

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MONTE A ROSE, JR., *et al.*,

Plaintiffs,

v.

ALEX M. AZAR II, *et al.*,

Defendants.

Civil Action No. 1:19-cv-2848 (JEB)

NOTICE BY FEDERAL DEFENDANTS

The Federal Defendants hereby notify this Court that on October 26, 2020, the Secretary of Health and Human Services approved, in part conditionally, Indiana’s request to extend its section 1115 demonstration project. *See* Ex. A, Letter from Anne Marie Costello, Acting Deputy Administrator & Director, Ctrs. for Medicare & Medicaid Servs., to Allison Taylor, Medicaid Director, Indiana Family & Social Servs. Admin. (Oct. 26, 2020). The project, entitled Healthy Indiana Plan (“HIP”), is the subject of the instant litigation.

The Secretary’s extension of HIP does not change the status quo in this litigation. The Secretary’s extension of HIP’s community-engagement requirement and lockout periods—which are challenged in this litigation—has been approved on the condition that the Supreme Court accepts for review and issues a decision in *Azar v. Gresham*, No. 20-37, that legally authorizes those particular components of the project.¹ Ex. A at 1, 2. Further, in light of the ongoing COVID-19 pandemic, Indiana has informed the Secretary that the state is not terminating Medicaid coverage for validly

¹ On July 13, 2020, the Government filed a petition for certiorari in *Azar v. Gresham*. Pet. for Cert., *Azar v. Gresham*, No. 20-37 (filed July 13, 2020). That petition remains pending at this time.

enrolled beneficiaries “consistent with the condition under [section] 6008(b) of the Families First Coronavirus Response Act (FFCRA)” to receive temporarily increased federal Medicaid funding.² *Id.* at 6; *see also id.* at 13, 15. Finally, Indiana has committed to not implementing HIP’s community engagement requirement during the pendency of this litigation, ECF No. 18-2, and to pausing implementation of the lockout provision, ECF No. 14 at 1; ECF No. 18 at 2; ECF No. 31 at 2 n.1. Accordingly, the Secretary’s conditional extension of HIP does not require any action by this Court, and this case should remain stayed at this time. *See* Minute Order of April 6, 2020.

Dated: October 29, 2020

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² *See* 42 U.S.C. § 1396d note (setting forth conditions on the receipt of temporary, increased federal Medicaid funding for states).

EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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October 26, 2020

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

Dear Ms. Taylor:

Under section 1115 of the Social Security Act (the Act), the Secretary of Health and Human Services may approve any experimental, pilot, or demonstration project that, in the judgment of the Secretary, is likely to assist in promoting the objectives of certain Act programs, including Medicaid. Congress enacted section 1115 of the Act to ensure that federal requirements did not “stand in the way of experimental projects designed to test out new ideas and ways of dealing with the problems of public welfare recipients.” S. Rep. No. 87-1589, at 19 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 1943, 1961. As relevant here, section 1115(a)(1) of the Act allows the Secretary to waive compliance with the Medicaid program requirements of section 1902 of the Act, to the extent and for the period he finds necessary to carry out the demonstration project. In addition, section 1115(a)(2) of the Act allows the Secretary to provide federal financial participation for demonstration costs that would not otherwise be considered as federally matchable expenditures under section 1903 of the Act, to the extent and for the period prescribed by the Secretary.

For the reasons discussed below, the Centers for Medicare & Medicaid Services (CMS) is approving, in part conditionally, Indiana’s request to extend its section 1115 demonstration project entitled, “Healthy Indiana Plan (HIP)” (Project Number 11-W-00296/5), in accordance with section 1115(a) of the Act.

CMS is only conditionally approving the state’s request to extend the community engagement and exclusions from eligibility components of its HIP demonstration. This conditional approval is contingent on the Supreme Court issuing a decision in *Azar v. Gresham*, No. 20-37 that legally authorizes these elements of the proposed extension to the demonstration. If the Supreme Court issues such a decision, no further action by CMS would be required in order for the state to begin implementation of these components of the demonstration, though we would expect that the state would consult with CMS to confirm that, in fact, the state was authorized to implement these elements based on the Supreme Court’s decision, if issued. In the event the Supreme Court does

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not accept the *Gresham* case for review, these elements of the extension would not be implemented absent some change in federal legislation.

CMS is extending the Substance Use Disorder (SUD) and Serious Mental Illness (SMI) authorities for the requested period of five years, effective January 1, 2021 through December 31, 2025. The community engagement and non-eligibility period authorities conditionally approved for a period of up to five years, effective following a Supreme Court decision authorizing them through December 31, 2025, upon which date, unless extended or otherwise amended, these authorities granted to operate this demonstration will expire. CMS is approving the rest of the demonstration components for a period of ten years, effective January 1, 2021 through December 31, 2030,¹ upon which date, unless extended or otherwise amended, these authorities granted to operate this demonstration will expire.

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

Objectives of the Medicaid Program

As noted above, the Secretary may approve a demonstration project under section 1115 of the Act if, in his judgment, the demonstration is likely to assist in promoting the objectives of title XIX. The purposes of Medicaid include an authorization of appropriation of funds to “enabl[e] each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care.” Act § 1901. This provision makes clear that an important objective of the Medicaid program is to furnish medical assistance and other services to vulnerable populations. As discussed more fully below, this demonstration would continue to do that by expanding the scope of coverage. We also conditionally are approving other elements of the State's extension application contingent on the Supreme Court reversing holdings in the *Gresham* decision of the Court of Appeals for the DC Circuit that we believe represent an overly restrictive reading of the objectives of Medicaid that can appropriately be promoted under a section 1115 demonstration. We are asking the Supreme Court to recognize that that the Secretary can advance the objectives of Medicaid by testing requirements that are designed to promote the provision of healthcare coverage by means of facilitating the transition of Medicaid

¹ While it cannot be known what the status of the current public health emergency for COVID-19 will be when the extension is implemented in 2021, it is worth noting that recent research during the COVID-19 pandemic indicates that factors such as a lack of economic participation, social isolation, and other economic stressors have negative impacts on mental and physical health. Structured properly, incentives and requirements that increase such participation may have a positive effect on beneficiary health and economic mobility. See, e.g., Nirmita Panchal et al., *The Implications of COVID-19 for Mental Health and Substance Use*, Kaiser Family Foundation. (Apr. 21, 2020), <https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/>.

beneficiaries to commercial coverage and improving their health. And even if the Court concludes that providing health care coverage is the exclusive objective of the Medicaid program, we are asking it to recognize that section 1115 empowers Secretary to approve demonstration projects designed to enable states to stretch their scarce Medicaid dollars, which in turn would enable states to expand or maintain coverage for needy individuals and thus promote Medicaid’s objective of providing health care coverage “as far as practicable under the conditions of such state.”

We are asking the Supreme Court to recognize that section 1115 demonstration projects should present an opportunity for states to experiment with reforms that go beyond just routine medical care and focus on interventions that drive better health outcomes and quality of life improvements, and that may increase beneficiaries’ financial independence. Such policies may include those designed to address certain health determinants and those that encourage beneficiaries to engage in health-promoting behaviors and to strengthen engagement by beneficiaries in their personal health care plans. These tests, if authorized by the Supreme Court, would necessarily mean a change to the status quo. They may have associated administrative costs, particularly at the initial stage, and section 1115 acknowledges that demonstrations may “result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing.” Act § 1115(d)(1). But in the long term, we believe such demonstrations could create incentives and opportunities that help enable many beneficiaries to enjoy the numerous personal benefits that come with improved health and financial independence.

We believe that section 1115 demonstration projects should also provide an opportunity for states to test policies that ensure the fiscal sustainability of the Medicaid program, better “enabling each [s]tate, as far as practicable under the conditions in such [s]tate” to furnish medical assistance, Act § 1901, while making it more viable for states to furnish medical assistance to a broader range of persons in need or providing additional benefits to existing beneficiaries. For instance, measures designed to improve health and wellness may reduce the volume of services consumed, as healthier, more engaged beneficiaries tend to consume fewer medical services and are generally less costly to cover. Further, measures that have the effect of helping individuals secure employer-sponsored or other commercial insurance or transition from Medicaid eligibility may decrease the number of individuals who need financial assistance, including medical assistance, from the state. Such measures may enable states to stretch their resources further and enhance their ability to provide medical assistance to a broader range of persons in need, including by expanding the services and populations they cover.² By the same

² States have considerable flexibility in the design of their Medicaid programs, within federal guidelines. Certain benefits are mandatory under federal law, but many benefits may be provided at state option, such as prescription drug benefits, vision benefits, and dental benefits. Similarly, states have considerable latitude to determine whom their Medicaid programs will cover. Certain eligibility groups must be covered under a state’s program, but many states opt to cover additional eligibility groups that are optional under the Medicaid statute. The optional groups include a new, non-elderly adult population that was added to the Act at section 1902(a)(10)(A)(i)(VIII) by the Patient Protection and Affordable Care Act (ACA). Coverage of this new adult group became optional as a result of the Supreme Court’s decision in *NFIB v. Sebelius*, 567 U.S. 519 (2012). Accordingly, several months after the *NFIB* decision was issued, CMS informed the states that they “have flexibility to start or stop the expansion.” CMS, *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* at 11 (Dec. 10, 2012). In addition to expanding Medicaid coverage by covering optional eligibility groups and benefits beyond what the Medicaid statute requires, many states also choose to cover benefits beyond what is authorized by statute by using expenditure

token, such measures may also preserve states’ ability to continue to provide the optional services and coverage they already have in place.

Our demonstration authority under section 1115 of the Act should be interpreted to allow us to offer states more flexibility to experiment with different ways of improving health outcomes and strengthening the financial independence of beneficiaries. Demonstration projects that seek to improve beneficiary health and financial independence improve the well-being of Medicaid beneficiaries and, at the same time, would allow states to maintain the long-term fiscal sustainability of their Medicaid programs and to provide more medical services to more Medicaid beneficiaries. Accordingly, we are asking the Supreme Court to recognize that such demonstration projects advance the objectives of the Medicaid program.

Extent and Scope of Demonstration

The 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. The state made several changes to HIP in the 2018 approval, which the state indicated were designed to improve beneficiary outcomes by improving utilization of tobacco cessation services, increasing utilization of and accessibility to SUD treatment, helping beneficiaries engage in the management of chronic diseases, and encouraging participation in community engagement activities. HIP also was designed 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.

With this extension approval, a few changes have been or, where conditioned on a Supreme Court decision, would be made to the demonstration. These changes include: (1) allowing the state flexibility to change premium and copayment amounts within the parameters described in the STCs; if authorized by a Supreme Court decision in connection with the community engagement program, (2) increasing the dependent age, from under 7 to under 13, for primary caregivers of dependent children to be exempt from community engagement; and if it becomes applicable based on a Supreme Court decision, (3) adding an exemption from the community engagement requirement for members of federally recognized tribes. With these changes, the HIP demonstration has been extended for a period of ten years except—as noted above—the following demonstration authorities which have been extended for a period of five years: SUD, SMI, community engagement, and non-eligibility periods. CMS has taken into consideration several factors in order to determine the approval period of the various HIP demonstration components. One consideration was the state’s request. The state requested a five-year approval period for the SUD and SMI authorities since these policies were only recently implemented in 2018 and 2019, respectively, and there was not sufficient experience for the state to request formal renewal or a longer-term extension. CMS also considered whether the authorities the

authority under section 1115(a)(2) of the Act. For example, recently, many states have been relying on this authority to expand the scope of services they offer to address substance use disorders beyond what the statute explicitly authorizes.

state requested for a 10-year extension had been previously or currently implemented over a sufficient period of time to support a long-term extension such as the ten-year period at issue here. As with the SUD and SMI demonstration elements, the community engagement and non-eligibility periods associated with community engagement and non-compliance with redetermination were only partially implemented, or had not been implemented. Accordingly, these elements of the state's demonstration similarly do not have sufficient implementation experience and data available to justify a long-term extension period, assuming that our contingent approval takes effect following a decision by the Supreme Court. In addition, CMS looked into the evidence available on the importance, performance, and potential effectiveness of the various HIP demonstration components in making a determination about the approval period.

The extension of this demonstration will require Indiana to continue to conduct robust and regular monitoring of the demonstration policies, per CMS guidelines, which means that the state will be reporting on CMS's standard metrics for SUD, SMI, community engagement (if implemented), premiums, non-eligibility periods, waiver of retroactive eligibility, and health behavior incentives, among others. This requirement of structured monitoring using CMS-provided metrics set for these policy areas is an enhancement to HIP demonstration STCs. Furthermore, the state will be required to prepare a rigorous demonstration evaluation design for the extension period that is subject to CMS approval, and conduct—in alignment with the evaluation design—three interim evaluations and one summative evaluation over the 10-year demonstration extension period. While the policies that have been in implementation for a limited duration (less than three years) or not at all implemented at the time of this extension are only extended (in some cases only conditionally) for five years, other policies—some of which have been long-standing features of the HIP demonstration are being approved for a period of ten years. However, as these long-standing policy features have evolved in design over time in Indiana, a comprehensive and conclusive impact analysis of these demonstration components has been difficult to accomplish. Many of the demonstration policies, which are being extended for ten years with this extension, have been challenging to evaluate due to relatively short implementation periods within each approval period and programmatic changes with each extension. The length of the implementation period may facilitate certain aspects of the rigor of the demonstration's evaluation; for example, it will enable the state to conduct well-designed longitudinal beneficiary surveys to track beneficiary outcomes over time, including after separation from the demonstration and the Medicaid program, and evaluate the program's longer-term effects on beneficiary health insurance/coverage, employment, income, and health outcomes. While some of these policies have never before been approved by CMS for a period longer than five years, CMS believes that—given the initial promising evidence for these policies, as described below—it is appropriate for CMS to extend this demonstration for a period of ten years. As described below, the extension includes robust guardrails, and the demonstration may be suspended or withdrawn, if monitoring and evaluation data raise concerning evidence.

Other than the three modifications noted above, all other aspects of the demonstration will continue without changes. Beneficiaries who consistently make required monthly contributions to their POWER Account maintain access to an enhanced benefit plan, known as "HIP Plus," which includes enhanced benefits such as dental, vision, and chiropractic coverage. The state applies a premium surcharge for HIP Plus beneficiaries who use tobacco, and who do not

participate in tobacco cessation activities. This increased premium is 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 the specific behavior of tobacco use, the state will continue to test whether incentivizing beneficiaries to change behavior and engage in their own healthcare will help achieve better health outcomes.

In addition, the state will continue to charge HIP Plus beneficiaries premiums based on income bands. Premiums will be capped at three percent of household income and the state will have the flexibility to change the premium amounts, up to that cap, without submitting an amendment to CMS. The STCs require the state to notify beneficiaries sixty days prior to making a change and the state must notify CMS by letter and include the information in a quarterly or annual monitoring report. As was previously approved in 2015 and reapproved in 2018, beneficiaries with incomes above 100 percent of the federal poverty level (FPL) who do not pay the premium will be disenrolled from the HIP Plus program. However, the state will be unable to subject beneficiaries to a six-month non-eligibility period unless the Supreme Court issues a decision in *Azar v. Gresham*, No. 20-37 that legally authorizes this element. Beneficiaries who are medically frail, section 1931 parents/caretakers, or suffering from a qualifying event, such as being a victim of domestic violence or obtaining and losing private insurance coverage, would never be subject to the period of non-eligibility. Given the Coronavirus Disease 2019 (COVID-19) public health emergency, while CMS is renewing this authority, the state is not terminating Medicaid coverage for beneficiaries, consistent with the condition under 6008(b) of the Families First Coronavirus Response Act (FFCRA) to receive the increased Federal Medical Assistance Percentages (FMAP).

Indiana has conditional authority to impose a community engagement requirement, which means Indiana is not able to implement the community engagement requirement as a condition of eligibility unless the Supreme Court issues a decision in *Azar v. Gresham*, No. 20-37 that legally authorizes this element of the extension to the demonstration. Under the community engagement requirement if implemented following a Supreme Court decision, Indiana would be permitted to require HIP beneficiaries, with exemptions for various groups, including: pregnant women, beneficiaries considered medically frail, and students to meet a community engagement requirement in order to maintain eligibility for HIP. To remain eligible, non-exempt beneficiaries would be required to complete a specific number of hours per week of community engagement activities, such as employment, education, job skills training, and community services for eight months in the 12-month calendar year. Beneficiaries would have their eligibility suspended in the next calendar year for failure to demonstrate compliance with the community engagement requirement during the prior calendar year. During an eligibility suspension, beneficiaries would be able to reactivate their eligibility in the month following notification to the state that they completed a calendar month of required hours. Indiana would allow circumstances that give rise to good cause for beneficiaries who cannot meet the requirement because of such circumstances.

In addition, the state has been granted conditional authority to impose a three-month non-eligibility period for beneficiaries who fail to complete the redetermination process timely. The state cannot implement this authority unless the Supreme Court issues a decision in *Azar v. Gresham*, No. 20-37 that legally authorizes this element of the extension to the demonstration.

HIP beneficiaries have their eligibility reconfirmed through a redetermination period, which begins 45 days prior to the end of the beneficiary’s eligibility period. If there is a favorable Supreme Court decision permitting implementation of this element of the proposed extension, beneficiaries who do not provide requested information to confirm eligibility during this period would be subject to disenrollment, unless otherwise exempted. However, beneficiaries subject to disenrollment would 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 would 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 would not be able to re-enroll in HIP for three months following the reconsideration period.

The HIP demonstration also includes a SUD program to ensure that a broad continuum of care is available to Indiana Medicaid beneficiaries with a SUD, which improves the quality, care, and health outcomes for those Medicaid beneficiaries. The SUD program is a component of Indiana’s comprehensive statewide strategy to combat prescription drug abuse and opioid use disorders, and the demonstration authority expands the SUD benefits package and allows the state to receive federal financial participation (FFP) to cover short-term residential services in a setting that meets the definition of an Institution of Mental Disease (IMD) for all Medicaid enrollees. In addition, through the SMI component of the HIP demonstration, the state has the authority to receive FFP for delivering high-quality, clinically appropriate treatment to beneficiaries ages 21 through 64 diagnosed with a SMI and receiving treatment while they are short-term residents in IMDs.

Elements of the Demonstration Request that CMS is Not Approving at This Time

In its application, Indiana requested to extend the Workforce Bridge Account program, which provides up to \$1,000 to pay for premiums, cost-sharing or direct costs of Medicaid coverable services to eligible individuals who have increased their income and are no longer eligible for Medicaid. This program is currently approved under Indiana’s “End-Stage Renal Disease” (ESRD) section 1115 demonstration, but has not yet been implemented due to the ongoing public health emergency. The ESRD demonstration expires December 31, 2020, and the state would like to extend the Workforce Bridge Account program under the HIP demonstration. CMS is continuing to work with Indiana on this request, but is not taking action on extension of this program component within the HIP demonstration at this time. Per longstanding policy, CMS considers each state amendment or demonstration request independently, and this action does not indicate likely approval or disapproval of any future requests.

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

For the reasons discussed below, the Secretary has determined that Indiana’s HIP demonstration is likely to assist in promoting the objectives of the Medicaid program.

The demonstration will expand coverage.

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, through the SUD component of the demonstration, beneficiaries ages 21 through 64 have access to expanded covered services provided while residing in an IMD for short-term SUD residential stays. The SUD program allows 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. The state’s SUD interim evaluation³ provides preliminary promising evidence for the usefulness of the program. For example—between Calendar Year (CY) 2017 and CY 2018—beneficiaries receiving any SUD treatment increased by 16 percent, and the number of beneficiaries receiving Medication Assisted Treatment (MAT) increased by 32 percent; rates of 7-day and 30-day follow-up after discharge from an emergency department visit for alcohol and other drug dependence, respectively, increased by 17.2 percent and 17.0 percent; and the average length of stay in an IMD decreased by 5.9 percent.

In addition to the SUD program, this demonstration also assists in delivering high-quality, clinically appropriate treatment to beneficiaries diagnosed with SMI and receiving treatment while they are short-term residents in free-standing psychiatric hospitals that qualify as IMDs. This program is designed to increase identification, initiation, and engagement of Medicaid beneficiaries with SMI, improve access to community-based services to address the chronic mental health care in the community following episodes of acute care in hospitals, and reduce inappropriate or preventable utilization of emergency departments and inpatient hospital settings through improved access to services through a continuum of care in an additional setting that, absent this demonstration, would be ineligible for Medicaid reimbursement for most Medicaid enrollees.⁴

The demonstration will furnish medical assistance in a manner that improves the sustainability of the safety net.

The demonstration’s incentives for individuals to enroll as soon as possible and to obtain preventive services and assess health risk have the potential to reduce the cost of providing Medicaid coverage to beneficiaries subject to these policies by reducing the incidence of chronic or preventable conditions, and by helping to ensure chronic conditions are well managed. CMS and the state also expect that the demonstration’s emergency department (ED) copayments will continue to decrease the use of inefficient and costly care in less appropriate settings, thereby making beneficiaries less expensive to care for and enabling Indiana to stretch its limited resources.

The waiver of NEMT is also likely to help promote Medicaid’s objectives by enabling the state to better contain Medicaid costs and more efficiently focus resources on providing accessible and

³ Interim Evaluation of Indiana’s Section 1115 Substance Use Disorder Waiver. Burns & Associates, Inc. April, 24, 2020. CMS is in the process of approving this interim evaluation report and it will be made available on Medicaid.gov (<https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/81641>).

⁴ The program has been in implementation for a limited period for the state to submit monitoring metrics to CMS or conduct an evaluation.

high-quality health coverage, thus improving the fiscal sustainability of the Medicaid program. Improved fiscal sustainability will help Indiana to continue to cover non-mandatory benefits and eligibility groups (such as the Patient Protection and Affordable Care Act (ACA) expansion population and dental and vision benefits). However, NEMT is a covered service for HIP State Plan and HIP Maternity, and three of the four Managed Care Entities (MCEs) offer NEMT to HIP Plus and HIP Basic members as an enhanced service. The state's NEMT evaluation conducted in 2016 reported that, although the state was not reimbursing for NEMT, *one* MCE still provided NEMT to HIP beneficiaries enrolled with that MCE.⁵ The evaluation—using data from that period—found that beneficiaries without MCE-provided NEMT services did not appear to be more likely to report missing an appointment and to report transportation as a reason for a missed appointment, relative to those with MCE-provided NEMT benefits.

If there is a favorable Supreme Court decision that permits making community engagement a condition of continued eligibility, Indiana would expect that some beneficiaries would transition from Medicaid to financial independence and commercial coverage. Additionally, participation in community engagement activities would be likely to lead to increased health and wellness of beneficiaries, which in turn would reduce the cost of providing them with health care coverage. Some beneficiaries could lose coverage if they elect to not comply with the demonstration's community engagement requirements, if implemented. However, we are asking the Supreme Court to recognize that it furthers Medicaid program's objectives to allow states to experiment with innovative means of deploying limited state resources in ways that could facilitate the state's ability to continue to provide services beyond the statutory minimum, as Indiana does by covering the adult expansion population. Enhancing fiscal sustainability allows the state to provide services to Medicaid beneficiaries that it could not otherwise provide. By incentivizing community engagement, the demonstration conditionally approved is designed to lead to higher quality care at a sustainable cost. Promoting improved health and wellness ultimately helps to keep health care costs at sustainable levels. To the extent that the demonstration, if implemented, helps individuals achieve improved health and financial independence, the demonstration may make these individuals less costly for Indiana to care for, thus further advancing the objectives of the Medicaid program, and helping to ensure that the health care safety net is available to those who need it most. And, to the extent that the community engagement requirement, if implemented, helps individuals achieve financial independence and transition to commercial coverage, the demonstration would enhance the state's ability to provide medical services to those who most need this critical safety net.

In keeping with the state's long-term goals for the demonstration as a whole, which include lowering costs, the state will evaluate the financial impacts of the entire demonstration. The extension STCs require the state to investigate cost outcomes for the demonstration as a whole, with evaluation research questions that include but are not limited to: the administrative costs of demonstration implementation and operation, Medicaid health service expenditures, and provider uncompensated care costs. In addition, the state must use results of hypothesis tests aligned with

⁵ Indiana HIP 2.0: Evaluation of Non-Emergency Medical Transportation (NEMT) Waiver. The Lewin Group, Inc. November 2, 2016. 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-nemt-final-evl-rpt-11022016.pdf>.

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other demonstration goals and cost analyses together to assess the demonstration’s effects on Medicaid program sustainability.⁶

The demonstration tests reforms designed to promote financial independence, which we expect to improve continuity of coverage and lead to better health outcomes.

Under the demonstration, Indiana and CMS will continue to evaluate the effectiveness of various policies that are designed to improve the health of Medicaid beneficiaries, and encourage them to make responsible decisions about their health and accessing health care because promoting beneficiary health and responsible health care decisions advances the objectives of the Medicaid program. Indeed, in 2012, HHS specifically encouraged states to develop demonstration projects “aimed at promoting healthy behaviors” and “individual ownership in health care decisions” as well as “accountability tied to improvement in health outcomes.”⁷

HIP includes a proposed community engagement requirement that, if implemented following a favorable Supreme Court decision, would be designed to encourage beneficiaries to obtain employment and/or undertake other community engagement activities that may lead to improved health and wellness. We believe that if implemented would also be likely to promote the objective of helping beneficiaries attain or retain financial independence. If implemented, the community engagement provisions generally would require demonstration beneficiaries to work, look for work, or engage in activities that enhance their employability, such as job-skills training, education, and community service. The demonstration would thus help the state and CMS understand whether the community engagement requirements adequately incentivize individuals to work as a condition of receiving Medicaid, and the state would be required to track the effects of the demonstration on employment, including new employment among beneficiaries.

The demonstration’s premiums and cost-sharing requirements are designed to improve beneficiary health and wellness by encouraging beneficiaries to take ownership of decisions about health care options and determine if it is more cost efficient and practical for them to enroll in an enhanced health package to receive vision and dental benefits. HIP beneficiaries with incomes up to and including 100 percent of the FPL have a choice to sign up with HIP Basic and receive no dental or vision benefits, and pay copayments for non-preventative services, or pay premiums to receive HIP Plus and receive vision and dental benefits with no copayments for any services (except for non-emergency use of the ED). HIP beneficiaries with incomes above 100 percent of the FPL must enroll in HIP Plus to receive Medicaid coverage.

