages health services, and Indiana 2-1-1, a non-profit organization that provides health care and other resource referrals to those in need. This service allows treatment facilities to list their vacancies in a real-time, broadly connected database and offers a comprehensive suite of information technology functionalities specific to mental health and SUD, and provides capability for: • Transparency regarding the capacity of inpatient services, including recovery housing and community services, to provide an immediate and accurate inventory of available resources • Secure and HIPAA-compliance digital communication for referrals with email and text notifications, including the ability to transmit client data, along with consent • Digital registration and authentication for health systems and organizations • Real-time analytics to track utilization and referral patterns across the region • Patient marketplace or "pull referral" functionality to expedite patient placement • Mobile platform

Prompts	Summary
	Future Status: FSSA is currently in the process of expanding use of OpenBeds beyond SUD to include tracking availability of psychiatric inpatient and crisis stabilization beds.
	Summary of Actions Needed: Expansion of OpenBeds contract in Fall 2019 to include psychiatric bed capacity.
3.d State requirement that providers use a widely recognized, publicly available patient assessment tool to determine appropriate level of care and length of stay	*Current Status:* Every individual served by a DMHA contracted provider receives a Child and Adolescent Needs and Strengths (CANS) or Adult Needs and Strengths Assessment (ANSA) to inform individualized treatment planning and level of care decision making. Individuals are reassessed every six months with adjustments to level of care and/or treatment plan being made accordingly. Further, as stated in Indiana Administrative Code 405 IAC 5-21.5, IHCP reimbursement for MRO services is available for members who meet specific diagnosis and level of need (LON) criteria under the approved DMHA assessment tool (ANSA or CANS). Additional MRO services beyond what is available for the assigned service package may be added with prior authorization (PA). MRO services are clinical behavioral health services provided to members and families of members living in the community who need aid intermittently for emotional disturbances, mental illness, and addiction. The CANS/ANSA also inform individual service needs and level of care that could include inpatient and/or residential services. In addition to use of the CANS and ANSA, determinations of medical necessity for behavioral health services are based on utilization management criteria implementation by the State's MCOs and utilization management vendor.
	Future Status: N/A
	Summary of Actions Needed: N/A
Other state requirements/policies to improve access to a full continuum of care including crisis stabilization	*Current Status:* Please refer to previous sections.
	Future Status: N/A
	Summary of Actions Needed: N/A
SMI/SED. Topic_4. Milestone 4: Earlier Identification and Engagement in Treatment, Including Through Increased Integration	
Critical strategies for improving care for individuals with SMI or SED include earlier identification of serious mental health conditions and focused efforts to engage individuals with these conditions in treatment sooner. To meet this milestone, state Medicaid programs must focus on improving mental health care by taking the following actions.	
Earlier Identification and Engagement in Treatment	
	Current Status: The Vocational Rehabilitation Services (VRS) is a program of FSSA's Division of Disability and Rehabilitative Services (DDRS). VRS are available statewide, in all regions of the state. Eligibility for

Prompts	Summary
4.a Strategies for identifying and engaging beneficiaries with or at risk of SMI or SED in treatment sooner, e.g., with supported education and employment	VRS is determined in accordance with federal requirements at 34 CFR 361.42(a). Accordingly, eligibility for VRS includes a determination that an applicant meets the following conditions: • Has a physical or mental impairment • This impairment constitutes or results in a substantial impediment to employment • VRS are required to prepare for, enter, engage in, or retain an employment outcome consistent with his or her abilities, capacities, career interests, and informed choice. Additionally, all applicants determined eligible for Social Security for Social Security Disability (SSDI) or Supplemental Security Income (SSI) are presumed eligible for VRS. Individuals receiving VRS have an Individualized Plan for Employment (IPE) based on the requirements at 34 CFR 361.45, following an assessment for determining vocational rehabilitation needs. VRS are provided in accordance with the IPE and may include: • Vocational counseling and guidance • Medical treatment to correct or modify the physical or mental impairment • Training (including vocational school, college or university, on-the-job, and other training) • Rehabilitation technology (assistive devices and services) • Placement assistance and follow-up (including supported employment) • Other planned goods and services determined to be necessary to address an identified substantial impediment to employment and to be required to enable the individual to prepare for, enter, engage in, or retain an employment outcome Supportive employment (SE) is available as a VRS. Through this service, individuals with the most severe disabilities are placed in competitive jobs with qualified job coaches/trainers to provide individualized, ongoing support services needed for each individual to retain employment. The employer is contacted monthly and the employee is visited twice monthly, either at or away from the workplace, to address any issues that may threaten the individual's ability to remain on the job. Additionally, several of Indiana's CMHCs provide supportive employment services, an evidence-based service to promote rehabilitation and return to productive employment for persons with serious mental illness. These programs use a team approach for treatment, with employment specialists responsible for carrying out all vocational services from intake through follow-along. Job placements are: community-based (i.e., not sheltered workshops, not onsite at SE or other treatment agency offices), competitive (i.e., jobs are not exclusively reserved for SE clients, but open to public), in normalized settings, and utilize multiple employers. The SE team has a small client to staff ratio. SE contacts occur in the home, at the job site, or in the community. The SE team is assertive in engaging and retaining clients in treatment, especially utilizing face-to-face community

