Exhibit I

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

Deputy Administrator
Washington, DC 20201

FEB - 1 2018

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 approving Indiana's request for CMS approval of its Medicaid demonstration entitled, "Healthy Indiana Plan (HIP)" (Project Number 11-W-00296/5) in accordance with section 1115(a) of the Social Security Act (the Act).

This approval is effective February 1, 2018, through December 31, 2020, upon which date, unless reauthorized or otherwise noted, all authorities granted to operate this demonstration will expire. CMS's approval is subject to the limitations specified in the attached expenditure authorities, waivers, and special terms and conditions (STC). The state may deviate from Medicaid state plan requirements only to the extent those requirements have been listed as waived or as not applicable to expenditures.

Extent and Scope of Demonstration

The current HIP section 1115 demonstration was implemented by the State of Indiana ("state") on February 1, 2015. The HIP program provides beneficiaries with a consumer-driven plan with required monthly contributions, supported by the Personal Wellness and Responsibility ("POWER") account, which is similar to a health savings account. With this approval, the state is authorized to make several changes to HIP, which the state has indicated are designed to improve member outcomes by targeting tobacco cessation, substance use disorder (SUD), chronic disease management, and community engagement. HIP also aims to help prepare beneficiaries for participation in the commercial insurance marketplace. The state's approach is designed to prepare beneficiaries for the personal responsibility required to maintain coverage and continuity of care they will experience when they seek commercial insurance coverage.

Indiana is making a change to how HIP Plus beneficiaries will be charged premiums. The state will apply a premium surcharge for HIP Plus beneficiaries who use tobacco, and who do not participate in tobacco cessation activities. This increased premium will be applied after the first year of enrollment, during which beneficiaries are encouraged to use the various state plan options available to cease tobacco use. By charging beneficiaries a surcharge related to a specific behavior (i.e., tobacco use), the state will test whether incentivizing beneficiaries to change behavior and engage in their own healthcare will achieve better health outcomes.

In addition, the state will be moving from charging HIP Plus beneficiaries a premium that is exactly two percent of household income to assessing premiums based on income bands, in which most beneficiaries will pay no more than two percent of household income.

In addition, beginning in 2019, Indiana will implement a community engagement requirement as a condition of continued coverage and eligibility for adult beneficiaries enrolled in HIP who are not exempt. The terms and conditions of Indiana's community engagement requirement that accompany this approval are aligned with the guidance provided to states through State Medicaid Director's Letter (SMD 18-0002), Opportunities to Promote Work and Community Engagement Among Medicaid Beneficiaries, issued on January 11, 2018.

Certain groups, including pregnant women, beneficiaries identified as medically frail, students, some caregivers of dependents, and beneficiaries in active SUD treatment will be exempt from this requirement. To maintain coverage, non-exempt members will be required to participate in community engagement activities that may include (but are not limited to) employment, education, job skills training, or volunteer work for a weekly hours requirement that will phase in over the life of the demonstration to eventually become a requirement of 20 hours per week. Compliance will be required for eight months of the 12-month calendar year (for a non-exempt beneficiary that participates for the full year). Beneficiaries will have four months (within a 12-month calendar year) in which they do not have to meet the community engagement requirement. Beneficiaries who fail to meet their required community engagement hours in the preceding calendar year will have their eligibility suspended in the new calendar year until the month following notification to the state that they have completed a calendar month of required hours. If a suspended beneficiary does not complete the one month of community engagement hours to reactivate coverage by their redetermination date, and does not qualify for an exemption, or qualify for another eligibility category that is not subject to the community engagement requirement in the month of redetermination, the individual will be disenrolled from Medicaid at that time, and will have to reapply to reenroll in Medicaid. 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. Indiana will allow good cause exemptions in certain circumstances for beneficiaries who cannot meet their requirement. With this policy, the state will test whether requiring some beneficiaries to engage in community engagement requirements will lead to improved health outcomes.

HIP enrollees have their eligibility reconfirmed through a redetermination period, which begins 45 days prior to the end of the beneficiary's eligibility period. Beneficiaries who do not provide requested information to confirm eligibility during this period will be subject to disenrollment, unless otherwise exempted. However, beneficiaries subject to disenrollment will have an "on-ramp" back into coverage during an additional 90-day reconsideration period, consistent with Medicaid regulations. During the 45-day redetermination period, the state and plans will conduct outreach to ensure understanding of paperwork requirements and encourage compliance. If an individual subject to disenrollment does not take advantage of the on-ramp and cannot show good cause for non-compliance, he or she will not be able to re-enroll in HIP for three months following the reconsideration period. With this policy, the state will test whether

incentivizing beneficiaries to follow established procedures and engage in maintaining their healthcare coverage will lead to improved health outcomes.

This HIP demonstration will also include a SUD program to ensure that a broad continuum of care is available to Indiana Medicaid beneficiaries with a SUD, which will help improve the quality, care, and health outcomes for those Medicaid beneficiaries. The SUD program contributes to a comprehensive statewide strategy to combat prescription drug abuse and opioid use disorders, and expands the SUD benefits package to cover short-term residential services for all Medicaid enrollees.

Determination that the demonstration project is likely to assist in promoting Medicaid's objectives

Demonstration projects under section 1115 of the Act offer a way to give states more freedom to test and evaluate innovative solutions to improve quality, accessibility and health outcomes in a budget-neutral manner, provided that, in the judgment of the Secretary, the demonstrations are likely to assist in promoting the objectives of Medicaid.

While CMS believes that states are in the best position to design solutions that address the unique needs of their Medicaid-eligible populations, the agency has an obligation to ensure that proposed demonstration programs are likely to better enable states to serve their low-income populations, through measures designed to improve health and wellness and help individuals and families attain or retain capability for independence or self-care. Medicaid programs are complex and shaped by a diverse set of interconnected policies and components, including eligibility standards, benefit designs, reimbursement and payment policies, information technology (IT) systems, and more. Therefore, in making this determination, CMS considers the proposed demonstration as a whole.

In its consideration of the proposed changes to HIP, CMS examined whether the demonstration was likely to assist in improving health outcomes; whether it would improve access to high-quality, person-centered services; whether it would address behavioral and social factors that influence health outcomes; whether it would incentivize beneficiaries to engage in their own healthcare and achieve better health outcomes; and whether it would familiarize beneficiaries with a benefit design that is typical of what they may encounter in the commercial market and thereby facilitate smoother beneficiary transition to commercial coverage. CMS has determined that the HIP demonstration is likely to promote Medicaid objectives, and that the waivers and expenditure authorities sought are appropriate to carry out the demonstration.

