EVALUATION DESIGN PLAN FOR INDIANA'S 1115 SUBSTANCE USE DISORDER DEMONSTRATION WAIVER EFFECTIVE JAN. 1, 2021 – DEC. 31, 2025

FINAL VERSION
DECEMBER 29, 2022

HEALTH MANAGEMENT ASSOCIATES

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Listing of Exhibits

Abbreviations List

Abbreviation	Meaning
AOD	Alcohol or Other Drug
ASAM	American Society for Addiction Medicine
B&A	Burns & Associates, Inc.
CMS	Centers for Medicare and Medicaid Services
CY	Calendar Year
DMHA	Division of Mental Health and Addiction
DOS	Date of Service
DR	Desk Review
DS	Descriptive Statistics
ED	Emergency Department
EDW	Enterprise Data Warehouse
FFS	Fee-For-Service
FQHC	Federally Qualified Health Center
FSSA	Indiana Family and Social Services Administration
FI	Facilitated Interviews
HIP	Healthy Indiana Plan
HMA-Burns	Burns & Associates, a Division of Health Management Associates
IDOC	Indiana Department of Corrections
IMD	Institution for Mental Disease
IPLA	Indiana Professional Licensing Agency

Abbreviation	Meaning
ISDH	Indiana State Department of Health
ITS	Single Segment Interrupted Time Series
MAT	Medication-Assisted Treatment
MCE	Managed Care Entity
MMIS	Medicaid Management Information System
NCQA	National Committee for Quality Assurance
NQF	National Quality Forum
OMPP	Office of Medicaid Policy and Planning
OR	Onsite Reviews
OUD	Opioid Use Disorder
PHE	Public Health Emergency
PDMP	Prescription Drug Monitoring Program
PQA	Pharmacy Quality Assurance
RCT	Randomized Control Trials
RHC	Rural Health Clinic
SAS	Statistical Analysis System
ST	Statistical Tests
STC	Special Terms and Conditions
SUD	Substance Use Disorder

SECTION I: GENERAL BACKGROUND INFORMATION

I.A Waiver Demonstration Information

The State of Indiana received authority in its Medicaid Section 1115 demonstration waiver to expand services for substance use disorder (SUD) effective February 1, 2018 through December 31, 2020. The waiver authority was selected as the means to ensure that a broad continuum of care is available to Indiana Medicaid beneficiaries with a SUD, including services that had previously not been available to Medicaid beneficiaries as well as services that are delivered in an Institution for Mental Disease (IMD) for which federal matching funds were not available absent the waiver authority.

The State applied for, and received, approval to extend its SUD waiver for an additional five years effective January 1, 2021[1]. This evaluation design plan covers the five-year renewal period shown below.

Name: Healthy Indiana Plan (HIP)
Project Number: 11-W-00296/5
Approval Date: October 26, 2020
Time Period Covered by Evaluation: January 1, 2021 through December 31, 2025

I.B Waiver Demonstration Goals

Indiana identified its primary goals for the SUD component of its waiver demonstration in its SUD Implementation Plan which was approved February 1, 2018. As per the SUD waiver renewal, the original SUD Implementation Plan is still in effect. Indiana chose to use the goals as outlined by the Centers for Medicare and Medicaid Services (CMS) as follows:

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 department and inpatient hospital settings for treatment where the utilization is preventable or medically in appropriate through improved access to other continuum of care services;
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
6. Improved access to care for physical health conditions among beneficiaries.

I.C Brief Description and History of Implementation

On February 1, 2018, Indiana received approval of its SUD Implementation Plan Protocol as required by special terms and conditions (STC) X.10 of the state's section 1115 Healthy Indiana Plan (HIP) demonstration for its initial SUD waiver covering the period February 1, 2018 – December 31, 2020. This SUD Implementation Plan also remains in effect for the SUD waiver renewal period from January 1, 2021

[1] in-healthy-indiana-plan-support-20-ca-01012021.pdf (medicaid.gov) CMS Approval- Extension Request, Indiana. October 26, 2020

– December 31, 2025.[2] In its, SUD Implementation Plan Protocol, Indiana is focusing on the following areas to supports its waiver demonstration goals: [3]

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

In support of these focus areas, Indiana Medicaid and CMS identified six key milestones, as described in their Protocol, which include:[4]

1. Access to critical levels of care for SUD treatment;

2. Use of evidence-based SUD-specific patient placement criteria;

3. Use of nationally recognized SUD-specific program standards to set provider qualifications for residential treatment facilities;

4. Sufficient provider capacity at critical levels of care, including medication assisted treatment for opioid use disorder (OUD);

5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD; and

6. Improved care coordination and transition between levels of care.

The Family and Social Services Administration's (FSSA's) Office of Medicaid Policy and Planning (OMPP) has responsibility for the administration and oversight of Indiana's Medicaid program under waiver and state authorities. Since the initial SUD waiver implementation began in early 2018, the OMPP has worked closely with the FSSA's Division of Mental Health and Addiction (DMHA) to implement the activities specified in the SUD Implementation Plan Protocol. In addition to the FSSA, the Indiana State Department of Health (ISDH), the Indiana Department of Corrections (IDOC), and the Indiana Professional Licensing Agency (IPLA) have all contributed to aspects of SUD waiver implementation activities.

The OMPP contracts with four managed care entities (MCEs) that are responsible for the delivery of services to most beneficiaries that are identified with SUD in Indiana's Medicaid program.

Exhibit 1 on the next page summarizes key implementation activities during the first SUD waiver period.

[2] Ibid. Special Terms and Conditions, Section X, Item 3, page 34 of 173.

[3] Ibid. Attachment C. Indiana 1115 SUD Waiver Implementation Plan, Updated January 2018, page 4.

[4] Ibid. Attachment C, pages 4 – 30.

Exhibit 1. Key Activities Implemented by Indiana in its SUD Implementation Protocol During Waiver Period 1, February 2018 – December 2020

Milestone	Implementation Activity	Implementation
Access to Critical Levels of Care for SUD Treatment	Pursued Indiana Administrative Code changes to expand coverage and reimbursement. Made systems changes to enroll and pay residential treatment facilities. Established criteria for authorizing inpatient detox.	2017 into 2018 Spring 2018 May 2018
Use of evidence-based SUD-specific patient placement criteria	Conducted provider education on ASAM criteria. Developed standard prior authorization form for SUD treatment across managed care plans. Issued draft level of care guidelines.	May 2018, Fall 2019, Spring 2020 (virtual) March 2019 January 2020
Use of nationally recognized SUD-specific program standards to set provider qualifications for residential treatment facilities	Finalized process for provisional ASAM designation for providers. Final designations became effective July 1, 2018. *As of July 1, 2021, there are now 322 ASAM 3.1 beds, 1,429 ASAM 3.3 beds, and 125 dually-licensed 3.1/3.5 beds in service.*	March 2018
Sufficient provider capacity at critical levels of care, including medication assisted treatment for OUD	Training materials to providers and Medicaid managed care plans on new waiver services. Create new provider specialty for residential treatment facilities in state's MMIS. Began partnership linking Open Beds with Indiana 211. Added midlevel practitioners to those who qualify to bill for services in and FQHC or RHC. Added licensed behavioral health professionals to eligible provider group.	January 2018 and throughout year March 2018 March 2018 October 2020 November 2020
Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD	Implemented a reimbursement system for emergency responders who use naloxone. Built short-term strategies to ensure continued access to services during the public health emergency and long-term strategies to continue after the PHE.	July 2020 March 2020 – ongoing
Improved care coordination and transition between levels of care	Extend case management delivered by managed care plans to individuals transitioning from residential treatment facilities Created/maintain a cross-Divisional SUD work group to address ongoing implementation tasks.	February 2018 Sept 2018 - ongoing