Prompts	Summary
	visits, rather than phone or mail contacts. The SE team consults/works with family and significant others when appropriate. SE services are frequently coordinated with Vocational Rehabilitation benefits.
	Future Status: Continued operation of current programming.
	Summary of Actions Needed: N/A
4.b Plan for increasing integration of behavioral health care in non-specialty settings to improve early identification of SED/SMI and linkages to treatment	*Current Status:* In 2012, FSSA in partnership with the Indiana State Department of Health (ISDH) launched the Primary Care and Behavioral Health Integration (PCBHI) initiative, to develop a statewide strategic plan to integrate primary and behavioral health care services in Indiana. As an outgrowth of this initiative, the State was awarded the SAMHSA and National Association of State Mental Health Program Directors (NASHMHPD) Transformation Transfer Initiative (TTI) Grant which allowed the State to implement a series of initiatives aimed at increased integration. Additionally, a process was established by which Community Mental Health Centers (CMHCs), Federally Qualified Health Centers (FQHCs), Community Health Centers (CHCs) and Rural Health Clinics (RHCs) could become a state certified integrated care entity (ICE). Currently, there are 13 ICE sites operating within the State. ICE core requirements include: • Core assessments for behavioral and physical health • Integrated care plans • Interdisciplinary team meetings • Real-time physician/pharmacy consults • Leadership support • Evidence based practice and training • Electronic health records and data sharing • Quality outcome measures The State has also focused on school-based initiatives to increase behavioral health integration. For example, CMHCs across the State work in close collaboration with Indiana schools. Currently, 85% of school districts have CMHCs providing services within their schools. Additionally, DMHA released an RFP in June 2019 to contract with no more than three regionally diverse social services providers to implement an evidence-based program that partners with school corporations, charter schools, and accredited nonpublic schools to provide social work services and evidence-based prevention programs to children, parents, caregivers, teachers, and the community to prevent substance abuse, promote healthy behaviors, and maximize student success. Further, the MCOs are contractually required to plan for, develop and/or enhance relationships with school-based health centers (SBHC) with the goal of providing accessible services to school-aged enrolled members.

Prompts	Summary
	SBHCs provide on-site comprehensive preventive and primary health services including behavioral health, oral health, ancillary and enabling services. Additionally, Indiana encourages the integration of primary and behavioral health care services through the use of an alternative payment methodology (APM) for federally qualified health centers (FQHCs) which consists of: (1) an adjustment to the FQHC's prospective payment system (PPS) rate; and (2) performance incentive payments limited to an established annual amount for each participating FQHC. To qualify for an APM, the FQHC must implement a care plan that fully integrates primary care and behavioral health at the FQHC through an integration plan approved by OMPP and DMHA which includes the following components: • Incorporation of screening and evaluation processes to identify targeted patient population • Establishment of appropriate levels of behavioral health staffing • Physical integration of the provision of primary and behavioral health care together at the same FQHC location • Performance of medical and behavioral health care services by the staff at the FQHC • Full integration of medical records, billing and other data relating to primary and behavioral health care services • Ongoing monitoring of the integration plan through data collection and evaluation
	Future Status: The State will ensure the financial sustainability of a physical health and behavioral health integration model following the end of the current grant funding.
	Summary of Actions Needed: OMPP, in partnership with DMHA is pursuing options for sustainability and expansion of the State's model for primary care and behavioral health integration. DMHA is submitting an application for SAMHSA's (FY) 2020 Promoting Integration of Primary and Behavioral Health Care (Short Title: PIPBHC) grant and OMPP is exploring implementation of a health homes state plan amendment in 2021.
F4.c Establishment of specialized settings and services, including crisis stabilization, for young people experiencing SED/SMI	*Current Status:* The State's review of the crisis continuum confirmed the following crisis services are being provided in addition to the CMHC mandated 24/7 crisis services: mobile crisis teams (5), assertive community treatment (ACT) (6), 23-hour crisis stabilization units (7), short-term crisis residential (2) and peer crisis services (2).
	Future Status: DMHA plans to pilot two Crisis Stabilization Units (CSU) in the northern and southern parts of the state. The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units. FSSA's OMPP, DMHA, and Division of Disability and Rehabilitative Services (DDRS) are partnering with the Department of Child Services (DCS) and Juvenile Justice agencies to explore piloting mobile response stabilization services (MRSS). MRSS would provide community-based crisis intervention including short term