1. **The demonstration is likely to assist in improving health outcomes through strategies that promote community engagement and address certain health determinants.**

HIP is a consumer-driven health plan that provides a combination of complementary incentives and disincentives that are intended to address certain health determinants, and promote increased upward mobility, greater independence, and improved quality of life. Indiana's community engagement requirement, an evolution of the state's existing Gateway to Work program, is an

incentive for beneficiaries to obtain employment or engage in other community activities that are correlated with improved health and wellness. As Indiana informed CMS in the request for approval of the community engagement program, Gateway to Work, the state's work referral program, did not prove to provide a sufficient incentive to influence many Medicaid beneficiaries to participate in employment. Despite the fact that around 244,000 HIP beneficiaries were unemployed and an additional 58,000 worked fewer than 20 hours per week, only 580 beneficiaries attended Gateway to Work orientations during the first 15 months of the program. By making participation in community engagement a requirement to receive benefits for most non-pregnant, non-medically frail beneficiaries who are not eligible for Medicaid on the basis of a disability, Indiana is incentivizing certain beneficiaries to participate in employment, volunteer work, education, or training. As noted in CMS' SMDL: 18-002, these activities have been shown to lead to healthier individuals.

Approving a range of community engagement incentive structures in various states is likely to give CMS and the states helpful information about how different incentive structures function; the evidence generated by a range of incentive structures designed around work and community engagement requirements will inform future agency decisions about which program features best promote the objectives of Medicaid. CMS has determined that the Indiana demonstration includes a meaningful incentive by requiring affected beneficiaries to demonstrate compliance with the community engagement requirements during the prior calendar year, or face a suspension in the next calendar year. CMS considered Indiana's experience in the existing Gateway to Work program and has determined that the proposal has been informed by this experience as the state seeks to strengthen the incentives for community engagement. Indiana has tailored the incentive structure to include beneficiary protections, such as the opportunity to reactivate suspended eligibility in the month following notification to the state that the beneficiary has completed a calendar month of required hours, as well as the opportunity to begin a new period of eligibility at the beneficiary's next redetermination date. The impact of this incentive, as well as other aspects of the demonstration, will be assessed through an evaluation designed to measure how the demonstration affects eligibility, behavior, and health outcomes over time for persons subject to the demonstration's policies.

2. **The demonstration is likely to improve health outcomes for beneficiaries with substance use disorder.**

The SUD program directly supports Medicaid's objectives by improving access to high-quality services, and it is critical to addressing Indiana's substance use epidemic. All Medicaid beneficiaries in Indiana will continue to have access to all current mental health and SUD benefits. In addition, all beneficiaries, ages 21 through 64, will have access to expanded covered services provided while residing in an Institution for Mental Diseases (IMD) for SUD short-term residential stays. The SUD program will allow beneficiaries with SUD to access benefits that include SUD residential treatment, crisis stabilization and withdrawal management services provided in IMDs, which would otherwise be excluded from federal reimbursement.

3. The demonstration is expected to strengthen beneficiary engagement in their personal health care, and provide incentives for responsible decision-making.

Indiana expects that requirements related to redetermination and reporting will also strengthen beneficiary engagement in their personal health care plan, and provide an incentive structure to support responsible consumer decision-making.

Indiana's previous HIP evaluation has indicated that some of the demonstration's prior features had a positive impact on beneficiary behavior.[1] For example, a majority of HIP beneficiaries opt into paying premiums in order to receive an enhanced benefit package. Therefore, the state is retaining this requirement, but adjusting the premium structure for administrative simplification so any slight fluctuation in a beneficiary's income will no longer always change the amount of the premium due. In a program enhancement, to encourage individuals to take advantage of the tobacco cessation options available through the state plan, beneficiaries who do not use tobacco will be charged a lower premium; beneficiaries who do identify as tobacco users will be given a year to stop using tobacco before paying the surcharge.

The waiver of retroactive eligibility encourages beneficiaries to obtain and maintain health coverage, even when healthy. This demonstration is intended to increase continuity of care by reducing gaps in coverage when beneficiaries churn on and off Medicaid or sign up for Medicaid only when sick.

Imposition of a non-eligibility period for failing to complete timely redetermination encourages individuals to maintain compliance with longstanding beneficiary responsibilities, as described in regulation, and helps to ensure Medicaid is covering only those individuals who are eligible for the program.

4. The demonstration will remove potential obstacles to a successful beneficiary transition to commercial coverage.

Indiana anticipates many Medicaid beneficiaries will transition to commercial health insurance since the demonstration seeks to provide members the tools to successfully utilize commercial market health insurance, thereby removing potential obstacles to a successful transition from Medicaid to commercial coverage. The demonstration includes several features that align with common features of commercial market plans. For instance, the demonstration includes premium payment requirements (with a non-eligibility period for non-payment for certain populations), limited managed care enrollment windows, and limited time periods to switch between managed care plans. The HIP Plus benefit package also provides enhanced medical benefits (e.g., vision and dental) above Medicaid state plan benefits, requires monthly member premiums, and initiates benefits prospectively from the initial premium payment.

This approval also gives Indiana additional tools to encourage HIP beneficiaries to complete the annual redetermination process (with a non-eligibility period for non-compliance for certain populations), which will help educate beneficiaries on the need to timely complete enrollment requirements. CMS notes that in the state's HIP 1.0 demonstration, Indiana successfully applied

[1] https://www.in.gov/fssa/files/Lewin_IN%20HIP%202%200%20Interim%20Evaluation%20Report_FINAL.pdf

a policy of non-eligibility for a small population of individuals who were in the expansion group who did not complete the redetermination process. CMS later did not allow the state to impose this policy on the new adult population as part of HIP 2.0, in part due to concerns about the impact of the policy on access to affordable coverage. CMS has reconsidered its earlier position and believes the state should be given the opportunity to test the efficacy of this policy in HIP , with the appropriate assurances of safeguards for individuals who may need an exception for good cause (such as hospitalization, domestic violence, or the death of a family member) or who have a disability. The state expects this policy will build on the successes of the redetermination and open enrollment policy in the original HIP program and, with continued beneficiary outreach efforts by the state and managed care entities, will result in improved compliance with redetermination requirements. CMS is approving the state's request to apply this policy to non-pregnant and non-medically frail HIP beneficiaries. Incentivizing beneficiaries to complete the annual redetermination process is likely to help educate beneficiaries on the need to timely complete enrollment requirements because of limited opportunities to enroll in coverage. Thus, in addition to the opportunity to enhance program integrity noted above, approval of this policy is likely to support the objectives of Medicaid to the extent that it prepares individuals for a smooth transition to commercial health insurance coverage and ensures that resources are preserved for individuals who meet eligibility requirements.