I.D Population Groups Impacted

Overdose deaths nationally increased to a new record in Calendar Year (CY) 2020 to 93,331, an increase of 29.4 percent from the CY 2019 total of 72,151.[5] In Indiana, the year-over-year increase was 33.1 percent, from 1,704 in CY 2019 to 2,268 in CY 2020. This placed Indiana 15th highest among states for overdose deaths in 2020. Indiana has also been adversely impacted by drug overdose using other measures, including the following:

- Over the five-year period from December 2015 to December 2020, Indiana has also outpaced overdose deaths nationwide with an increase of 84.1 percent compared to the U.S. average increase of 77.4 percent.[6]

- Using CY 2019 data, Indiana ranked 18th highest among states on a per 100,000 resident basis for drug overdose mortality.[7]

- In 2017, the drug overdose death rate was 29.4 deaths per 100,000 in Indiana compared to motor vehicle traffic-related deaths of 12.9 per 100,000.[8]

For the Summative Evaluation of Indiana's first SUD demonstration period, the evaluators used CMS's specifications for SUD Metric #3 (Medicaid Beneficiaries with SUD Diagnosis) to assess the trend in the Medicaid population most likely to be impacted by the demonstration. Exhibit 2, which appears on the next page, shows the trend on this measure on a quarterly basis from Q1-2016 to Q4-2020. This period is roughly the two-year period prior to the start of the initial demonstration and the three years during the SUD demonstration.

Medicaid beneficiaries with a SUD diagnosis grew consistently during the five-year period examined, from 43,063 in Q1-2016 to 114,317 as of Q4-2020. Over the course of the demonstration, the population of beneficiaries with SUD grew 23 percent (92,642 in Q1-2018 to 114,317 in Q4-2020).

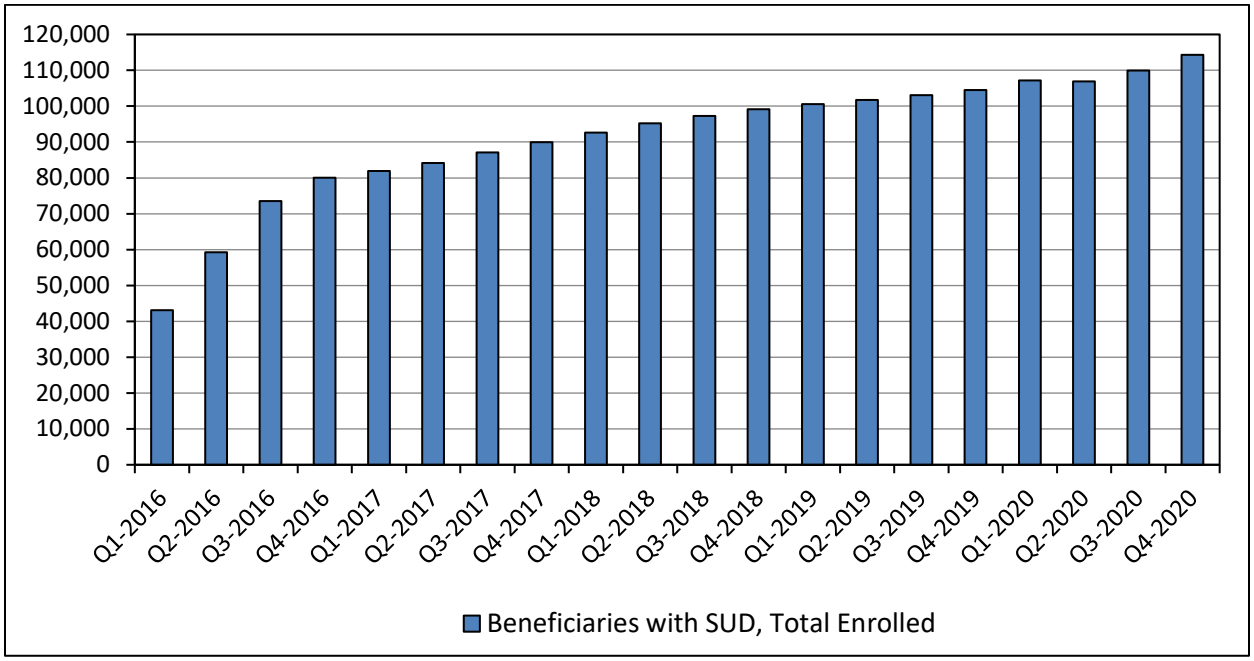
[5] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm National Vital Statistics System, information retrieved July 20, 2021

[6] Ibid.

[7] https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm Data is age-adjusted by state, information retrieved July 20, 2021

[8] 2017-SER.pdf (in.gov) Special Emphasis Report: Drug Overdose Deaths 1999-2017, retrieved July 20, 2021

Exhibit 2. Count of Indiana Medicaid Members Meeting CMS Metric #3 Criteria, CY 2016 – CY 2020



Overall, Medicaid members with a SUD diagnosis represented 6.2 percent of the total Medicaid population at the start of the demonstration in February 2018. By the end of the first SUD demonstration period in December 2020, these members represented 6.5 percent of total enrollees.

Exhibit 3 on the next page compares the percent of total enrollees with SUD against the overall Medicaid population across a number of subpopulations. As expected, non-elderly adults represent approximately half of total Medicaid enrollment, but more than 12 percent of non-elderly adults have a SUD diagnosis.

Dual eligibles, the criminally involved, and beneficiaries enrolled in the Medicaid Rehabilitation Option (MRO) benefit are also over-represented within the total population with SUD compared to their proportional enrollment in Medicaid overall (i.e., each subpopulation has a higher percentage of its members with SUD than the statewide percentage shown at the top of the exhibit).

The FSSA maps each of Indiana's 92 counties into one of eight regions shown in the exhibit. There has been modest change over the demonstration period of the percentage of the Medicaid population with SUD at the region level, but all regions did see an increase. Medicaid enrollees in the East Central, Southwest, and Southeast regions are over-represented in the percentage with SUD compared to the statewide average.