Prompts	Summary
	follow-up and support for the youth and family to prevent reescalation, emergency department utilization and/or inpatient admission.
	Summary of Actions Needed: The CSU is proposed for implementation in SFY2020. The timeline for MRSS is currently under review.
4.d Other state strategies to increase earlier identification/engagement, integration, and specialized programs for young people	*Current Status:* Please refer to previous sections.
	Future Status: N/A
	Summary of Actions Needed: N/A
SMI/SED.Topic_5. Financing Plan	
te Medicaid programs should detail plans to support improved availability of non-hospital, non-residential mental health services including crisis stabilization and on-going community-based care. The financing plan should describe state efforts to increase access to community-based mental health providers for Medicaid beneficiaries throughout the state, including through changes to reimbursement and financing policies that address gaps in access to community-based providers identified in the state's assessment of current availability of mental health services included in the state's application.	
F.a Increase availability of non-hospital, non-residential crisis stabilization services, including services made available through crisis call centers, mobile crisis units, observation/assessment centers, with a coordinated community crisis response that involves collaboration with trained law enforcement and other first responders.	*Current Status:* The State's review of the crisis continuum confirmed the following crisis services are being provided in addition to the CMHC mandated 24/7 crisis services: mobile crisis teams (5), assertive community treatment (ACT) (6), 23-hour crisis stabilization units (7), short-term crisis residential (2) and peer crisis services (2). Effective July 1, 2019, in accordance with the CMS approval of SPA TN 18-012, Indiana Medicaid expanded crisis intervention services, intensive outpatient program services and peer recovery services to all Indiana Medicaid programs; these services were previously limited to the MRO option. This change will expand the available provider base from the Indiana's CMHCs to all Medicaid enrolled providers meeting the applicable criteria.
	Future Status: The State will annually monitor access to non-residential crisis stabilization services through an agreed upon methodology. In addition, the State will encourage and support non-CMHC providers to increase access to intensive outpatient, peer support and crisis intervention services. DMHA plans to pilot two Crisis Stabilization Units (CSU) in the northern and southern parts of the state. The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units. FSSA's OMPP, DMHA, and Division of Disability and Rehabilitative Services (DDRS) are partnering with the Department of Child Services (DCS) and Juvenile Justice agencies to explore piloting mobile response

Prompts	Summary
	stabilization services (MRSS). MRSS would provide community-based crisis intervention including short term follow-up and support for the youth and family to prevent reescalation, emergency department utilization and/or inpatient admission.
	Summary of Actions Needed: The CSU is proposed for implementation in SFY2020. The timeline for MRSS is currently under review.
F.b Increase availability of on-going community-based services, e.g., outpatient, community mental health centers, partial hospitalization/day treatment, assertive community treatment, and services in integrated care settings such as the Certified Community Behavioral Health Clinic model.	*Current Status:* As described throughout this template, and as outlined in the attached "Overview of the Assessment of the Availability of Mental Health Services" template, Indiana offers a comprehensive continuum of community-based services. Effective July 1, 2019, in accordance with the CMS approval of SPA TN 18-012, Indiana Medicaid expanded crisis intervention services, intensive outpatient program services and peer recovery services to all Indiana Medicaid programs; these services were previously limited to the MRO option. This change will expand the available provider base from the Indiana's CMHCs to all Medicaid enrolled providers meeting the applicable criteria.
	Future Status: The State will annually monitor access to community-based services through an agreed upon methodology. In addition, the State will specifically monitor any changes to non-CMHC providers and the impact on access to intensive outpatient, peer support and crisis intervention services.
	Summary of Actions Needed: OMPP will annually identify geographic shortage areas and Provider Enrollment will conduct targeted outreach to non-Medicaid enrolled providers in those areas.