Similar to how commercial coverage operates, coverage eligibility will continue to be impacted under this approval for certain HIP Plus beneficiaries with income over 100 percent of the FPL for non-payment of premiums. Unless exempt, such beneficiaries will be disenrolled and have a six month non-eligibility period. The demonstration includes special exemptions for those that lose private insurance coverage or are the victim of domestic violence. CMS also notes that Indiana has taken steps to minimize beneficiary harm by exempting certain vulnerable populations, such as pregnant women and individuals who are medically frail, from disenrollment for non-payment of premiums.

Overall, CMS believes that HIP has been designed to empower individuals to improve their health and well-being. If successful in its objectives, HIP will improve health outcomes, promote increased upward mobility and improve quality of life, increase individual engagement in health care decisions, and prepare individuals who transition to commercial health insurance coverage to be successful in this transition. At the same time, HIP ensures vulnerable individuals, like people with disabilities and pregnant women, continue to receive medical assistance.

Consideration of Public Comments

Both Indiana and CMS received a large volume of comments during the state and federal public comment periods. Consistent with federal transparency requirements, CMS reviewed all of the materials submitted by the state, as well as all the public comments it received, when evaluating whether the demonstration project as a whole was likely to promote the objectives of the Medicaid program, and whether the waiver and expenditure authorities sought were necessary and appropriate to implement the demonstration. In addition, CMS took public comments submitted during the federal comment period into account as it worked with Indiana to develop the STCs that accompany this approval, and that will bolster beneficiary protections, including specific state assurances around these protections to further support beneficiaries.

In both the state and federal comment periods, there were comments in support of the application, specifically the state's efforts to promote beneficiary responsibility and accountability, and enhance sustainability of the program in the long-term. Supporters noted that the demonstration has provided them with affordable, accessible, and comprehensive health coverage, while others agreed with the state's move to realigning POWER account contributions to a simpler income-band approach. Some supporters also noted their agreement with the principle that working-age adults who are not eligible for Medicaid on the basis of a disability must meet community engagement requirements as a condition of eligibility. Many commenters supported the state's efforts to expand services for substance use disorder by requesting expenditure authority for residential SUD services in an IMD and by incentivizing tobacco cessation.

In the state and federal comment periods, opposing commenters expressed general disagreement with the continued efforts of the state to utilize non-traditional means to expand Medicaid. Commenters indicated they would rather the state expand through the state plan, without an accompanying section 1115 demonstration, because they found the enrollment process confusing and a barrier to care. Some offered more specific feedback regarding individual elements of the demonstrations or the impact of certain provisions on distinct populations. In addition, some commenters were concerned that the qualifying activities and list of exemptions were not broad enough.

Some commenters asserted that the premium provisions in the HIP 2.0 demonstration had resulted in a higher rate of disenrollment due to nonpayment, citing the state's independent evaluation on this project. We continue to believe that the demonstration's premium provisions are appropriate to prepare beneficiaries to participate in the commercial market. We note that the independent evaluation has reported several positive impacts from the demonstration to date, namely that HIP 2.0 has reduced the number of uninsured low-income Indiana residents, many of whom were previously uninsured or underinsured, and that at least a portion of those who disenrolled showed the primary reason was a change in income or having secured insurance from another source.

Other commenters expressed concerns that the community engagement requirements, or that the requirements for beneficiaries to cooperate with the redetermination process, would be burdensome on families or create barriers to coverage for non-exempt people who might have trouble accessing care. We believe that the community engagement requirements create appropriate incentives for beneficiaries to gain employment. Given that employment is positively correlated with health outcomes, it serves the purposes of the Medicaid statute to impose these requirements, both to improve beneficiaries' health and to encourage beneficiaries to gain independence and to transition to private coverage.

Additional comments characterized the provisions to lock beneficiaries out of coverage for failure to participate in the redetermination process as "punitive," and characterized the state's paperwork requirements as confusing and complicated. We disagree with these characterizations. We believe that it is appropriate to protect the integrity of the program by expecting beneficiaries to cooperate with the state in providing necessary documentation to determine their eligibility. Far from a "punitive" process, the demonstration calls for the state to

assist individuals over a 45-day period in completing redetermination, and an individual is disenrolled, for a limited three-month period, only if that individual has not cooperated with the state before the end of the expiration of the reconsideration period.

In response to the comments submitted to the state, the state added participation in accredited English as a Second Language courses to the list of qualifying activities; beneficiaries who meet the Supplemental Nutrition Assistance Program (SNAP) work requirements were added to the list of those who would be considered to have met the community engagement requirement. Responding to the comments to expand the list of exemptions for community engagement requirements, the state added beneficiaries who are homeless or receiving Temporary Assistance for Needy Families (TANF) to the exemption list. Some commenters requested that the state exclude former foster care youth under age 26 from the community engagement requirement; however, this population is not covered under the demonstration and therefore, not subject to the community engagement requirement. The state also assures that it will make good faith efforts to connect beneficiaries to existing community supports that are available to assist beneficiaries in meeting community engagement requirements, such as available non-Medicaid assistance with transportation and child care.

To help determine whether the demonstration is meeting its goals of improving quality, accessibility, and health outcomes, Indiana will submit, for CMS comment and approval, a draft evaluation design with implementation timeline, no later than 180 days after demonstration approval. CMS will work with Indiana to ensure that the comments received also inform the monitoring and evaluation design and the necessary oversight is in place to provide for program adjustments when necessary.

The CMS' approval of this demonstration is conditioned upon compliance with the enclosed list of waiver and expenditure authorities and STCs defining the nature, character and extent of anticipated federal involvement in the project. The award is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter.

Your project officer for this demonstration is Ms. Shanna Janu. She is available to answer any questions concerning your section 1115 demonstration. Ms. Janu's contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-03-17
7500 Security Boulevard
Baltimore, MD 21244-1850
E-mail: Shanna.Janu@cms.hhs.gov

Official communications regarding program matters should be sent simultaneously to your project officer and Ms. Ruth Hughes, Associate Regional Administrator in our Chicago Regional Office. Ms. Hughes's contact information is as follows:

Ms. Ruth Hughes
Associate Regional Administrator
Centers for Medicare & Medicaid Services
Division of Medicaid and Children Health Operations
233 N. Michigan Avenue, Suite 600
Chicago, IL 60601-5519
Email: Ruth.Hughes@cms.hhs.gov

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

Thank you for all your work with us, as well as stakeholders in Indiana, over the past months to reach approval.