Exhibit 3. Comparison of Medicaid Members with SUD Diagnosis to Total Enrollment at the Start and End of the Initial Demonstration Period

	February 2018 start of demonstration period			December 2020 end of demonstration period		
Category	**Total Enrollment**	**Percent of Total Enrolled**	**Percent of Total Enrolled with SUD**	**Total Enrollment**	**Percent of Total Enrolled**	**Percent of Total Enrolled with SUD**
Total Demonstration Population	**1,479,615**	**100.0%**	**6.2%**	**1,768,040**	**100.0%**	**6.5%**
By Age Group						
Age Less than 18	682,021	46.1%	0.5%	744,466	42.1%	0.3%
Age 18 to 64	693,346	46.9%	12.4%	899,695	50.9%	12.0%
Age 65 and Over	104,248	7.0%	2.8%	123,879	7.0%	3.7%
By Cohort Population						
Dual Eligible	139,958	9.5%	7.0%	154,786	8.8%	7.6%
Pregnant	30,615	2.1%	5.5%	50,000	2.8%	6.4%
Criminally Involved	6,597	0.4%	7.7%	4,780	0.3%	7.2%
MRO	41,290	2.8%	16.6%	45,242	2.6%	19.0%
By FSSA Region						
Northwest	192,804	13.0%	5.0%	222,042	12.6%	5.1%
North Central	129,899	8.8%	2.9%	152,652	8.6%	2.8%
Northeast	162,746	11.0%	5.7%	197,275	11.2%	5.9%
West Central	110,129	7.4%	5.7%	130,064	7.4%	6.3%
Central	473,723	32.0%	5.6%	575,984	32.6%	5.9%
East Central	132,971	9.0%	7.2%	156,655	8.9%	8.4%
Southwest	147,762	10.0%	8.5%	177,387	10.0%	8.8%
Southeast	128,810	8.7%	10.3%	155,742	8.8%	10.4%

SECTION II: EVALUATION QUESTIONS AND HYPOTHESES

II.A Translating Demonstration Goals into Quantifiable Targets for Improvement

The Burns & Associates division of Health Management Associates (HMA-Burns)[9], the independent evaluator of Indiana's SUD demonstration waiver, examined the relationships among the State's (and CMS's) SUD demonstration goals to develop hypotheses related to Indiana's SUD waiver renewal. Given the experience of the HMA-Burns team with evaluating Indiana's first SUD waiver along with our understanding of the specific items identified and carried out in the State's SUD implementation plan since the initial waiver was approved, the approach by the HMA-Burns team for Indiana's second SUD waiver is to evaluate the pace of improvement in the access, utilization and delivery of SUD treatment services to Medicaid beneficiaries that builds on the foundation established in the first SUD waiver period.

Although Indiana's initial SUD waiver period was short in duration (35 months instead of a typical 60 months), the State undertook significant steps to expand SUD treatment coverage immediately upon waiver initiation. It should be recognized, however, that the delivery of community-based SUD treatment in Indiana's Medicaid program at a broad statewide level is still a relatively new undertaking.

II.B Defining Relationships: Waiver Policy, Short-term and Longer-term Outcomes

The HMA-Burns team constructed a logic model with the long-term outcome being a reduction in overdose deaths in Indiana. The logic model appears as Exhibit 4 on the next page. Based on key actions taken by the State either at the start of the initial SUD waiver demonstration or since the demonstration's initiation, eight short-term outcomes have been identified.

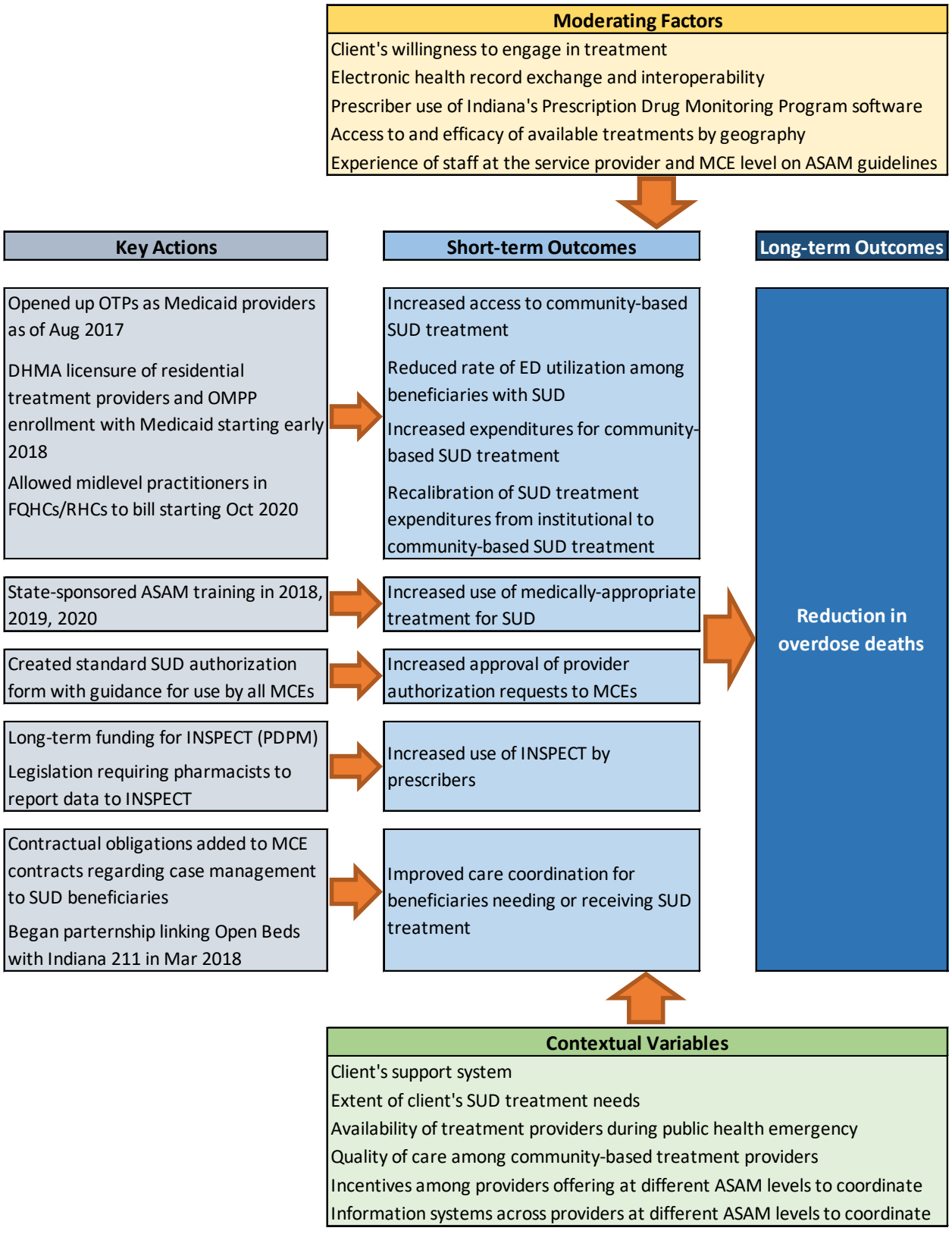
The short-term outcomes all tie to eight hypotheses and eight research questions which are introduced in Section II.C.

There is recognition that the success of short-term and long-term outcomes may be moderated by factors such as the client's willingness to engage in SUD treatment, the access to and efficacy of available treatments for SUD throughout Indiana, the experience of the staff among MCEs and service providers on ASAM guidelines, and the availability and use of technology by providers and service coordinators to effectively coordinate SUD treatment.

Contextual variables to the success of short-term and long-term outcomes include the extent of need by each client and where the client is located in the state, the client's support system to initiate or continue engagement in treatment, and incentives or disincentives for providers at different ASAM levels to coordinate the transition of care from one ASAM level to another.

[9] Burns & Associates, Inc. (B&A) was engaged by Indiana's Family and Social Services Administration to conduct the evaluation of Indiana's initial SUD waiver. B&A was acquired by Health Management Associates effective September 1, 2020. The initial B&A team that worked on the initial SUD waiver evaluation continues this work at HMA. This same team will also serve as the evaluation team of Indiana's second SUD waiver evaluation.