<table>
<tr><th>Prompts</th><th>Summary</th></tr>
<tr><td colspan="2">SMI/SED. Topic_6. Health IT Plan</td></tr>
<tr><td colspan="2">outlined in State Medicaid Director Letter (SMDL) #18-011, “[s]tates seeking approval of an SMI/SED demonstration … will be expected to submit a Health IT Plan (“HIT Plan”) that describes the state’s ability to leverage health IT, advance health information exchange(s), and ensure health IT interoperability in support of the demonstration’s goals.”[5] The HIT Plan should also describe, among other items, the:
Role of providers in cultivating referral networks and engaging with patients, families and caregivers as early as possible in treatment; and
Coordination of services among treatment team members, clinical supervision, medication and medication management, psychotherapy, case management, coordination with primary care, family/caregiver support and education, and supported employment and supported education.
ease complete all Statements of Assurance below—and the sections of the Health IT Planning Template that are relevant to your state’s demonstration proposal.</td></tr>
<tr><td colspan="2">Statements of Assurance</td></tr>
<tr><td>Statement 1: Please provide an assurance that the state has a sufficient health IT infrastructure/ecosystem at every appropriate level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration. If this is not yet the case, please describe how this will be achieved and over what time period</td><td>As outlined in Indiana’s State Medicaid Health Information Technology Plan (SMHP), Indiana’s HIT environment is active with multi-faceted efforts to support provider HIT capacity and foster the sharing of clinical and administrative data to improve health care and support system improvements. The State has taken an active role through its state health agencies and Medicaid program to promote HIT adoption and HIE development, building upon its private health care marketplace.

As outlined in the table below, the State is home to four well-established health information exchange networks operated by Health Information Organizations (HIOs), each functioning in different capacities for community partners.

<table>
<tr><th>Regional HIO</th><th>June 2019 Status</th></tr>
<tr><td>HealthBridge (includes greater Cincinnati tristate area)</td><td>Utilization of the Health Collaborative’s HealthBridge Suite (hb/suite):
58 hospitals
8,901 providers
160 million clinical results processed
15 million monthly messages</td></tr>
<tr><td>HealthLINC</td><td>Delivers more than 175,000 medical results per month among hospitals, office and clinic practices and under-served clinics
Health service directory that includes more than 350 physicians and other providers</td></tr>
</table>
</td></tr>
</table>

[5] See SMDL #18-011, “Opportunities to Design Innovative Service Delivery Systems for Adults with a Serious Mental Illness or Children with a Serious Emotional Disturbance.” Available at https://www.medicaid.gov/federal-policy-guidance/downloads/smd18011.pdf.

<table>
<tr><th>Prompts</th><th>Summary</th></tr>
<tr><td></td><td>
<table>
<tr><td>Indiana Health Information Exchange (IHIE)</td><td>• Connection to 117 hospitals representing 38 health systems
• Over 17,055 practices
• Over 47,452 providers
• Over 14,847,271 patients
• Over 12,510,420,163 clinical data elements</td></tr>
<tr><td>Michiana Health Information Network (MHIN)</td><td>• Over 576 data sources
• 3.9 million transactions inbound per month
• 20,304 providers connected</td></tr>
</table>