With this approval, Indiana will be expected to collect additional data to determine whether this structure encourages beneficiaries to choose to pay for premiums in order to receive an enriched benefit package. In 2018, for instance, while 84 percent of HIP beneficiaries had income at or below 100 percent of the FPL, approximately 55 percent of beneficiaries were enrolled only in

⁶ The state is also expected to include cost and sustainability assessment for the HIP demonstration approval period 2018-2020 in the summative evaluation report, draft of which is due to CMS in June 30, 2022. More details will be available in the forthcoming CMS-approved evaluation design from this period (to be made available on Medicaid.gov).

⁷ CMS, Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid at 15 (Dec. 10, 2012).

HIP Plus during the year⁸ The HIP Plus beneficiaries are also more likely to engage in behaviors that may improve health outcomes. For example, the state’s independent evaluation reported that HIP Plus members had higher participation and utilization rates for preventive services, primary care, and specialty services, as well as better prescription adherence rates compared to HIP Basic members (e.g., differences in participation rates for preventive services, primary care visits, specialty care services, and prescription drug adherence rates between HIP Plus Only and HIP Basic Only members in 2018 were 26 percentage points, 24 percentage points, 23 percentage points, and 3.7 percentage points, respectively). Since additional factors such as case mix (10 percent of HIP Basic members were medically frail as compared to 17 percent of HIP Plus members) and health literacy could contribute to these differences between benefit plan groups, with this approval, the state will be expected to evaluate rigorously whether the consumer-driven approach indeed helps drive more conscious health behaviors and service utilization. The STCs include specific references for monitoring and evaluating the demonstration, and give CMS authority to require the state to submit a corrective action plan, which could include temporary suspension of implementation of the demonstration, if monitoring or evaluation findings indicate substantial and sustained directional change inconsistent with state targets (such as substantial, sustained trends indicating increased disenrollment due to non-payment of premiums, or increased difficulty accessing services). CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

The waiver of retroactive eligibility is also expected to help promote Medicaid’s objectives by improving uptake of preventive services, thus improving beneficiary health. Indiana is testing whether waiving retroactive eligibility for certain groups of Medicaid beneficiaries will encourage them to obtain and maintain health coverage, even when healthy, or to obtain health coverage as soon as possible after becoming eligible, rather than potentially waiting until they are sick, knowing that the costs of the illness would be covered by a retroactive eligibility period.⁹ To increase awareness of the waiver of retroactive eligibility and promote the objectives of the Medicaid program (e.g., continuity of coverage and care), Indiana will continue to provide outreach and education about how to apply for and receive HIP coverage to the public and to Medicaid providers, particularly providers who serve vulnerable populations who may be affected by this policy. This will help to ensure that eligible individuals apply for and receive Medicaid coverage in a timely manner, as well as help to ensure that providers understand how to assist individuals in gaining coverage. The state will continue to employ an outreach strategy in which materials will be made available through various methods such as mailings and on the state’s Medicaid website. Furthermore, the state will continue evaluating the waiver of retroactive eligibility to understand how the policy affects outcomes, such as enrollment and enrollment continuity, enrollment when people are healthy, and health status (as a result of

⁸ Healthy Indiana Plan Interim Evaluation Report. The Lewin Group, Inc. April 29, 2020. CMS is in the process of approving this interim evaluation report and it will be made available on Medicaid.gov (<https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/81641>).

⁹ The state’s Prior Claims Payment Program Report from October 27, 2015 found that the Program was not widely used by beneficiaries in the state, since just 10 percent (628 of 5,950) of eligible members had claims under the Program.

greater enrollment continuity).¹⁰

The state will also continue to provide presumptive eligibility, which provides Medicaid coverage for a limited time while a formal Medicaid application is submitted and an eligibility determination is made by the state Medicaid agency. In addition, Indiana also utilizes the “Fast Track” payment system, where individuals can submit \$10 for a premium payment with the Medicaid application and if that individual is deemed eligible for HIP, coverage will begin on the first day of the month in which the Fast Track payment is made. The state’s interim evaluation report⁸, however, showed that the percentage of individuals using the presumptive eligibility process and Fast Track is declining. Specifically, the percentage of new HIP Plus beneficiaries enrolling via Fast Track decreased from 9.9 percent of all new beneficiaries in 2017 to 7.4 percent of all new beneficiaries in 2018. The percentage of new HIP beneficiaries enrolling using presumptive eligibility decreased from 17.3 percent to 14.4 percent from 2016 to 2018. Approximately 30.3 percent of Fast Track beneficiaries were enrolled for six months or more in 2018 as compared to 33.7 percent of members using presumptive eligibility. As part of this extension, the state will continue to test and evaluate whether to retain these program components.

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 beneficiaries 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 that is conditional on the Supreme Court authorizing this element of the demonstration), 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, dental, and enhanced chiropractic services) requires monthly premiums, and initiates benefits in the month of initial premium payment.

Similar to how commercial coverage operates, if a Supreme Court decision authorizes the state to continue implementation of this element of the demonstration, eligibility would 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 would be disenrolled and have a six month non-eligibility period (the non-eligibility period being conditional on the Supreme Court authorizing this element of the demonstration). The demonstration would include special exemptions for those that lose private insurance coverage or are the victim of domestic violence. CMS also notes that Indiana would take steps to minimize beneficiary harm by exempting certain vulnerable populations, such as pregnant women and individuals who are medically frail,

¹⁰ The state is also expected to include evaluation of the waiver of retroactive policy for the HIP demonstration approval period 2018-2020 in the summative evaluation report, draft of which is due to CMS in June 30, 2022. More details will be available in the forthcoming CMS-approved evaluation design from this period (to be made available on Medicaid.gov).

from disenrollment for non-payment of premiums. Furthermore, to facilitate streamlining of administrative processes and beneficiary access to coverage, the demonstration flexibilities would allow beneficiaries to retain the same POWER Account and the same MCE, even if the beneficiary were disenrolled, as long as the beneficiary were to be reenrolled in HIP within the same calendar year. As noted above, given the COVID-19 public health emergency, while CMS is renewing this authority, the state is not terminating Medicaid coverage for beneficiaries, consistent with the condition under 6008(b) of the FFCRA to receive the increased FMAP. Overall, the design of the HIP demonstration is expected to empower individuals to improve their health and well-being. If implemented as intended following a favorable Supreme Court decision authorizing full implementation, and successful in its objectives, HIP would 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 would if fully implemented ensure vulnerable individuals, like people with disabilities and pregnant women, continue to receive medical assistance.

Consideration of Public Comments

To increase the transparency of demonstration projects, sections 1115(d)(1) and (2) of the Act directed the Secretary to issue regulations providing for two periods of public comment on a state's application for a section 1115 demonstration that would result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing. The first comment period occurs at the state level before submission of the section 1115 application, and the second comment period occurs at the federal level after the application is received by the Secretary.

The Affordable Care Act ACA specified that comment periods should be "sufficient to ensure a meaningful level of public input," section 1115(d)(2)(A) & (C) of the Act, but the statute imposes no additional requirement on the states or the Secretary to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not provide written responses to public comments.

The federal public comment period was open from February 12, 2020 through March 21, 2020. The federal public comment period was extended due to a delay in public notification of the application submission. CMS received 259 comments during the federal comment period on the state's application for the HIP section 1115 demonstration. Although CMS is not legally required to provide written responses to comments, CMS is addressing some of the central issues raised by the commenters and summarizing CMS's analysis of those issues for the benefit of stakeholders. After carefully reviewing the public comments submitted during the federal comment period, CMS has concluded that the demonstration project advances the objectives of Medicaid.

General Comments

The majority of the comments CMS received opposed either the demonstration as a whole or only certain features of it. Most of those comments expressed general concerns that the

community engagement requirement would result in many low-income citizens losing Medicaid, or would create a barrier to accessing Medicaid. CMS shares the commenters' concern that everyone who needs Medicaid and meets programmatic eligibility criteria should have access to Medicaid. As of October 2019, the community engagement requirement as a condition of continued eligibility was suspended. The approval of this element of the demonstration is conditional on the Supreme Court issuing a decision in *Azar v. Gresham*, No. 20-37 that legally authorizes this element. However, continuing testing this feature of the demonstration, if implemented following a Supreme Court decision, would allow the state and CMS to determine whether there is a more effective way to furnish medical assistance to the extent practicable under the conditions in Indiana. Even if the program, if implemented following a Supreme Court decision, may at the outset appear competing with the objective of Medicaid to provide health coverage, CMS believes that – overall- the program would have the potential to achieve the core objectives of the Medicaid program while ensuring enhanced beneficiary engagement and fiscal sustainability. As such, conditional on the Supreme Court's authorizing implementation, CMS is approving the extension of this demonstration component.

Safeguards would continue to be incorporated into the STCs that would be intended to minimize coverage loss due to non-compliance, and if implemented CMS is committed to partnering with Indiana to ensure that the requirement is appropriately incentivizing community engagement, and not acting as an onerous barrier to eligibility. These safeguards include providing for a range of qualifying activities, such as community service, education, and volunteer work. Also, CMS continues to include the following list of circumstances that would give a beneficiary the avail of a *good cause* for failing to comply: if the beneficiary is a victim of domestic violence; and if 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 (P.L. 111-148), and was unable to meet the requirement for reasons related to that disability, but was not exempted from the community engagement requirement.

The STCs also contain a series of assurances that would apply if the community engagement requirement is implemented, including, but not limited to, that the state would: screen beneficiaries and determine eligibility for other bases of Medicaid eligibility and review for eligibility for insurance affordability programs prior to disenrollment; provide full appeal rights prior to disenrollment; and ensure that there are timely and adequate beneficiary notices provided in writing which address community engagement features. Also included is a provision granting CMS the authority to discontinue the demonstration if the agency determines that it is not promoting Medicaid's objectives. Moreover, CMS will continue to regularly monitor the demonstration and will work with Indiana to resolve any issues that arise.

In addition, we think the demonstration, if implemented following a Supreme Court, ruling would provide sufficient guardrails to address concerns raised about the demonstration regarding the impact to people with health issues, but also to other groups like low-income families and people who are lesbian, gay, bisexual, and transgender. Not only would we require the state to operate within civil rights laws and provide for reasonable accommodations, we have also included specific assurances in STCs VI.9, which address the disparate impact of the demonstration on people protected by such laws, including race and those who are lesbian, gay, bisexual, and transgender.

Reductions in Medicaid’s overall costs can further the objectives of the program, such as when the reductions stem from reduced need for the safety net or reduced costs associated with healthier, more independent beneficiaries. These outcomes promote the best interest of the beneficiaries whose health and independence are improved, while also helping states stretch limited Medicaid resources and ensure the long-term fiscal sustainability of the state’s Medicaid program.

A number of the commenters expressed an increased concern of citizens losing Medicaid during the COVID-19 public health emergency. CMS also understands the concerns raised by commenters that beneficiaries could lose coverage under this demonstration during the COVID-19 pandemic. Pursuant to section 6008(b)(3) of the FFCRA, in order for the state to qualify for increased FMAP, states may not terminate individuals enrolled for Medicaid benefits as of March 18, 2020, or determined eligible on or after that date¹¹. This includes continuing coverage for individuals who experience a change in circumstances that impacts eligibility or are determined eligible based on self-attestation for certain criteria, if the state has adopted post-enrollment verification of the criterion. Thus, if a state is able to process a change in circumstances prior to the end of the month in which the public health emergency ends, and determines that a beneficiary no longer meets all eligibility criteria for coverage, the state must postpone taking adverse action until after the end of the month in which the emergency ends in order to qualify for the temporary FMAP increase. Indiana is currently complying with this requirement.

Comments on Community Engagement

Most commenters expressed concern that the community engagement requirement would cause some individuals to lose Medicaid coverage, and for that reason, the demonstration as proposed cannot be considered to be consistent with the objectives of the Medicaid program. It is important to CMS that for any community engagement demonstration implemented, compliance be achievable for every beneficiary subject to the requirement, such that every beneficiary enrolled in Medicaid would be able to stay enrolled in Medicaid unless and until they move into other forms of coverage or become ineligible for reasons such as income. In light of the safeguards discussed above, CMS has determined that compliance with Indiana’s community engagement requirement would, if implemented following a Supreme Court decision providing authority, be achievable for every beneficiary. Furthermore, the state would be required to comprehensively monitor and evaluate the community engagement program, if implemented. The state prepared an evaluation design for the demonstration’s approval period from February 1, 2018 through December 31, 2020, proposing appropriate hypotheses and research questions and robust methodologies and data sources to assess the effects of the program. However, since the program was not fully operationalized beyond the voluntary reporting period, the evaluation for the 2018-2020 approval period will not be able to execute the proposed evaluation design for this program. Any future evaluation of this policy if implemented would be required to focus on outcomes such as employment, income, transitions to commercial health insurance, coverage after separation from the demonstration, and health status. The state would also examine, for

¹¹ COVID-19 Frequently Asked Questions for State Medicaid and Children’s Health Insurance Program Agencies. Available at: <https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf>.

instance, beneficiary compliance with demonstration requirements and enrollment continuity to understand the effectiveness of the disenrollment and non-eligibility period features attached to the community engagement policy. In addition, monitoring of the demonstration would not only support collecting operational monitoring data on the ongoing activities of community engagement program, but Indiana would also be required to report metrics on beneficiary enrollment, suspension, and disenrollment, beneficiaries in a non-eligibility period, reinstatement of benefits after suspension, and re-entry after disenrollment, among others, in its quarterly and/or annual monitoring reports.

We also note that Indiana provides coverage to individuals in the new adult group (described at section 1902(a)(10)(A)(i)(VIII) of the Act) that the state is not required to cover. Any potential loss of coverage that could result from the community engagement requirement if implemented would be properly considered in the context of the state's substantial discretion to eliminate non-mandatory benefits or to eliminate coverage for existing (but not mandatory) populations, such as (in light of the Supreme Court's ruling in *NFIB v. Sebelius*) the ACA adult expansion population. Moreover, conditioning eligibility for Medicaid coverage on compliance with certain measures would if implemented be an important element of the state's efforts, through experimentation, to improve beneficiaries' health and independence and enhance programmatic sustainability. To create an effective incentive for beneficiaries to take measures that promote health and independence, we believe that it may be necessary for states to attach penalties to failure to take those measures, including with conditions designed to promote health and financial independence. This may mean that if the community engagement requirement were implemented, beneficiaries who fail to comply would lose Medicaid coverage, at least temporarily. However, the incentive included in Indiana's demonstration is not designed to encourage this result; rather, it is intended to incorporate achievable conditions of continued coverage. And, any loss of coverage as a result of noncompliance would have to be weighed against the benefits Indiana hopes to achieve through the demonstration, including both the improved health and independence of the beneficiaries who comply and the state's enhanced ability to stretch its Medicaid resources and maintain the fiscal sustainability of the program.

Comments Addressing Coverage Losses

Some commenters cited loss of Medicaid coverage as a rationale for not supporting this demonstration. Specifically, some commenters asserted that the community engagement requirement would lead to loss of coverage among current Medicaid beneficiaries who are unable to comply. The state has assessed that in July of 2019, out of approximately 380,000 fully enrolled beneficiaries, 73 percent were exempt, 8 percent who were not exempt met the requirement because they reported they were employed, and the remaining 19 percent would need to report either hours or an exemption. Effective October 2019, the disenrollment and non-eligibility period was suspended.

While CMS and the state acknowledge that, if the community engagement requirement were implemented, some beneficiaries may choose not to meet the requirements, the state is required to implement a number of strategies and supports to minimize coverage loss due to non-compliance with the community engagement requirement. For example, the state would conduct active outreach and education, beyond standard noticing, to help ensure that applicants and

beneficiaries understand the requirements and how to comply with them. Indiana would maintain such information on its public-facing website and employ other broad outreach activities that are specifically targeted at beneficiaries. As required in the STCs, the state would be required to submit its Implementation Plan no later than 90 days after the approval of the extension. Indiana voluntarily submitted an Implementation Plan for the community engagement component of the demonstration. Should the condition of approval for the community engagement component be met, CMS would work with the state to finalize its Implementation Plan. The STCs also would require the state to provide outreach and education to stakeholders regarding the community engagement requirement, including but not limited to updating the state's website and training employees. While some beneficiaries may choose not to comply with the community engagement requirement, if it is implemented, and forgo coverage, the goal is for everyone participating in the program to successfully complete its requirements.

Comments on the Premium Requirements and Cost Sharing

Some commenters expressed concerns regarding the complexity of the POWER Account program and indicated this could inhibit access to certain services available through the POWER Account. During its renewal, the state will continue to provide robust outreach and education to beneficiaries about how to operate the POWER Account and how to access services through the Account. Additionally, commenters indicated that premium amounts were burdensome to beneficiaries and would prevent individuals from maintaining coverage. Through the premium policies in the demonstration, if the Supreme Court Decision allows the state to continue with the implementation of the non-eligibility period,¹² CMS and the state would be testing the effectiveness of an incentive structure that attaches penalties to failure to take certain measures. Specifically, beneficiaries with household income over 100 percent of the FPL could be disenrolled for failing to pay premiums under the demonstration. It is important to note that beneficiaries with household income at or below 100 percent of the FPL would not be disenrolled for nonpayment of premiums. These beneficiaries would have the option to pay premiums, which provides a more enhanced benefit package that includes, dental, vision and some chiropractic services. If these beneficiaries do not pay a premium, they would still have access to a basic benefit package and will be required to pay copayments. However, other commenters expressed similar concerns as with premiums regarding these cost sharing aspect of this demonstration.

The state's interim evaluation report⁸ noted that beneficiaries generally found premiums and copayments affordable. The report also showed that the number and proportion of individuals disenrolled due to non-payment decreased over time. Specifically, trends—without statistical significance tests—in the disenrollment rate due to non-payment displayed a decline from an average of 3.1 percent in 2016 to an average of 2.2 percent in 2018. However, the report also noted that transition from HIP Plus to HIP Basic in a year ranged between 5.9 percent and 7.9 percent from February 2015 to December 2018.

To assure that the premiums and cost sharing policies are helping the state attain its demonstration objectives, without creating undue disadvantage for beneficiaries, the state will

¹² During the COVID-19 public health emergency, the state of Indiana has suspended all premiums and copayments for HIP beneficiaries.

ensure that beneficiaries do not incur cost sharing and premiums that, combined, exceed five percent of their aggregate household income. Further, and in accordance with 42 CFR 447.56(f), once a household reaches the cap, no further co-payments can be charged to beneficiaries, and the premium amount will be reduced for the remainder of the quarter. The state maintains that inclusion of premiums and cost sharing in this demonstration provides beneficiaries with an experience similar to commercial health insurance. This will continue to help prepare beneficiaries for their transition from Medicaid into a commercial health insurance plan. Building personal responsibility through financial contributions towards their healthcare will empower beneficiaries to more actively engage in their own health and develop important skills needed for a smooth transition into commercial insurance. These transitions are especially critical to maintain health outcomes that beneficiaries may achieve through this demonstration and to avoid potential disruptions in insurance status as a member transitions out of Medicaid.

The state will rigorously monitor and continue conducting evaluation of the overall premiums and cost sharing features of the HIP demonstration. The state's ongoing evaluation activities during the 2018-2020 approval period will provide additional evidence in the summative evaluation report on beneficiary understanding of these policies, the impact of the premiums and cost sharing structure on efficient use of health services and enrollment and enrollment continuity. Evaluation is also expected to examine the effectiveness of the tobacco surcharge policy. Evaluation for these policies will continue with this demonstration extension to understand more conclusively the effects of the demonstration policies. In addition, the state will collect monitoring data on enrollment by premium payment status and disenrollment or suspension for failure to pay, among others.

Comments on Non-Eligibility Periods for Failure to Pay Premiums or Failure to Complete Redetermination Requirements

Some commenters suggested that non-eligibility periods create a gap in health coverage for vulnerable beneficiaries. These features of Indiana's demonstration, if implemented following a favorable Supreme Court decision, are designed to incentivize program compliance and familiarize beneficiaries with the functioning of commercial insurance. For these features of the demonstration, if implemented, the state would not apply a non-eligibility period to beneficiaries that are pregnant, medically frail, or parents or caretakers under section 1931 of the Act. The state also would provide for a good cause exception if the beneficiary provides verification of that exception. These elements of the demonstration have been approved on the condition that the Supreme Court issues a decision in *Azar v. Gresham*, No. 27-37 that legally authorizes these elements of the demonstration. If implemented, the state would be required to monitor and evaluate these demonstration aspects rigorously.

Comments on Waiver of Retroactive Eligibility

A few commenters expressed concerns that the waiver of retroactive eligibility will create economic hardships and reduce coverage. Indiana's demonstration is designed to prepare beneficiaries for commercial insurance and to improve the uptake of preventive services, thus improving beneficiary health. Indiana is testing whether waiving retroactive eligibility for certain groups of Medicaid beneficiaries will encourage them to obtain and maintain health

coverage, even when healthy, or to obtain health coverage as soon as possible after becoming eligible. The state will conduct an evaluation of this policy during the current demonstration approval period (2018-2020) focusing on beneficiary understanding of the policy, barriers to timely renewal, enrollment and enrollment continuity, health outcomes, and beneficiary medical debt, and will include findings in the summative evaluation report, the draft of which is due to CMS in June 30, 2022.¹⁰ Going forward, in addition to continuing careful evaluation of the policy, the state will be required to report monitoring metrics, as may be feasible and appropriate, for example, about beneficiaries who indicate that they have unpaid medical bills at the time of application (if available) and number of beneficiaries using Fast Track and presumptive eligibility.

Comments on Waiver of NEMT

A few commenters expressed concerns that the NEMT waiver will negatively impact Medicaid recipients in rural areas who lack consistent transportation options. Commenters also suggested that this waiver of NEMT will harm vulnerable beneficiaries. To limit the impact on vulnerable beneficiaries, Indiana chose to apply this waiver to only the new adult group, and exempt pregnant women, beneficiaries who are medically frail, and section 1931 parents and caretakers. CMS believes this approach adequately addresses commenters' concern, as it minimizes the impact on vulnerable beneficiaries while also achieving the state's goal of recreating the experience of commercial insurance market, which does not offer the NEMT benefit. This component of Indiana's demonstration is expected to improve the fiscal sustainability of the state's safety net and contribute to the provision of additional services offered through HIP. As previously described, evaluation findings for this policy did not indicate evidence of adverse effects on beneficiaries subjected to this policy. Therefore, CMS believes that the benefit of offering NEMT to the new adult group is outweighed by enhancements to programmatic sustainability and the value of the optional services Indiana offers.

Comments on the 10-Year Extension

Some commenters expressed concerns with Indiana requesting an extension of the HIP demonstration for a 10-year period, stating that the demonstration has not proven to be successful and does not represent a non-complex demonstration to meet CMS's criteria for a 10-year extension. CMS has considered factors such as policy complexity, implementation status, Indiana's objectives and consideration for pursuing the demonstration policies, and evidence on the performance of the demonstration and specific policies, where available, in making a determination about the length of an extension period approved for elements of the HIP demonstration. Some of these policies have been long-standing features of the HIP demonstration and are being approved for a period of ten years. Many of the demonstration policies that are being extended for ten years with this extension have been challenging to evaluate due to relatively short implementation periods within each approval period and programmatic changes with each extension. With this extension, the length of the implementation period may facilitate certain aspects of the rigor of the demonstration's evaluation; for example, it will enable the state to conduct well-designed longitudinal beneficiary surveys to track beneficiary outcome over time, including after separation from the demonstration and the Medicaid program, and evaluate the program's longer-term effects on

beneficiary health insurance/coverage, employment, income, and health outcomes. As noted above, for elements of the demonstration with a shorter implementation period and limited track record of performance, such as the SUD and SMI components, and if implemented following a Supreme Court decision, for the community engagement and eligibility loss provisions, approval would be for only five years.

Additionally, the STCs include comprehensive requirements for monitoring and evaluating the demonstration. These include, but are not limited to, quarterly and annual reporting of standard monitoring metrics for policies such as SUD, SMI, premiums, waiver of retroactive eligibility, health behavior incentives, and if implemented, community engagement, and non-eligibility periods as well as three interim evaluation reports and one summative evaluation report over the 10-year demonstration approval period. All this will enable CMS to understand the performance and effectiveness of the demonstration in a timely fashion and eventually garner conclusive evidence on the impact of the demonstration policies. The STCs also give CMS authority to require the state to submit a corrective action plan, which could include temporary suspension of implementation of the demonstration, if monitoring or evaluation findings indicate substantial and sustained directional change inconsistent with state targets (such as substantial and sustained trends indicating increased difficulty accessing services, increased premium non-payment and disenrollment, increases in provider uncompensated care costs and unpaid medical bills, etc.). CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

Comments on Substance Use Disorder

Several comments raised concerns regarding HIP's SUD component of the demonstration. One commenter raised concerns that providing funding for IMDs risks diverting resources away from community-based services and undermining community integration. Nothing in the SUD component of this demonstration requires that services be provided to any individual in any particular setting, nor does it limit the availability of community-based settings. In fact, the state will be working to promote coordinated transitions to community-based services from inpatient and institutional care. Nonetheless, CMS has indicated to Indiana that it should ensure that inpatient and residential care will supplement and coordinate with community-based care. In addition, this initiative should not reduce or divert state spending on mental health and addiction treatment services as a result of available federal funding for services in IMDs.

Commenters also expressed concern that the SUD component in HIP fails to provide sufficient guarantee that beneficiaries in IMDs will receive evidence-based treatment. Before a state can start to receive FFP for SUD services rendered in an IMD, the state must submit and have approved an implementation plan. This plan outlines the state's strategic approach and detail project implementation for meeting milestones, which reflect the key goals and objectives of the SUD demonstration. Indiana has an approved implementation plan that includes but is not limited to: access to critical levels of care for SUDs, use of evidence-based SUD-specific patient placement criteria, use of nationally recognized SUD-specific program standards for residential treatment, and sufficient provider capacity at critical levels of care including MAT.

Supportive Comments Regarding Other Elements of the Demonstration

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Lastly, some commenters expressed support for the HIP demonstration in general. Among such comments, most indicated that this demonstration delivers critical health care services to eligible individuals in the state of Indiana. The HIP demonstration has provided healthcare to individuals that have no other way to receive care while reducing costs by encouraging beneficiaries to utilize preventive health screenings.