Exhibit 4. Logic Model for Indiana's SUD Demonstration: Reduce Overdose Deaths



II.C Hypotheses and Research Questions

Exhibit 5 identifies the hypotheses developed for Indiana's SUD waiver demonstration renewal and the research questions associated with each hypothesis. A full listing of the measures associated with each hypothesis and research question appears in Section III.G of the Methodology section. For each hypothesis, a reference is made to compare against either the initial demonstration period (February 2018 to December 2020) or prior to the initial demonstration period (prior to February 2018). When statistically significant improvement was reported in the Summative Evaluation between the initial demonstration period and the pre-demonstration period on measures tied to hypotheses, then the comparison period is the initial demonstration period. When statistically significant improvement was not reported in the Summative Evaluation, then the comparison period is the pre-demonstration period.

Exhibit 5. Hypotheses and Research Questions Developed for the Evaluation of Indiana's SUD Waiver Demonstration Renewal

Hypothesis (H)		Research Question (RQ)	
H1	The demonstration will decrease the rate of overdose deaths in Indiana since prior to the initial demonstration period.	**RQ1**	Is the rate of drug overdose deaths in Indiana impacted by the demonstration?
H2	The demonstration will increase the percentage of Medicaid beneficiaries who initiate and engage in treatment for OUD and other SUDs since the initial demonstration period.	**RQ2**	Does the demonstration increase the percentage of beneficiaries who initiate and engage in treatment for OUD and other SUDs?
H3	The demonstration will decrease the rate of emergency department visits among Medicaid beneficiaries with SUD since the initial demonstration period.	**RQ3**	Does the demonstration decrease the rate of emergency department visits among Medicaid beneficiaries with SUD?
H4	The demonstration will decrease the rate of hospital readmissions among Medicaid beneficiaries with SUD since prior to the initial demonstration period.	**RQ4**	Does the demonstration decrease the rate of hospital readmissions among Medicaid beneficiaries with SUD?
H5	The demonstration will increase the percentage of Medicaid beneficiaries who receive care for comorbid conditions since prior to the initial demonstration period.	**RQ5**	Does the demonstration increase the percentage of Medicaid beneficiaries with SUD who receive care for comorbid conditions?
H6	The demonstration will improve access to community-based services for SUD treatment since the initial demonstration period.	**RQ6**	Does the demonstration increase the level of access to community-based SUD treatment for Medicaid beneficiaries with SUD?
H7	Care coordination and transitions between ASAM levels of care will improve during the demonstration period.	**RQ7**	Does the demonstration improve transitions between ASAM levels of care?
H8	The demonstration will further rebalance Medicaid expenditures for treatment of SUD more toward community-based care since the initial demonstration period.	**RQ8**	Does the demonstration rebalance Medicaid expenditures for SUD treatment away from institutional toward community-based care?

The number of hypotheses and research questions shown in Exhibit 5 was reduced from the number included in the initial demonstration period for a variety of reasons:

1. Some hypotheses and research questions were specifically targeted towards aspect of implementation of a new program which is not relevant to the renewal demonstration period. One example is research questions related to the enrollment of residential treatment providers.

2. Some hypotheses and research questions in the initial demonstration were specifically focused on implementation tasks that were intended to occur but were never implemented. One example is the universal adoption of the Child and Adolescent Needs and Strengths (CANS) and Adult Needs and Strengths Assessment (ANSA) to place beneficiaries in ASAM levels of care.

3. Measures that were utilized to answer many research questions during the initial demonstration period will continue to be examined in the new demonstration period, but these measures are now mapped to a more general research question in this evaluation design. Specific examples pertain to care coordination and transitions of care research questions in the initial demonstration evaluation design that have been subsumed under Research Question #7 in this evaluation design.

II.D Alignment with Demonstration Goals

To ensure that the evaluation hypotheses and research questions are responsive to the CMS guidance in the approved waiver standard terms and conditions, HMA-Burns has mapped the hypotheses to the waiver demonstration goals. Each hypothesis addresses at least one demonstration goal and, in many cases, map to multiple goals. Exhibit 6 presents a visualization of this mapping.

Exhibit 6. Alignment of Hypotheses with Demonstration Goals

		Waiver Goal					
		1	2	3	4	5	6
		Increase identi-fication, initiation, engagement	Increase adherence to and retention in treatment	Reductions in overdose deaths, particularly opioids	Reduced utilization of ED and hospital settings	Fewer readmits to same or higher level of care	Improved access to care for physical health conditions
Hypothesis							
H1	Decrease the rate of overdose deaths			X			
H2	Increase the percentage of initiation and engagement in treatment	X					
H3	Decrease the rate of emergency department visits				X		
H4	Decrease the rate of hospital readmissions					X	
H5	Increase the rate of beneficiaries who receive care for comorbid						X
H6	Improve access to community-based services for SUD treatment		X				
H7	Improve care coordination and transitions between ASAM levels		X				
H8	Rebalance Medicaid expenditures toward community-based care	X					

SECTION III: METHODOLOGY

III.A Evaluation Design

The evaluation design is a mixed-methods approach, drawing from a range of data sources, measures, and analytics to best produce relevant and actionable study findings. The HMA-Burns team tailored the approach for each of the eight research questions described in Section II, Evaluation Questions and Hypotheses. The evaluation plan reflects a range of data sources, measures, and perspectives.

Indiana's Medicaid population with a SUD diagnosis is the predominant population examined in the evaluation but, at times, the entire adult Medicaid population will be used as a comparison. Within the Medicaid population with SUD, a number of study sub-populations will also be examined and tested against the overall SUD population. These are identified in Section III.B.

The five analytic methods proposed for use across the eight hypotheses and eight research questions include:

1. Chi-square (Chi),
2. Interrupted Time Series (ITS),
3. Onsite reviews (OR)
4. Desk reviews (DR) and,
5. Facilitated interviews (FI).

Exhibit 7 on the next page presents a chart displaying which method(s) are used for each hypothesis. The five methods are ordered and abbreviated as described above.

Exhibit 7. Summary of Five Analytic Methods by Hypothesis

Hypothesis (H)		Method					Data Sources
		Chi	ITS	OR	DR	FI	
H1	The demonstration will decrease the rate of overdose deaths in Indiana since prior to the initial demonstration period.	X			X		Claims data, vital statistics, PDMP stats
H2	The demonstration will increase the percentage of Medicaid beneficiaries who initiate and engage in treatment for OUD and other SUDs since the initial demonstration period.	X	X		X	X	Claims data, enrollment data
H3	The demonstration will decrease the rate of emergency department visits among Medicaid beneficiaries with SUD since the initial demonstration period.		X		X		Claims data, enrollment data
H4	The demonstration will decrease the rate of hospital readmissions among Medicaid beneficiaries with SUD since prior to the initial demonstration period.	X			X		Claims data, enrollment data
H5	The demonstration will increase the percentage of Medicaid beneficiaries who receive care for comorbid conditions since prior to the initial demonstration period.		X		X		Claims data, enrollment data
H6	The demonstration will improve access to community-based services for SUD treatment since the initial demonstration period.			X	X	X	Claims data, enrollment data, MCE data files, MCE case files
H7	Care coordination and transitions between ASAM levels of care will improve during the demonstration period.			X	X	X	Claims data, enrollment data, MCE data files, MCE case files
H8	The demonstration will further rebalance Medicaid expenditures for treatment of SUD more toward community-based care since the initial demonstration period.		X		X		Claims data, enrollment data

Chi = Chi-square; ITS = Interrupted Time Series; OR = Onsite Reviews; DR = Desk Reviews; FI = Facilitated Interviews

III.B Target Population and Comparison Groups

Target Population

The target population is any Indiana Medicaid beneficiary with a diagnosis of SUD in the study period. HMA-Burns will use the specification described in the CMS-approved Monitoring Plan for identification of beneficiaries with SUD to flag individuals as an indicator of those most likely to have exposure to the changes in the waiver.