However, a March 2019 assessment of Indiana’s health information sharing (HIS), conducted based on capability maturity guidance from CMS and the Office of the National Coordination for Health Information Technology (ONC), revealed opportunities for increased electronic documentation and standardization among settings and providers not previously addressed through Meaningful Use, including behavioral health providers. Through this HIT Plan, the State intends to drive improvements in this area.
</td></tr>
<tr><td>Statement 2: Please confirm that your state’s SUD Health IT Plan is aligned with the state’s broader State Medicaid Health IT Plan and, if applicable, the state’s Behavioral Health IT Plan. If this is not yet the case, please describe how this will be achieved and over what time period.</td><td>This HIT Plan is aligned with the State’s broader State Medicaid Health IT Plan (SMHP). The State is in the process of completing an updated SMHP with targeted completion by the end of calendar year 2019. Through this update process, areas of prioritization will take into consideration the milestones of this waiver.</td></tr>
<tr><td>Statement 3: Please confirm that the state intends to assess the applicability of standards referenced in the Interoperability Standards Advisory (ISA)[6] and 45 CFR 170 Subpart B and, based on that assessment, intends to include them as appropriate in</td><td>Indiana will review the applicability of standards referenced in the Interoperability Standards Advisory (ISA) and 45 CFR 170 Subpart B for potential inclusion into our MCO contracts. The following standards are currently utilized by our MCOs:
• Documenting and Sharing Care Plans – The MCOs are contractually obligated to share care plans with primary medical providers (PMPs) and behavioral health providers with appropriate consent.
• The MCOs have agreements with health information exchanges, such as the Indiana Health Information Exchange (IHIE) and the Michiana Health Information Network (MHIN).</td></tr>
</table>

[6] Available at https://www.healthit.gov/isa/.

Prompts	Summary
subsequent iterations of the state's Medicaid Managed Care contracts. The ISA outlines relevant standards including but not limited to the following areas: referrals, care plans, consent, privacy and security, data transport and encryption, notification, analytics and identity management.	• Clinical Quality Measurement and Reporting – The MCEs report on the following HEDIS quality measures related to behavioral health: ○ Follow-up care for children prescribed ADHD medication, initiation phase ○ Follow-up care for children prescribed ADHD medication, maintenance phase ○ 30-day follow-up after hospitalization for mental illness ○ 7-day follow-up after hospitalization for mental illness ○ Use of multiple concurrent antipsychotics in children and adolescents up to age 17 ○ Use of first-line psychosocial care for children/adolescents on antipsychotics up to age 17 ○ Antidepressant medication management, acute phase ○ Antidepressant medication management, continuation phase ○ 30-day follow-up after emergency department (ED) visit for mental illness ○ 7-day follow-up after ED visit for mental illness
To assist states in their health IT efforts, CMS released SMDL #16-003 which outlines enhanced federal funding opportunities available to states "for state expenditures on activities to promote health information exchange (HIE) and encourage the adoption of certified Electronic Health Record (EHR) technology by certain Medicaid providers." For more on the availability of this "HITECH funding," please contact your CMS Regional Operations Group contact. [7] *Enhanced administrative match may also be available under MITA 3.0 to help states establish crisis call centers to connect beneficiaries with mental health treatment and to develop technologies to link mobile crisis units to beneficiaries coping with serious mental health conditions. States may also coordinate access to outreach, referral, and assessment services—for behavioral health care--through an established "No Wrong Door System."*[8]	
Closed Loop Referrals and e-Referrals (Section 1)	
1.1 Closed loop referrals and e-referrals from physician/mental health provider to physician/mental health provider	*Current State:* The State does not have readily accessible data on the exact number of Medicaid-enrolled behavioral health providers who have adopted certified EHRs and are utilizing them for e-referrals and/or closed loop referrals. With multiple HIEs and large health systems that have been able to exchange effectively via EHR and prescription software vendors, it is difficult to accurately assess participation. Each HIE is able to easily report on its participants but the extent to which non-participating organizations are identified and assessed individually is meticulous work. It is known that certain hospital, facility, and provider types that were not eligible for Meaningful Use (Promoting Interoperability) are not participating due to lagging technology and/or regulatory barriers, such as with CFR 42 Part 2.

[7] See SMDL #16-003, "Availability of HITECH Administrative Matching Funds to Help Professionals and Hospitals Eligible for Medicaid EHR Incentive Payments Connect to Other Medicaid Providers." Available at https://www.medicaid.gov/federal-policy-guidance/downloads/smd16003.pdf.

[8] Guidance for Administrative Claiming through the "No Wrong Door System" is available at https://www.medicaid.gov/medicaid/finance/admin-claiming/no-wrong-door/index.html.