Sincerely,

[redacted]

Demetrios Kouzoukas
Principal Deputy Administrator

Enclosures

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. 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. 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 disease (IMD).

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, except for non-emergency use of the emergency department, 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 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 & MCO Enrollment
X. Substance Use Disorder (SUD)
XI. Delivery System
XII. General Reporting Requirements
XIII. General Financial Requirements
XIV. Budget Neutrality Determination
XV. 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 (reserved)
Attachment E: SUD Monitoring Plan 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 will implement a community engagement requirement as a condition of eligibility for HIP beneficiaries, with exemptions for various groups, including: pregnant women, beneficiaries considered medically frail, members in active substance use disorder (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 will also include a substance use disorder 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.

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; and
- Charging beneficiaries an increased monthly contribution for tobacco use will discourage tobacco use and increase the utilization of tobacco cessation benefits.

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. 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, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 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.

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, 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 6 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 ages 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 STC. 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 ages 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. 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 below.

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 requirement 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 requirement 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 100% of the FPL	$15.00	$7.50	$22.50	$7.50 & $11.25	$11.25
Above 100% of the FPL and up to and including 133% of the FPL	$20.00	$10.00	$30.00	$10.00 & $15.00	$15.00

f. The state allows for a ten dollar ($10.00) initial fast track POWER Account payment that makes available immediate enrollment into HIP Plus effective the first date of the month in the month in which payment is received, once an individual has been determined eligible. This option is available via both fast track invoicing from the

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

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

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

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

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

4. **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 this STC.

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 this STC.

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 2. 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 XII 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 XII STC 1 for each incident of insufficient progress or failure to report in each reporting quarter.

7. **Deferral of Federal Financial Participation (FFP) from IMD claiming for Insufficient Progress Toward Milestones.** Up to $5M 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 $5M 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 VX 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 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

[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*.

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 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

[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.

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. 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.

XII. 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 XIII 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 XIV 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 STC 7 of section III, 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.

XIII. 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

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.

XIV. 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 XIII 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 initiative, the state may receive FFP for the continuum of services specified in Table 6 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 Table 6 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 services.

   a. The SUD MEG listed in the table below is included in SUD budget neutrality test.

   b. SUD expenditures cap are calculated by multiplying the projected PMPM for each SUD MEG, each DY, by the number of actual eligible SUD 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 budget neutrality test is a comparison between the federal share of SUD expenditure cap and total FFP reported by the state for the SUD MEG.

Eligibility Group	Trend Rate	DY 4	DY5	DY 6
SUD	4.9%	$6,834.71	$7,169.61	$7,520.92

   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 MEG.

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 XIII 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.

XV. 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

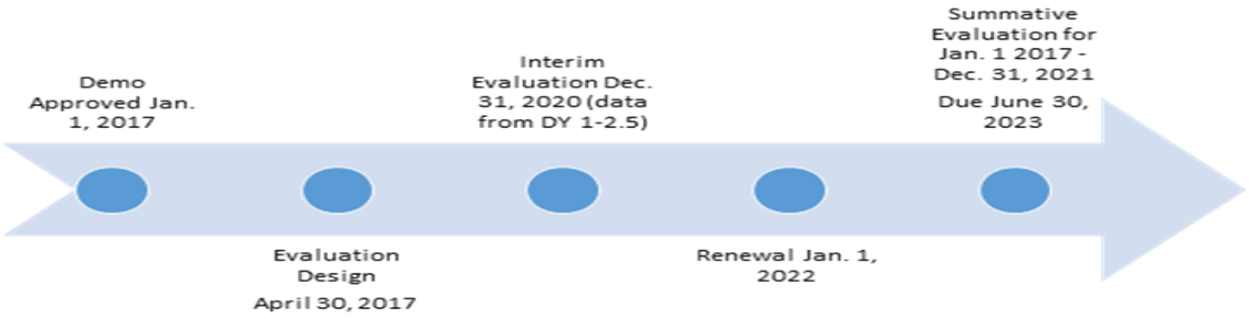
Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified 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

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

FINAL DRAFT
MARCH 21, 2019

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TABLE OF CONTENTS

LIST OF FIGURES

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)

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

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

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

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

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.

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

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

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

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:

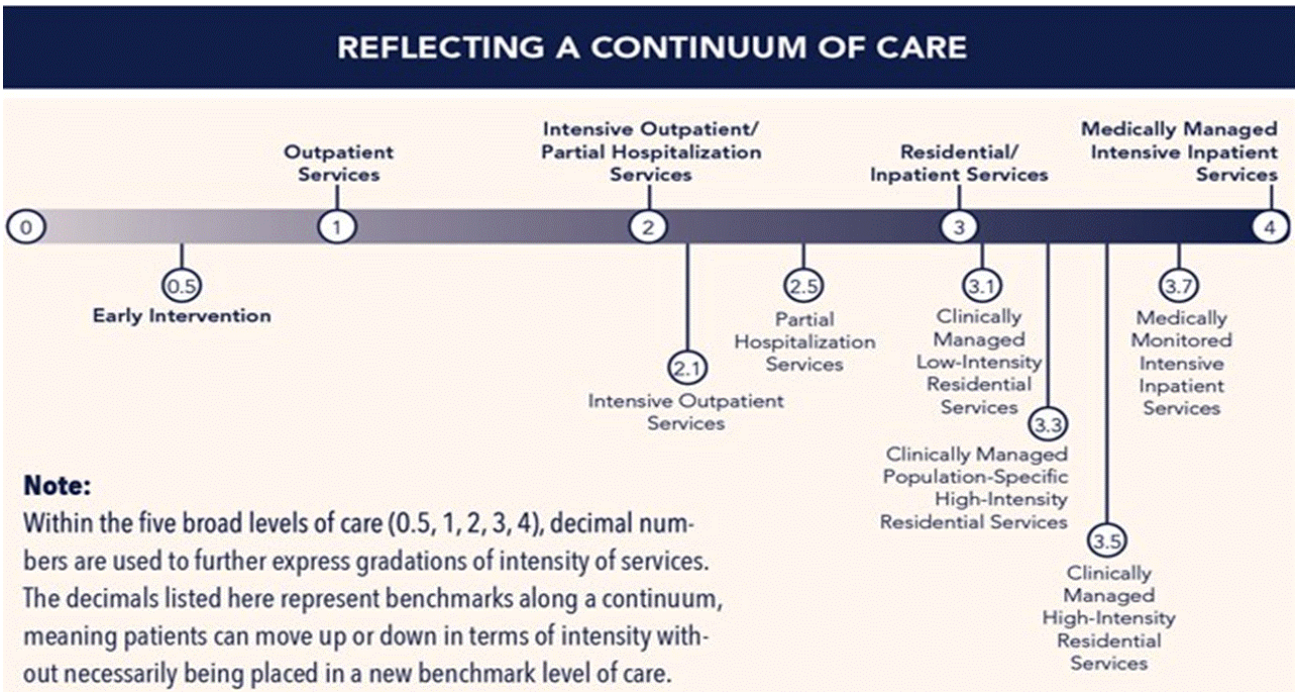
        - 17 recommendations in total;
        - 3 recommendations related to enforcement; and
        - 14 recommendations related to treatment, including pursuit of a Medicaid 1115 Demonstration Waiver for individuals with SUD.
- Gold Card Program
    - Implemented late 2015.
    - Program allows qualified 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.