While the key study population is the overall SUD population, a standardized set of sub-populations will be identified and examined. HMA-Burns will sub-set the SUD population, at minimum, by common demographic groups such as by age (adolescent, non-elderly adults, elderly), by delivery system (i.e., managed care or fee-for-service), and by eight geographic regions (mapping each of Indiana's 92 counties to one of the eight regions defined). In addition, there are nuances in the 1115 waiver changes which warrant identification and stratification of the data into a number of sub-populations such as the following:

- ASAM Levels: It is possible that outcomes may differ among the SUD population based on their access to services. HMA-Burns will examine the outcomes by those accessing a particular level of care for differences in health outcomes or cost in the post-waiver period compared to the pre-wavier period.

- Opioid Use Disorder (OUD): It is likely that beneficiaries with OUD, compared to those with other types of SUD, may have different health outcomes and access a different mix of services. Therefore, it is possible that the waiver impacts these populations differently. HMA-Burns will identify OUD beneficiaries (using the CMS-defined specification) to examine these individuals as a separate sub-population.

- New Member/COVID: Beneficiaries who became newly eligible for Medicaid due to the financial impact of the pandemic will be separately identified. A combination of aid category and time of enrollment will be used to identify this population.

Comparison Groups

As described in III.C below, HMA-Burns will create groups of Medicaid beneficiaries with SUD across four time periods in order to compare outcomes. In addition, a sensitivity analysis will be conducted on selected measures using enrollment duration as the control group. Refer to Section III.F for more details.

III.C Evaluation Period

Monthly Measures

For measures which are computed on a monthly basis, statistical testing using Interrupted Time Series (ITS) will be applied. HMA-Burns will consider four different time periods when conducting ITS. Each time period will contain 25 observations (months). While the initial demonstration evaluation design intended for 2015 data to be included in the pre-demonstration period, the independent evaluators did not include it as the conversion from ICD-9 to ICD-10 took place during this year. An examination of the mapping of ICD-9 to ICD-10 codes found that only 45% of the ICD-10 SUD Value Set codes had a 1:1

conversion to ICD-9. The remaining 55% of the ICD-10 codes mostly matched to multiple ICD-9 codes, with one code having no match at all.

- Time Period #1: Pre-Demonstration. This is the period just prior to the approval of Indiana's first SUD demonstration, from January 2016 through January 2018.

- Time Period #2: Demonstration 1 period. This is the first 25 months of Indiana's initial SUD demonstration, from February 2018 through March 2020. Indiana's initial SUD demonstration ended in December 2020. The first 25 months of the demonstration are included in the analysis instead of the last 25 months of the demonstration because the last nine months of Indiana's truncated 35-month demonstration period were during the onset of the public health emergency (PHE).

- Time Period #3: Demonstration 2 initial period. This is the 25-month period from December 2021 through December 2023. Time Period #3 will be compared to either Time Period #1 or Time Period #2 when ITS testing is conducted for reporting in the Interim Evaluation.

- Time Period #4: Demonstration 2 later period. This is the 25-month period from December 2023 through December 2025. Time Period #4 will be compared to either Time Period #1 or Time Period #2 when ITS testing is conducted for reporting in the Summative Evaluation.

The determination of whether Time Periods #3 and #4 are tested against either Time Period #1 or Time Period #2 are based on the results that HMA-Burns found in its Summative Evaluation of Indiana's first SUD demonstration.

- If it was found in the Summative Evaluation of the first demonstration period when ITS was run that there was not a statistically significant finding for a given measure, then HMA-Burns will run ITS on that measure using Time Period #3 (for Interim Evaluation) or Time Period #4 (for Summative Evaluation) against Time Period #1.

- If it was found in the Summative Evaluation of the first demonstration period when ITS was run that there was a statistically significant finding for a given measure, then HMA-Burns will run ITS on that measure using Time Period #3 (for Interim Evaluation) or Time Period #4 (for Summative Evaluation) against Time Period #2. Since it was already established in the first demonstration evaluation that statistically significant improvement was found, for the second demonstration evaluation HMA-Burns will assess if improvement continued and if the pace of this improvement was statistically significant compared to the findings from the first demonstration period.

Annual Measures

For measures which are computed on an annual basis, statistical testing using chi-square will be applied. HMA-Burns will consider four different time periods when conducting chi-square. While the initial demonstration evaluation design intended for calendar year 2015 data to be included in the pre-demonstration period, the independent evaluators did not include it as the conversion from ICD-9 to ICD-10 took place during this year. An examination of the mapping of ICD-9 to ICD-10 codes found that only 45% of the ICD-10 SUD Value Set codes had a 1:1 conversion to ICD-9. The remaining 55% of the ICD-10 codes mostly matched to multiple ICD-9 codes, with one code having no match at all.

- Time Period #1: Pre-Demonstration. This will include the average results for Calendar Years 2016 and 2017.

- Time Period #2: Demonstration 1 period. This will include the average results for Calendar Years 2018 and 2019.

- Time Period #3: Demonstration 2 initial period. This will include the average results for Calendar Years 2022 and 2023.

- Time Period #4: Demonstration 2 later period. This will include the average results for Calendar Years 2024 and 2025.

Similar to the approach that will be used for monthly measures, the determination of whether Time Periods #3 and #4 are tested against either Time Period #1 or Time Period #2 are based on the results that HMA-Burns found in its Summative Evaluation of Indiana's first SUD demonstration.

- If it was found in the Summative Evaluation of the first demonstration period when chi-square was run that there was not a statistically significant finding for a given measure, then HMA-Burns will run chi-square on that measure using Time Period #3 (for Interim Evaluation) or Time Period #4 (for Summative Evaluation) against Time Period #1.

- If it was found in the Summative Evaluation of the first demonstration period when chi-square was run that there was a statistically significant finding for a given measure, then HMA-Burns will run chi-square on that measure using Time Period #3 (for Interim Evaluation) or Time Period #4 (for Summative Evaluation) against Time Period #2.

III.D Evaluation Measures

The HMA-Burns team identified 32 measures in the evaluation design plan that directly relate to the outcomes described the logic model shown in Section II, the overall demonstration goals, and the research questions developed for this demonstration evaluation. The measures include those with national measure stewards, those specified by CMS, and evaluator-derived measures. Of the total 32 measures, 23 of them are currently SUD monitoring measures required by CMS for SUD waiver reporting by states. The CMS-defined metrics will be computed monthly and/or annually as deemed appropriate to each measure specification and will use the CMS technical specifications for computation.

Exhibit 8 on the next two pages summarizes the list of measures included in the evaluation design plan. Each measure is mapped to a hypothesis and research question. There is an indicator whether ITS or chi-square will be used as the basis for statistical testing on the measure. Additionally, there is an indicator if the measure will be subject to sensitivity analysis. The statistical tests using ITS or chi-square will be completed on each measure shown and reported in both the Interim and Summative Evaluations.

A comprehensive list of measures as well as a description of numerators and denominators can be found in the detailed matrices shown in Section III.G.