Prompts	Summary
	The aforementioned March 2019 HIS Assessment did reveal provider tracking of referrals may be facilitated by tools within the EHR but most still struggle with closing the referral loop.
	Future State: The State will conduct a survey to identify the volume of providers utilizing closed loop referrals and e-referrals to identify the baseline of current activity and identify options for increasing provider uptake.
	Summary of Actions Needed: The provider survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
1.2 Closed loop referrals and e-referrals from institution/hospital/clinic to physician/mental health provider	*Current State:* The State does not have readily accessible data on the exact number of Medicaid-enrolled behavioral health providers who have adopted certified EHRs and are utilizing them for e-referrals and/or closed loop referrals. The aforementioned March 2019 HIS Assessment did reveal provider tracking of referrals may be facilitated by tools within the EHR but most still struggle with closing the referral loop.
	Future State: The State will conduct a survey to identify the volume of providers utilizing closed loop referrals and e-referrals to identify the baseline of current activity and identify options for increasing provider uptake.
	Summary of Actions Needed: The provider survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
1.3 Closed loop referrals and e-referrals from physician/mental health provider to community based supports	*Current State:* The State does not have readily accessible data on the exact number of Medicaid-enrolled behavioral health providers who have adopted certified EHRs and are utilizing them for e-referrals and/or closed loop referrals. The aforementioned March 2019 HIS Assessment did reveal provider tracking of referrals may be facilitated by tools within the EHR but most still struggle with closing the referral loop.
	Future State: The State will conduct a survey to identify the volume of providers utilizing closed loop referrals and e-referrals to identify the baseline of current activity and identify options for increasing provider uptake.
	Summary of Actions Needed: The provider survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
Electronic Care Plans and Medical Records (Section 2)	
2.1 The state and its providers can create and use an electronic care plan	*Current State:* The aforementioned March 2019 HIS Assessment revealed that while electronic care plans are utilized they are not standardized. HIEs receive what the provider delivers via continuity of care documents (CCD) but content and format are variable.
	Future State: The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. Additionally, FSSA will survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.
	Summary of Actions Needed: FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. The IMD survey will be conducted by FSSA. The dates for

Prompts	Summary
	completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
2.2 E-plans of care are interoperable and accessible by all relevant members of the care team, including mental health providers	*Current State:* Indiana contracts with the Indiana Health Information Exchange (IHIE) to aggregate Medicaid claims with medical and pharmacy data in its repository to create a continuity of care (CCD) record that can be shared between Medicaid providers. The aforementioned March 2019 HIS Assessment indicates some MCOs and providers are receiving admit-discharge-transfer (ADT), CCDs or other clinical data points and incorporating directly into their work flow for care coordination and quality management. Additionally, the majority of community mental health centers have certified EHRs and utilize Viewpoint, a referral portal, to communicate among entities.
	Future State: As previously described, OMPP is exploring submitting a health homes state plan amendment. A key component of this initiative will include leveraging HIT for enhanced integration and coordination. OMPP is currently in the process of developing HIT standards and requirements for participating providers. Additionally, the State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. FSSA will also survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.
	Summary of Actions Needed: OMPP is exploring submitting a health homes state plan amendment with an implementation date by 2021. FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. The IMD survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
2.3 Medical records transition from youth-oriented systems of care to the adult behavioral health system through electronic communications	*Current State:* State psychiatric hospitals utilize one EHR system which permits tracking of records as youth transition to adulthood.
	Future State: The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. Additionally, FSSA will survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.
	Summary of Actions Needed: FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. The IMD survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
2.4 Electronic care plans transition from youth-oriented systems of care to the adult behavioral health system through electronic communications	*Current State:* State psychiatric hospitals utilize one EHR system which permits tracking of care plans as youth transition to adulthood.
	Future State: The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. FSSA will also survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.

Prompts	Summary
	Summary of Actions Needed: FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. The IMD survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.

2.5 Transitions of care and other community supports are accessed and supported through electronic communications	*Current State:* In 2017, DMHA released an RFP to procure a new EHR system to be used collectively by all state psychiatric hospitals. The State's expectation is that a modern EHR will facilitate interoperability. The required HIE functionality put forth in FSSA's statement of work for this project include:
	• Admission, discharge and transfer (ADT) and census
	  o Collecting and updating patient demographic information, family contact data, alerts, insurance coverage, management of room and bed, census activities, and leave-of-absence
	  o Fully integrating the aforementioned data across the other core functions
	• Clinical documentation: Includes assessments, treatment, treatment plans, and nursing care plans, including, but not limited to, historical patient data, patient risk criteria, electronic document system capturing interdisciplinary Plans of Care and reporting, automated work lists, clinical decision support, and patient education tracking. The system must support multiple modes of data entry including, but not limited to, template notes, third-party dictation, and voice recognition. This also includes fully integrating this data across the other core functions.
	• Interfaces, data sharing and interoperability:
	  o Using common standards and implementation specifications for electronic exchange of information in accordance with MU Stage 2 guidance.
	  o Actual electronic exchange of clinical information with acute care hospitals, CMHCs, Public Health registries, LTC facilities, private practitioners, pharmacies, correctional facilities, judicial bodies, laboratories, and healthcare payers (e.g., Medicaid, Medicare, commercial insurance, Social Security Administration [SSA], private pay, etc.)
	• Case management: Functionality includes, but is not limited to, the ability for designated staff to track, manage, document, and receive alerts for case management activities.
	