<u>6. Improved care coordination and transitions between levels of care</u>

- 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	Current Coverage	Future Coverage	Implementation Timeline
OTP	Opioid Treatment Program	Pharmacological and non-pharmacological treatment in an office-based setting (methadone)	Currently covered for all (as of September 2017)	Continued oversight of new policy	December 31, 2018
0.5	Early Intervention	Services for individuals who are at risk of developing substance-related disorders	Currently covered for all	No change expected	
1	Outpatient Services	Outpatient treatment (usually less than 9 hours a week), including counseling, evaluations, and interventions	Currently covered for all	No change expected	
2.1	Intensive Outpatient Services	9-19 hours of structured programming per week (counseling and education about addiction-related and mental health programs)	Currently MRO-only	Will be covered for all individuals	December 31, 2018
2.5	Partial Hospitalization	20 or more hours of clinically intensive programming per week	Covered for all	No change expected	
3.1	Clinically Managed Low- Intensity Residential	24-hour supportive living environment; at least 5 hours of low-intensity treatment per week	No coverage	Bundled daily rate for residential treatment	March 1, 2018
3.5	Clinically Managed High- Intensity Residential	24-hour living environment, more high-intensity treatment (level 3.7 without intensive medical and nursing component)	No coverage	Bundled daily rate for residential treatment	March 1, 2018
3.7	Medically Monitored Intensive Inpatient	24-hour professionally directed evaluation, observation, medical monitoring, and addiction treatment in an inpatient setting	Covered for all (based on medical necessity)	Align authorization criteria with ASAM	Fall 2018
4	Medically Managed Intensive Inpatient	24-hour inpatient treatment requiring the full resources of an acute care or psychiatric hospital	Covered for all (based on medical necessity)	Align authorization criteria with ASAM	Fall 2018
Sub-Support	Addiction Recovery Management Services	Services to help people overcome personal and environmental obstacles to recovery, assist the newly recovering person into the recovering community, and serve as a personal guide and mentor toward the achievement of goals	No coverage	Covered for all individuals	December 31, 2018
Sub-Support	Supportive Housing Services	Services for individuals who are transitioning or sustaining housing.	No coverage	Explore options for coverage	Begin in 2018

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

Figure 3. Indiana SUD Waiver Implementation Activities and Timeline[10]

Waiver Goal	Activities	Implementation Timeline
Improve access to critical levels of care for SUD treatment	Pursue Indiana Administrative Code (IAC) change for coverage and reimbursement of OTPs	Will be filed by December 31, 2018
	Pursue IAC amendments to Mental Health Services Rule for outpatient services	Will be filed by December 31, 2018
	Pursue IAC and SPA amendments to move IOT coverage from MRO to State Plan	IAC will be filed by December 31, 2018. SPA amendment filed by June 30, 2018.
	Pursue amendment to 1915(b)(4) waiver	Will be filed by June 30, 2018
	Make necessary systems changes to CoreMMIS related to IOT coverage change	Will be completed by June 30, 2018
	Develop provider communication over new IOT benefits	Contingent upon approval of SPA (formal notification will be delivered at least 30 days prior to launch)
	Make necessary system changes to CoreMMIS to enroll residential addiction facilities and to reimburse for residential treatment	Will be completed by March 1, 2018
	Develop provider communication over new residential treatment facility benefits	Ongoing as part of roll-out; formal communication will be released with at least 30
	Determine final action and necessary system changes to CoreMMIS to allow reimbursement for inpatient SUD stays on a per diem basis	Fall 2018
	Develop provider communication over changes in reimbursement structure	Ongoing as part of roll-out; formal communication will be released with at least 30 days-notice ahead of launch
	Make necessary system changes to allow reimbursement for Addiction Recovery Management	Spring 2018
	Pursue State Plan Amendment (SPA) to add coverage and reimbursement of services. Coverage of services will begin upon approval of SPA	Spring 2018
	Pursue IAC changes to add coverage of Addiction Recovery Management Services	Will be filed by December 31, 2018
	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