Exhibit 8. Summary of Measures and Steward, by Research Question

H = Hypothesis

H	Research Question (RQ) / Measures Associated with Each RQ		Measure Steward	CMS Metric	Interrupted Time Series Test	Sensitivity to ITS Tested	Chi-square Test
H1	RQ1	Is the rate of drug overdose deaths in Indiana impacted by the demonstration?					
	1	Rate of overdose deaths	HMA	#26			
	2	Use of opioids at high dosage in persons without cancer	NCQA, NQF #2940	#18			X
	3	Use of opioids from multiple providers in persons w/o cancer	PQA, NQF #2950	#19			X
	4	Concurrent use of opioids and benzodiazepines	PQA, NQF #3389	#21			X
	5	Number of prescribers accessing INSPECT	HMA	n/a			
H2	RQ2	Does the demonstration increase the percentage of beneficiaries who initiate and engage in treatment for OUD and other SUDs?					
	6	Initiation of AOD Dependence Treatment, Total Population	NCQA, NQF #0004	#15			X
	7	Initiation of AOD Dependence Treatment, Alcohol Abuse Only	NCQA, NQF #0004	#15			X
	8	Initiation of AOD Dependence Treatment, Opioid Abuse Only	NCQA, NQF #0004	#15			X
	9	Initiation of AOD Dependence Treatment, Abuse Other than Alcohol or Opioid	NCQA, NQF #0004	#15			X
	10	Engagement of AOD Dependence Treatment, Total Population	NCQA, NQF #0004	#15			X
	11	Engagement of AOD Dependence Treatment, Alcohol Abuse Only	NCQA, NQF #0004	#15			X
	12	Engagement of AOD Dependence Treatment, Opioid Abuse Only	NCQA, NQF #0004	#15			X
	13	Engagement of AOD Dependence Treatment, Abuse Other than Alcohol/Opioid	NCQA, NQF #0004	#15			X
	14	Follow-up After ED Visits for AOD Dependence, 7 days	NCQA, NQF #3488	#17			X
	15	Continuity of Pharmacotherapy for Opioid Use Disorder	USC, NQF #3175	#22			X
	16	Rate of Medicaid beneficiaries receiving outpatient services	CMS	#8	X	X	
	17	Rate of Medicaid beneficiaries receiving intensive outpatient or partial hosp	CMS	#9	X	X	
	18	Rate of Medicaid beneficiaries receiving residential or hospital treatment	CMS	#10	X	X	
	19	Rate of Medicaid beneficiaries receiving withdrawal management	CMS	#11	X	X	
	20	Rate of Medicaid beneficiaries receiving medication assisted treatment	CMS	#12	X	X	

H = Hypothesis

H	Research Question (RQ) / Measures Associated with Each RQ		Measure Steward	CMS Metric	Interrupted Time Series Test	Sensitivity to ITS Tested	Chi-square Test
H3	RQ3	Does the demonstration decrease the rate of emergency department visits among Medicaid beneficiaries with SUD?					
	21	ED utilization per 1,000 among beneficiaries with SUD	CMS	#23	X	X	
H4	RQ4	Does the demonstration decrease the rate of hospital readmissions among benefic. with SUD?					
	22	Readmissions among beneficiaries with SUD	CMS	#25			X
H5	RQ5	Does the demonstration increase the percentage of beneficiaries with SUD who receive care for comorbid conditions?					
	23	Access to Preventive Health for Adult Beneficiaries with SUD	NCQA, AAP	#32	X	X	
H6	RQ6	Does the demonstration increase the level of access to community-based SUD treatment for beneficiaries with SUD?					
	24	ASAM 3.x bed capacity for Medicaid beneficiaries	HMA	n/a			
	25	MAT prescribers in Indiana accepting Medicaid clients	HMA	n/a			
	26	Authorized residential treatment days as percent of total requested	HMA	n/a			
	27	Average distance travelled by Medicaid beneficiaries seeking residential Tx	HMA	n/a			
H7	RQ7	Does the demonstration improve transitions between ASAM levels of care?					
	28	Pct of discharges from inpatient/residential treatment for SUD which were followed by SUD treatment	RTI, NQF #3590	n/a			
	29	Pct of discharges from inpatient/residential treatment for SUD that readmit for inpt/resid within 180 days of initial discharge	HMA	n/a			
	30	Pct of beneficiaries enrolled in managed care and actively engaged in case or care management with their MCE	HMA	n/a			
H8	RQ8	Does the demonstration rebalance Medicaid expenditures for treatment of SUD away from institutional care toward community-based care?					
	31	PMPM costs, beneficiaries with SUD, all services	CMS	n/a	X	X	
	32	PMPM costs, beneficiaries with SUD, for SUD services	CMS	#25	X	X	

III.E Data Sources

As described in Section III.A, Evaluation Design, HMA-Burns will use existing secondary data sources as well as collect primary data. The evaluation design relies most heavily on the use of Indiana Medicaid administrative data, such as enrollment, claims, and encounter data. Supplemental administrative data, such as service authorization approvals and denials, will also be incorporated. Primary data will be limited and include data created by desk review and facilitated interview instruments. A brief description of these data and their strengths and weaknesses appears below.

Indiana Medicaid Administrative Data

Claims and encounters with dates of service (DOS) from January 1, 2016 and ongoing will be collected from the FSSA Enterprise Data Warehouse (EDW), facilitated by FSSA's EDW vendor, Gainwell Technologies. Managed care encounter data has the same record layout as fee-for-service claims in the EDW and includes variables such as charges and payments at the header and line level. Payment data for MCE encounters represents actual payments made to providers by the MCEs. In total, four MCEs will have encounter data in the dataset.

Because the HMA-Burns team already has built a relationship with the FSSA Data Analytics team and with Gainwell, the HMA-Burns team currently receives monthly tables from the EDW representing member enrollment and demographic information, provider enrollment and demographic information, and claims and encounter data at the detail claim line level. Data has already been received, validated, and used by HMA-Burns for the pre-waiver period. On an ongoing basis today and throughout the second demonstration period, the HMA-Burns team will continue to receive these files on a monthly basis from the EDW. The evaluation team will read in, validate, and append new data to the existing Indiana SUD evaluation database that has already been developed.

The last query of the EDW will occur at the end of December 2026 to allow for a 12-month submission lag for services rendered up until the end of the demonstration on December 31, 2025. All data delivered to HMA-Burns from the FSSA will come directly from the EDW. HMA-Burns will leverage all data validation techniques used by Gainwell before the data is submitted to the EDW. HMA-Burns will also conduct its own validations upon receipt of each monthly file from the EDW to ensure accuracy and completeness when creating our multi-year historical database.

When additional data is deemed necessary for the evaluation, HMA-Burns will outreach directly to the MCEs when they are determined to be the primary source. HMA-Burns will build data validation techniques specific to the data received from ad hoc requests made to the MCEs.

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

Indiana Vital Statistic Data

In collaboration with FSSA, vital statistics cause of death data will be transferred from the Department of Health to the evaluators for purposes of calculating overdose rates. This is currently underway for the first SUD demonstration evaluation and will continue in this second demonstration evaluation. More information on vital statistics can be found at: https://www.in.gov/health/vital-records/death-information/death-information/

Prescription Drug Monitoring Program (PDMP) Data

In accordance with state guidelines, the states PDMP (named INSPECT) collects information on queries and unique users which will be provided by the Indiana Professional Licensing Agency in collaboration from FSSA. Where possible, data available in the public domain via quarterly reports will be collected and used. Information on the Indiana's PDMP can be found at: https://www.in.gov/pla/inspect/

Facilitated Interview Data

HMA-Burns will construct facilitated interview guide instruments as a means to collect primary data for the focus studies planned in this evaluation related to service authorizations, care coordination, and transitions to care. The types of respondents that the evaluators propose to interview include the MCEs, SUD providers and SUD beneficiaries. Where focused interviews are used to collect data, HMA-Burns will use semi-structured interview protocols that are intended to be standardized within the population being interviewed. The interview protocols will vary, however, for each population interviewed due to the type of information that is intended to be collected. Although semi-structured in nature, each stakeholder will have the opportunity to convey additional information that he/she would like to convey to the evaluators in an open-ended format at the conclusion of each interview.