	Having the State Psychiatric Hospitals interface with an HIE will give the Medicaid providers operating within the SPHs the capability to exchange health information with adjacent acute care facilities/hospitals, CMHCs, and other healthcare partners along the continuum of care. This specifically will allow Medicaid providers the capability to meet MU stage 3. More specifically the SPHs will be capable of bi-directionally exchanging summary of care records and CCDs when referring or receiving a Medicaid patient to or from another care setting. In addition, SPHs interfacing with the HIE will be capable of sending and receiving ADT notifications. These activities allow Medicaid providers within the SPHs to fulfill the objectives and enables them to report measures in accordance with MU stage 3 for HIE.

Prompts	Summary
	Future State: FSSA will survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.
	Summary of Actions Needed: The IMD survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.
Consent - E-Consent (42 CFR Part 2/HIPAA) (Section 3)	
3.1 Individual consent is electronically captured and accessible to patients and all members of the care team, as applicable, to ensure seamless sharing of sensitive health care information to all relevant parties consistent with applicable law and regulations (e.g., HIPAA, 42 CFR part 2 and state laws)	*Current State:* Consent/privacy is managed in a multitude of mechanisms across the Medicaid Health Information Sharing Enterprise, many still very manual, non-standardized and not electronically transmitted. HIEs rely on the participants to manage what information is delivered to them. Substance abuse disorder laws (42 CFR Part 2) require explicit patient consent and therefore typically are only shared in a one-off manual manner. Consent, segregation of highly sensitive records, and secure transport are difficult to implement and manage and therefore infrequently done electronically. Indiana is an opt-out state for HIE. Responsibility is on provider to communicate with patients. Patient data can be shared with HIE unless the patient explicitly requests it not to be.
	Future State: To be determined based on prioritization of initiatives during the aforementioned SMHP update process.
	Summary of Actions Needed: To be determined based on prioritization of initiatives during the aforementioned SMHP update process.
Interoperability in Assessment Data (Section 4)	
4.1 Intake, assessment and screening tools are part of a structured data capture process so that this information is interoperable with the rest of the HIT ecosystem	*Current State:* Within the integrated care entities (ICE), core assessments and adjudicated Medicaid claims data are aggregated and available via the Relias ProAct Tool. This tool exclusively houses Medicaid patients and an external facing interface is provided for each ICE and applies 400+ measures to Medicaid claims and non-claims data. It provides individual patient history, as well as population demographics and associated costs of diagnoses, medications and utilization.
	Future State: The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule.
	Summary of Actions Needed: FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly.
Electronic Office Visits – Telehealth (Section 5)	
5.1 Telehealth technologies support collaborative care by facilitating broader availability of integrated mental health care and primary care	*Current State:* Indiana received $16 million from the Federal Communications Commission's (FCC's) Rural Health Care Pilot Program, and as a result, created the Indiana Telehealth Network (ITN). ITN formed an FCC Rural Health Care Steering Committee, which was made up of representatives from healthcare providers, telecommunication companies, representatives from the Indiana Office of Community & Rural Affairs, and representatives from the Indiana Rural Health Association, the lead entity for the ITN. The five-year project was divided into three phases and the work successfully concluded in 2015. The table below presents a summary of the project phases.