Other Information

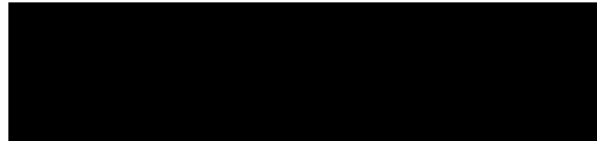
CMS's approval of this demonstration is conditioned upon compliance with the enclosed list of waiver and expenditure authorities and STCs defining the nature, character and extent of anticipated federal involvement in the project. The award is subject to our receiving your written acknowledgement of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

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

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

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

Sincerely,



Anne Marie Costello
Acting Deputy Administrator and Director

Enclosure

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

**CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST**

NUMBER: No. 11-W- 00296/5

TITLE: Healthy Indiana Plan (HIP)

AWARDEE: Indiana Family and Social Services Administration (FSSA)

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

The demonstration will operate under these waiver authorities beginning January 1, 2021. The waivers will continue through December 31, 2030, 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)

This waiver authority is conditional on the Supreme Court issuing a decision in *Azar v. Gresham*, No. 20-37 that legally authorizes this element of the demonstration and if so authorized would continue through December 31, 2025.

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)

This waiver authority is conditional on the Supreme Court issuing a decision in *Azar v. Gresham*, No. 20-37 that legally authorizes this element of the demonstration, and if so authorized would continue through December 31, 2025.

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

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

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

5. Methods of Administration

Section 1902(a)(4) insofar as it incorporates 42 CFR 431.53

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

6. Comparability

**Sections 1902(a)(17) and
1902(a)(10)(B)**

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

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

7. Retroactivity

Section 1902(a)(34)

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

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

NUMBER: No. 11-W- 00296/5

TITLE: Healthy Indiana Plan (HIP)

AWARDEE: Indiana Family and Social Services Administration (FSSA)

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the state for the items identified below (which would not otherwise be included as matchable expenditures under section 1903 of the Act) shall, for the period beginning January 1, 2021 through December 31, 2030, unless otherwise specified, be regarded as matchable expenditures under the state's Medicaid state plan, but are further limited by the special terms and conditions (STC) for the HIP section 1115 demonstration.

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

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

- 1. Managed Care Expenditures.** Expenditures under contracts with managed care entities that do not meet the requirements in section 1903(m)(2)(A) of the Act specified below. Indiana's managed care organizations (MCO) participating in the demonstration will have to meet all the requirements of section 1903(m) except the following:
 - a. Section 1903(m)(2)(A)(vi) of the Act insofar as it requires compliance with requirements in section 1932(a)(4) of the Act and 42 CFR 438.56(c)(2)(i) that enrollees be permitted an initial period to disenroll without cause, except as described in the terms and conditions.
 - b. Section 1903(m)(2)(A)(vi) of the Act insofar as it requires compliance with requirements in section 1932(a)(4) of the Act and 42 CFR 438.56(g) that automatic MCO reenrollment occur only if the beneficiary's disenrollment was due to a Medicaid eligibility lapse of two months or less, as described in the terms and conditions.
- 2. Residential and Inpatient Treatment for Individuals with Substance Use Disorder.** This expenditure authority will begin January 1, 2021 and continue through December 31, 2025. Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).

Healthy Indiana Plan
January 1, 2021 through December 31, 2030

- 3. Inpatient Treatment for Individuals with Serious Mental Illness.** This expenditure authority will begin January 1, 2021 and continue through December 31, 2025. Expenditures for Medicaid state plan services furnished to eligible individuals who are primarily receiving short-term treatment services for a serious mental illness (SMI) in facilities that meet the definition of an IMD.

**CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS**

NUMBER: 11-W- 00296/5

TITLE: Healthy Indiana Plan (HIP)

AWARDEE: Indiana Family and Social Services Administration

I. PREFACE

The following are the special terms and conditions (STC) for the Healthy Indiana Plan (HIP) section 1115(a) Medicaid demonstration (hereinafter “demonstration”) to enable Indiana to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted a waiver of requirements under section 1902(a) of the Social Security Act (the Act). These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS during the life of the demonstration. The demonstration will be statewide and is approved for a ten-year period, from January 1, 2021 through December 31, 2030, unless otherwise specified for specific HIP demonstration components in the waiver and expenditure authorities.

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 Account
- VIII. HIP Cost Sharing
- IX. Redetermination & Managed Care Organization (MCO) Enrollment
- X. Substance Use Disorder (SUD)
- XI. Serious Mental Illness (SMI)
- XII. Delivery System
- XIII. General Reporting Requirements
- XIV. General Financial Requirements
- XV. Budget Neutrality Determination
- XVI. Evaluation of the Demonstration

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

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

Attachment D: SUD Monitoring Protocol (reserved)
 Attachment E: SUD Evaluation Design (reserved)
 Attachment F: SMI Implementation Plan (includes Financing Plan)
 Attachment G: SMI Monitoring Protocol (reserved)
 Attachment H: SMI Evaluation Design (reserved)
 Attachment I: Eligibility and Coverage Implementation Plan (reserved)
 Attachment J: Eligibility and Coverage Monitoring Protocol (reserved)
 Attachment K: Eligibility and Coverage Evaluation Design (including any HIP policies other than SUD and SMI/SED) (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 has been granted the authority to change premium and copayment amounts without submitting an amendment to CMS. In the event that approval of implementation of the community engagement program occurs following a Supreme Court decision reversing the DC Circuit's *Azar v. Gresham* decision, the state has included an exemption from what would be a community engagement requirement for members of federally recognized tribes, and would increase the dependent age from under 7 to under 13. Approval of the community engagement, a change in dependent age for caregivers, and exclusions from eligibility components of this demonstration is conditional on the Supreme Court issuing a decision in *Azar v. Gresham*, No. 20-37 that legally authorizes these elements of the proposed extension to the demonstration. If the Supreme Court issues such a decision, no further action by CMS would be required in order for the state to begin implementation of these components of the demonstration.

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 monthly contributions would be disenrolled and, in the event that the Supreme Court issues a decision in *Azar v. Gresham* that would so authorize, subject to 6-month non-eligibility period. . 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. Along with POWER Account contributions, the demonstration allows for Indiana to impose a tobacco user surcharge.

In addition, Indiana, in the event of a favorable Supreme Court decision, would have the authority to implement community engagement requirements as a condition of eligibility for HIP beneficiaries, with exemptions for various groups, including: pregnant women, beneficiaries

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

Under HIP, in the event of a favorable Supreme Court decision, Indiana would have the authority to implement a non-eligibility period for a period of three months after the 90-day reconsideration period for beneficiaries failing to complete the redetermination process in a timely manner, with the exception of pregnant women and women in the 60-day post-partum period.

The HIP demonstration also includes a SUD program available to all Medicaid beneficiaries to ensure that a broad continuum of care is available to beneficiaries with SUD, which will help improve the quality, care, and health outcomes for Indiana Medicaid beneficiaries. In an amendment to this demonstration dated December 20, 2019, the state also received authority under the demonstration to receive federal financial participation (FFP) for delivering high-quality, clinically appropriate treatment to beneficiaries ages 21 through 64 diagnosed with a serious mental illness (SMI) and receiving treatment while they are short-term residents in settings that meet the definition of an Institution for Mental Diseases (IMD).

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

- Improve health care access, appropriate utilization, and health outcomes among HIP members;
- Increase community engagement leading to sustainable employment and improved health outcomes among HIP members;
- Discourage tobacco use among HIP members through premium surcharge and the utilization of tobacco cessation benefits;
- Promote member understanding and increase compliance with payment requirements by changing the monthly POWER Account payment requirement to a tiered structure;
- Ensure HIP program policies align with commercial policies, encourage members understanding, and promote positive member experience and minimize gaps in coverage;
- Assess the costs to implement and operate HIP and other non-cost outcomes for the demonstration; and
- Receiving FFP for Medicaid services rendered in an IMD for beneficiaries with an SMI and/or a SUD reduces utilization and length of stays in emergency departments and preventable readmissions to acute care hospitals and residential settings.

Monitoring and evaluation sections in the STCs specify that CMS has the authority to require the state to submit a corrective action plan if monitoring or evaluation data indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid. The STCs further specify that any such corrective action plan, submitted by the state, could include a temporary suspension of implementation of demonstration programs, in circumstances where data indicate substantial, sustained directional change inconsistent with state targets (such as substantial, sustained trends indicating increased difficulty accessing services, increases in disenrollment from coverage, and increased instances of unpaid medical bills). These corrective actions will aid the state in measuring and tracking the demonstration's impact on beneficiaries affected by it, and give CMS additional tools to protect applicants and beneficiaries if necessary. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act (Section 1557). Such compliance includes providing reasonable accommodations to individuals with disabilities under the ADA, Section 504, and Section 1557 with eligibility and documentation requirements, understanding program rules and notices, to ensure they understand program rules and notices, as well as meeting other program requirements necessary to obtain and maintain benefits.
- 2. Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program expressed in federal law, regulation, and written policy, not expressly waived or identified as not applicable in the waiver and expenditure authority documents, of which these terms and conditions are part, must apply to the demonstration.
- 3. Changes in Federal Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7 of this section. CMS will notify the state within thirty (30) business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.
- 4. Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**

- a. To the extent that a change in federal law, regulation, or policy requires a change in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
 - b. If mandated changes in 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 last 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 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.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or service-based expenditures, will be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 of this section, except as provided in STC 3 of this section.
- 7. Amendment Process.** Requests to amend the demonstration must be submitted to CMS prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:
- a. An explanation of the public process used by the state, consistent with the requirements listed in STC 12 of this section. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;

- b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
 - c. A data analysis worksheet which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis must 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; and
 - d. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.
- 8. Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 442 Code of Federal Regulations (CFR) 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit a phase out plan consistent with the requirements of STC 9 of this section.
- 9. Demonstration Phase Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
- a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit its notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration’s suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12 of this section, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered comments received when developing the revised transition and phase-out plan.
 - b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary’s appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries e, as well as any community outreach activities the

state will undertake to notify affected beneficiaries, including community resources that are available.

- c. Transition and Phase-Out Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
- d. Transition and Phase-out Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, and 431.213. In addition, the state must assure all applicable appeal and hearing rights afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to termination, 42 CFR 435.916. For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).
- e. Exemption from Public Notice Procedures 42.CFR 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
- f. Enrollment Limitations during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstrations, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.
- g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers suspended by the state, FFP must be limited to normal closeout costs associated with termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals and administrative costs of disenrolling beneficiaries.

10. Withdrawal of Waiver Authority. CMS reserves the right to withdraw waivers and/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. CMS must promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn 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.

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

- 12. 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 the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

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

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

- 14. Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

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

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

| Medicaid State Plan Group | Population Description |
|---|---|
| Adult group under 42 CFR 435.119, including individuals who are medically frail | Individuals age 19 through 64 who are eligible in the 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). |
| Parents & caretaker relatives eligible under 42 CFR 435.110 | Parents and other caretaker relatives, as defined in 42 CFR 435.4, with household income at or below the income standard established by the state, consistent with section 1931 of the Act |

| Medicaid State Plan Group | Population Description |
|---|---|
| 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 6 and a maximum of 12 months of continued coverage under Transitional Medical Assistance. |
| Pregnant women, age 19 and older, eligible under 42 CFR 435.116 | Pregnant women with incomes up to 133 % of FPL who are enrolled in HIP at the time they become pregnant or are determined eligible for HIP after applying for benefits. |

- 2. HIP Demonstration 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 of HIP enrollment. PE members will receive HIP Plus or HIP Basic coverage following transition to HIP per the standard processes.

- a. At state option, Indiana can reclassify presumptively eligible individuals as eligible in the new adult group for up to 3 months prior to the effective date of coverage as outlined in STC 3 of this section. Members transitioned from Adult PE who do not make a POWER Account payment in the 60-day time frame and who have household incomes greater than 100 percent of the FPL will be terminated from HIP.

5. **Pregnant Women.** Pregnant women eligible under 42 CFR 435.116 with income under 133 percent of the FPL will be enrolled into HIP. Women who are enrolled in HIP and report a pregnancy will begin to receive state plan equivalent benefits that are equal to or more generous in all categories than the benefits provided in the HIP ABPs and all required prenatal services. Pregnant beneficiaries have no cost sharing and receive 60 days of postpartum coverage. After the completion of postpartum coverage, the beneficiaries will seamlessly transition back to the appropriate Medicaid eligibility category and will be provided an option to pay for HIP Plus benefits. Newly eligible adults who are pregnant can continue to be claimed by the state at the enhanced match until redetermination, at which time, if the beneficiary identifies as pregnant, that beneficiary must be claimed at the applicable match for pregnant women.
6. **Transitional Medical Assistance.** Beneficiaries whose job income increases to over 133 percent of the FPL can either attain or remain in HIP Plus coverage for up to twelve months. If after the first six months of TMA coverage income remains over 133 percent of the FPL, but below 185 percent of the FPL, coverage can extend an additional six months as long as POWER Account contributions are paid. Except for the income limit and frequency of reporting, all other existing TMA rules will be used for the over 133 percent of the FPL parent/caretaker group. All other individuals that would have previously qualified as TMA with income over the section 1931 limit, but less than 133 percent of FPL will be enrolled directly in HIP and receive the applicable HIP Basic or HIP Plus ABP.

V. BENEFITS

1. **HIP Benefits.** HIP beneficiaries, other than section 1931 parents and caretaker relatives and pregnant women, will receive benefits available in one of the state's approved ABPs. These beneficiaries will have access to the HIP Plus plan containing an enhanced benefit package that includes adult chiropractic, vision, and dental as additional state plan services. Such beneficiaries with income at or below 100 percent of the FPL (other than AI/AN individuals) who do not make their required monthly POWER account contributions within the 60-day payment period, will be defaulted to the HIP Basic benefit plan. Beneficiaries who are section 1931 parents and caretaker relatives will be enrolled in HIP, but will receive all benefits as described in the state plan. Beneficiaries in the new adult group who qualify as medically frail will be enrolled in HIP, but will also receive ABP coverage equivalent to coverage in the state plan.
2. **Calendar Year Benefit Period.** Members have 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 as a voluntary program 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. In the event that the United States Supreme Court issues a decision that would authorize doing so, the state intends to build upon its experience with Gateway to Work, by making 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 would be exempt from the community engagement requirements in the event it is implemented:
 - Students (full-time and part-time);

- Pregnant women;
- Beneficiaries who are a primary caregiver of a dependent child under age 13 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;
- Beneficiaries determined eligible for a good cause exemption as described in STC 7 of this section; and
- Beneficiaries who are members of a federally recognized tribe.

Beneficiaries meeting one or more of the above listed exemptions would 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. In the event a mandatory community engagement requirement is authorized by the Supreme Court, HIP beneficiaries would be able to 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

If the Supreme Court authorizes a community engagement requirement, beneficiaries without an exemption would be required to 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 if authorized by the Supreme Court, the community engagement requirements for all beneficiaries in the HIP demonstration would 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 would be able 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.** In the event the proposed community engagement program is authorized by the Supreme Court, the state would be required to 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 would also be required to 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 would be required to 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 would be required to ascertain individuals' ability to participate and the types of reasonable modifications and supports needed.

- 7. Measurement and Non-Compliance.** If implementation is authorized by the Supreme Court, beneficiaries would not be subject to a review of their community engagement hours until each December. Each December, the state would assess whether a beneficiary has met the community engagement hours requirement for the prior 12-month calendar year. All beneficiaries would be required to meet the community engagement requirements for eight months per calendar year. Some beneficiaries would 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) would also not be counted. Beneficiaries who would be exempt for a partial year, or who participated in the program for a partial year, would still have four months per each calendar year, in which they do not have to complete the community engagement requirements or qualify for an exemption. Months for which the beneficiary has requested an appeal of/has successfully appealed the state's determination of noncompliance (according to state procedures) would 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 would 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 would 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 would 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 would be required to 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 would not be factored into the state's determination of their eligibility for reenrollment into HIP.

- a. Good Cause Exemption. The recognized good cause exemptions that would apply if implementation of the community engagement program is authorized 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;
 - iii. The beneficiary experiences a natural or human- caused disaster (including public health emergency); and
 - iv. 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 would be permitted to 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 if implemented would be effective the first day of the new calendar year.

8. Re-activation During Suspension for Non-Compliance. During suspension for community engagement non-compliance if authorized by the Supreme Court, beneficiaries would be able to 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 would occur based on the specific member eligibility criteria:

- a. If a beneficiary were to become 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 if authorized by the Supreme Court, 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 at least 10 days advance notice in accordance with 42 CFR 431.206-214 and 42 CFR 435.917 and 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 an individual has been screened and determined ineligible for all other bases of Medicaid eligibility prior to disenrollment or denial of 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.
- n. Assess appropriately—including through demonstration evaluation—that there is not a disparate impact on certain beneficiaries based on various sociodemographic characteristics, including gender, sexual orientation, race or ethnicity.

VII. HIP POWER ACCOUNT

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 at least 10 days advance notice in accordance with 42 CFR 431.206-214 and 42 CFR 435.917 and if authorized by the Supreme Court, 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 11(d) of this section. If authorized by the Supreme Court, individuals who do not pay their initial contribution and never fully enroll in HIP Plus would not be subject to non-eligibility period for non-payment. If authorized by the Supreme Court, 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 100 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** would 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 would have cost sharing described in STC 11(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 4 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. POWER Account contribution amounts shall not exceed three (3) percent of household income. 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 9 and 10 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. Changes in POWER Account Contribution Tier Amount.** The state will annually assess the amount of the contribution tiers and reserves the right to modify the POWER Account contribution tiers within the limitations set forth in these STCs at STC VII.3.a in response to findings from this annual assessment. The state will notify CMS of upcoming POWER Account contribution changes through a monitoring

report described in these STCs, as well as send a letter stating such changes. The state will notify beneficiaries at least 60 days prior to implementing a POWER Account contribution change.

5. **Grace Period/Payment Period.** Applicants and beneficiaries will have 60 days from the date of the payment invoice to make the required monthly contribution.
6. **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.
7. **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.
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 a 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 would be disenrolled, and if authorized by the Supreme Court, 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 would be required to 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 would have to 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 would be required to 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, would be exempt from any period of non-eligibility that may be implemented.
- 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 could be reinstated to HIP prior to the expiration of the six month non-eligibility period (should the non-eligibility period be authorized by the Supreme Court), 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.

If loss of eligibility is implemented, the state may add additional circumstances for granting exceptions, as it deems necessary. If any of the above criteria are met, the individual could 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 would be required to 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. At 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. The state may assess the nominal copayments, as described in 42 CFR 447.52(b), 447.53(b), and 447.54(b), on any item or service listed in Table 5 up to the maximum allowable amounts for each service.
2. **New Co-payments.** In order to assess a copayment on a new item or service that is not

described in Table 5, the state will submit an amendment and receive approval from CMS before assessing the copayment.

- 3. Changes to Co-payments.** The maximum allowable amounts are updated annually and co-payment amounts described in Table 5 show the allowable amounts for FFY21. The state may assess a lower copayment without the need for an amendment. The state will supply general public and beneficiary notices consistent with 42 CFR 447.57(a) and (b) prior to implementing changes. The state will notify beneficiaries at least 60 days prior to implementing a co-payment change.

| Table 5. Co-payments for FFY21 | |
|---|---------|
| HIP Basic | |
| Preventive Care Services (including family planning and maternity services) | \$0 |
| Outpatient Services | \$4.70 |
| Inpatient Services | \$87.90 |
| Preferred Drugs | \$4.70 |
| Non-Preferred Drugs | \$9.40 |
| HIP Basic & HIP Plus | |
| Non-emergent use of the ER | \$8 |

- 4. Beneficiary and State Contributions: State Assurances.** The state shall make the general assurance that it is in compliance with protections for beneficiaries related to Section III STC 2, and will:
- Permit the MCO to attempt to collect the unpaid premiums from the beneficiary, but the MCO may not report the premium amount owed to credit reporting agencies, place a lien on a beneficiary's home, refer the case to debt collectors, file a lawsuit, or seek a court order to seize a portion of the beneficiary's earnings for enrollees at any income level. The state will not "sell" the obligation for collection by a third-party. Further, while the amount is collectible by the state, re-enrollment is not conditioned upon repayment.
 - Monitor that beneficiaries do not incur household cost sharing and premiums that, when combined, exceed five (5) percent of the aggregate household income, in accordance with 42 CFR 447.56(f), without regard to MCO enrollment of members in the household. Once a household reaches the cap, the state assures that no further copayments can be charged to beneficiaries, and the premium amount will be reduced for the remainder of the quarter.
 - Charge copayment amounts, if applicable, that do not exceed Medicaid cost sharing permitted by federal law and regulation in accordance with 42 CFR 447.52-56 and the terms of this demonstration.

- d. Ensure that the state, or its designee, does not pass along the cost of any surcharge associated with processing payments to the beneficiary. Any surcharges or other fees associated with payment processing are considered an administrative expense by the state.
- e. Ensure that all payments from the beneficiary, or on behalf of the beneficiary, are accurately credited toward unpaid premiums in a timely manner, and provide the beneficiary an opportunity to review and seek correction of the payment history.
- f. Ensure that the state has a process to refund any POWER Account contributions paid for a month in which the beneficiary is ineligible for Medicaid services for that month.
- g. Ensure that a beneficiary will not be charged a higher premium the following month due to nonpayment or underpayment of a premium in the previous month(s), except that amounts outstanding and due from the previous month/s may be reflected separately on subsequent invoices.
- h. Conduct outreach and education to beneficiaries to ensure that they understand the program policies regarding good cause, premiums and associated consequences for nonpayment. Beneficiaries must be informed of how premium payments should be made; the potential impact of a change in income on premium payments owed; the consequences of failure to report a change in income or circumstances that affect eligibility; the time period over which income is calculated (e.g., monthly income); the deadline for reporting changes in circumstances; and how to reenroll if disenrolled for non-payment of premiums.
- i. Provide all applicants timely determinations of eligibility in accordance with 42 CFR 435.912.
- j. Provide all applicants and beneficiaries with timely and adequate written notices of any decision affecting their eligibility, including an approval, denial, termination, or suspension of eligibility, or a denial or change in benefits and services pursuant to 42 CFR 435.917 and consistent with 42 CFR 435.905(b) and 431.206-214.
- k. The state must send a notice at least 10 days in advance of the date of action (as defined at 42 CFR 431.201 pursuant to 42 CFR 431.211-214).
- l. Provide all applicants and beneficiaries with fair hearing rights consistent with 42 CFR part 431, subpart E.
- m. Ensure program information is available, and accessible in accordance with 42 CFR 435.901 and 435.905.
- n. Provide beneficiaries written notice of requirements to qualify for reactivation of Medicaid coverage following disenrollment due to non-payment of POWER Account contributions described in Section VII STC 11.
- o. Provide notice (consistent with 42 CFR 435.917 and 431.206-214) in advance of any adverse action, including information about the non-eligibility period with an explanation of

what the status means, including but not limited to: the right to appeal; the right to apply for Medicaid on a basis not affected by this status; what the suspension status means with respect to the 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 to do if 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.

- p. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable accommodations related to premium payments.
- q. Maintain a system that identifies, confirms, and provides reasonable accommodations related to the obligation to pay premiums 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.
- r. Assess appropriately—including through demonstration evaluation—that there is not a disparate impact on certain beneficiaries based on various sociodemographic characteristics, including gender, sexual orientation, race or ethnicity

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. In the event a loss of eligibility is implemented following a Supreme Court decision, individuals who do not complete this request prior to the expiration of their HIP coverage will be disenrolled, and the individual will be prohibited from re-enrollment as described in STC 2 of this section.
2. **Failure to Complete a Redetermination.** Beneficiaries that fail to provide necessary information or documentation to complete the redetermination process will be disenrolled from HIP, in accordance with Medicaid regulations. Redetermination begins 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 disenrolled from the program. Beneficiaries subject to disenrollment will be granted a 90-day reconsideration period to submit their redetermination paperwork to be reenrolled in HIP without submitting a new application consistent with 42 CFR 435.916(a)(3)(iii). 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 will not be able to terminate eligibility if the beneficiary has provided documentation that the state has not processed yet, provided the beneficiary returned the required documentation prior to the end of the eligibility period consistent with 42 CFR 435.930(b). The state must also determine the beneficiary ineligible for all other bases of Medicaid eligibility prior to disenrollment and review him/her for eligibility for other insurance affordability programs in accordance with 42 CFR 435.916(f).
 - b. If implemented following a Supreme Court decision, the state would not be permitted to 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. If implemented following a Supreme Court decision, any beneficiary who becomes pregnant or is determined to be medically frail during the non-eligibility period can reapply and if determined eligible, re-enroll, 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 would be 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) would also be 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, would, if a non-eligibility period is implemented, be permitted to re-enroll prior to the expiration of the three-month non-eligibility period by providing verification of the exception.
 - e. If a non-eligibility period is implemented, the state would not be permitted to 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.** If a non-eligibility period is implemented following a Supreme Court decision the State would be required to do the following:

- a. Have a renewal process, including ex parte renewals and use of pre-populated forms, consistent with all applicable Medicaid requirements, for at least twelve months prior to implementation of the demonstration.
- b. Maintain or improve upon systems in place with the goal of completing to complete ex parte renewals based on available information for at least 75 percent of their beneficiaries, not including beneficiaries in a non-eligibility period or suspension at the time of the redetermination.
- c. Maintain timely processing of applications to avoid further delays in accessing benefits once the non-eligibility period is over.
- d. Include good cause exceptions to the non-eligibility period that would allow beneficiaries to re-enroll under certain conditions without waiting three months, including but not limited to the following:
 - i. Obtained and subsequently lost private insurance coverage;
 - ii. Had a loss of income after disqualification due to increased income;
 - iii. Took up residence in another state and later returned;
 - iv. Is a victim of domestic violence;
 - v. Was residing in a county subject to a disaster declaration made in accordance with IC 10-14-3-12 at the time the member was terminated for non-payment or at any time in the 60 calendar days prior to date of member termination for non-payment;
 - vi. The beneficiary is hospitalized, otherwise incapacitated, or has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and as a result was unable to provide information necessary to complete the redetermination during the entire ninety redetermination or reconsideration reporting period, or is a person with a disability who was not provided with reasonable modifications needed to complete the process, or is a person with a disability and there were no reasonable modifications that would have enabled the individual to complete the process; or
 - vii. A member of the beneficiary's immediate family who was living in the home with the beneficiary was institutionalized or died during the redetermination reporting period or the immediate family member has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and caretaking or other disability-related responsibilities resulted in an inability to complete redetermination.

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

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

allow them to re-enroll during a non-eligibility period. Such notice must include an explanation of the availability of good cause exceptions, as indicated in STC3(d) of this section.