III.F Analytic Methods

Exhibit 7 depicted the five analytic methods to be used in the analysis. A detailed discussion of each method is described below. It should be noted that whether the statistical test that is applied is ITS or chi-square, for every measure HMA-Burns will also compile descriptive statistics to assess overall longitudinal trends. The descriptive statistics will be performed on the overall demonstration population as well as the subpopulations described in III.B.

Method 1: Chi-square

A chi-square test will be used for measures that are computed annually. Measures where chi-square testing is used will utilize two calendar year time periods, as defined in III.C. The evaluators will consider results significant at a level of probability of $p < .05$. A test statistic will be generated in the SAS© statistical program.

The chi-square test for goodness of fit would determine if the observed frequencies were different than expected; in other words, whether the difference in the pre- and post-outcomes were significantly different statistically than what would have been expected given the pre-period. The null hypothesis, therefore, is that the expected frequency distribution of all wards is the same. Rejecting the null would indicate the differences were statistically significant (i.e., exceeded difference than would be expected at a given confidence level).

The assumptions of the chi-square are:

- Simple random sample
- Sample size. Small samples subject to Type II error.
- Expected cell count. Recommended 5-10 expected counts.
- Independence. Evaluation of the appropriateness of a McNemar's test may be warranted.

Method 2: Interrupted Time Series (ITS)

Per CMS technical guidance, ITS is the preferred alternative approach to randomized control trials in the absence of an available, adequate comparison group for conducting cost-related evaluation analyses.

An ITS analysis relies on a continuous sequence of observations on a population taken at equal intervals over time in which an underlying trend is "interrupted" by an intervention. In this evaluation, the waiver is the intervention and it occurs at a known point in time. The trend in the post-waiver is compared against the expected trend in the absence of the intervention.

A reliability threshold of having a denominator of a minimum number of 100 observations at the monthly level will be used to determine if ITS analysis will ultimately be used. The current evaluation design contemplates using ITS on measures where a minimum denominator of 100 does not appear to be an issue. For all measures where ITS will be applied, descriptive statistics (e.g., mean, median, minimum, maximum, standard deviation) will be inspected for identification of anomalies and trends prior to conducting the test. Scatter plots of each measure will be created and examined to determine any seasonal trends or outliers. Moreover, each outcome will undergo bivariate comparisons; a Pearson correlation coefficient will be produced for each measure compared to the others as well as each measure in the pre- and post- periods.

Regression Analysis

Wagner et al. described the single segmented regression equation as[10]:

$$\hat{Y}_t = \beta_0 + \beta_1 * \text{time}_t + \beta_2 * \text{intervention}_t + \beta_3 * \text{time\_after\_intervention}_t + e_t$$

- Y_t is the outcome
- *time* indicates the number of months or quarters from the start of the series
- *intervention* is a dummy variable taking the values 0 in the pre-intervention segment and 1 in the post-intervention segment
- *time_after_intervention* is 0 in the pre-intervention segment and counts the quarters in the post-intervention segment at time t
- β_0 estimates the base level of the outcome at the beginning of the series
- β_1 estimates the base trend, i.e. the change in outcome in the pre-intervention segment
- β_2 estimates the change in level from the pre- to post-intervention segment
- β_3 estimates the change in trend in the post-intervention segment
- e_t estimates the error

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

Each outcome will be assessed through visualization for one of the following types of relationships in the pre- and post-waiver period: (a) Level change; (b) Slope change; (c) Level and slope change; (d) Slope change following a lag; (e) Temporary level change; (f) Temporary slope change leading to a level change.

Seasonality and Autocorrelation

One strength of the ITS approach is that it is less sensitive to typical confounding variables which remain fairly constant, such as population age or socio-economic status, as these changes relatively slowly over time. However, ITS may be sensitive to seasonality. To account for seasonality in the data, the same time period, measured in months or quarters, will be used in the pre- and post-waiver period. Should it be necessary, a dummy variable can be added to the model to account for the month or quarter of each observation to control for the seasonal impact.

An assumption of linear regression is that errors are independent. When errors are not independent, as is often the case for time series data, alternative methods may be warranted. To test for the independence, the evaluators will review a residual time series plot and/or autocorrelation plots of the residuals. In addition, a Durbin-Watson test will be constructed to detect the presence of autocorrelation. If the Durbin-Watson test statistic value is well below 1.0 or well above 3.0, there is an indication of serial correlation. If autocorrelation is detected, an autoregressive regression model, like the Cochrane-Orcutt model, will be used in lieu of simple linear regression.

Other assumptions of linear regression are that data are linear and that there is constant variance in the errors versus time. Heteroscedasticity will be diagnosed by examining a plot of residuals verses predicted values. If the points are not symmetrically distributed around a horizontal line, with roughly constant variance, then the data may be nonlinear and transformation of the dependent variable may be warranted. Heteroscedasticity often arises in time series models due to the effects of inflation and/or real compound growth. Some combination of logging and/or deflating may be necessary to stabilize the variance in this case.

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

Controls and Stratification

As described in Section III.B, for some of the monthly measures, the ITS will be run both on the entire SUD target population as well as by a sub-population of the SUD target population that was continuously enrolled for at least 12 months within the 25-month study period examined. Results from the ITS under each scenario will be compared to determine the sensitivity of the findings using the entire SUD population.

Method #3: Onsite Reviews

In order to fill gaps and address questions for which claims-based data and other sources are insufficient, onsite reviews are proposed to gain insight on nuanced differences in approach, use and

effectiveness of different MCE and FSSA approaches to two topics—(1) care coordination and case management and (2) SUD service authorizations.

The onsite reviews will be conducted at each MCE office. Reviews will include both a standardized set of interview questions that will capture information on process and documentation as well as a review of beneficiary-level records. A sampling approach will be developed from a desk review conducted prior to the onsite review whereby a limited number of beneficiaries are selected based on a set of criteria. Internal records specific to those beneficiaries stored at each MCE will be reviewed. The criteria for sampling will be developed to reflect the representativeness of the demonstration population or sub-population served by each MCE. The same team of reviewers will be used for each MCE onsite review to strengthen inter-reliability.

Method #4: Desk Reviews

To supplement the care coordination/case management and SUD service authorization focus studies mentioned above, desk reviews will also be conducted. HMA-Burns will provide to each MCE a data reporting template where individual records—such as beneficiary records for case management or individual service authorization requests for the SUD authorization study—will be requested from each MCE for a defined time period.

Once the data is delivered to HMA-Burns by the MCEs, the evaluation team will compile and analyze the data first to ensure face validity. Later, measures will be computed to ensure consistency, accuracy, and completeness of the data across MCEs (e.g., service authorization requests for 1,000 SUD members). Statistics will be tabulated on process measures (e.g., average duration enrolled in case management, turnaround time for service authorization decisions) and compared across the MCEs. The information tabulated in the desk review will be used to develop the sample of records reviewed while at onsite at the MCE offices.