<table>
<tr><th>Prompts</th><th>Summary</th></tr>
<tr><td></td><td>
<table>
<tr><th>Phase 1</th><th>Phase 2</th><th>Phase 3</th></tr>
<tr><td>• Reduced bandwidth costs
• Reduced Primary Rate Interface (PRI) costs
• Doubled the speed of existing broadband connections
• 85% funding for construction of fiber to their hospitals
• Completed ability to transmit images
• Improved economic opportunities</td><td>• Expanded ability to conduct Telehealth encounters over a dedicated health care network
• Disaster Recovery
• E-Learning
• Internet Access
• Videoconferencing</td><td>• Seamless interfaces with the Indiana Health Information Organizations (HIOs)</td></tr>
</table>

As of December 2016, ITN’s healthcare participants included 153 critical access hospitals, rural hospitals, urban partner hospitals, rural health clinics, urban partner hospitals, rural health clinics, federally qualified health centers, community mental health centers and data centers.

Additionally, as part of the 21st Century Cures Act, a portion of Indiana’s awarded funding is being utilized to implement Project-ECHO-Extension for Community Healthcare Outcomes. The primary goal of ECHO is to enable rural and traditionally underserved populations to receive high-quality care, when they need it, close to home. This low-cost, high-impact intervention is achieved by leveraging technology to connect expert mentors and multiple local primary care providers in online video-conferencing TeleECHO clinics.

Future State: Continued operation of current programing.

Summary of Actions Needed: N/A</td></tr>
<tr><td>Alerting/Analytics (Section 6)</td><td></td></tr>
<tr><td rowspan="3">6.1 The state can identify patients that are at risk for discontinuing engagement in their treatment, or have stopped engagement in their treatment, and can notify their care teams in order to ensure treatment continues or resumes (Note:</td><td>Current State: Some providers may have this capability, but the current volume is unknown.</td></tr>
<tr><td>Future State: As previously described, OMPP is exploring submitting a health homes state plan amendment. A key component of this initiative will include leveraging HIT for enhanced integration and coordination. OMPP is currently in the process of developing HIT standards and requirements for participating providers.</td></tr>
<tr><td>Summary of Actions Needed: OMPP is exploring submitting a health homes state plan amendment with implementation by 2021.</td></tr>
</table>

Prompts	Summary
research shows that 50% of patients stop engaging after 6 months of treatment[9])	
6.2 Health IT is being used to advance the care coordination workflow for patients experiencing their first episode of psychosis	*Current State:* Some providers may have this capability, but the current volume is unknown.
	Future State: As previously described, OMPP is exploring submitting a health homes state plan amendment, with implementation 2021. A key component of this initiative will include leveraging HIT for enhanced integration and coordination. OMPP is currently in the process of developing HIT standards and requirements for participating providers.
	Summary of Actions Needed: OMPP is exploring submitting a health homes state plan amendment by the end of 2020 with implementation by 2021.
Identity Management (Section 7)	
7.1 As appropriate and needed, the care team has the ability to tag or link a child's electronic medical records with their respective parent/caretaker medical records	*Current State:* The State's eligibility and enrollment system can link children and parents on the same case.
	Future State: To be determined based on prioritization of initiatives during the aforementioned SMHP update process.
	Summary of Actions Needed: To be determined based on prioritization of initiatives during the aforementioned SMHP update process.
7.2 Electronic medical records capture all episodes of care, and are linked to the correct patient	*Current State:* The aforementioned March 2019 assessment of Indiana's HIS indicates patient/client identification is inconsistent between entities. Patient matching is an issue for all entities. Health systems employ entire departments to deal with multiple issues surrounding the record integrity that include duplicate records or documenting on the wrong patient record. Resolving a merged record and identifying who may have received erroneous information may take many hours of work per case. Additionally, Indiana is currently participating in the National Governor's Association "Harnessing the Power of Data to Achieve State Policy Goals: The Foundation for State Success in Improving Quality and Reducing Costs" initiative, intended to address governance, cross-sector data sharing and systems capabilities.
	Future State: The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule.
	Summary of Actions Needed: FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly.

[9] Interdepartmental Serious Mental Illness Coordinating Committee. (2017). *The Way Forward: Federal Action for a System That Works for All People Living With SMI and SED and Their Families and Caregivers*. Retrieved from https://www.samhsa.gov/sites/default/files/programs_campaigns/ismicc_2017_report_to_congress.pdf

Section 3: Relevant documents

Please provide any additional documentation or information that the state deems relevant to successful execution of the implementation plan. This information is not meant as a substitute for the information provided in response to the prompts outlined in Section 2. Instead, material submitted as attachments should support those responses.

Attachment H: SMI/SED Monitoring Protocol
[To be incorporated after CMS approval]