- g. Provide notice to beneficiaries, prior to adverse action, regarding the non-eligibility period, and explaining what this status means, including but not limited to: their right to appeal, their right to apply for Medicaid on a basis not affected by this status, what this status means with respect to their ability to access other coverage (such as coverage in a qualified health plan through the Exchange, or access to premium tax credits through the Exchange), what they should do if their circumstances change such that they may be eligible for coverage in another Medicaid category, as well as any implications with respect to whether they have minimum essential coverage.
 - h. Provide beneficiary education and outreach that supports compliance with redetermination requirements, such as through communications or coordination with state-sanctioned assistors, providers, MCOs, or other stakeholders.
 - i. Provide full appeal rights prior to disenrollment and observe all requirements for due process for beneficiaries who will be disenrolled for failing to provide the necessary information to the state to complete their redeterminations to allow beneficiaries the opportunity to raise additional issues in a hearing, including whether the beneficiary should be subject to the non-eligibility period and/or provide additional documentation through the appeals process.
 - j. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable modifications that will assist them in meeting redetermination requirements
 - k. Provide reasonable modifications to the annual redetermination process to beneficiaries with disabilities protected by the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Patient Protection and Affordable Care Act to enable and assist them in completing the annual redetermination process.
- 4. MCO Selection Period.** MCO selection is held annually from November 1 – December 15. During this period, beneficiaries can switch MCO plans. If an individual is in a non-eligibility period, should one be imposed following a Supreme Court decision, 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 | Services provided to individuals in IMDs |

| | | |
|--|------------------------------|--|
| | anticipated SPA approval) | |
|--|------------------------------|--|

- 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 a 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, 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.** The state's SUD Implementation Plan, initially approved for the period from February 1, 2018 through December 31, 2020, remains in effect for the approval period from January 1, 2021 through December 31, 2025, and is affixed to the STCs as Attachment C. Any future modifications to the approved Implementation Plan will require CMS approval. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral.

The approved SUD Implementation Plan describes 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 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 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 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. **MAT 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 9 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 a SUD Monitoring 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. The state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs as Attachment D. Progress on the performance measures identified in the Monitoring Protocol must be reported via the quarterly and annual monitoring reports. Components of the Monitoring Protocol include:
- a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 3 of this section and reporting relevant information to the state's Health IT plan described in STC 9;
 - b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section XIII of the demonstration; and
 - c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.
5. **Mid-Point Assessment.** The state must conduct an independent mid-point assessment by December 31, 2023. In the design, planning and conduction of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including,

but not limited to: representatives of managed care organizations (MCO), SUD treatment providers, beneficiaries, and other key partners.

The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 days after December 31, 2023. This timeline will allow for the assessment report to capture approximately the first two-and-a-half years of demonstration program data, accounting for data run-out and data completeness. The state must brief CMS on the report.

For milestones and measure targets at medium to high risk of not being achieved, the state must submit to CMS modifications to the SUD Implementation Plan and the SUD Monitoring Protocol for ameliorating these risks. Modifications to the Implementation Plan and Monitoring Protocol are subject to CMS approval. Elements of the mid-point assessment include:

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

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 Plan, as determined by CMS, or fails to report data as approved in the SUD Monitoring Protocol, CMS will defer funds in the amounts specified in Section XIII STC 1 for each incident of insufficient progress or failure to report in each reporting quarter.

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

quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.

8. **SUD Evaluation.** The SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections XIII (General Reporting Requirements) and XVI (Evaluation of the Demonstration) of these STCs. The state will follow CMS guidelines to ensure the evaluation design is developed and amended to support a rigorous evaluation of the SUD component of the demonstration.
9. **SUD Health Information Technology (Health IT).** The state has provided 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, has been included as a section of the state’s Implementation Plan (see STC 3 of this section). The SUD Health IT Plan does detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The Plan also is used to identify areas of SUD health IT ecosystem improvement.
 - a. The SUD Health IT section of the Implementation Plan includes implementation milestones and dates for achieving them (see Attachment C).
 - 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. Components of the Health IT Plan include:
 - i. The SUD Health IT Plan describes the state’s goals, each DY, to enhance the state’s prescription drug monitoring program’s (PDMP).¹
 - ii. The Health IT Plan must address how the state’s PDMP will enhance ease of use for prescribers and other state and federal stakeholders.² This must also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients’ history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.

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.*

- iii. The 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 Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.
- iv. The Health IT Plan will describe how the activities described in (i), (ii) and (iii) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.³
- v. The Health IT Plan will describe the state's current and future capabilities to support providers implementing or expanding Health IT functionality in the following areas: 1) Referrals, 2) Electronic care plans and medical records, 3) Consent, 4) Interoperability, 5) Telehealth, 6) Alerting/analytics, and 7) Identity management.
- vi. In developing the Health IT Plan, states should use the following resources:
 - i. States may use federal resources available on Health IT.Gov (<https://www.healthit.gov/topic/behavioral-health>) including but not limited to “Behavioral Health and Physical Health Integration” and “Section 34: Opioid Epidemic and Health IT” (<https://www.healthit.gov/playbook/health-information-exchange/>).
 - 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.
- vii. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

XI. SERIOUS MENTAL ILLNESS

³ Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017;66. Page 38 of 173

- 1. Serious Mental Illness (SMI) Program Benefits.** Under this demonstration, beneficiaries will have access to high quality, evidence-based behavioral health treatment services. These services will range in intensity from short-term acute care in settings that qualify as an IMD to ongoing chronic care for such conditions in cost-effective community-based settings. The state must achieve a statewide average length of stay (ALOS) of no more than 30 days in inpatient treatment settings, to be monitored pursuant to the SMI Monitoring Plan as outlined in STCs 4 of this section.

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

| Table 7. SMI Benefits Coverage | | | |
|---|-------------|--|--|
| Benefit | Type | Medicaid Authority | Expenditure Authority |
| Crisis Stabilization Services | SMI/ SED | State plan (Individual services covered) | N/A |
| Outpatient services | SMI/SED | State plan (Individual services covered) | N/A |
| Intensive outpatient treatment (IOT) services | SMI/SED | State plan (Individual services covered) | N/A |
| Inpatient (acute) services | SMI | State plan (Individual services covered) | Services provided to individuals in IMDs |
| Medicaid Rehabilitation Option (MRO) | SMI/SED | State plan (Individual services covered) | N/A |
| Adult Mental Health Habilitation | SMI | State plan (Individual services covered) | N/A |
| Children's Mental Health Wraparounds | SMI/SED | State plan (Individual services covered) | N/A |
| Behavioral & Primary Healthcare Coordination | SMI | State plan (Individual services covered) | N/A |

2. SMI Implementation Plan.

- a. The state's SMI Implementation Plan, initially approved by CMS on December 20, 2019 for the period from January 1, 2020 through December 31, 2020, remains in effect for the approval period from January 1, 2021 through December 31, 2025, and is affixed to the STCs as Attachment F. Any future modifications to the approved Implementation Plan will require CMS approval. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral as described in Section X STC7.

- b. The approved SMI Implementation Plan describes the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:

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

- A. Participating hospitals must be licensed or approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals prior to the state claiming FFP for services provided to beneficiaries residing in a hospital that meets the definition of an IMD. In addition, hospitals must be in compliance with the conditions of participation set forth in 42 CFR Part 482 and be either: a) certified by the state agency as being in compliance with those conditions through a state agency survey, or b) deemed status to participate in Medicare as a hospital through accreditation by a national accrediting organization whose psychiatric hospital accreditation program or acute hospital accreditation program has been approved by CMS.
- B. Establishment of an oversight and auditing process that includes unannounced visits for ensuring participating psychiatric hospitals meet state licensure or certification requirements as well as a national accrediting entity's accreditation requirements;
- C. Use of a utilization review entity (for example, a managed care organization or administrative service organization) to ensure beneficiaries have access to the appropriate levels and types of care and to provide oversight to ensure lengths of stay are limited to what is medically necessary and only those who have a clinical need to receive treatment in psychiatric hospitals are receiving treatment in those facilities;
- D. Establishment of a process for ensuring that participating psychiatric hospitals meet federal program integrity requirements and establishment of a state process to conduct risk-based screening of all newly enrolling providers, as well as revalidating existing providers (specifically, under existing regulations, the state must screen all newly enrolling providers and reevaluate existing providers pursuant to the rules in 42 CFR Part 455 Subparts B and E, ensure treatment providers have entered into Medicaid provider agreements pursuant to 42 CFR 431.407, and establish rigorous program integrity protocols to safeguard against fraudulent billing and other compliance issues);
- E. Implementation of a state requirement that participating psychiatric hospitals screen enrollees for co-morbid physical health conditions and substance use disorders (SUDs) and demonstrate the capacity to address co-morbid physical health conditions during short-term stays in inpatient treatment settings (e.g., with on-site staff, telemedicine, and/or partnerships with local physical health providers).

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

- A. Implementation of a process to ensure that psychiatric hospitals provide intensive pre-discharge, care coordination services to help beneficiaries transition out of those settings into appropriate community-based outpatient services, including requirements that community-based providers participate in transition efforts (e.g., by allowing initial services with a community-based provider while a beneficiary is still residing in these settings and/or by hiring peer support specialists to help beneficiaries make connections with available community-based providers, including, where applicable, plans for employment);
- B. Implementation of a process to assess the housing situation of a beneficiary transitioning to the community from psychiatric hospitals and to connect beneficiaries who are homeless or who have unsuitable or unstable housing with community providers that coordinate housing services, where available;
- C. Implementation of a requirement that psychiatric hospitals have protocols in place to ensure contact is made by the treatment setting with each discharged beneficiary within 72 hours of discharge and to ensure follow-up care is accessed by individuals after leaving those facilities by contacting the individuals directly and by contacting the community-based provider they were referred to;
- D. Implementation of strategies to prevent or decrease the length of stay in emergency departments among beneficiaries with SMI (e.g., through the use of peers and psychiatric consultants in EDs to help with discharge and referral to treatment providers);
- E. Implementation of strategies to develop and enhance interoperability and data sharing between physical, SUD, and mental health providers, with the goal of enhancing coordination so that disparate providers may better share clinical information to improve health outcomes for beneficiaries with SMI.

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

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

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

- A. Implementation of strategies for identifying and engaging individuals, particularly adolescents and young adults, with SMI in treatment sooner, including through supported employment and supported education programs;
 - B. Increasing integration of behavioral health care in non-specialty care settings, including schools and primary care practices, to improve identification of SMI conditions sooner and improve awareness of and linkages to specialty treatment providers;
 - C. Establishment of specialized settings and services, including crisis stabilization services, focused on the needs of young people experiencing SMI.
3. **SMI Health IT Plan.** The Health IT plan is intended to apply only to those State Health IT functionalities impacting beneficiaries within this demonstration and providers directly funded by this demonstration. 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. If the state is unable to provide such an assurance, it will submit to CMS a Health IT Plan, to be included as a section of the applicable Implementation Plan (see STC 2 of this section), to develop the infrastructure/capabilities of the state's health IT infrastructure.

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

The state will include in its Monitoring Plans (see STC 4 of this section) an approach to monitoring its SMI/SED Health IT Plan which will include performance metrics to be approved in advance by CMS.

The state will monitor progress, each DY, on the implementation of its SMI/SED Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Report (see STC 6 of this section).

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

Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally-recognized standards, barring another compelling state interest.

Where there are opportunities at the state- and provider-level to leverage federal funds

associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling state interest.

Components of the Health IT Plan include:

- A. The 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 *SED/SMI* care delivery. 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.
 - i. The Health IT Plan will describe the state's current and future capabilities to support providers implementing or expanding Health IT functionality in the following areas: 1) Referrals, 2) Electronic care plans and medical records, 3) Consent, 4) Interoperability, 5) Telehealth, 6) Alerting/analytics, and 7) Identity management.
 - ii. In developing the Health IT Plan, states should use the following resources:
 1. States may use federal resources available on Health IT.Gov (<https://www.healthit.gov/topic/behavioral-health>) including but not limited to "Behavioral Health and Physical Health Integration" and "*Section 34: Opioid Epidemic and Health IT*" (<https://www.healthit.gov/playbook/health-information-exchange/>).
 2. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at <https://www.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.
 3. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.
- d. **SMI Financing Plan.** As part of the approved SMI implementation plan referred to in STC 2 of this section, the state's SMI Financing Plan is also incorporated into the STCs as part of the SMI Implementation Plan in Attachment F. Further alterations require CMS approval. Components of the financing plan includes:
 - i. A plan to increase the availability of non-hospital, non-residential crisis stabilization services, including but not limited to the following: services made available through crisis call centers, mobile crisis units, coordinated community response services that includes law enforcement and other first responders, and observation/assessment centers; and
 - ii. A plan to increase availability of ongoing community-based services such as intensive outpatient services, assertive community treatment, and services delivered in integrated care settings;

- iii. A plan to ensure the on-going maintenance of effort (MOE) on funding outpatient community-based services to ensure that resources are not disproportionately drawn into increasing access to treatment in inpatient and residential settings at the expense of community-based services.

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

- a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 2 of this section reporting relevant information to the state's SMI financing plan described in Attachment F, and reporting relevant information to the state's Health IT plans described in STC 3 of this section;
- b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section XIII of the demonstration; and
- c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

5. **SMI Mid-Point Assessment.** The state must conduct an independent mid-point assessment by December 31, 2023. In the design, planning and conduct of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of MCOs, SMI providers, and beneficiaries.

The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 days after December 31, 2023. The state must brief CMS on the report.

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

Elements of the mid-point assessment include:

- a. An examination of progress toward meeting each milestone and timeframe approved in

- the SMI, the SMI Financing Plan, and toward meeting the targets for performance measures as approved in the SMI Monitoring Protocol;
- b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;
 - c. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets;
 - d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's SMI or SMI Financing Plan or to pertinent factors that the state can influence that will support improvement; and
 - e. An assessment of whether the state is on track to meet the budget neutrality
6. **Evaluation.** The SMI Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections XIII (General Reporting Requirements) and XVI (Evaluation of the Demonstration) of these STCs. The state will follow CMS guidelines to ensure the evaluation design is developed and amended to support a rigorous evaluation of the SMI component of the demonstration.
7. **Availability of FFP for the SMI Services under the SMI IMD expenditure authority.** FFP is only available for services provided to beneficiaries during short term stays for acute care in IMDs. The state may claim FFP for stays up to 60 days as long as it shows at its midpoint assessment that it is meeting the requirement of a 30 day or less average length of stay (ALOS). Stays in IMDs that exceed 60 days are not eligible for FFP under this demonstration. If the state cannot show that it is meeting the 30 day or less ALOS requirement within one standard deviation at the mid-point assessment, the state may only claim FFP for stays up to 45 days until such time that the state can demonstrate that it is meeting the 30 day or less ALOS requirement. The state assures that it will provide coverage for stays that exceed 60 days—or 45 days, as relevant—with other sources of funding if it is determined that a longer length of stay is medically necessary for an individual beneficiary.
8. **Unallowable Expenditures Under the SMI IMD Expenditure Authority.** In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:
- a. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.
 - b. Costs for services provided in a nursing facility as defined in section 1919 of the Act that qualifies as an IMD.
 - c. Costs for services provided to individuals who are involuntarily residing in a psychiatric hospital or residential treatment facility by operation of criminal law.
 - d. Costs for services provided to beneficiaries under age 21 residing in an IMD unless the IMD meets the requirements for the “inpatient psychiatric services for individuals under age 21” benefit under 42 CFR 440.160, 441 Subpart D, and 483 Subpart G.

XII. DELIVERY SYSTEM

1. **Managed Care Requirements.** The state must comply with the managed care regulations published at 42 CFR 438. Capitation rates shall be developed and certified as actuarially sound, in accordance with 42 CFR 438.4 through 438.8.
2. **Public Contracts.** Payments under contracts with public agencies, that are not competitively bid in a process involving multiple bidders, shall not exceed the documented costs incurred in furnishing covered services to eligible individuals (or a reasonable estimate with an adjustment factor no greater than the annual change in the consumer price index).
3. **Network Requirements.** The state must deliver all covered benefits, ensuring high quality care. Services must be delivered in a culturally competent manner, and the MCO network must be sufficient to provide access to covered services. In addition, the MCO must coordinate health care services for demonstration populations. The following requirements must be included in the state's MCO contracts:
 - a. **Special Health Care Needs.** Beneficiaries with special health care needs must have direct access to a specialist, as appropriate for the individual's health care condition, as specified in 42 CFR 438.208(c)(4).
 - b. **Out of Network Requirements.** The state, through its contracts with the HIP MCOs, will require the MCOs to provide out of network benefits in the following situations:
 - i. Each MCO must allow access to non-network providers, when services cannot be provided consistent with the timeliness standards required by the state.
 - ii. During the transition of beneficiaries into HIP MCOs, for any provider seen by the beneficiary during the month in which enrollment is effectuated, MCOs will honor previous care authorizations for a minimum of 30 calendar days from the member's date of enrollment with the MCO, or date the member paid their contribution (whichever is later) even on a non-network basis.
4. **HIP Managed Care Organizations (MCO).** HIP beneficiaries shall be enrolled to receive service through an MCO under contract to the state, as provided under the state plan. The MCOs are subject to the federal laws and regulations in 42 CFR Part 438. The HIP beneficiary will be given an opportunity to select an MCO at the time of application. A HIP beneficiary who does not make an MCO selection at the time of application may be auto-assigned to a HIP MCO by the state. Except in cases of presumptive eligibility, auto-assignment may occur after the date in which the state determined their eligibility.

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

methodology must be approved by CMS before implementation.

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

5. MCO Information and Selection. The state shall contract with an enrollment broker to assist interested applicants with their MCO selection so they can make an informed decision in compliance with 42 CFR 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 the remainder of the current calendar year, with exceptions specified in STC 6 of this section.

6. Beneficiary's Right to Change MCOs.

- a. A beneficiary will be automatically re-enrolled into the beneficiary's prior MCO, even if the beneficiary disenrolls and re-enrolls in HIP coverage during the 12-month benefit year.
- b. A beneficiary may change HIP MCOs without cause if the change is requested prior to (i) the date the beneficiary pays their initial POWER account contribution or fast track POWER account prepayment, or (ii) has defaulted into HIP Basic for non-payment of fast-track prepayment or POWER Account contribution whichever comes first. Beneficiaries may seek assistance from the enrollment broker in choosing an MCO. Disenrollment without cause for the reasons identified in 42 CFR 438.56(c)(2)(ii), (iii) and (iv) will also be permitted.
- c. Each November 1- December 15th, beneficiaries will have the opportunity to select their MCO for the coming benefit period. Prior to the open selection period, beneficiaries will be reminded of their ability to select a new MCO. Beneficiaries may make a selection by contacting the enrollment broker.
- d. **For Cause.** A beneficiary may change MCOs for cause at any time and will include this information in all communications about POWER account contributions. "Cause" is defined in 42 CFR 438.56(d)(2). Other reasons as described in 42 CFR 438.56(d)(2)(v), includes, but is not limited to, the following:
 - i. Receiving poor quality care;
 - ii. Failure of the Insurer to provide covered services;
 - iii. Failure of the Insurer to comply with established standards of medical care administration;

- iv. Lack of access to providers experienced in dealing with the enrollee's health care needs;
- v. Significant language or cultural barriers;
- vi. Corrective Action levied against the Insurer by the Family and Social Services Administration (FSSA);
- vii. Limited access to a primary care clinic or other health services within reasonable proximity to a beneficiary's residence;
- viii. A determination that another MCO's formulary is more consistent with a new beneficiary's existing health care needs; or
- ix. Other circumstances determined by FSSA or its designee to constitute poor quality of health care coverage
- x. If a beneficiary was unable to participate in MCO selection period for a qualified reason, they may change their MCO during the first 60 days of the new benefit period or within 60 days of transfer into HIP. Qualified reason for being unable to participate in the MCO selection period include:
 - Member transitioned from other Indiana health care program to HIP.
 - Member was in a non-eligibility period during MCO selection, and returned to the program via a reauthorized case.
 - Member was not fully eligible during MCO selection time.
- xi. The beneficiary must submit his or her request for change to the enrollment broker either orally or in writing. The beneficiary shall still have access to the grievance and appeals process required under the managed care regulations.
- e. If a beneficiary misses the MCO selection period due to temporary loss of eligibility, and then reenrolls in the subsequent benefit year, the beneficiary would be able to change plans when they reenroll.
- f. If the state fails to make a determination by the first day of the second month following the month in which the beneficiary files the request, the request for change will be considered approved and the beneficiary will be transferred into the new MCO.
- g. If a beneficiary is transferred from the MCO, the MCO, must return the remaining balance of the individual's POWER account to the state within 120 days of the last date of participation with the MCO. The state shall then provide the entire remaining

POWER account balance to the new MCO with the information needed to properly track the individual's contribution.

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

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

XIII. GENERAL REPORTING REQUIREMENTS

- 1. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of \$5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singularly or collectively referred to as "deliverable(s)")) are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the demonstration paid under section 1115(a)(2). The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

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

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
- b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.
- c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.

- d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations, and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

2. **Submission of Post-Approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.
3. **Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:
 - a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
 - b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
 - c. Submit deliverables to the appropriate system as directed by CMS.
4. **Implementation Plan.** The state must submit a draft Implementation Plan to CMS for review and comment no later than ninety (90) calendar days after the approval of the demonstration. The state must submit a revised Implementation Plan within sixty (60) calendar days after receipt of CMS's comments. The Implementation Plan must cover at least the key policies being tested under this demonstration, including community engagement, non-eligibility periods, premiums or POWER Account contributions, and waivers of retroactive eligibility. Additionally, the state may be expected to provide additional details not captured in the STCs regarding implementation of the other demonstration policies, such as incentives for healthy behaviors, waiver of NEMT, and the processes involved in modifying POWER Account contributions amount and/or co-payments and any annual assessments that may be undertaken for making such changes. . Once determined complete by CMS, the Implementation Plan will be incorporated into the STCs, as Attachment I. At a minimum, the Implementation Plan must include definitions and parameters of key policies, and describe the state's strategic approach to implementing the policies, including timelines for meeting milestones associated with these key policies. Other topics to be discussed in the Implementation Plan include application assistance, reporting, insurance affordability program; appeal; renewals; coordination with other state agencies; beneficiary protections; and outreach. The state will continue to operate in compliance with information included in the Implementation Plan that CMS will determine complete. Any changes to the operations of the policy components must be consulted with CMS, and may require a formal amendment to the Implementation Plan and resubmission to CMS.
5. **Monitoring Protocol.** The state must submit to CMS a draft Monitoring Protocol no later than one hundred and fifty (150) calendar days after the approval of the demonstration. The

state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments. Once approved, the Monitoring Protocol will be incorporated into the STCs, as Attachment J.

At a minimum, the Monitoring Protocol will affirm the state's commitment to conduct quarterly and annual monitoring in accordance with CMS's templates. Any proposed deviations from CMS's templates should be documented in the Monitoring Protocol. The Monitoring Protocol will describe the quantitative and qualitative elements on which the state will report through quarterly and annual monitoring reports. For quantitative metrics (e.g., performance metrics as broadly described in STC 6 below), CMS will provide the state with performance metrics, and technical specifications for data collection and analysis covering key policies being tested under this demonstration, including but not limited to, community engagement, premiums and cost-sharing, incentives for healthy behaviors, and waiver of retroactive eligibility. The state is also expected to report monitoring data for TMA beneficiaries subject to premiums, including enrollment and disenrollment. The Monitoring Protocol will specify the methods of data collection and timeframes for reporting on the state's progress as part of the quarterly and annual monitoring reports. For the qualitative elements (e.g., operational updates as described in STC 6 below), CMS will provide the state with guidance on narrative and descriptive information which will supplement the quantitative metrics on key aspects of the demonstration policies. The quantitative and qualitative elements will comprise the state's quarterly and annual monitoring reports.

6. **Monitoring Reports.** The state must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth-quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Monitoring Report is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework to be provided by CMS, which will be organized by milestones. The framework is subject to change as monitoring systems are developed/evolve, and will be provided in a structured manner that supports federal tracking and analysis.
 - a. Operational Updates – The operational updates will focus on progress towards meeting the milestones identified in CMS's framework. Additionally, per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments

received through post-award public forums regarding the progress of the demonstration.

- b. Performance Metrics – The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration’s annual goals and overall targets as will be identified in the approved Monitoring Protocol, and will cover key policies under this demonstration, including but not limited to community engagement, premiums and POWER Account payments, including tobacco surcharge, and waivers of retroactive eligibility. The performance metrics will also reflect all other components of the state’s demonstration. For example, these metrics will cover enrollment, disenrollment or suspension by specific demographics (and policy, as applicable), reenrollment after suspension and reentry after disenrollment, participation in community engagement qualifying activities, completion of incentivized health behaviors and rewards granted, unpaid medical bills at application (if available), access to care, and quality of care and health outcomes.

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 the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

- c. Budget Neutrality and Financial Reporting Requirements – Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the CMS-64.
- 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. **Corrective Action Plan Related to Monitoring.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of

implementation of demonstration programs, in circumstances where monitoring indicates indicate substantial and sustained directional change inconsistent with state targets (such as substantial and sustained trends indicating increased difficulty accessing services, increased premium non-payment and disenrollment, unpaid medical bills, etc.). A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in Section III STC 10. CMS will withdraw an authority, as described in Section III STC 10, when metrics indicate substantial, sustained directional change, inconsistent with state targets, and the state has not implemented corrective action. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

8. **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 calendar days after receipt of CMS' comments.
 - e. A delay in submitting the draft or final version of the Close Out Report may subject the state to penalties described in STC 1 of this section.
9. **Monitoring Calls.** CMS will convene periodic conference calls with the state.
 - a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, and progress on evaluation activities.
 - b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
 - c. The state and CMS will jointly develop the agenda for the calls.
10. **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six (6) 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 thirty (30) days prior to the date of the planned public forum, the state must publish the date, time, and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website

with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

XIV. GENERAL FINANCIAL REQUIREMENTS

1. **Standard Medicaid Funding Process.** The standard Medicaid funding process must be used during the demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this Medicaid section 1115 demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state must estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the Form CMS-37 for both the Medical Assistance Payments (MAP) and State and Local Administration Costs (ADM). CMS 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.
2. **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 for the following, subject to the budget neutrality expenditure limits described in section XVI: Budget Neutrality Determination.
 - 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 and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.
3. **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 must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.
 - a. 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.

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

- a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.
- b. To the extent the state utilizes certified public expenditures (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 expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching

funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.