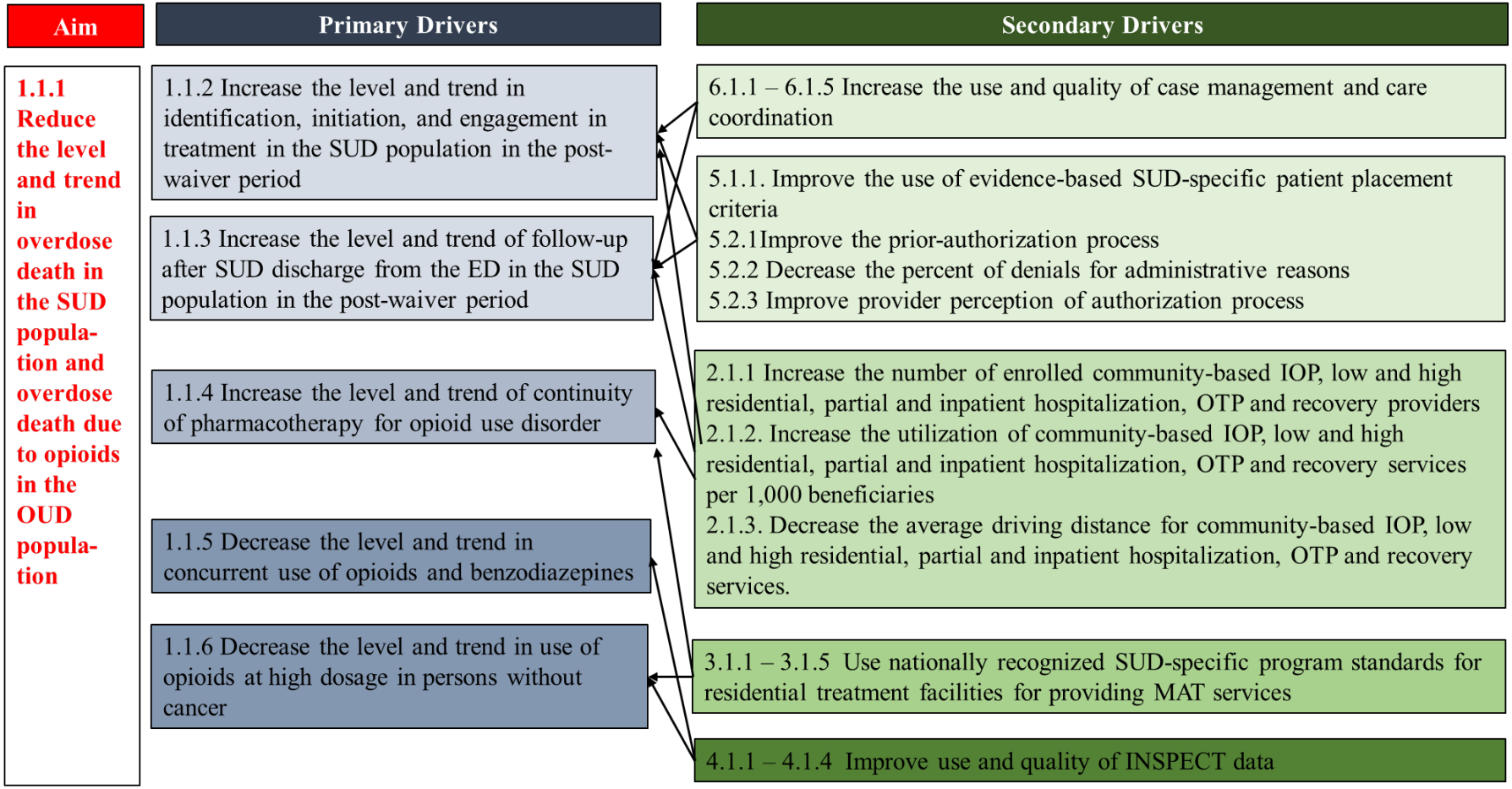
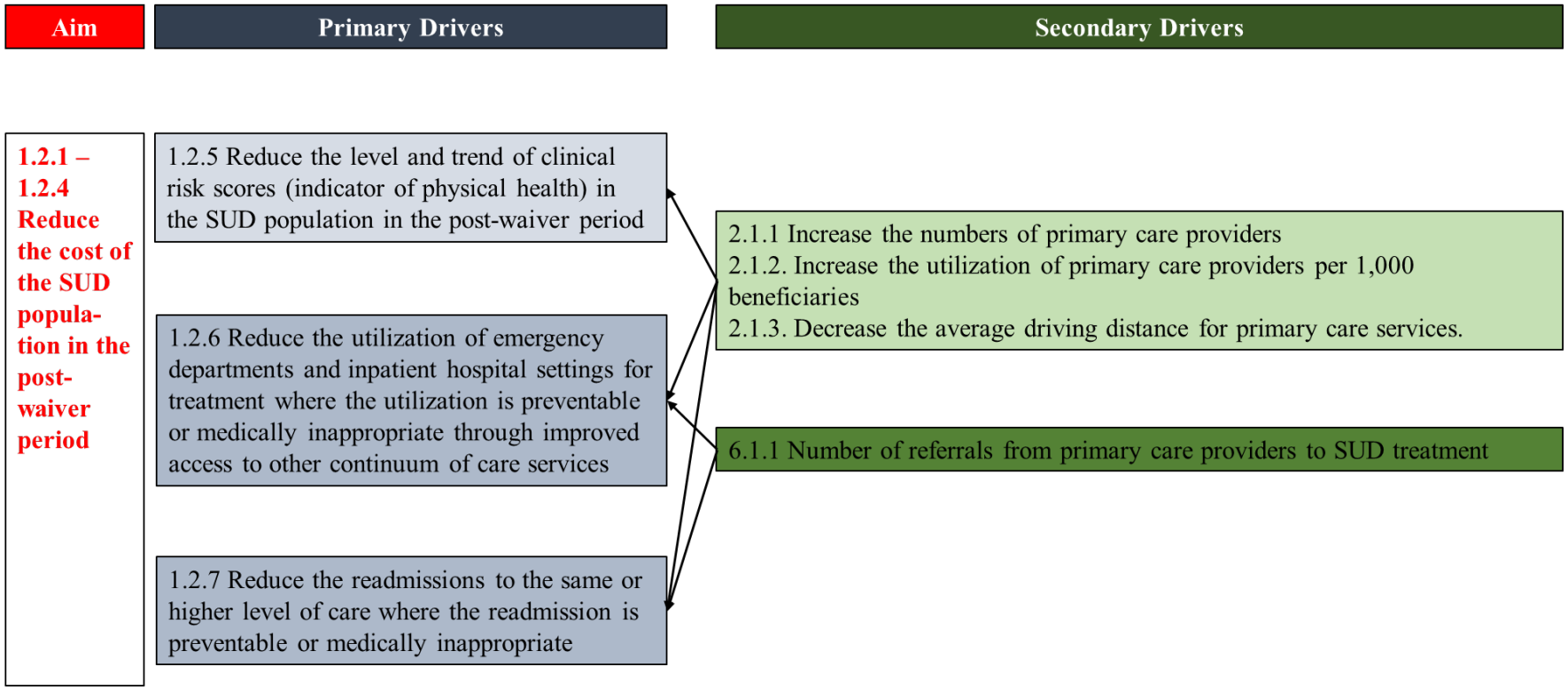


Figure 5. Driver Diagram 1.2 Target Health Outcome: Reductions in Per Capita Cost



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

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

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

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

Figure 7. List of Measures by Domain

Quality

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

Access

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

Financial

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

III.E Data Sources

As described in section III.A, Evaluation Design, B&A will use existing secondary data sources as well as collect primary data. The evaluation design relies most heavily on the use of Indiana Medicaid administrative data, i.e., enrollment, claims and encounter data. Supplemental administrative data, such as prior approval denials and authorizations, will also be incorporated. Primary data will be limited and include data created by surveys, desk review and facilitated interview instruments. A brief description of these data and their strengths and weaknesses are below.