- d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of Title XIX payments.
 - e. Under all circumstances, health care providers must retain 100 percent of the HIP reimbursement amounts claimed by the state as demonstration expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, 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.
- 5. Program Integrity.** The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.
- 6. Medicaid Expenditure Groups (MEG).** MEGs are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The following table provides a master list of MEGs defined for this demonstration.

| Table 4: Master MEG Chart | | | | | |
|----------------------------------|--|-----------------------|----------------------|-----------|------------------------------|
| MEG | To Which BN Test Does This Apply? | WOW Per Capita | WOW Aggregate | WW | Brief Description |
| SUD | Hypo 1 | X | | X | See Expenditure Authority #2 |

| | | | | | |
|-------------------------|--------|---|--|---|------------------------------|
| SMI FFS | Hypo 2 | X | | X | See Expenditure Authority #3 |
| SMI Managed Care | Hypo 3 | X | | X | See Expenditure Authority #3 |

7. Reporting Expenditures and Member Months. The state must report all demonstration expenditures under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00296/5). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of services associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state must also report member months of eligibility for specified MEGs.

- a. Cost Settlements. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.
- b. 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. Pharmacy Rebates. Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.
- d. Administrative Costs. The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the table below, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.
- e. Member Months. As part of the Quarterly and Annual Monitoring Reports described in Section XIII STC 6, the state must report the actual number of “eligible member months” for all demonstration enrollees for all MEGs identified as WOW Per Capita and as also months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.
- f. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state’s Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 3: MEG Detail for Expenditure and Member Month Reporting

| MEG (Waiver Name) | Detailed Description | Exclusions | CMS-64.9 Line(s) To Use | How Expend. Are Assigned to DY | MAP or ADM | Report Member Months (Y/N) | MEG Start Date | MEG End Date |
|-------------------|---|------------|-------------------------|--------------------------------|------------|----------------------------|----------------|--------------|
| SUD | FFS expenditures and managed care capitation for SUD services | | SUD | Date of service | MAP | Y | 02/01/2018 | 12/31/2025 |

| | | | | | | | | |
|-------------------------|--|--|------------------|-----------------|-----|---|------------|------------|
| SMI FFS | FFS expenditure for SMI services | | SMI FFS | Date of service | MAP | Y | 01/01/2020 | 12/31/2025 |
| SMI Managed Care | Managed Care capitation for SMI services | | SMI Managed Care | Date of service | MAP | Y | 01/01/2020 | 12/31/2025 |

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

| Table 4: Demonstration Years | | |
|-------------------------------------|--------------------------------------|-----------|
| Demonstration Year 7 | January 1, 2021 to December 31, 2021 | 12 months |
| Demonstration Year 8 | January 1, 2022 to December 31, 2022 | 12 months |
| Demonstration Year 9 | January 1, 2023 to December 31, 2023 | 12 months |
| Demonstration Year 10 | January 1, 2024 to December 31, 2024 | 12 months |
| Demonstration Year 11 | January 1, 2025 to December 31, 2025 | 12 months |

- 9. Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the “Schedule C Report” for comparing demonstration’s actual expenditures to the budget neutrality expenditure limits described in section XVI STC 7. CMS will provide technical assistance, upon request.⁴
- 10. Claiming Period.** The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be

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

made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

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

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

XV. BUDGET NEUTRALITY DETERMINATION

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

demonstration.

2. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions; however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.
3. **Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.
4. **Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.
5. **Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be “hypothetical;” that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS’s current view that states should not have to “pay for,” with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical

expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending by savings elsewhere in the demonstration or to refund the FFP to CMS.

- 6. Hypothetical Budget Neutrality Test 1: SMI/SED and SUD Initiative.** The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

| Table 6: Hypothetical Budget Neutrality Test | | | | | | | | |
|--|------------|----------------------------|-------|------------|------------|------------|------------|------------|
| MEG | PC or Agg* | WOW Only, WW Only, or Both | TREND | DY 7 | DY 8 | DY 9 | DY 10 | DY 11 |
| SUD | PC | Both | 4.9% | \$7,889.45 | \$8,276.03 | \$8,681.56 | \$9,106.95 | \$9,553.19 |
| SMI FFS | PC | Both | 4.6% | \$5,603.27 | \$5,861.02 | \$6,130.62 | \$6,412.63 | \$6,707.61 |
| SMI Managed Care | PC | Both | 4.6% | \$1,144.80 | \$1,197.46 | \$1,252.54 | \$1,310.16 | \$1,370.43 |

- 7. Composite Federal Share.** The Composite Federal Share is the ration that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on the Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed method. Each Main or Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

- 8 Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from January 1, 2021 to December 31, 2025. If at the end of the demonstration period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.
- 9 Mid-Course Correction.** If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Hypothetical Budget Neutrality Test(s)

| Table 10: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations | | |
|--|--|-------------|
| | Cumulative Target Definition | Percentage |
| DY 7 | Cumulative budget neutrality limit plus: | 2.0 percent |
| DY 7 through DY 8 | Cumulative budget neutrality limit plus: | 1.5 percent |
| DY 8 through DY 9 | Cumulative budget neutrality limit plus: | 1.0 percent |
| DY 9 through DY 10 | Cumulative budget neutrality limit plus: | 0.5 percent |
| DY 10 through DY 11 | Cumulative budget neutrality limit plus: | 0.0 percent |

XVI. EVALUATION OF THE DEMONSTRATION

- 1. 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; providing data and analytic files to CMS; 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 that collect, produce, or maintain data and files for the demonstration, a requirement that they make 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 Section XIII STC1.
- 2. 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 state must require the independent party to sign an agreement to conduct the demonstration evaluation in an independent manner in accord with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

3. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than 180 calendar days after the approval of the demonstration. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable.

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

- a. Attachment A (Developing the Evaluation Design) of these STCs, and all applicable technical assistance on applying robust evaluation approaches, including using comparison groups and beneficiary surveys to develop a Draft Evaluation Design.
 - b. All applicable evaluation design guidance, including guidance about substance use disorder, serious mental illness, community engagement, premiums, waiver of NEMT, co-payment for non-emergent use of emergency department, waiver of retroactive eligibility, and overall demonstration sustainability.
4. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within 60 calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as attachment K 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. Hypotheses for the SUD program must 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. Hypotheses for the SMI component of the demonstration must relate to (but are not limited to): utilization and length of stay in emergency departments, reductions in preventable readmissions to acute care hospitals and residential settings, availability of crisis stabilization services, and care coordination. Community engagement hypotheses must relate to (but are not limited to) the following outcomes: employment levels, income, transitions to commercial health insurance, and health status. Hypotheses for premiums and beneficiary account payments must relate to (but are not limited to) the following outcomes: beneficiary familiarity with premiums as a feature of commercial coverage, efficient use of health services (applicable to states with beneficiary accounts only), and likelihood of enrollment and enrollment continuity. Evaluation of premiums should also account for effectiveness of the tobacco surcharge policy. Hypotheses for disenrollment for non-compliance must relate to (but are not limited to) the following outcomes: beneficiary compliance with demonstration requirements, enrollment

continuity, and health status (as a result of greater enrollment continuity). Hypotheses for the waiver of retroactive eligibility must relate to (but are not limited to) the following outcomes: likelihood of enrollment and enrollment continuity, enrollment when people are healthy, and health status (as a result of greater enrollment continuity). Hypotheses for copayment for non-emergent use of emergency department (ED) must relate to (but are not limited to) the following outcomes: number of ED visits per 1,000 beneficiaries for emergent as well as non-emergent conditions, number of visits per 1,000 beneficiaries to primary care, urgent care clinic, and retail clinic, and average ED waiting time. In addition, the state must investigate cost outcomes for the demonstration as a whole, including but not limited to: administrative costs of demonstration implementation and operation, Medicaid health service expenditures, and provider uncompensated costs. Finally, the state must use results of hypothesis tests and cost analyses to assess demonstration effects on Medicaid program sustainability.

5. **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.
6. **Interim Evaluation Report.** The state must submit Interim Evaluation Reports for the approved evaluation design for the completed years of the demonstration specified in subparagraph c, 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 Reports will discuss evaluation progress and present findings to date as per the approved Evaluation Design.
 - b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
 - c. The state must provide a draft Interim Evaluation Report for the corresponding years, as described in 1-3 below. The state must submit a revised Interim Evaluation Report for each Interim Evaluation Report sixty (60) calendar days after receiving CMS comments on the corresponding draft Report and post the documents to the state's website.
 - 1) A Draft Interim Evaluation Report for demonstration years 1-3 (calendar years 2021 – 2023) will be due no later than December 31, 2024.
 - 2) A Draft Interim Evaluation Report for demonstration years 1-5 (calendar years 2021 – 2025) will be due no later than June 30, 2027.

- 3) A Draft Interim Evaluation Report for demonstration years 1-8 (calendar years 2021 – 2028) will be due no later than December 31, 2029.
 - d. If the state is seeking to renew or extend the demonstration, the last draft Interim Evaluation Report, representing demonstration years 1-8 (calendar years 2021-2028) is due when the application for renewal is submitted.
 - e. The Interim Evaluation Reports 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 a revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.
 - b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.
- 8. Corrective Action Plan Related to Evaluation.** If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of a renewal process when associated with the state's Interim Evaluation Report. A state corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with state targets (such as substantial and sustained trends indicating increased difficulty accessing services, increased premium non-payment and disenrollment, increases in provider uncompensated care costs and unpaid medical bills, etc.) A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in Section III STC 10. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.
- 9. State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.
- 10. Public Access.** The state shall post the final documents (e.g., Monitoring Reports, Close Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 calendar days of approval by CMS.

11. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party connected to the demonstration over which the state has control. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials 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.

Technical assistance resources for constructing comparison groups, identifying causal inferences, phasing implementation to support evaluation, and designing and administering beneficiary surveys are available on Medicaid.gov: <https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html>.

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:
- 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.
 - 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.
 - 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).
 - The application of sensitivity analyses, as appropriate, should be considered.

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.

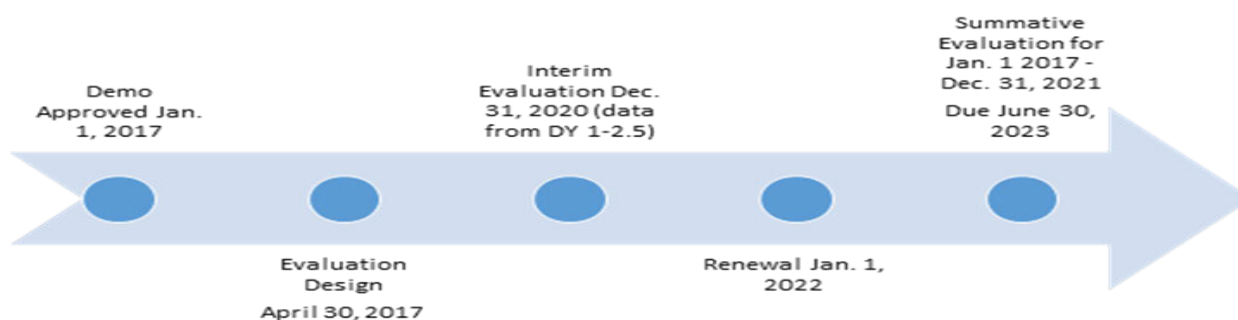
The format for the Interim and Summative Evaluation reports are as follows:

- 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.

A. Methodological Limitations

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

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

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

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

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

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

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

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

F. Attachment

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

Attachment C: SUD Implementation Plan Protocol

State of Indiana 1115 SUD Waiver Implementation Plan

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



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Introduction

Indiana is experiencing the opioid epidemic that has been devastating the United States. Nearly six times as many Hoosiers died from drug overdoses in 2014 as did in 2000, and the number of heroin overdose deaths has increased by nearly 25 times between 2000 and 2014¹. 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 2016².

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

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

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

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

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

Access to Critical Levels of Care for SUD Treatment

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

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

² Based on ICD-10 claims analysis for claims with a date a service between January 1 and December 31, 2016. Excludes tobacco use disorder.

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

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

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

Level of Care: OTS (Opioid Treatment Services)

Summary of Actions Needed:

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

Current State:

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

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

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

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

Future State:

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

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

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

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

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

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

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

Level of Care: 0.5 (Early Intervention)

Summary of Actions Needed:

- None anticipated

Current State:

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

Future State:

No changes are expected at this ASAM level of care.

Level of Care: 1.0 (Outpatient Services)

Summary of Actions Needed:

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

Current State:

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

Office-Based Treatment

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

Community-Based Treatment

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

Services billable through MRO include the following:

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

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

Future State:

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

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

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

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

Level of Care: 2.1 (Intensive Outpatient Services)

Summary of Actions Needed:

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

Current State:

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

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

For providers billing on a UB-04 claim form:

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

For providers billing on a CMS-1500 claim form:

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

Future State:

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

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

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

Level of care: 2.5 (Partial Hospitalization)

Summary of Actions Needed:

- None anticipated

Current State:

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

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

Future State:

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

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

Summary of Action Items:

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

Current State:

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

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

Future State:

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

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

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

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

| | | | |
|--------------|-----------|-------|---------|
| Drug Testing | Encounter | 80101 | \$19.03 |
|--------------|-----------|-------|---------|

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

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

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

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

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

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

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

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

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

Summary of Action Items:

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

Current State:

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

Future State:

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

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

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

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

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

Sub Support Service – Addiction Recovery Management Services

Summary of Action Items:

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

Current State:

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

Future State:

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

- Peer Recovery Support
- Recovery-Focused Case Management

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

| | Peer Recovery Support | Recovery-Focused Case Management |
|----------------|--|---|
| Coding | H0038 (SUD modifier) | T1016 (SUD modifier) |
| Provider Types | <ul style="list-style-type: none"> • Addiction Peer Recovery Coach <p>Other licensed professionals will be allowed to provide this service as long as they are trained as an Addiction Peer Recovery Coach.</p> | <ul style="list-style-type: none"> <input type="checkbox"/> Licensed professionals <ul style="list-style-type: none"> ○ Psychiatrist ○ Licensed Addiction Counselor (LAC) ○ Licensed Clinical Social Worker (LCSW) ○ Licensed Mental Health Counselor (LMHC) ○ Licensed Marriage and Family Therapist (LMFT) ○ Licensed Clinical Addiction Counselor (LCAC) <input type="checkbox"/> Qualified Behavioral Health Provider (QBHP) |
| Eligibility | <ul style="list-style-type: none"> • All Indiana Medicaid members (except for those eligible only for family planning services, emergency services, or QMB-only/SLMB-only/QI coverage) | |

- | | |
|--|---|
| | <ul style="list-style-type: none"> • Must meet medical necessity (have a primary or secondary diagnosis of substance use disorder) |
|--|---|

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

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

Sub Support Service – Supportive Housing Services

Summary of Action Items:

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

Current State:

Indiana Medicaid currently provides no coverage for supportive housing services.

Future State:

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

- Transitioning Services

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

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

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

Withdrawal Management Services (Inpatient Detoxification)

Summary of Action Items:

- Conversation with MCEs regarding authorization criteria

Current State

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

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

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

Indiana Medicaid released [BT201632](#) announcing that inpatient detoxification criteria may be based upon one of the following:

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

Future State:

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

Use of Evidenced-Based SUD-Specific Patient Placement Criteria

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

Patient Assessment

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

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

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

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

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

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

Utilization Management

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sufficient Provider Capacity at Critical Levels of Care

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

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

Addiction Treatment Services Provider (Regular)

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

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

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

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

Addiction Treatment Services Provider (Outpatient)

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

Provider Enrollment

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

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

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

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

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

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

Overall Provider Strategy

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

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

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

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

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

Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse

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

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

Enforcement Recommendations:

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

Treatment Recommendations:

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

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

Gold Card Program

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

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

Buprenorphine Prior Authorization Criteria

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

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

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

Indiana Attorney General's Prescription Drug Abuse Prevention Task Force

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

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

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

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

Prescribing Guidelines

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

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

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

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

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

Expanded Access to Naloxone

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

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

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

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

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

Prescription Drug Monitoring Program

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

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

Improved Care Coordination and Transitions Between Levels of Care

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

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

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

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

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

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

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

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

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

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

Abbreviations

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

Opioid use disorders= OUDs

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

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

Guideline Summary:

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

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

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

Treatment for opioid use disorders shall be comprehensive and include:

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

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

Introduction:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Introduction:

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

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

(i) *Opioid maintenance treatment options:*

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

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

“(1) Opioid-dependent patients should wait until they are experiencing mild to moderate opioid withdrawal before taking the first dose of buprenorphine to reduce the risk of precipitated withdrawal. Generally, buprenorphine initiation should occur at least 6–12 hours after the last use of heroin or other short-acting opioids, or 24–72 hours [or more for individuals taking high doses of opioids] after their last use of long-acting opioids such as methadone.

(2) Induction of buprenorphine should start with a dose of 2–4 mg, [with 8mg inductions being appropriate for a greater degree of physiologic dependence]. Dosages [are often] increased in increments of 2–4mg.

(3) Clinicians should observe patients in their offices during induction.

(4) Buprenorphine doses after induction and titration should be, on average, at least 8mg per day. However, if patients are continuing to use opioids, consideration should be given to increasing the dose by 4–8mg (daily doses of 12–16mg). [While the US FDA approves dosing to a limit of 24mg per day, there is little evidence for clinical benefit beyond 16mg. Dosing beyond 24 mg is not recommended.] In addition, the use of higher doses may increase the risk of diversion.

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

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

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

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

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

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

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

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

(ii) *Detoxification:*

- A. Buprenorphine detoxification (excerpted from ASAM Guidelines [1]): “Buprenorphine can be used for the medically supervised withdrawal of patients from both self-administered opioids and from opioid agonist treatment with methadone.... The goal of using buprenorphine for medically supervised withdrawal from opioids is to provide a transition from the state of physical dependence on opioids to an opioid-free state, while minimizing withdrawal symptoms. Medically supervised withdrawal with buprenorphine consists of an induction phase and a dose-reduction phase. The consensus panel recommends that patients dependent on short acting opioids (e.g., hydromorphone, oxycodone, heroin) who will be receiving medically supervised withdrawal be inducted directly onto buprenorphine/naloxone tablets. The use of buprenorphine (either as buprenorphine monotherapy or buprenorphine/naloxone combination treatment) to taper off long acting opioids should be considered only for those patients who have evidence of sustained medical and psychosocial stability, and should be undertaken in conjunction and in coordination with patients’ OTPs.”
- B. Clonidine detoxification (excerpted from the APA guidelines [2]): “Clonidine is a [non-addictive] centrally acting α_2 -adrenergic antihypertensive medication that effectively decreases the noradrenergic hyperactivity associated with opioid withdrawal. Clonidine is not approved for opioid withdrawal in the United States but has been extensively studied and used for this indication elsewhere. Clonidine reduces withdrawal symptoms such as nausea, vomiting, diarrhea, cramps, and sweating but, unlike methadone, does little to reduce other symptoms such as muscle aches, insomnia, distress, and drug craving [3, 4]. As a non-opioid medication, clonidine has some advantages over methadone for withdrawal. For example, clonidine does not produce opioid-like tolerance or dependence or the post-methadone rebound in withdrawal symptoms [5]. In addition, patients completing a course of clonidine-assisted withdrawal can immediately be given an opioid antagonist (e.g., naltrexone) if indicated. The disadvantages of clonidine include its aforementioned inability to improve certain opioid withdrawal symptoms, associated hypotension that can be profound despite the use of low doses of this medication, and its possible sedative effects. Contraindications to the use of clonidine include acute or chronic cardiac disorders, renal or metabolic disease, and moderate to severe hypotension [6]. On the first day of clonidine-aided detoxification, a clonidine dose of 0.1 mg three times daily (totaling 0.3 mg per 24 hours) is usually sufficient to suppress signs of opioid withdrawal; inpatients can generally receive higher doses to block withdrawal symptoms because of the availability of medical staff to monitor the patient for hypotension and sedation. The dose is adjusted until withdrawal symptoms are reduced. If the patient’s blood pressure falls below 90/60 mm Hg, the next dose should be withheld, after which tapering can be resumed while the patient is monitored for signs of withdrawal. In the case of short-acting opioids such as heroin, clonidine-aided withdrawal usually takes 4–6 days. Other medications may be used along with clonidine to treat withdrawal symptoms. In general, clonidine-assisted detoxification is easier to carry out and monitor in inpatient settings. Clonidine-induced sedation is also less of a problem for inpatients.”

- C. Clonidine-Naltrexone (Excerpted from APA [2]): “The combined use of clonidine and naltrexone for rapidly withdrawing patients from an opioid has been demonstrated to be safe and effective. Essentially, naltrexone-precipitated withdrawal is avoided by pretreating the patient with clonidine. This technique is most useful for opioid dependent patients who are in transition to narcotic antagonist treatment [e.g., naltrexone]. The limitations of this method include the need to monitor patients for 8 hours on the first day because of the potential severity of naltrexone-induced withdrawal and the need for careful blood pressure monitoring during the entire detoxification procedure.”
- D. Supplementary Medications (Excerpted from APA [2]): “Some clinicians and treatment programs have used medications targeting the symptoms of opioid withdrawal as the primary means for treating this condition. For example,..., antiemetics are prescribed to treat nausea and vomiting, NSAIDs are provided for muscle cramps, and antispasmodics [(e.g., dicyclomine)] are used to treat gastrointestinal cramping. There are limited controlled data about the use of such medications for the treatment of opioid withdrawal [8]...Diphenhydramine, hydroxyzine, and sedating antidepressants (e.g., doxepin, amitriptyline, trazodone) have been used for [insomnia and anxiety.] It should be noted that these medications have also been abused, although much less often than benzodiazepines [9]. Other medications such as NSAIDs and antispasmodics may be safely provided but appear to be less effective than mu agonist opioids for symptom relief.”

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

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

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

(iv) *Relapse prevention:*

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

Naltrexone (ASAM guidelines [1]):

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 3. Switching between medications that treat OUDs

Introduction:

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

(Excerpted from ASAM guidelines [1]):

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

- (1) Patient experiences intolerable methadone side effects.
- (2) Patient has not experienced a successful course of treatment on methadone.
- (3) Patient wants to change and is a candidate for the alternative treatment. Transfer of medications should be planned, considered, and monitored. Particular care should be taken in reducing methadone dosing before transfer to avoid precipitating a relapse. If the patient becomes unstable and appears at risk for relapse during the transfer of medications, reinstating methadone may be the best option.

(II) Switching from methadone to buprenorphine:

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

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

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

(III) Switching from Methadone to Naltrexone

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

(IV) Switching from Buprenorphine to Naltrexone

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

(V) Switching to Methadone

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

Section 4. Counseling and Ancillary services for OBOT providers

Introduction:

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

Excerpted from APA Guidelines [2]:

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

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

“1. Cognitive-behavioral therapies

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

2. Behavioral therapies

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

3. Psychodynamic and interpersonal therapies

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

4. Family therapies

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

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

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

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

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

Introduction:

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

Excerpted from ASAM guidelines [1]:

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

- (1) Employment, engagement in mutual help programs, or involvement in other meaningful activities.
- (2) Sustained abstinence from opioid and other drugs during treatment.
- (3) Positive changes in the psychosocial environment.
- (4) Evidence of additional psychosocial supports.
- (5) Persistent engagement in treatment for ongoing monitoring past the point of medication discontinuation.

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

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

(1) Minimal Prescriber Requirements for Buprenorphine Prescribing

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

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

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

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

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

(3) Requirements for INSPECT reviews when prescribing opioids

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

Section 7. Addressing benzodiazepine use

Introduction:

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

Excerpted from Management of Benzodiazepines in Medication-Assisted Treatment

[44]:

“Generally:

1. Individuals must be agreeable to engage in a plan to address their benzodiazepine use before beginning MAT.
2. [The evidence base does not support the use of chronic] benzodiazepines in a person presenting for MAT with methadone or buprenorphine is contraindicated. It presents an extremely high risk for adverse drug reaction involving overdose and/or death during the induction process. [A closely supervised, short-term benzodiazepine taper is indicated in this instance.]
3. CNS [central nervous system] depressant use is not an absolute contraindication for either methadone or buprenorphine, but is a reason for caution because of potential respiratory depression. Serious overdose and death may occur if MAT is administered in conjunction with benzodiazepines, sedatives, tranquilizers, anti- depressants, or alcohol.
4. Individuals who use benzodiazepines, even if used as a part of long-term therapy, should be considered at risk for adverse drug reactions including overdose and death....
6. If a person presenting for MAT will not allow a clinician to coordinate care, he or she [is not] appropriate for methadone and/or buprenorphine

Section 8. Managing Relapse

Introduction:

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

Excerpted from APA guidelines [2]:

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

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

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

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

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

Introduction:

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

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

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

Benefits and advantages

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

Risks and downsides

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

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

Benefits and advantages

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

Risks and downsides

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

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

Benefits and advantages

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

Risks and downsides

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

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

Benefits and advantages

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

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

Risks and downsides

- Naltrexone may cause opioid withdrawal symptoms if started before someone has detoxed from opioids.
- Can cause serious liver problems, although this is more likely when taking high doses of the oral form. Opioid pain medications will not work as well when taking naltrexone. The injection can cause some discomfort, rarely could become infected. Individuals can still overdose on opioids, while taking naltrexone.
- Should not be started during pregnancy.

This information has been reviewed with the client, by the signing physician. Signature of

Client: date:

Signature of

Physician: date:

Section 10. Drug Testing

Introduction:

Testing biological samples for the presence of drugs of abuse is an essential part of the treatment of OUDs. Best practices of drug screening are detailed here.

Excerpted from APA[2]:

“Urine drug testing, or other reliable biological tests for the presence of drugs, during the initial evaluation and frequently throughout treatment, is highly recommended. Results from some studies have indicated that more intensive monitoring of substance use may increase recovery rates from a substance use disorder...There are a variety of toxicology tests available, some with greater and lesser reliability and validity. Urine testing is useful for detecting substance use over the preceding 5-day period for common substances of abuse (cocaine, opiates, cannabis, amphetamines, benzodiazepines, and PCP); however, certain opioids (buprenorphine, oxycodone, hydrocodone, and fentanyl) cannot be detected with routine methods and require special assays. [It is important to screen for the metabolites of the prescribed opioid agonist (e.g. norbuprenorphine), to ensure compliance with the treatment. Point of care testing (e.g., urine testing) is needed to make rapid clinical decisions, supplemented by “send out,” confirmatory

laboratory values.] The person who is interpreting these labs should be very familiar with the methodology and the reliability.

There is little research on the optimal frequency of testing, [however, random drug testing is optimal.]...The frequency of drug testing will be determined by a number of factors, including the stability of the patient, the type of treatment, the treatment setting, and the half-life of drugs in the matrix being tested. Patients will likely require more testing early in treatment or during periods of relapse. Patients participating in office based treatment with buprenorphine may be tested at each office visit.

Opioids are detectable in the urine for 1–3 days after use. A negative urine test combined with no history of withdrawal may indicate a lack of physical dependence.

However, a negative urine test does not rule out opioid use, disorder, or physical dependence. Urine testing is also helpful to identify

- (1) Use of other psychoactive substances.
- (2) If a patient tests positive for an illegal drug...or a controlled substance that the patient is not taking as part of the treatment plan, then the provider needs to review the treatment plan and consider changes with the goal of opioid abstinence.”

Section 11. Pregnant Women with OUDs

Introduction:

Pregnant women have unique needs and require treatment customized to their situation. Best practices for their treatment are highlighted here.

(Excerpted from ASAM guidelines [1])

- “(1) The first priority in “treating” pregnant women for opioid use disorder should be to identify emergent or urgent medical conditions that require immediate referral for clinical evaluation.
- (2) A medical examination and psychosocial assessment is recommended when evaluating pregnant women for opioid use disorder.
- (3) Obstetricians and gynecologists should be alert to signs and symptoms of opioid use disorder. Pregnant women with opioid use disorder are more likely to seek prenatal care late in pregnancy, miss appointments, experience poor weight gain, or exhibit signs of withdrawal or intoxication.

- (4) [As with all patients with OUDs,] psychosocial treatment is [strongly] recommended in the treatment of pregnant women with opioid use disorder.
- (5) Counseling and testing for HIV should be provided in accordance with state law. Tests for hepatitis B and C and liver function are also suggested. Hepatitis A and B vaccination is recommended for those whose hepatitis serology is negative.
- (6) Urine drug testing may be used to detect or confirm suspected opioid and other drug use with informed consent from the mother, realizing that there may be adverse legal and social consequences of her use. State laws differ on reporting substance use during pregnancy. Laws that penalize women for use and for obtaining treatment serve to prevent women from obtaining prenatal care and worsen outcomes.
- (7) Pregnant women who are physically dependent on opioids should receive treatment using methadone or buprenorphine mono-product rather than withdrawal management or abstinence.
- (8) Care for pregnant women with opioid use disorder should be co-managed by an obstetrician and an addiction specialist physician. Release of information forms need to be completed to ensure communication among healthcare providers.
- (9) Treatment with [buprenorphine or] methadone [(within a licensed Opioid Treatment Program)] should be initiated as early as possible during pregnancy.
- (10) Hospitalization during initiation of methadone and treatment with buprenorphine may be advisable due to the potential for adverse events, especially in the third trimester.
- (14) Clinicians should be aware that the pharmacokinetics of [buprenorphine] are affected by pregnancy....Increased or split doses may be needed as pregnancy progresses. After child birth, doses may need to be adjusted.
- (15) Buprenorphine monoprodukt is a reasonable and recommended alternative to methadone for pregnant women. Whereas there is evidence of safety, there is insufficient evidence to recommend the combination buprenorphine/ naloxone formulation.
- (16) If a woman becomes pregnant while she is receiving naltrexone, it is appropriate to discontinue the medication if the patient and doctor agree that the risk of relapse is low. If the patient is highly concerned about relapse and wishes to continue naltrexone, she should be informed about the risks of staying on naltrexone and provide her consent for ongoing treatment. If the patient wishes to discontinue naltrexone, but then reports relapse to opioid use, it may be appropriate to consider treatment with methadone or treatment with buprenorphine.
- (17) Naloxone is not recommended for use in pregnant women with opioid use disorder except in situations of life-threatening overdose.

(18) Mothers receiving methadone and buprenorphine monoprodukt for the treatment of opioid use disorders should be encouraged to breastfeed.

(19) [Naltrexone may be appropriate for a mother after delivery who is capable of detoxification and at risk of relapse.]

Methadone Versus Buprenorphine

The discussion and decision for medication should be reviewed with the patient and documented in her chart. For women who are pregnant or breastfeeding, opioid agonist treatment with methadone or buprenorphine is seen as the most appropriate treatment, taking into consideration effects on the fetus, neonatal abstinence syndrome, and impacts on perinatal care and parenting of young children. Methadone is the accepted standard of care for use during pregnancy; however, buprenorphine monoprodukt is a reasonable alternative and also has some advantages over methadone. Infants born to mothers treated with buprenorphine had shorter hospital stays (10 vs. 17.5 days), had shorter treatment durations for neonatal abstinence syndrome (NAS) (4.1 vs. 9.9 days), and required a lower cumulative dose of morphine (1.1 vs. 10.4 mg) compared to infants born to mothers on treatment with methadone.

Combination Buprenorphine/Naloxone

There is some evidence suggesting that buprenorphine/ naloxone is equivalent in safety and efficacy to the monoprodukt for pregnant women...At present, however, this evidence is insufficient to recommend the combination buprenorphine/naloxone formulation in this population.”

References

1. Sandra Comer, P., et al., National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. 2015, American Society of Addiction Medicine. p. 1-66.
2. WORK GROUP ON SUBSTANCE USE DISORDERS, A.P.A., PRACTICE GUIDELINE for the Treatment of Patients With Substance Use Disorders. 2006.
3. Charney, D.S., et al., The clinical use of clonidine in abrupt withdrawal from methadone. Effects on blood pressure and specific signs and symptoms. Arch Gen Psychiatry, 1981. 38(11): p. 1273- 7.
4. Kleber, H.D., et al., Clonidine in outpatient detoxification from methadone maintenance. Arch Gen Psychiatry, 1985. 42(4): p. 391-4.

5. Cami, J., et al., Efficacy of clonidine and of methadone in the rapid detoxification of patients dependent on heroin. *Clin Pharmacol Ther*, 1985. 38(3): p. 336-41.
6. Jasinski, D.R., R.E. Johnson, and T.R. Kocher, Clonidine in morphine withdrawal. Differential effects on signs and symptoms. *Arch Gen Psychiatry*, 1985. 42(11): p. 1063-6.
7. Collins, E.D., et al., Anesthesia-assisted vs buprenorphine- or clonidine-assisted heroin detoxification and naltrexone induction: a randomized trial. *JAMA*, 2005. 294(8): p. 903-13.
8. O'Connor, P.G., et al., Ambulatory opiate detoxification and primary care: a role for the primary care physician. *J Gen Intern Med*, 1992. 7(5): p. 532-4.
9. Collins ED and K. H, Opioids: detoxification, in *The American Psychiatric Publishing Textbook of Substance Abuse Treatment*, K. Galanter M, Editor. 2004, American Psychiatric Publishing: Washington DC. p. 265-289.
10. HB, G. and A. H, Opioid analgesics, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 10th editon, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, Hardman JG, Limbird LE, and G. AG, Editors. 2001, McGraw-Hill: New York. p. 51.
11. Martin, W.R., Naloxone. *Ann Intern Med*, 1976. 85(6): p. 765-8.
12. S, D., Opioids, in *Emergency Medicine: A Comprehensive Study Guide*, K.G. Tintinalli JE and S. JS, Editors. 2004, McGraw-Hill: New York. p. 1071-1074.
13. Berkowitz, R.L., B.W. Bonta, and J.E. Warshaw, The relationship between premature rupture of the membranes and the respiratory distress syndrome. *Am J Obstet Gynecol*, 1976. 124(7): p. 712-8.
14. Watson, W.A., et al., Opioid toxicity recurrence after an initial response to naloxone. *J Toxicol Clin Toxicol*, 1998. 36(1-2): p. 11-7.
15. Hubbard RL, Marsden ME, and R. JV:, *Drug Abuse Treatment: A National Study of Effectiveness*. Chapel Hill, University of North Carolina Press, 1989.
16. Simpson, D.D., G.W. Joe, and S.A. Bracy, Six-year follow-up of opioid addicts after admission to treatment. *Arch Gen Psychiatry*, 1982. 39(11): p. 1318-23.
17. Simpson, D.D., L.J. Savage, and M.R. Lloyd, Follow-up evaluation of treatment of drug abuse during 1969 to 1972. *Arch Gen Psychiatry*, 1979. 36(7): p. 772-80.
18. Simpson, D.D. and S. Sells, *Opioid Addiction and Treatment: A 12-Year Follow-Up*. 1990.
19. Nyswander, M., The treatment of drug addiction. *Med Clin North Am*, 1958. 42(3): p. 815-22.

20. Woody, G.E., et al., Psychotherapy for opiate addicts. Does it help? Arch Gen Psychiatry, 1983. 40(6): p. 639-45.
21. Woody, G.E., et al., Sociopathy and psychotherapy outcome. Arch Gen Psychiatry, 1985. 42(11): p. 1081-6.
22. Woody, G.E., et al., Twelve-month follow-up of psychotherapy for opiate dependence. Am J Psychiatry, 1987. 144(5): p. 590-6.
23. Woody, G.E., et al., Psychotherapy in community methadone programs: a validation study. Am J Psychiatry, 1995. 152(9): p. 1302-8.
24. Woody, G.E., A.T. McLellan, and C.P. O'Brien, Treatment of behavioral and psychiatric problems associated with opiate dependence. NIDA Res Monogr, 1984. 46: p. 23-35.
25. O'Neill, K., et al., Evaluation of a cognitive-behavioural intervention for pregnant injecting drug users at risk of HIV infection. Addiction, 1996. 91(8): p. 1115-25.
26. McAuliffe, W.E., A randomized controlled trial of recovery training and self-help for opioid addicts in New England and Hong Kong. J Psychoactive Drugs, 1990. 22(2): p. 197-209.
27. McLellan, A.T., et al., The effects of psychosocial services in substance abuse treatment. JAMA, 1993. 269(15): p. 1953-9.
28. Silverman, K., et al., Sustained cocaine abstinence in methadone maintenance patients through voucher-based reinforcement therapy. Arch Gen Psychiatry, 1996. 53(5): p. 409-15.
29. Silverman, K., et al., Broad beneficial effects of cocaine abstinence reinforcement among methadone patients. J Consult Clin Psychol, 1998. 66(5): p. 811-24.
30. Iguchi MY, et al., Contingent reinforcement of group participation versus abstinence in methadone maintenance program. Exp Clin Psychopharmacol, 1996. 4: p. 7.
31. Stitzer, M. and G. Bigelow, Contingency management in a methadone maintenance program: availability of reinforcers. Int J Addict, 1978. 13(5): p. 737-46.
32. Stitzer, M.L., et al., Effect of methadone dose contingencies on urinalysis test results of polydrug- abusing methadone-maintenance patients. Drug Alcohol Depend, 1986. 18(4): p. 341-8.
33. Stitzer, M.L., M.Y. Iguchi, and L.J. Felch, Contingent take-home incentive: effects on drug use of methadone maintenance patients. J Consult Clin Psychol, 1992. 60(6): p. 927-34.
34. Carroll, K.M., et al., Targeting behavioral therapies to enhance naltrexone treatment of opioid dependence: efficacy of contingency management and significant other involvement. Arch Gen Psychiatry, 2001. 58(8): p. 755-61.

35. Carroll, K.M., et al., Contingency management to enhance naltrexone treatment of opioid dependence: a randomized clinical trial of reinforcement magnitude. *Exp Clin Psychopharmacol*, 2002. 10(1): p. 54-63.
36. Grabowski, J., et al., Effects of contingent payment on compliance with a naltrexone regimen. *Am J Drug Alcohol Abuse*, 1979. 6(3): p. 355-65.
37. Greenstein R, Fudala PJ, and O.B. CP, Alternative pharmacotherapies for opiate addiction, in *Substance Abuse: A Comprehensive Textbook*, Lowinson JH, et al., Editors. 1997, Williams and Wilkins: New York. p. 415-424.
38. Meyer, R.E., et al., A behavioral paradigm for the evaluation of narcotic antagonists. *Arch Gen Psychiatry*, 1976. 33(3): p. 371-7.
39. Preston, K.L., et al., Improvement in naltrexone treatment compliance with contingency management. *Drug Alcohol Depend*, 1999. 54(2): p. 127-35.
40. Rounsaville, B.J., Can psychotherapy rescue naltrexone treatment of opioid addiction? *NIDA Res Monogr*, 1995. 150: p. 37-52.
41. Khantzian EJ, Halliday KS, and M. WE, *Addiction and the Vulnerable Self: Modified Dynamic Group Therapy for Substance Abusers*. 1990.
42. Fals-Stewart W, O'Farrell TJ, and B. GR, Behavioral couples therapy for male methadone maintenance patients: effects on drug using behavior and relationship adjustment. *Behavioral therapy*, 2001. 32: p. 391-411.
43. Fals-Stewart, W. and T.J. O'Farrell, Behavioral family counseling and naltrexone for male opioid- dependent patients. *J Consult Clin Psychol*, 2003. 71(3): p. 432-42.
44. *Management of Benzodiazepines in Medication-Assisted Treatment*. 2013, Institute for Research, Evaluation and Training in Addictions with Support from Community Care Behavioral Health Organization. p. 1-26.
45. Connors, G.J., K.S. Walitzer, and K.H. Dermen, Preparing clients for alcoholism treatment: effects on treatment participation and outcomes. *J Consult Clin Psychol*, 2002. 70(5): p. 1161-9.
46. Miller WR and R. S, *Motivational Interviewing: Preparing People for Change*. 2002, New York: Guildford.
47. Chan, K.K., C. Neighbors, and G.A. Marlatt, Treating addictive behaviors in the employee assistance program: implications for brief interventions. *Addict Behav*, 2004. 29(9): p. 1883-7.
48. Domino, K.B., et al., Risk factors for relapse in health care professionals with substance use disorders. *JAMA*, 2005. 293(12): p. 1453-60.
49. Zarkin, G.A., J.W. Bray, and J. Qi, The effect of Employee Assistance Programs use on healthcare utilization. *Health Serv Res*, 2000. 35(1 Pt 1): p. 77-100.

50. Lowman, C., J. Allen, and R.L. Stout, Replication and extension of Marlatt's taxonomy of relapse precipitants: overview of procedures and results. The Relapse Research Group. *Addiction*, 1996. 91 Suppl: p. S51-71.
51. Stewart, J., Pathways to relapse: the neurobiology of drug- and stress-induced relapse to drug- taking. *J Psychiatry Neurosci*, 2000. 25(2): p. 125-36.
52. Substance Abuse and Mental Health Services Administration: Report to Congress on the Prevention and Treatment of Co-Occurring Substance Abuse Disorders and Mental Disorders., U.D.o.H.a.H. Services, Editor. 2002: Washinton DC.
53. Galanter, M., Network therapy for addiction: a model for office practice. *Am J Psychiatry*, 1993. 150(1): p. 28-36.
54. Khantzian, E.J., The primary care therapist and patient needs in substance abuse treatment. *Am J Drug Alcohol Abuse*, 1988. 14(2): p. 159-67.
55. Us Department of Health and Human Services: Brief Interventions and Brief Therapies for Substance Abuse: Treatment Improvement Protocol (TIP) Series, U.S.A.a.M.H.S. Administration, Editor. 1999, DHHS Publication: Rockville, Md.
56. Daley DC and M. GA, Relapse prevention: cognitive and behavioral interventions, in *Substance Abuse: A Comprehensive Textbook*, Lowinson JH, et al., Editors. 1992, Williams and Wilkins: Baltimore, Md. p. 533-542.
57. Miller WR and H. RK, The effectiveness of alcoholism treatment: what research reveals, in *Treating Addictive Behaviors: Processes of Change*. 1986: p. 53.

Attachment D: SUD Monitoring Plan Protocol (reserved)

Attachment E: SUD Evaluation Design (reserved)

Attachment F: SMI Implementation Plan

Section 1115 SMI/SED Demonstration Implementation Plan

Overview: The implementation plan documents the state’s approach to implementing SMI/SED demonstrations. It also helps establish what information the state will report in its quarterly and annual monitoring reports. The implementation plan does not usurp or replace standard CMS approval processes, such as advance planning documents, verification plans, or state plan amendments.

This template only covers SMI/SED demonstrations. The template has three sections. Section 1 is the uniform title page. Section 2 contains implementation questions that states should answer. The questions are organized around six SMI/SED reporting topics:

1. Milestone 1: Ensuring Quality of Care in Psychiatric Hospitals and Residential Settings
2. Milestone 2: Improving Care Coordination and Transitioning to Community-Based Care
3. Milestone 3: Increasing Access to Continuum of Care, Including Crisis Stabilization Services
4. Milestone 4: Earlier Identification and Engagement in Treatment, Including Through Increased Integration
5. Financing Plan
6. Health IT Plan

State may submit additional supporting documents in Section 3.

Implementation Plan Instructions: This implementation plan should contain information detailing state strategies for meeting the specific expectations for each of the milestones included in the State Medicaid Director Letter (SMDL) on “Opportunities to Design Innovative Service Delivery Systems for Adults with [SMI] or Children with [SED]” over the course of the demonstration. Specifically, this implementation plan should:

1. Include summaries of how the state already meets any expectation/specific activities related to each milestone and any actions needed to be completed by the state to meet all of the expectations for each milestone, including the persons or entities responsible for completing these actions; and
2. Describe the timelines and activities the state will undertake to achieve the milestones.

The tables below are intended to help states organize the information needed to demonstrate they are addressing the milestones described in the SMDL. States are encouraged to consider the evidence-based models of care and best practice activities described in the first part of the SMDL in developing their demonstrations.

The state may not claim FFP for services provided to Medicaid beneficiaries residing in IMDs, including residential treatment facilities, until CMS has approved a state’s implementation plan.

Memorandum of Understanding: The state Medicaid agency should enter into a Memorandum of Understanding (MOU) or another formal agreement with its State Mental Health Authority, if one does not already exist, to delineate how these agencies will work together to design, deliver, and monitor services for beneficiaries with SMI or SED. This MOU should be included as an attachment to this Implementation Plan.

State Response: In accordance with Indiana's approved Medicaid State Plan, the Office of the Secretary of the Family and Social Services Administration (FSSA) is the single state agency. The Division of Mental Health and Addiction (DMHA) is within the FSSA; therefore, no MOU is applicable to this waiver request.

State Point of Contact: Please provide the contact information for the state's point of contact for the implementation plan.

Name and Title: Amy Owens
Federal Relations Lead, Indiana Medicaid
Telephone Number: 317-233-7007
Email Address: Amy.Owens@fssa.IN.gov

1. Title page for the state's SMI/SED demonstration or SMI/SED components of the broader demonstration

The state should complete this transmittal title page as a cover page when submitting its implementation plan.

| | |
|----------------------------|---|
| State | <i>Indiana</i> |
| Demonstration name | <i>Healthy Indiana Plan – Project Number 11-W-00296/5</i> |
| Approval date | <i>TBD – Amendment submitted August 30, 2019</i> |
| Approval period | <i>January 1, 2020 – December 31, 2020</i> |
| Implementation date | <i>January 1, 2020</i> |

2. Required implementation information, by SMI/SED milestone

Answer the following questions about implementation of the state's SMI/SED demonstration. States should respond to each prompt listed in the tables. Note any actions that involve coordination or input from other organizations (government or non-government entities). Place "NA" in the summary cell if a prompt does not pertain to the state's demonstration. Answers are meant to provide details beyond the information provided in the state's special terms and conditions. Answers should be concise, but provide enough information to fully answer the question.

This template only includes SMI/SED policies.

| Prompts | Summary |
|---|---|
| SMI/SED. Topic 1. Milestone 1: Ensuring Quality of Care in Psychiatric Hospitals and Residential Settings | |
| <p><i>To ensure that beneficiaries receive high quality care in hospitals and residential settings, it is important to establish and maintain appropriate standards for these treatment settings through licensure and accreditation, monitoring and oversight processes, and program integrity requirements and processes. Individuals with SMI often have co-morbid physical health conditions and substance use disorders (SUDs) and should be screened and receive treatment for commonly co-occurring conditions particularly while residing in a treatment setting. Commonly co-occurring conditions can be very serious, including hypertension, diabetes, and substance use disorders, and can also interfere with effective treatment for their mental health condition. They should also be screened for suicidal risk.</i></p> <p><i>To meet this milestone, state Medicaid programs should take the following actions to ensure good quality of care in psychiatric hospitals and residential treatment settings.</i></p> | |
| Ensuring Quality of Care in Psychiatric Hospitals and Residential Treatment Settings | |
| Assurance that participating hospitals and residential settings are licensed or otherwise authorized by the state primarily to provide mental health treatment; and that residential treatment facilities are accredited by a nationally recognized accreditation entity prior to participating in Medicaid | <p><i>Current Status:</i> In accordance with Indiana Administrative Code (440 IAC 1.5), all free-standing psychiatric hospitals must be licensed as a private mental health institution (PMHI)⁵ by the Indiana Division of Mental Health and Addiction (DMHA). PMHI licensure must be renewed annually. Additionally, all entities must be accredited by an agency approved by DMHA, which currently include the following:</p> <ul style="list-style-type: none"> • National Committee for Quality Assurance (NCQA) • CARF – The Rehabilitation Accreditation Commission • Joint Commission on Accreditation of Healthcare Organizations (JCAHO) <p>The following general components are required for licensure:</p> <ul style="list-style-type: none"> • A governing board |

⁵ Defined as an inpatient hospital setting, including inpatient and outpatient services provided in that setting, for the treatment and care of individuals with psychiatric disorders or chronic addictive disorders, or both, that is physically, organizationally, and programmatically independent of any hospital or health facility licensed by the Indiana State Department of Health.

| Prompts | Summary |
|---------|--|
| | <ul style="list-style-type: none"> • Medical or professional staff organization • A quality assessment and improvement program • Dietetic service • Infection control program • Medical record services • Nursing service • Physical plan, maintenance and environmental services • Intake and treatment services • Discharge planning services • Pharmacy services • A plan for special procedures <p>An entity seeking a license as a PMHI must file an application with DMHA which includes, at minimum:</p> <ul style="list-style-type: none"> • A description of the organizational structure and mission of the applicant • The location of all operational sites of the applicant • The consumer population to be served and program focus • A list of governing board members and executive staff • A copy of the applicant's procedures to ensure protection of consumer rights and confidentiality • Written evidence of an onsite review and inspection by the Indiana Department of Health and Department of Homeland Security Division of Fire and Building Safety and the correction of any deficiencies identified • Proof of accreditation including site survey recommendations from the accrediting agency and the applicant's response to such recommendations <p>To maintain licensure, a PMHI must meet the following conditions:</p> <ul style="list-style-type: none"> • Maintain accreditation from a DMHA approved accrediting agency • Maintain compliance with required health, building, fire and safety codes as prescribed by federal, state and local law • Have written policies and enforce these policies to support and protect the fundamental human, civil, constitutional and statutory rights of each consumer • Comply with requirements for providing, posting and documenting consumer statement of rights under Indiana Code 12-27 • Respond to complaints from the consumer service line in a timely manner |

| Prompts | Summary |
|---|---|
| | <p><i>Future Status:</i> Continued operation of current requirements.</p> <p><i>Summary of Actions Needed:</i> N/A –milestone requirements already met.</p> |
| Oversight process (including unannounced visits) to ensure participating hospital and residential settings meet state’s licensing or certification and accreditation requirements | <p><i>Current Status:</i> DMHA currently conducts annual unannounced site visits of each PMHI. Site visits are conducted using a checklist which crosswalks with all licensure requirements.</p> <p><i>Future Status:</i> Continued operation of current requirements.</p> <p><i>Summary of Actions Needed:</i> N/A –milestone requirements already met.</p> |
| Utilization review process to ensure beneficiaries have access to the appropriate levels and types of care and to provide oversight on lengths of stay | <p><i>Current Status:</i> In accordance with 405 IAC 5-3-13, all inpatient psychiatric, substance abuse and rehabilitation admissions require prior authorization to ensure the appropriate level of care. Medical necessity reviews are completed by Indiana’s managed care organizations (MCOs) and the State’s fee-for-service prior authorization (PA) entity, based on the individual’s enrollment. The PA entity utilizes Milliman Care Guidelines and OMPP reviews the MCO’s UM practices.</p> <p>As described in the Indiana Medicaid Medical Policy Manual, acute psychiatric inpatient admissions are available for enrollees with a sudden onset of a psychiatric condition manifesting itself by acute symptoms of such severity that the absence of immediate medical attention could reasonably be expected to result in one or more of the following:</p> <ul style="list-style-type: none"> • Danger to the individual • Danger to others • Death of the individual <p>Reimbursement is available for inpatient care only when the need for admission has been certified. Emergency and nonemergency admissions require telephonic precertification review. The precertification review must be followed by a written certification of need through completion of State Form 44697 – Certification of the Need for Inpatient Psychiatric Hospital Services (1261A form) along with a written plan of care. This form documents the enrollee’s:</p> <ul style="list-style-type: none"> • Psychiatric and medical evaluation • Functional capacity • Prognoses • Recommendations |

| Prompts | Summary |
|---|---|
| | <ul style="list-style-type: none"> • Certification by an interdisciplinary team that based upon physical, mental and social evaluations the individual requires inpatient psychiatric treatment and available alternative community resources do not meet the patient's mental health care needs <p>All requests for PA are reviewed on a case-by-case basis. The MCO or PA entity reviews each State Form 44697 to determine whether the requested acute inpatient services meet medical necessity. Reimbursement is denied for any days the facility cannot justify a need for inpatient care. If the provider fails to complete a telephone PA precertification, reimbursement will be denied from the admission to the actual date of notification.</p> <p>Additionally, in accordance with 440 IAC 1.5-3-9, all PMHIs must have policies and procedures that govern the intake and assessment process to determine eligibility for services. Each admitted Medicaid enrollee must have a preliminary treatment plan formulated within 60 hours of admission on the basis of the intake assessment at admission, which must specify the services necessary to meet the consumer's needs and contain discharge or release criteria and the discharge plan. Further, progress notes must be entered daily and the consumer's treatment plan must be reviewed at least every seven days.</p> <p><i>Future Status:</i> OMPP will develop a report to monitor average length of stay (ALOS) for all Medicaid programs. All reporting will follow CMS monitoring guidance. Additionally, OMPP will review timeline requirements for submission of the 1261A form.</p> <p><i>Summary of Actions Needed:</i> The Quality and Outcomes section of OMPP, in coordination with the evaluation vendor and MCOs, will develop reporting specifications to implement monitoring for implementation. OMPP will make necessary updates to the provider manuals to reflect any changes by Q2 of 2020. Providers were notified of program changes via bulletin on November 26, 2019.</p> |
| Compliance with program integrity requirements and state compliance assurance process | <p><i>Current Status:</i> In order to receive reimbursement under Medicaid, participating psychiatric hospitals must be enrolled to participate in Indiana Medicaid. Provider enrollment processes fully comply with 42 CFR Part 455 Subparts B&E. As MCOs have been reimbursing IMDs as an in lieu of service and are only permitted to contract with Indiana Medicaid screened and enrolled providers, the State is currently screening and revalidating this provider type.</p> <p><i>Future Status:</i> Continued operation of current requirements.</p> <p><i>Summary of Actions Needed:</i> N/A –milestone requirements already met.</p> |