Indiana Medicaid Administrative Data

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

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

Additional data from the MCEs and the State will be collected on prior authorizations, denials, denial reason codes as well as data on care coordination activities. There could be some data validity or quality issues with these sources as they are not as rigorously collected as claims and encounters data. That being said, we will use a standard quality review and data cleaning protocol in order to validate these data, as well as provide detailed specifications and reporting tools to the MCEs and the state to minimize potential for differences in reporting of the requested ad-hoc data.

Survey and Facilitated Interview Data

N-SSATS

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

Provider Survey or Interview Guides

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

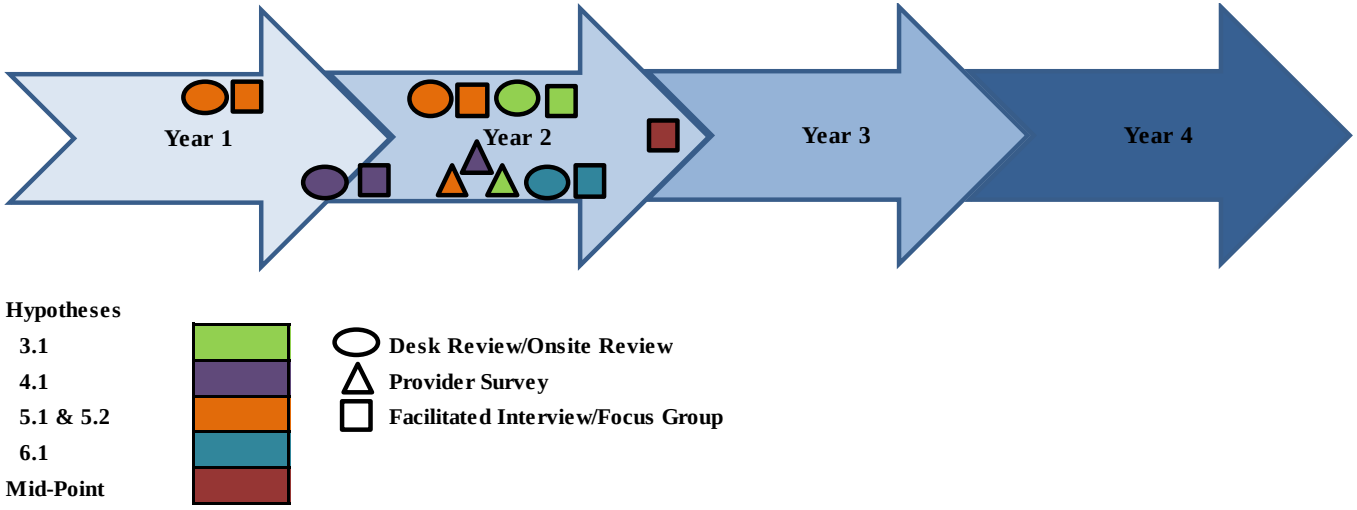
anticipated that once the survey instruments are approved by CMS, they will be fielded for one month before initial results would be tabulated. Where focused interviews are used to collect data, B&A will hold a sufficient number of sessions to collect the required data in accordance with the research 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 quarters in the post-intervention segment at time t

β_0 estimates the base level of the outcome at the beginning of the series

β_1 estimates the base trend, i.e. the change in outcome in the pre-intervention segment

β_2 estimates the change in level from the pre- to post-intervention segment

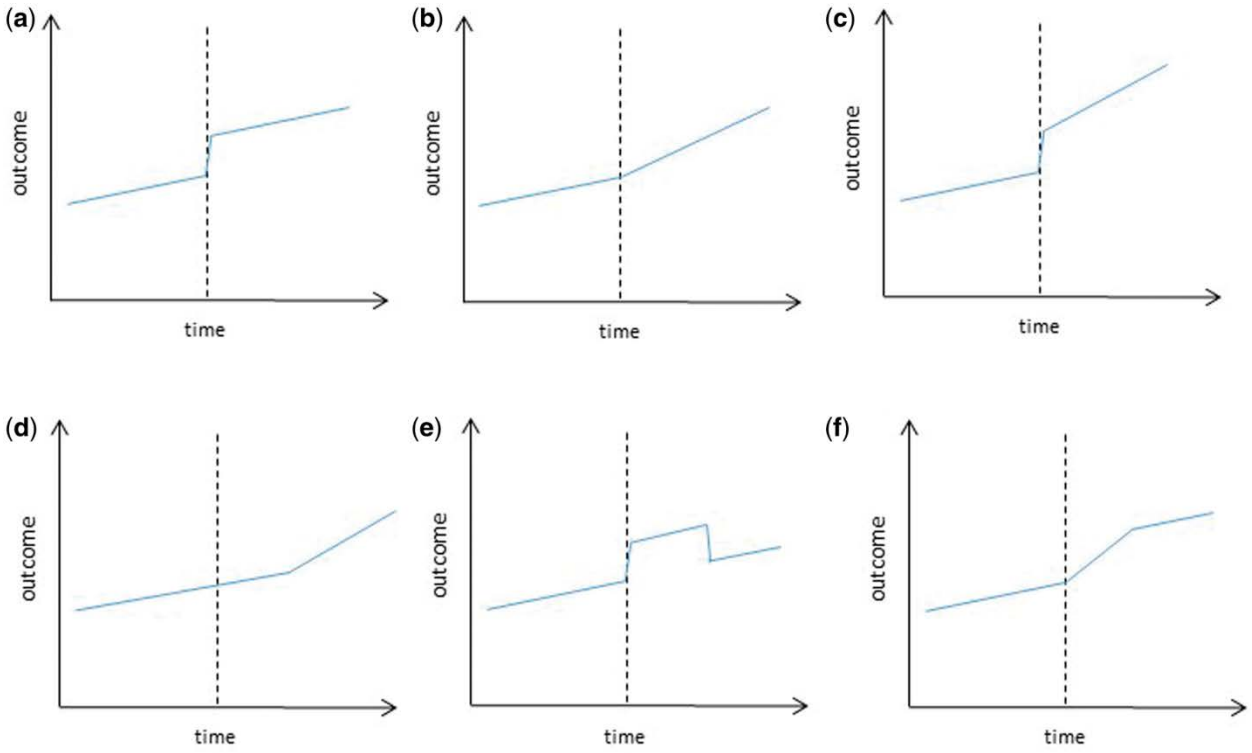
β_3 estimates the change in trend in the post-intervention segment

e_t estimates the error

Visualization and interpretation will be done as depicted in the Figure 10. Each outcome will be assessed for one of the following types of relationships in the pre- and post- wavier period: (a) Level change; (b) Slope change; (c) Level and slope change; (d) Slope change following a lag; (e) Temporary level change; (f) Temporary slope change leading to a level change.