| Prompts | Summary |
|---|---|
| State requirement that psychiatric hospitals and residential settings screen beneficiaries for co-morbid physical health conditions, SUDs, and suicidal ideation, and facilitate access to treatment for those conditions | <p><i>Current Status:</i> Indiana Administrative Code (440 IAC 1.5-3-9) details a series of required policies and procedures for intake and assessment processes. This includes, but is not limited to completion of the following assessments:</p> <ul style="list-style-type: none"> Physical examination by a licensed physician, advance practice nurse or physician's assistant Emotional, behavioral, social and legal assessment <p>Compliance with these requirements, including screening for SUD, is reviewed during annual site reviews conducted by the DMHA.</p> <p><i>Future Status:</i> Compliance will continue to be monitored via the annual unannounced site visits of hospitals as part of their recertification.</p> <p><i>Summary of Actions Needed:</i> N/A –milestone requirements already met.</p> |
| Other state requirements/policies to ensure good quality of care in inpatient and residential treatment settings. | <p><i>Current Status:</i> DMHA conducts the Mental Health Statistical Improvement Project Survey for Adults and Youth (MHSIP), an annual consumer satisfaction surveys for all individuals who have been served by DMHA contracted providers. In addition, the MCOs conduct annual consumer assessment of healthcare providers and systems (CAHPS) surveys which provide insight into the consumer experience with their healthcare providers. Findings from these surveys are utilized in quality assurance and improvement activities as needed.</p> <p><i>Future Status:</i> Continued operation of current consumer satisfaction surveys.</p> <p><i>Summary of Actions Needed:</i> N/A –milestone requirements already met.</p> |
| SMI/SED. Topic 2. Milestone 2: Improving Care Coordination and Transitioning to Community-Based Care | |
| <i>Understanding the services needed to transition to and be successful in community-based mental health care requires partnerships between hospitals, residential providers, and community-based care providers. To meet this milestone, state Medicaid programs, must focus on improving care coordination and transitions to community-based care by taking the following actions.</i> | |
| Improving Care Coordination and Transitions to Community-based Care | |
| Actions to ensure psychiatric hospitals and residential settings carry out intensive pre-discharge planning, and include community-based providers in care transitions. | <p><i>Current Status:</i> Indiana Administrative Code (440 IAC 1.5-3-10) outlines minimum requirements for discharge planning. Hospitals are required to initiate discharge planning at admission that includes the following:</p> <ul style="list-style-type: none"> Facilitates the provision of follow-up care. Transfers or refers consumers, along with necessary medical information and records, to appropriate facilities, agencies, or outpatient services for follow-up or ancillary care. Required minimum information to be transferred includes: <ul style="list-style-type: none"> Medical history Current medications Available social, psychological and educational services Nutritional needs Outpatient service needs |

| Prompts | Summary |
|---|---|
| | <ul style="list-style-type: none"> ○ Follow-up care needs <p>Additionally, in accordance with the Indiana Medicaid Medical Policy Manual, all plans of care must document a post-discharge plan and a plan for coordination of inpatient services with partial discharge plans, including appropriate services in the member's community to ensure continuity of care when the patient returns to his or her family and community upon discharge.</p> <p>Community mental health centers (CMHCs) are required, as codified in Indiana Administrative Code (440 IAC 9-2-4), to be involved in the planning of treatment for and the discharge of consumers during the time a consumer is in inpatient care, to maintain continuity of care.</p> <p>Additionally, MCOs are contractually required to provide case management services for any member discharged from an inpatient psychiatric or substance abuse hospitalization for no fewer than 90 calendar days following discharge. MCO contracts also require case managers to contact members during an inpatient hospitalization, or immediately upon receiving notification of a member's inpatient behavioral health hospitalization and must schedule an outpatient follow-up appointment to occur no later than seven calendar days following the inpatient behavioral health hospitalization discharge. If a member misses an outpatient follow-up or continuing treatment, the MCO is contractually required to ensure that a behavioral health care provider or the MCO's behavioral health case manager contacts that member within three business days of notification of the missed appointment.</p> <p><i>Future Status:</i> Continued operation of current requirements.</p> <p><i>Summary of Actions Needed:</i> N/A –milestone requirements already met.</p> |
| 2.b Actions to ensure psychiatric hospitals and residential settings assess beneficiaries' housing situations and coordinate with housing services providers when needed and available. | <p><i>Current Status:</i> MCOs are contractually required to provide case management services for any member at risk for or discharged from an inpatient psychiatric or substance abuse hospitalization. Case managers must contact members during an inpatient hospitalization and as a component of case management, must make every effort to assist members in navigating community resources and linking members with community-based services such as Connect2Help211, food pantries, housing and housing supports, legal, employment and disaster services.</p> <p>Additionally, CMHCs are required, in accordance with IAC 440 IAC 9-2-10, as a component of case management, to provide advocacy and referral including helping individuals access entitlement and other services, such as Medicaid, housing, food stamps, educational services, recovery groups, and vocational services.</p> |

| Prompts | Summary |
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| | <p><i>Future Status:</i> Indiana Medicaid Provider Manual will be updated to explicitly require psychiatric hospitals have protocols in place to assess for housing insecurity as part of the social work assessment and discharge planning processes and to refer to appropriate resources. Compliance will be monitored via the annual unannounced site visits of hospitals as part of their recertification. Post-discharge follow-up will continue to be provided by MCOs and providers eligible to deliver case management services.</p> <p><i>Summary of Actions Needed:</i> Provider Manual will be updated by OMPP by Q2 2020. The State issued provider communication materials detailing the requirements on November 26, 2019.</p> |
| 2.c State requirement to ensure psychiatric hospitals and residential settings contact beneficiaries and community-based providers through most effective means possible, e.g., email, text, or phone call within 72 hours post discharge | <p><i>Current Status:</i> MCOs currently undertake the primary responsibility for assuring enrollees access follow-up care post-discharge. They are contractually required to schedule an outpatient follow-up appointment to occur no later than seven calendar days following an inpatient behavioral health hospitalization discharge. If a member misses an outpatient follow-up appointment, the MCO must ensure that a behavioral health provider or the MCO's case manager contacts that member within three business days of notification of the missed appointment.</p> <p>Additionally, Indiana Medicaid provides coverage for bridge appointments, which are follow-up appointments after inpatient hospitalization for behavioral health issues, when no outpatient appointment is available within seven days of discharge. The goal of the bridge appointment is to provide proper discharge planning while establishing a connection between the member and the outpatient treatment provider.</p> <p>During the bridge appointment, the provider ensures, at minimum, the following:</p> <ul style="list-style-type: none"> • The member understands the medication treatment regimen as prescribed. • The member has ongoing outpatient care. • The family understands the discharge instructions for the member. • Barriers to continuing care are addressed. • Any additional questions from the member or family are answered. <p><i>Future Status:</i> Indiana Medicaid Provider Manual will be updated to explicitly require psychiatric hospitals have protocols in place to ensure contact is made by the treatment setting with each discharged beneficiary within 72 hours of discharge and follow-up care is accessed. Compliance will be monitored via the annual unannounced site visits of hospitals as part of their recertification.</p> <p><i>Summary of Actions Needed:</i> Provider Manual will be updated by OMPP by Q2 2020. A provider bulletin detailing these requirements was published on November 26, 2019.</p> |
| 2.d Strategies to prevent or decrease lengths of stay in EDs | <p><i>Current Status:</i> MCOs are required to identify high utilizers of ED services and ensure members are coordinated and participating in the appropriate disease management or care management services. Any member with ED utilizations at least three standard deviations from the mean are referred to care coordination.</p> |

| Prompts | Summary |
|---|---|
| among beneficiaries with SMI or SED prior to admission | <p><i>Future Status:</i> OMPP, in collaboration with its Provider Relations contractor, will monitor provider network capacity on an annual basis and identify underserved areas for targeted provider recruitment. Additionally, DMHA plans to pilot two Crisis Stabilization Units (CSU) in the northern and southern parts of the state. The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units.</p> <p>FSSA's OMPP, DMHA, and Division of Disability and Rehabilitative Services (DDRS) are partnering with the Department of Child Services (DCS) and Juvenile Justice agencies to explore piloting mobile response stabilization services (MRSS). MRSS would provide community-based crisis intervention including short term follow-up and support for the youth and family to prevent reescalation, emergency department utilization and/or inpatient admission.</p> <p><i>Summary of Actions Needed:</i> OMPP will annually identify geographic shortage areas and Provider Enrollment will conduct targeted outreach to non-Medicaid enrolled providers in those areas.</p> <p>The CSU is proposed for implementation in SFY2020. The timeline for a potential MRSS is currently under review.</p> |
| 2.e Other State requirements/policies to improve care coordination and connections to community-based care | <p><i>Current Status:</i> Please refer to previous sections.</p> <p><i>Future Status:</i> N/A</p> <p><i>Summary of Actions Needed:</i> N/A</p> |
| SMI/SED. Topic 3. Milestone 3: Increasing Access to Continuum of Care, Including Crisis Stabilization Services | |
| <p><i>Adults with SMI and children with SED need access to a continuum of care as these conditions are often episodic and the severity of symptoms can vary over time. Increased availability of crisis stabilization programs can help to divert Medicaid beneficiaries from unnecessary visits to EDs and admissions to inpatient facilities as well as criminal justice involvement. On-going treatment in outpatient settings can help address less acute symptoms and help beneficiaries with SMI or SED thrive in their communities. Strategies are also needed to help connect individuals who need inpatient or residential treatment with that level of care as soon as possible. To meet this milestone, state Medicaid programs should focus on improving access to a continuum of care by taking the following actions.</i></p> | |
| Access to Continuum of Care Including Crisis Stabilization | |
| 3.a The state's strategy to conduct annual assessments of the availability of mental health providers including psychiatrists, other practitioners, outpatient, community mental health | <p><i>Current Status:</i> Indiana provides a comprehensive statewide service array inclusive of:</p> <ul style="list-style-type: none"> • Outpatient behavioral health services currently delivered by providers across the State, as delineated in the attached Mental Health Services Availability Assessment Template. • Medicaid rehabilitation option (MRO) delivered by the State's 24 CMHCs. All 92 counties in Indiana have at least one CMHC delivering care in the geographical area and most counties in the state, other than very rural ones, have more than one CMHC offering services within a county. |

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| <p>centers, intensive outpatient/partial hospitalization, residential, inpatient, crisis stabilization services, and FQHCs offering mental health services across the state, updating the initial assessment of the availability of mental health services submitted with the state's demonstration application. The content of annual assessments should be reported in the state's annual demonstration monitoring reports. These reports should include which providers have waitlists and what are average wait times to get an appointment</p> | <ul style="list-style-type: none"> • Three 1915(i) programs serving individuals with behavioral health needs. • Expanded SUD services in accordance with the State's approved SUD waiver. • Partial hospitalization programs which are time-limited medical services intended to provide a transition from inpatient psychiatric hospitalization to community-based care or, in some cases, substitute for an inpatient admission. <p>Indiana Administrative Code and DMHA contracts require CMHCs to provide a defined continuum of care directly, or through subcontract which includes:</p> <ul style="list-style-type: none"> • Individualized treatment planning to increase patient coping skills and symptom management • 24/7 crisis intervention • Case management to fulfill individual patient needs, including assertive case management • Outpatient services, including intensive outpatient services, substance abuse services, counseling and treatment • Acute stabilization, including detoxification services • Residential services • Day treatment • Family support services • Medication evaluation and monitoring • Services to prevent unnecessary and inappropriate treatment and hospitalization and the deprivation of a person's liberty <p>Further, House Enrolled Act 1175, passed in the 2019 legislative session, will expand access to behavioral health providers for Medicaid enrollees. Under this law, licensed clinical social workers, licensed mental health counselors, licensed clinical addiction counselors and licensed marriage and family therapists will be eligible providers for the supervision of a plan of treatment for a patient's outpatient mental health or substance abuse treatment services. Prior to this legislation, midlevel behavioral health practitioners were not eligible to independently enroll in Indiana Medicaid and were required to bill under the supervision of an HSPP or psychiatrist.</p> <p>Additionally, effective July 1, 2019, in accordance with the CMS approval of SPA TN 18-012, Indiana Medicaid expanded crisis intervention services, intensive outpatient program services and peer recovery services to all Indiana Medicaid programs; these services were previously limited to the MRO option. This change will expand the available provider base from the Indiana's CMHCs to all Medicaid enrolled providers meeting the applicable criteria.</p> |

| Prompts | Summary |
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| | <p>OMPP and DMHA continually assess access and availability of behavioral health services. For example, in accordance with the State's approved §1915(b)(4) waivers for MRO services and §1915(i) programs, FSSA utilizes information gathered from analysis of Indiana's MMIS, site reviews, and recipient reports and complaints to evaluate the need to expand provider agencies and/or provide training and/or corrective actions to assist provider agencies in increasing efficiencies for timely access to services. When "timely access" is identified as a provider agency issue, the State uses a request for corrective action and provides technical assistance and training in order to assist the agency in correcting the issue. If the issue is not remediated satisfactorily, further sanctions are applied, up to and including decertification of the agency as an MRO or §1915(i) provider.</p> <p>Further, OMPP's Provider Relations contractor identifies underserved areas by calculating the ratio of providers to members by county. Recruiting efforts are intensified in counties that are identified as not meeting HRSA provider-to-member ratio standards. Utilizing the results of this analysis, the Provider Relations team outreaches to behavioral health providers not currently Medicaid enrolled. Provider Relations employs the following strategy to reach out to potential providers:</p> <ul style="list-style-type: none"> ● Analyze the provider-to-population report to prioritize the geographic areas to be targeted. ● Analyze NPI reports to determine which specialties are underrepresented in the selected geographic region. ● Collaborate with residency programs to educate graduating classes about the benefits of providing services to the Medicaid population and encourage enrollment in Medicaid when residents graduate. ● Contact providers by telephone or via on-site visit. During the contact, Provider Relations will: <ul style="list-style-type: none"> ○ Invite the provider to consider Medicaid enrollment. ○ Explain the benefits of Medicaid enrollment. ○ Educate the provider regarding any misconceptions about Medicaid. ○ Mitigate the provider's objections. ○ Offer to make an on-site visit to discuss enrollment and help the provider complete the online enrollment application, if applicable. ○ Ascertain the reasons the provider chooses not to enroll, if applicable. <p>Additionally, MCOs are contractually required to meet network adequacy standards for behavioral health providers in accordance with 42 CFR §438.68. Corrective action is implemented when standards are not met.</p> |

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| | <p><i>Future Status:</i> OMPP will continue to monitor provider network capacity on an annual basis. Additionally, DMHA plans to pilot two Crisis Stabilization Units (CSU) in the northern and southern parts of the state. The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units.</p> <p>FSSA's OMPP, DMHA, and Division of Disability and Rehabilitative Services (DDRS) are partnering with the Department of Child Services (DCS) and Juvenile Justice agencies to explore piloting mobile response stabilization services (MRSS). MRSS would provide community-based crisis intervention including short term follow-up and support for the youth and family to prevent reescalation, emergency department utilization and/or inpatient admission.</p> <p><i>Summary of Actions Needed:</i> OMPP will annually identify geographic shortage areas and Provider Enrollment will conduct targeted outreach to non-Medicaid enrolled providers in those areas.</p> <p>The CSU is proposed for implementation in SFY2020. The timeline for MRSS is currently under review.</p> |
| 3.b Financing plan | <p><i>Current Status:</i> Please refer to Financing Plan below.</p> <p><i>Future Status:</i> Please refer to Financing Plan below.</p> <p><i>Summary of Actions Needed:</i> Please refer to Financing Plan below.</p> |
| 3.c Strategies to improve state tracking of availability of inpatient and crisis stabilization beds | <p><i>Current Status:</i> In March 2018, FSSA implemented a new tool to help Hoosiers seeking treatment for SUD immediately connect with available inpatient or residential treatment services. This new tool is made possible by a partnership between the State, OpenBeds, a software platform that manages health services, and Indiana 2-1-1, a non-profit organization that provides health care and other resource referrals to those in need.</p> <p>This service allows treatment facilities to list their vacancies in a real-time, broadly connected database and offers a comprehensive suite of information technology functionalities specific to mental health and SUD, and provides capability for:</p> <ul style="list-style-type: none"> • Transparency regarding the capacity of inpatient services, including recovery housing and community services, to provide an immediate and accurate inventory of available resources • Secure and HIPAA-compliance digital communication for referrals with email and text notifications, including the ability to transmit client data, along with consent • Digital registration and authentication for health systems and organizations • Real-time analytics to track utilization and referral patterns across the region • Patient marketplace or "pull referral" functionality to expedite patient placement • Mobile platform |

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| | <p><i>Future Status:</i> FSSA is currently in the process of expanding use of OpenBeds beyond SUD to include tracking availability of psychiatric inpatient and crisis stabilization beds.</p> <p><i>Summary of Actions Needed:</i> Expansion of OpenBeds contract in Fall 2019 to include psychiatric bed capacity.</p> |
| 3.d State requirement that providers use a widely recognized, publicly available patient assessment tool to determine appropriate level of care and length of stay | <p><i>Current Status:</i> Every individual served by a DMHA contracted provider receives a Child and Adolescent Needs and Strengths (CANS) or Adult Needs and Strengths Assessment (ANSA) to inform individualized treatment planning and level of care decision making. Individuals are reassessed every six months with adjustments to level of care and/or treatment plan being made accordingly. Further, as stated in Indiana Administrative Code 405 IAC 5-21.5, IHCP reimbursement for MRO services is available for members who meet specific diagnosis and level of need (LON) criteria under the approved DMHA assessment tool (ANSA or CANS). Additional MRO services beyond what is available for the assigned service package may be added with prior authorization (PA). MRO services are clinical behavioral health services provided to members and families of members living in the community who need aid intermittently for emotional disturbances, mental illness, and addiction. The CANS/ANSA also inform individual service needs and level of care that could include inpatient and/or residential services.</p> <p>In addition to use of the CANS and ANSA, determinations of medical necessity for behavioral health services are based on utilization management criteria implementation by the State's MCOs and utilization management vendor.</p> <p><i>Future Status:</i> N/A</p> <p><i>Summary of Actions Needed:</i> N/A</p> |
| Other state requirements/policies to improve access to a full continuum of care including crisis stabilization | <p><i>Current Status:</i> Please refer to previous sections.</p> <p><i>Future Status:</i> N/A</p> <p><i>Summary of Actions Needed:</i> N/A</p> |
| SMI/SED. Topic 4. Milestone 4: Earlier Identification and Engagement in Treatment, Including Through Increased Integration | |
| <i>Critical strategies for improving care for individuals with SMI or SED include earlier identification of serious mental health conditions and focused efforts to engage individuals with these conditions in treatment sooner. To meet this milestone, state Medicaid programs must focus on improving mental health care by taking the following actions.</i> | |
| Earlier Identification and Engagement in Treatment | |
| | <i>Current Status:</i> The Vocational Rehabilitation Services (VRS) is a program of FSSA's Division of Disability and Rehabilitative Services (DDRS). VRS are available statewide, in all regions of the state. Eligibility for |

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| <p>4.a Strategies for identifying and engaging beneficiaries with or at risk of SMI or SED in treatment sooner, e.g., with supported education and employment</p> | <p>VRS is determined in accordance with federal requirements at 34 CFR 361.42(a). Accordingly, eligibility for VRS includes a determination that an applicant meets the following conditions:</p> <ul style="list-style-type: none"> • Has a physical or mental impairment • This impairment constitutes or results in a substantial impediment to employment • VRS are required to prepare for, enter, engage in, or retain an employment outcome consistent with his or her abilities, capacities, career interests, and informed choice. <p>Additionally, all applicants determined eligible for Social Security for Social Security Disability (SSDI) or Supplemental Security Income (SSI) are presumed eligible for VRS.</p> <p>Individuals receiving VRS have an Individualized Plan for Employment (IPE) based on the requirements at 34 CFR 361.45, following an assessment for determining vocational rehabilitation needs. VRS are provided in accordance with the IPE and may include:</p> <ul style="list-style-type: none"> • Vocational counseling and guidance • Medical treatment to correct or modify the physical or mental impairment • Training (including vocational school, college or university, on-the-job, and other training) • Rehabilitation technology (assistive devices and services) • Placement assistance and follow-up (including supported employment) • Other planned goods and services determined to be necessary to address an identified substantial impediment to employment and to be required to enable the individual to prepare for, enter, engage in, or retain an employment outcome <p>Supportive employment (SE) is available as a VRS. Through this service, individuals with the most severe disabilities are placed in competitive jobs with qualified job coaches/trainers to provide individualized, ongoing support services needed for each individual to retain employment. The employer is contacted monthly and the employee is visited twice monthly, either at or away from the workplace, to address any issues that may threaten the individual's ability to remain on the job.</p> <p>Additionally, several of Indiana's CMHCs provide supportive employment services, an evidence-based service to promote rehabilitation and return to productive employment for persons with serious mental illness. These programs use a team approach for treatment, with employment specialists responsible for carrying out all vocational services from intake through follow-along. Job placements are: community-based (i.e., not sheltered workshops, not onsite at SE or other treatment agency offices), competitive (i.e., jobs are not exclusively reserved for SE clients, but open to public), in normalized settings, and utilize multiple employers. The SE team has a small client to staff ratio. SE contacts occur in the home, at the job site, or in the community. The SE team is assertive in engaging and retaining clients in treatment, especially utilizing face-to-face community</p> |

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| | visits, rather than phone or mail contacts. The SE team consults/works with family and significant others when appropriate. SE services are frequently coordinated with Vocational Rehabilitation benefits. |
| | <i>Future Status:</i> Continued operation of current programming. |
| | <i>Summary of Actions Needed:</i> N/A |
| 4.b Plan for increasing integration of behavioral health care in non-specialty settings to improve early identification of SED/SMI and linkages to treatment | <p><i>Current Status:</i> In 2012, FSSA in partnership with the Indiana State Department of Health (ISDH) launched the Primary Care and Behavioral Health Integration (PCBHI) initiative, to develop a statewide strategic plan to integrate primary and behavioral health care services in Indiana. As an outgrowth of this initiative, the State was awarded the SAMHSA and National Association of State Mental Health Program Directors (NASMHPD) Transformation Transfer Initiative (TTI) Grant which allowed the State to implement a series of initiatives aimed at increased integration.</p> <p>Additionally, a process was established by which Community Mental Health Centers (CMHCs), Federally Qualified Health Centers (FQHCs), Community Health Centers (CHCs) and Rural Health Clinics (RHCs) could become a state certified integrated care entity (ICE). Currently, there are 13 ICE sites operating within the State. ICE core requirements include:</p> <ul style="list-style-type: none"> • Core assessments for behavioral and physical health • Integrated care plans • Interdisciplinary team meetings • Real-time physician/pharmacy consults • Leadership support • Evidence based practice and training • Electronic health records and data sharing • Quality outcome measures <p>The State has also focused on school-based initiatives to increase behavioral health integration. For example, CMHCs across the State work in close collaboration with Indiana schools. Currently, 85% of school districts have CMHCs providing services within their schools. Additionally, DMHA released an RFP in June 2019 to contract with no more than three regionally diverse social services providers to implement an evidence-based program that partners with school corporations, charter schools, and accredited nonpublic schools to provide social work services and evidence-based prevention programs to children, parents, caregivers, teachers, and the community to prevent substance abuse, promote healthy behaviors, and maximize student success.</p> <p>Further, the MCOs are contractually required to plan for, develop and/or enhance relationships with school-based health centers (SBHC) with the goal of providing accessible services to school-aged enrolled members.</p> |

| Prompts | Summary |
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| | <p>SBHCs provide on-site comprehensive preventive and primary health services including behavioral health, oral health, ancillary and enabling services.</p> <p>Additionally, Indiana encourages the integration of primary and behavioral health care services through the use of an alternative payment methodology (APM) for federally qualified health centers (FQHCs) which consists of: (1) an adjustment to the FQHC's prospective payment system (PPS) rate; and (2) performance incentive payments limited to an established annual amount for each participating FQHC. To qualify for an APM, the FQHC must implement a care plan that fully integrates primary care and behavioral health at the FQHC through an integration plan approved by OMPP and DMHA which includes the following components:</p> <ul style="list-style-type: none"> • Incorporation of screening and evaluation processes to identify targeted patient population • Establishment of appropriate levels of behavioral health staffing • Physical integration of the provision of primary and behavioral health care together at the same FQHC location • Performance of medical and behavioral health care services by the staff at the FQHC • Full integration of medical records, billing and other data relating to primary and behavioral health care services • Ongoing monitoring of the integration plan through data collection and evaluation <p><i>Future Status:</i> The State will ensure the financial sustainability of a physical health and behavioral health integration model following the end of the current grant funding.</p> <p><i>Summary of Actions Needed:</i> OMPP, in partnership with DMHA is pursuing options for sustainability and expansion of the State's model for primary care and behavioral health integration. DMHA is submitting an application for SAMHSA's (FY) 2020 Promoting Integration of Primary and Behavioral Health Care (Short Title: PIPBHC) grant and OMPP is exploring implementation of a health homes state plan amendment in 2021.</p> |
| F4.c Establishment of specialized settings and services, including crisis stabilization, for young people experiencing SED/SMI | <p><i>Current Status:</i> The State's review of the crisis continuum confirmed the following crisis services are being provided in addition to the CMHC mandated 24/7 crisis services: mobile crisis teams (5), assertive community treatment (ACT) (6), 23-hour crisis stabilization units (7), short-term crisis residential (2) and peer crisis services (2).</p> <p><i>Future Status:</i> DMHA plans to pilot two Crisis Stabilization Units (CSU) in the northern and southern parts of the state. The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units.</p> <p>FSSA's OMPP, DMHA, and Division of Disability and Rehabilitative Services (DDRS) are partnering with the Department of Child Services (DCS) and Juvenile Justice agencies to explore piloting mobile response stabilization services (MRSS). MRSS would provide community-based crisis intervention including short term</p> |

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| | <p>follow-up and support for the youth and family to prevent reescalation, emergency department utilization and/or inpatient admission.</p> <p><i>Summary of Actions Needed:</i> The CSU is proposed for implementation in SFY2020. The timeline for MRSS is currently under review.</p> |
| 4.d Other state strategies to increase earlier identification/engagement, integration, and specialized programs for young people | <p><i>Current Status:</i> Please refer to previous sections.</p> <p><i>Future Status:</i> N/A</p> <p><i>Summary of Actions Needed:</i> N/A</p> |
| SMI/SED.Topic 5. Financing Plan | |
| <p><i>te Medicaid programs should detail plans to support improved availability of non-hospital, non-residential mental health services including crisis stabilization and on-going community-based care. The financing plan should describe state efforts to increase access to community-based mental health providers for Medicaid beneficiaries throughout the state, including through changes to reimbursement and financing policies that address gaps in access to community-based providers identified in the state's assessment of current availability of mental health services included in the state's application.</i></p> | |
| F.a Increase availability of non-hospital, non-residential crisis stabilization services, including services made available through crisis call centers, mobile crisis units, observation/assessment centers, with a coordinated community crisis response that involves collaboration with trained law enforcement and other first responders. | <p><i>Current Status:</i> The State's review of the crisis continuum confirmed the following crisis services are being provided in addition to the CMHC mandated 24/7 crisis services: mobile crisis teams (5), assertive community treatment (ACT) (6), 23-hour crisis stabilization units (7), short-term crisis residential (2) and peer crisis services (2).</p> <p>Effective July 1, 2019, in accordance with the CMS approval of SPA TN 18-012, Indiana Medicaid expanded crisis intervention services, intensive outpatient program services and peer recovery services to all Indiana Medicaid programs; these services were previously limited to the MRO option. This change will expand the available provider base from the Indiana's CMHCs to all Medicaid enrolled providers meeting the applicable criteria.</p> <p><i>Future Status:</i> The State will annually monitor access to non-residential crisis stabilization services through an agreed upon methodology. In addition, the State will encourage and support non-CMHC providers to increase access to intensive outpatient, peer support and crisis intervention services.</p> <p>DMHA plans to pilot two Crisis Stabilization Units (CSU) in the northern and southern parts of the state. The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units.</p> <p>FSSA's OMPP, DMHA, and Division of Disability and Rehabilitative Services (DDRS) are partnering with the Department of Child Services (DCS) and Juvenile Justice agencies to explore piloting mobile response</p> |

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| | <p>stabilization services (MRSS). MRSS would provide community-based crisis intervention including short term follow-up and support for the youth and family to prevent reescalation, emergency department utilization and/or inpatient admission.</p> <p><i>Summary of Actions Needed:</i> The CSU is proposed for implementation in SFY2020. The timeline for MRSS is currently under review.</p> |
| F.b Increase availability of on-going community-based services, e.g., outpatient, community mental health centers, partial hospitalization/day treatment, assertive community treatment, and services in integrated care settings such as the Certified Community Behavioral Health Clinic model. | <p><i>Current Status:</i> As described throughout this template, and as outlined in the attached “Overview of the Assessment of the Availability of Mental Health Services” template, Indiana offers a comprehensive continuum of community-based services.</p> <p>Effective July 1, 2019, in accordance with the CMS approval of SPA TN 18-012, Indiana Medicaid expanded crisis intervention services, intensive outpatient program services and peer recovery services to all Indiana Medicaid programs; these services were previously limited to the MRO option. This change will expand the available provider base from the Indiana’s CMHCs to all Medicaid enrolled providers meeting the applicable criteria.</p> <p><i>Future Status:</i> The State will annually monitor access to community-based services through an agreed upon methodology. In addition, the State will specifically monitor any changes to non-CMHC providers and the impact on access to intensive outpatient, peer support and crisis intervention services.</p> <p><i>Summary of Actions Needed:</i> OMPP will annually identify geographic shortage areas and Provider Enrollment will conduct targeted outreach to non-Medicaid enrolled providers in those areas.</p> |

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| SMI/SED. Topic 6. Health IT Plan | | | | | | | |
| <p>outlined in State Medicaid Director Letter (SMDL) #18-011, “[s]tates seeking approval of an SMI/SED demonstration ... will be expected to submit a Health IT Plan (“HIT Plan”) that describes the state’s ability to leverage health IT, advance health information exchange(s), and ensure health IT interoperability in support of the demonstration’s goals.”⁶ The HIT Plan should also describe, among other items, the:</p> <ul style="list-style-type: none"> • Role of providers in cultivating referral networks and engaging with patients, families and caregivers as early as possible in treatment; and • Coordination of services among treatment team members, clinical supervision, medication and medication management, psychotherapy, case management, coordination with primary care, family/caregiver support and education, and supported employment and supported education. <p>ase complete all Statements of Assurance below—and the sections of the Health IT Planning Template that are relevant to your state’s demonstration proposal.</p> | | | | | | | |
| Statements of Assurance | | | | | | | |
| Statement 1: Please provide an assurance that the state has a sufficient health IT infrastructure/ecosystem at every appropriate level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration. If this is not yet the case, please describe how this will be achieved and over what time period | <p>As outlined in Indiana’s State Medicaid Health Information Technology Plan (SMHP), Indiana’s HIT environment is active with multi-faceted efforts to support provider HIT capacity and foster the sharing of clinical and administrative data to improve health care and support system improvements. The State has taken an active role through its state health agencies and Medicaid program to promote HIT adoption and HIE development, building upon its private health care marketplace.</p> <p>As outlined in the table below, the State is home to four well-established health information exchange networks operated by Health Information Organizations (HIOs), each functioning in different capacities for community partners.</p> <table border="1"> <thead> <tr> <th>Regional HIO</th><th>June 2019 Status</th></tr> </thead> <tbody> <tr> <td>HealthBridge (includes greater Cincinnati tristate area)</td><td> <p>Utilization of the Health Collaborative’s HealthBridge Suite (hb/suite):</p> <ul style="list-style-type: none"> • 58 hospitals • 8,901 providers • 160 million clinical results processed • 15 million monthly messages </td></tr> <tr> <td>HealthLINC</td><td> <ul style="list-style-type: none"> • Delivers more than 175,000 medical results per month among hospitals, office and clinic practices and under-served clinics • Health service directory that includes more than 350 physicians and other providers </td></tr> </tbody> </table> | Regional HIO | June 2019 Status | HealthBridge (includes greater Cincinnati tristate area) | <p>Utilization of the Health Collaborative’s HealthBridge Suite (hb/suite):</p> <ul style="list-style-type: none"> • 58 hospitals • 8,901 providers • 160 million clinical results processed • 15 million monthly messages | HealthLINC | <ul style="list-style-type: none"> • Delivers more than 175,000 medical results per month among hospitals, office and clinic practices and under-served clinics • Health service directory that includes more than 350 physicians and other providers |
| Regional HIO | June 2019 Status | | | | | | |
| HealthBridge (includes greater Cincinnati tristate area) | <p>Utilization of the Health Collaborative’s HealthBridge Suite (hb/suite):</p> <ul style="list-style-type: none"> • 58 hospitals • 8,901 providers • 160 million clinical results processed • 15 million monthly messages | | | | | | |
| HealthLINC | <ul style="list-style-type: none"> • Delivers more than 175,000 medical results per month among hospitals, office and clinic practices and under-served clinics • Health service directory that includes more than 350 physicians and other providers | | | | | | |

⁶ See SMDL #18-011, “Opportunities to Design Innovative Service Delivery Systems for Adults with a Serious Mental Illness or Children with a Serious Emotional Disturbance.” Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18011.pdf>.

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| | Indiana Health Information Exchange (IHIE) | <ul style="list-style-type: none"> • Connection to 117 hospitals representing 38 health systems • Over 17,055 practices • Over 47,452 providers • Over 14,847,271 patients • Over 12,510,420,163 clinical data elements |
| | Michiana Health Information Network (MHIN) | <ul style="list-style-type: none"> • Over 576 data sources • 3.9 million transactions inbound per month • 20,304 providers connected |
| | <p>However, a March 2019 assessment of Indiana's health information sharing (HIS), conducted based on capability maturity guidance from CMS and the Office of the National Coordination for Health Information Technology (ONC), revealed opportunities for increased electronic documentation and standardization among settings and providers not previously addressed through Meaningful Use, including behavioral health providers. Through this HIT Plan, the State intends to drive improvements in this area.</p> | |
| Statement 2: Please confirm that your state's SUD Health IT Plan is aligned with the state's broader State Medicaid Health IT Plan and, if applicable, the state's Behavioral Health IT Plan. If this is not yet the case, please describe how this will be achieved and over what time period. | <p>This HIT Plan is aligned with the State's broader State Medicaid Health IT Plan (SMHP). The State is in the process of completing an updated SMHP with targeted completion by the end of calendar year 2019. Through this update process, areas of prioritization will take into consideration the milestones of this waiver.</p> | |
| Statement 3: Please confirm that the state intends to assess the applicability of standards referenced in the Interoperability Standards Advisory (ISA) ⁷ and 45 CFR 170 Subpart B and, based on that assessment, intends to include them as appropriate in | <p>Indiana will review the applicability of standards referenced in the Interoperability Standards Advisory (ISA) and 45 CFR 170 Subpart B for potential inclusion into our MCO contracts. The following standards are currently utilized by our MCOs:</p> <ul style="list-style-type: none"> • Documenting and Sharing Care Plans – The MCOs are contractually obligated to share care plans with primary medical providers (PMPs) and behavioral health providers with appropriate consent. • The MCOs have agreements with health information exchanges, such as the Indiana Health Information Exchange (IHIE) and the Michiana Health Information Network (MHIN). | |

⁷ Available at <https://www.healthit.gov/isa/>.

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| subsequent iterations of the state's Medicaid Managed Care contracts. The ISA outlines relevant standards including but not limited to the following areas: referrals, care plans, consent, privacy and security, data transport and encryption, notification, analytics and identity management. | <ul style="list-style-type: none"> • Clinical Quality Measurement and Reporting – The MCEs report on the following HEDIS quality measures related to behavioral health: <ul style="list-style-type: none"> ○ Follow-up care for children prescribed ADHD medication, initiation phase ○ Follow-up care for children prescribed ADHD medication, maintenance phase ○ 30-day follow-up after hospitalization for mental illness ○ 7-day follow-up after hospitalization for mental illness ○ Use of multiple concurrent antipsychotics in children and adolescents up to age 17 ○ Use of first-line psychosocial care for children/adolescents on antipsychotics up to age 17 ○ Antidepressant medication management, acute phase ○ Antidepressant medication management, continuation phase ○ 30-day follow-up after emergency department (ED) visit for mental illness ○ 7-day follow-up after ED visit for mental illness |
| <p><i>To assist states in their health IT efforts, CMS released SMDL #16-003 which outlines enhanced federal funding opportunities available to states “for state expenditures on activities to promote health information exchange (HIE) and encourage the adoption of certified Electronic Health Record (EHR) technology by certain Medicaid providers.” For more on the availability of this “HITECH funding,” please contact your CMS Regional Operations Group contact.⁸</i></p> <p><i>Enhanced administrative match may also be available under MITA 3.0 to help states establish crisis call centers to connect beneficiaries with mental health treatment and to develop technologies to link mobile crisis units to beneficiaries coping with serious mental health conditions. States may also coordinate access to outreach, referral, and assessment services—for behavioral health care--through an established “No Wrong Door System.”⁹</i></p> | |
| Closed Loop Referrals and e-Referrals (Section 1) | |
| 1.1 Closed loop referrals and e-referrals from physician/mental health provider to physician/mental health provider | <p><i>Current State:</i> The State does not have readily accessible data on the exact number of Medicaid-enrolled behavioral health providers who have adopted certified EHRs and are utilizing them for e-referrals and/or closed loop referrals. With multiple HIEs and large health systems that have been able to exchange effectively via EHR and prescription software vendors, it is difficult to accurately assess participation. Each HIE is able to easily report on its participants but the extent to which non-participating organizations are identified and assessed individually is meticulous work. It is known that certain hospital, facility, and provider types that were not eligible for Meaningful Use (Promoting Interoperability) are not participating due to lagging technology and/or regulatory barriers, such as with CFR 42 Part 2.</p> |

⁸ See SMDL #16-003, “Availability of HITECH Administrative Matching Funds to Help Professionals and Hospitals Eligible for Medicaid EHR Incentive Payments Connect to Other Medicaid Providers.” Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd16003.pdf>.

⁹ Guidance for Administrative Claiming through the “No Wrong Door System” is available at <https://www.medicaid.gov/medicaid/finance/admin-claiming/no-wrong-door/index.html>.

| Prompts | Summary |
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| | <p>The aforementioned March 2019 HIS Assessment did reveal provider tracking of referrals may be facilitated by tools within the EHR but most still struggle with closing the referral loop.</p> <p><i>Future State:</i> The State will conduct a survey to identify the volume of providers utilizing closed loop referrals and e-referrals to identify the baseline of current activity and identify options for increasing provider uptake.</p> <p><i>Summary of Actions Needed:</i> The provider survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.</p> |
| 1.2 Closed loop referrals and e-referrals from institution/hospital/clinic to physician/mental health provider | <p><i>Current State:</i> The State does not have readily accessible data on the exact number of Medicaid-enrolled behavioral health providers who have adopted certified EHRs and are utilizing them for e-referrals and/or closed loop referrals. The aforementioned March 2019 HIS Assessment did reveal provider tracking of referrals may be facilitated by tools within the EHR but most still struggle with closing the referral loop.</p> <p><i>Future State:</i> The State will conduct a survey to identify the volume of providers utilizing closed loop referrals and e-referrals to identify the baseline of current activity and identify options for increasing provider uptake.</p> <p><i>Summary of Actions Needed:</i> The provider survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.</p> |
| 1.3 Closed loop referrals and e-referrals from physician/mental health provider to community based supports | <p><i>Current State:</i> The State does not have readily accessible data on the exact number of Medicaid-enrolled behavioral health providers who have adopted certified EHRs and are utilizing them for e-referrals and/or closed loop referrals. The aforementioned March 2019 HIS Assessment did reveal provider tracking of referrals may be facilitated by tools within the EHR but most still struggle with closing the referral loop.</p> <p><i>Future State:</i> The State will conduct a survey to identify the volume of providers utilizing closed loop referrals and e-referrals to identify the baseline of current activity and identify options for increasing provider uptake.</p> <p><i>Summary of Actions Needed:</i> The provider survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.</p> |
| Electronic Care Plans and Medical Records (Section 2) | |
| 2.1 The state and its providers can create and use an electronic care plan | <p><i>Current State:</i> The aforementioned March 2019 HIS Assessment revealed that while electronic care plans are utilized they are not standardized. HIEs receive what the provider delivers via continuity of care documents (CCD) but content and format are variable.</p> <p><i>Future State:</i> The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. Additionally, FSSA will survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.</p> <p><i>Summary of Actions Needed:</i> FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. The IMD survey will be conducted by FSSA. The dates for</p> |

| Prompts | Summary |
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| | completion will be based on prioritization of this activity as determined during completion of the updated SMHP. |
| 2.2 E-plans of care are interoperable and accessible by all relevant members of the care team, including mental health providers | <p><i>Current State:</i> Indiana contracts with the Indiana Health Information Exchange (IHIE) to aggregate Medicaid claims with medical and pharmacy data in its repository to create a continuity of care (CCD) record that can be shared between Medicaid providers. The aforementioned March 2019 HIS Assessment indicates some MCOs and providers are receiving admit-discharge-transfer (ADT), CCDs or other clinical data points and incorporating directly into their work flow for care coordination and quality management. Additionally, the majority of community mental health centers have certified EHRs and utilize Viewpoint, a referral portal, to communicate among entities.</p> <p><i>Future State:</i> As previously described, OMPP is exploring submitting a health homes state plan amendment. A key component of this initiative will include leveraging HIT for enhanced integration and coordination. OMPP is currently in the process of developing HIT standards and requirements for participating providers. Additionally, the State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. FSSA will also survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.</p> <p><i>Summary of Actions Needed:</i> OMPP is exploring submitting a health homes state plan amendment with an implementation date by 2021. FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. The IMD survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.</p> |
| 2.3 Medical records transition from youth-oriented systems of care to the adult behavioral health system through electronic communications | <p><i>Current State:</i> State psychiatric hospitals utilize one EHR system which permits tracking of records as youth transition to adulthood.</p> <p><i>Future State:</i> The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. Additionally, FSSA will survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.</p> <p><i>Summary of Actions Needed:</i> FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. The IMD survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.</p> |
| 2.4 Electronic care plans transition from youth-oriented systems of care to the adult behavioral health system through electronic communications | <p><i>Current State:</i> State psychiatric hospitals utilize one EHR system which permits tracking of care plans as youth transition to adulthood.</p> <p><i>Future State:</i> The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. FSSA will also survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.</p> |

| Prompts | Summary |
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| | <p><i>Summary of Actions Needed:</i> FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. The IMD survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.</p> |
| <p>2.5 Transitions of care and other community supports are accessed and supported through electronic communications</p> | <p><i>Current State:</i> In 2017, DMHA released an RFP to procure a new EHR system to be used collectively by all state psychiatric hospitals. The State's expectation is that a modern EHR will facilitate interoperability. The required HIE functionality put forth in FSSA's statement of work for this project include:</p> <ul style="list-style-type: none"> • Admission, discharge and transfer (ADT) and census <ul style="list-style-type: none"> ○ Collecting and updating patient demographic information, family contact data, alerts, insurance coverage, management of room and bed, census activities, and leave-of-absence ○ Fully integrating the aforementioned data across the other core functions • Clinical documentation: Includes assessments, treatment, treatment plans, and nursing care plans, including, but not limited to, historical patient data, patient risk criteria, electronic document system capturing interdisciplinary Plans of Care and reporting, automated work lists, clinical decision support, and patient education tracking. The system must support multiple modes of data entry including, but not limited to, template notes, third-party dictation, and voice recognition. This also includes fully integrating this data across the other core functions. • Interfaces, data sharing and interoperability: <ul style="list-style-type: none"> ○ Using common standards and implementation specifications for electronic exchange of information in accordance with MU Stage 2 guidance. ○ Actual electronic exchange of clinical information with acute care hospitals, CMHCs, Public Health registries, LTC facilities, private practitioners, pharmacies, correctional facilities, judicial bodies, laboratories, and healthcare payers (e.g., Medicaid, Medicare, commercial insurance, Social Security Administration [SSA], private pay, etc.) • Case management: Functionality includes, but is not limited to, the ability for designated staff to track, manage, document, and receive alerts for case management activities. <p>Having the State Psychiatric Hospitals interface with an HIE will give the Medicaid providers operating within the SPHs the capability to exchange health information with adjacent acute care facilities/hospitals, CMHCs, and other healthcare partners along the continuum of care. This specifically will allow Medicaid providers the capability to meet MU stage 3. More specifically the SPHs will be capable of bi-directionally exchanging summary of care records and CCDs when referring or receiving a Medicaid patient to or from another care setting. In addition, SPHs interfacing with the HIE will be capable of sending and receiving ADT notifications. These activities allow Medicaid providers within the SPHs to fulfill the objectives and enables them to report measures in accordance with MU stage 3 for HIE.</p> |

| Prompts | Summary |
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| | <p><i>Future State:</i> FSSA will survey IMDs to identify the baseline of current activities to identify options for increasing IMD activity in this area.</p> <p><i>Summary of Actions Needed:</i> The IMD survey will be conducted by FSSA. The dates for completion will be based on prioritization of this activity as determined during completion of the updated SMHP.</p> |
| Consent - E-Consent (42 CFR Part 2/HIPAA) (Section 3) | |
| 3.1 Individual consent is electronically captured and accessible to patients and all members of the care team, as applicable, to ensure seamless sharing of sensitive health care information to all relevant parties consistent with applicable law and regulations (e.g., HIPAA, 42 CFR part 2 and state laws) | <p><i>Current State:</i> Consent/privacy is managed in a multitude of mechanisms across the Medicaid Health Information Sharing Enterprise, many still very manual, non-standardized and not electronically transmitted. HIEs rely on the participants to manage what information is delivered to them. Substance abuse disorder laws (42 CFR Part 2) require explicit patient consent and therefore typically are only shared in a one-off manual manner. Consent, segregation of highly sensitive records, and secure transport are difficult to implement and manage and therefore infrequently done electronically. Indiana is an opt-out state for HIE. Responsibility is on provider to communicate with patients. Patient data can be shared with HIE unless the patient explicitly requests it not to be.</p> <p><i>Future State:</i> To be determined based on prioritization of initiatives during the aforementioned SMHP update process.</p> <p><i>Summary of Actions Needed:</i> To be determined based on prioritization of initiatives during the aforementioned SMHP update process.</p> |
| Interoperability in Assessment Data (Section 4) | |
| 4.1 Intake, assessment and screening tools are part of a structured data capture process so that this information is interoperable with the rest of the HIT ecosystem | <p><i>Current State:</i> Within the integrated care entities (ICE), core assessments and adjudicated Medicaid claims data are aggregated and available via the Relias ProAct Tool. This tool exclusively houses Medicaid patients and an external facing interface is provided for each ICE and applies 400+ measures to Medicaid claims and non-claims data. It provides individual patient history, as well as population demographics and associated costs of diagnoses, medications and utilization.</p> <p><i>Future State:</i> The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule.</p> <p><i>Summary of Actions Needed:</i> FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly.</p> |
| Electronic Office Visits – Telehealth (Section 5) | |
| 5.1 Telehealth technologies support collaborative care by facilitating broader availability of integrated mental health care and primary care | <p><i>Current State:</i> Indiana received \$16 million from the Federal Communications Commission's (FCC's) Rural Health Care Pilot Program, and as a result, created the Indiana Telehealth Network (ITN). ITN formed an FCC Rural Health Care Steering Committee, which was made up of representatives from healthcare providers, telecommunication companies, representatives from the Indiana Office of Community & Rural Affairs, and representatives from the Indiana Rural Health Association, the lead entity for the ITN. The five-year project was divided into three phases and the work successfully concluded in 2015. The table below presents a summary of the project phases.</p> |

| Prompts | Summary | | |
|---|--|---|--|
| | Phase 1 | Phase 2 | Phase 3 |
| | <ul style="list-style-type: none">• Reduced bandwidth costs• Reduced Primary Rate Interface (PRI) costs• Doubled the speed of existing broadband connections• 85% funding for construction of fiber to their hospitals• Completed ability to transmit images• Improved economic opportunities | <ul style="list-style-type: none">• Expanded ability to conduct Telehealth encounters over a dedicated health care network• Disaster Recovery• E-Learning• Internet Access• Videoconferencing | <ul style="list-style-type: none">• Seamless interfaces with the Indiana Health Information Organizations (HIOs) |
| | As of December 2016, ITN’s healthcare participants included 153 critical access hospitals, rural hospitals, urban partner hospitals, rural health clinics, urban partner hospitals, rural health clinics, federally qualified health centers, community mental health centers and data centers. | | |
| | Additionally, as part of the 21 st Century Cures Act, a portion of Indiana’s awarded funding is being utilized to implement Project-ECHO-Extension for Community Healthcare Outcomes. The primary goal of ECHO is to enable rural and traditionally underserved populations to receive high-quality care, when they need it, close to home. This low-cost, high-impact intervention is achieved by leveraging technology to connect expert mentors and multiple local primary care providers in online video-conferencing TeleECHO clinics. | | |
| | <i>Future State:</i> Continued operation of current programing. | | |
| <i>Summary of Actions Needed:</i> N/A | | | |
| Alerting/Analytics (Section 6) | | | |
| 6.1 The state can identify patients that are at risk for discontinuing engagement in their treatment, or have stopped engagement in their treatment, and can notify their care teams in order to ensure treatment continues or resumes (Note: | <i>Current State:</i> Some providers may have this capability, but the current volume is unknown. | | |
| | <i>Future State:</i> As previously described, OMPP is exploring submitting a health homes state plan amendment. A key component of this initiative will include leveraging HIT for enhanced integration and coordination. OMPP is currently in the process of developing HIT standards and requirements for participating providers. | | |
| | <i>Summary of Actions Needed:</i> OMPP is exploring submitting a health homes state plan amendment with implementation by 2021. | | |

| Prompts | Summary |
|---|--|
| research shows that 50% of patients stop engaging after 6 months of treatment ¹⁰) | |
| 6.2 Health IT is being used to advance the care coordination workflow for patients experiencing their first episode of psychosis | <i>Current State:</i> Some providers may have this capability, but the current volume is unknown. |
| | <i>Future State:</i> As previously described, OMPP is exploring submitting a health homes state plan amendment, with implementation 2021. A key component of this initiative will include leveraging HIT for enhanced integration and coordination. OMPP is currently in the process of developing HIT standards and requirements for participating providers. |
| | <i>Summary of Actions Needed:</i> OMPP is exploring submitting a health homes state plan amendment by the end of 2020 with implementation by 2021. |
| Identity Management (Section 7) | |
| 7.1 As appropriate and needed, the care team has the ability to tag or link a child's electronic medical records with their respective parent/caretaker medical records | <i>Current State:</i> The State's eligibility and enrollment system can link children and parents on the same case. |
| | <i>Future State:</i> To be determined based on prioritization of initiatives during the aforementioned SMHP update process. |
| | <i>Summary of Actions Needed:</i> To be determined based on prioritization of initiatives during the aforementioned SMHP update process. |
| 7.2 Electronic medical records capture all episodes of care, and are linked to the correct patient | <i>Current State:</i> The aforementioned March 2019 assessment of Indiana's HIS indicates patient/client identification is inconsistent between entities. Patient matching is an issue for all entities. Health systems employ entire departments to deal with multiple issues surrounding the record integrity that include duplicate records or documenting on the wrong patient record. Resolving a merged record and identifying who may have received erroneous information may take many hours of work per case. |
| | Additionally, Indiana is currently participating in the National Governor's Association "Harnessing the Power of Data to Achieve State Policy Goals: The Foundation for State Success in Improving Quality and Reducing Costs" initiative, intended to address governance, cross-sector data sharing and systems capabilities. |
| | <i>Future State:</i> The State will work toward compliance with the forthcoming CMS Interoperability and Patient Access final rule. |
| | <i>Summary of Actions Needed:</i> FSSA will monitor for CMS release of the final rule and determine required steps and timeline for compliance accordingly. |

¹⁰ Interdepartmental Serious Mental Illness Coordinating Committee. (2017). *The Way Forward: Federal Action for a System That Works for All People Living With SMI and SED and Their Families and Caregivers*. Retrieved from https://www.samhsa.gov/sites/default/files/programs_campaigns/ismicc_2017_report_to_congress.pdf

Section 3: Relevant documents

Please provide any additional documentation or information that the state deems relevant to successful execution of the implementation plan. This information is not meant as a substitute for the information provided in response to the prompts outlined in Section 2. Instead, material submitted as attachments should support those responses.

Attachment G: SMI Monitoring Protocol (reserved)

Attachment H: SMI Evaluation Design (reserved)

Attachment I: Eligibility and Coverage Implementation Plan

Attachment J: Eligibility and Coverage Monitoring Protocol (reserved)

Attachment K: Eligibility and Coverage Evaluation Design (reserved)