[19] Wagner AK , Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther 2002;27:299-309.

Figure 10. Illustration of Potential ITS 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

[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.

variance, then the data may be nonlinear and transformation of the dependent variable may be warranted. Heteroscedasticity often arises in time series models due to the effects of inflation and/or real compound growth. Some combination of logging and/or deflating may be necessary to stabilize the variance in this case.

For these reasons and in accordance with CMS technical guidance specific to models with cost-based outcomes, B&A will use log costs rather than untransformed costs, as costs are often not normally distributed. For example, many person-months may have zero healthcare spending and other months very large values. To address these issues, B&A will use a two-part model that includes zero costs (logit model) and non-zero costs (generalized linear model).

Controls and Stratification

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

Method #2: Descriptive Statistics

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

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

Method #3: Provider Surveys (PS)

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

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

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

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 ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]

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 <u>Description</u> Number of Indiana Medicaid members who have initiated treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter, or partial hospitalization within 14 days of a diagnosis (or two or more additional services within 30 days of the visit). Computed Monthly or Quarterly **if denominator is <100 at this level, compute annual and use for descriptive analysis only*	<u>Numerator</u> 1. Members who initiated treatment within 14 days of the diagnosis 2. Members who initiated treatment and who had two or more additional services with a diagnosis within 30 days of the initiation visit <u>Denominator</u> Individuals who were diagnosed with alcohol or drug dependency during a visit within the previous rolling 11 months <u>Age</u> 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. <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]

1.1 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 <u>Description</u> The percentage of ED visits for members 18 years of age and older with a primary diagnosis of alcohol and other drug (AOD) dependence, who had an outpatient visit, an intensive outpatient encounter, or a partial hospitalization for AOD. Computed Monthly or Quarterly **if denominator is <100 at this level, compute annual and use for descriptive analysis only*	<u>Numerator</u> 1. Members who had a follow-up visit to an ED visit with a SUD indicator within 7 days of discharge within the previous rolling 12 months. 2. Members who had a follow-up visit to and ED visit with a SUD indicator within 30 days of Discharge within the previous rolling 12 months. <u>Denominator</u> Individuals with an ED visit (with SUD indicator) within the previous rolling 12 months <u>Age</u> 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 follow up after discharge 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]

1.1 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 ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]

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 Opioid Use ASAM Levels [2.1; 3.1; 3.5; 4; OTP; RS]

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 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**
1.2.1. Does the level and trend in overall spending for the SUD population decrease in the post waiver period?	• Total Spending o Estimated State and Federal Share • Per Capita Spending o 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 o 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 o Non-emergency Outpatient o Emergency Department Outpatient o Inpatient o Pharmacy o Long Term Care o Professional Services: Primary versus Specialty o 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 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 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. <u>Pre-intervention Timeframe</u> Quarterly or Annually CY2015-CY2017 <u>Post-intervention Timeframe</u> 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	<u>Numerator</u> Number of providers enrolled as of last day of quarter. <u>Denominator</u> Individuals with SUD as of the last day of the quarter. <u>Age</u> 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. <u>Pre-intervention Timeframe</u> Quarterly CY2015-CY2017 <u>Post-intervention Timeframe</u> 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]
	• 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 counts of providers by ASAM level, MCE and region.

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?	• Utilization of ASAM-specific services per 1,000 • Utilization of primary care services per 1,000 Computed Quarterly	<u>Numerator</u> Number of unique SUD and primary care services as of last day of quarter. <u>Denominator</u> Individuals with SUD as of the last day of the quarter. <u>Age</u> 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. <u>Pre-intervention Timeframe</u> Quarterly CY2015-CY2017 <u>Post-intervention Timeframe</u> 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]

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	<u>Numerator</u> Number of unique SUD and primary care services as of last day of quarter. <u>Denominator</u> Individuals with SUD as of the last day of the quarter. <u>Age</u> 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. <u>Pre-intervention Timeframe</u> Quarterly CY2015-CY2017 <u>Post-intervention Timeframe</u> 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]

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	<u>Numerator</u> Number of beneficiaries who received an ASAM in a given calendar year and received a service within two months within that ASAM level. <u>Denominator</u> Number of beneficiaries who received each ASAM designation in a calendar year. <u>Age</u> 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)	<u>Numerator</u> Number of beneficiaries who received care coordination in a calendar year. <u>Denominator</u> Number of beneficiaries with SUD in a calendar year. <u>Age</u> All ages <u>Numerator</u> Number of providers reporting offering case management services. <u>Denominator</u> 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 2	Contract Year 3	Contract Year 4	Contract Year 5	Contract Years 1-5
2.4.1 Evaluation Design	$ 27,500.00					132.00
2.4.2 Quarterly Monitoring Reports - Q1		$ 57,325.00	$ 57,325.00			578.00
2.4.2 Quarterly Monitoring Reports - Q2	$ 57,325.00	$ 57,325.00	$ 57,325.00			867.00
2.4.2 Quarterly Monitoring Reports - Q3	$ 57,325.00	$ 57,325.00	$ 57,325.00			867.00
2.4.3 Annual Monitoring Reports		$ 105,595.00	$ 105,595.00	$ 105,595.00		1,620.00
2.4.4 Mid-Point Assessment		$ 121,830.00				621.00
2.4.5 Interim Evaluation Report		$ 132,485.00				663.00
2.4.6 Final Summative Evaluation Report					$ 138,990.00	693.00
Total for all Deliverables	**$ 142,150.00**	**$ 531,885.00**	**$ 277,570.00**	**$ 105,595.00**	**$ 138,990.00**	**6,041.00**

Total Bid Amount	$ 1,196,190.00

Blended Hourly Rate	$ 198.01

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

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 D: SUD Implementation Plan Protocol
[To be incorporated after CMS approval]

Attachment E: SUD Monitoring Plan Protocol
[To be incorporated after CMS approval]