Another focus study related to transitions of care will be completed as a desk review only. HMA-Burns will use encounters submitted by the MCEs for this study. Using a defined anchor event such as an ASAM level 3 or 4 treatment stay, services utilized by each SUD client will be examined for a 12-week period prior to the anchor event (admission to residential treatment or a hospital) and for a 12-week period after discharge. Trends will be examined on changes in utilization patterns in the pre- and post-anchor event period to determine not only if appropriate transitions occurred post-discharge but also the effectiveness of the residential treatment on patient outcomes (e.g., reduction in hospital emergency department use after the anchor event). HMA-Burns will request case and care management rosters from each MCE to assess the transitions of members after the anchor event discharge date for those enrolled in case/care management with the MCE against those who are not enrolled in case/care management.

Method #5 Facilitated and/or Focus Group Interviews

HMA-Burns will construct facilitated interview guide instruments as a means to collect qualitative information from stakeholders. Intended respondents will include the MCEs, SUD providers and SUD beneficiaries. Where focused interviews are used to collect data, HMA-Burns will use semi-structured interview protocols that are intended to be standardized within the population being interviewed. The interview protocols will vary, however, for each population interviewed due to the type of information that is intended to be collected. Although semi-structured in nature, each stakeholder will have the

opportunity to convey additional information that he/she would like to convey to the evaluators in an open-ended format at the conclusion of each interview.

The approach to obtain qualitative feedback is as follows:

- *Interviews with the MCEs*. Interviews will be conducted with members of each MCE staff individually as part of the onsite reviews related to care coordination/case management and SUD service authorizations. These interviews will be with subject matter experts related to each topic. Additionally, interviews will be conducted with representatives from leadership from all MCEs in a joint setting to discuss the effectiveness of the demonstration as well as opportunities to strengthen the delivery of SUD services in Indiana's Medicaid program.

- *Interviews with providers*. Interviews will be conducted through a web-based tool for groups of providers in a small focus group as well as 1:1 with individual providers either in person or via web-based tool. HMA-Burns aims to conduct at least three focus groups with providers before submission of the Interim Evaluation and three focus groups before submission of the Summative Evaluation. The representation in each focus group will be centered on the primary service offered by the providers (e.g., MAT, intensive outpatient, or residential treatment). Additionally, HMA-Burns aims to conduct at least ten 1:1 interviews with individual providers across the ASAM continuum of services prior to the Interim Evaluation and another 10 prior to the Summative Evaluation.

- *Interviews with beneficiaries*. Interviews will be conducted either at provider locations or via a web-based tool. HMA-Burns aims to conduct at least three focus groups with members as well as a minimum of 15 1:1 interviews prior to the Interim Evaluation and the same number prior to the Summative Evaluation. For the focus groups, HMA-Burns will stratify the groups into populations with similar characteristics (e.g., pregnant women, adolescents, adult women, adult men, geographic considerations). The 1:1 interviews will ensure representation from beneficiaries who received SUD services from Medicaid providers across the ASAM continuum. As a means to incentive participation by beneficiaries, HMA-Burns will offer gift cards from Wal-Mart or Target as a gesture of thanks. The gift cards will be distributed immediately after the focus group or interview concludes.

III.G Other Additions

Beginning on the next page, Exhibit 9 provides information on each measure selected for use in the evaluation. The measures are mapped to their associated hypothesis and research question.

Exhibit 9. Summary of Evaluation Questions, Evaluation Hypotheses, Data Sources, and Analytic Approaches

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #1: ***Is the rate of drug overdose deaths in Indiana impacted by the demonstration?***					
Demonstration Goal: Reduction in overdose deaths, particularly those due to opioids.					
Evaluation Hypothesis #1: The demonstration will decrease the rate of overdose deaths in Indiana since prior to the demonstration period.					
Rate of overdose deaths, specifically overdose deaths due to any opioid	HMA-Burns, CMS SUD Monitoring Metric #27	Number of overdose deaths per month and per year	Total number of beneficiary member months (result of this formula then expressed as per 1,000 member months)	Vital statistics, claims data	Descriptive statistics (frequencies and percentages)
Use of opioids at high dosage in persons without cancer	PQA, NQF #2940, CMS SUD Monitoring Metric #18	Number of beneficiaries with opioid prescription claims where the morphine equivalent dose for 90 consecutive days or longer is greater than 120 mg	Number of beneficiaries with two or more prescription claims for opioids filled on at least two separate dates, for which the sum of the days' supply is greater than or equal to 15	Claims and enrollment data	Descriptive statistics, chi-square tests
Use of opioids from multiple providers in persons without cancer	PQA, NQF #2950, CMS SUD Monitoring Metric #19	Number of beneficiaries >=18 who received prescriptions for opioids from >=4 prescribers and >=4 pharmacies within 180 days	Number of Medicaid beneficiaries >=18 that are not excluded due to cancer diagnosis	Claims and enrollment data	Descriptive statistics, chi-square tests
Concurrent use of opioids and benzodiazepines	PQA, NQF #3389, CMS SUD Monitoring Metric #21	Number of beneficiaries with concurrent use of prescription opioids and benzodiazepines	Number of Medicaid beneficiaries >=18 with two or more prescription claims for opioids filled on two or more separate days, for which the sum of the supply is 15 or more days	Claims and enrollment data	Descriptive statistics, chi-square tests
Number of clinicians accessing the PDMP	HMA-Burns	Number of clinicians accessing the PDMP monthly	N/A	PDMP data	Descriptive statistics (frequencies and percentages)

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #2: ***Does the demonstration increase the percentage of beneficiaries who initiate and engage in treatment for OUD and other SUDs?***					
Demonstration Goal: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs.					
Evaluation Hypothesis #2: The demonstration will increase the percentage of beneficiaries who initiate and engage in treatment for OUD and other SUDs since the initial demonstration period.					
Initiation and engagement of alcohol and other drug dependence treatment	NCQA, NQF #0004, CMS SUD Monitoring Metric #15	***Initiation*** : Number of patients who began initiation of treatment within 14 days of the index episode start date.	Patients who were diagnosed with a new episode of alcohol or drug dependency during the first 10 and ½ months of the measurement year.	Claims data	***For both measures*** : Analysis will be conducted on all 4 sub-populations (total, alcohol only, opioid only, other than alcohol or opioid). Descriptive statistics, chi-square tests.
Initiation and engagement of alcohol and other drug dependence treatment	NCQA, NQF #0004, CMS SUD Monitoring Metric #15	***Engagement*** : Initiation of treatment and two or more defined SUD visits within 30 days after the date of the initiation encounter.	Patients who were diagnosed with a new episode of alcohol or drug dependency during the first 10 and ½ months of the measurement year.	Claims data	
Follow-Up After Discharge from the Emergency Department for Alcohol or Other Drug (AOD) Dependence	NCQA, CMS SUD Monitoring Metric #17(1)	1. Members who had a follow-up visit to an ED visit with a SUD indicator within 7 days of discharge within the previous rolling 12 months.	Individuals with an ED visit (with SUD indicator) within the previous rolling 12 months.	Claims data	***For both measures*** : Descriptive statistics, chi-square tests
	NCQA, Monitoring Metric #17(2)	2. Same as above for members who had a follow-up visit within 30 days.	Individuals with an ED visit (with SUD indicator) within the previous rolling 12 months.	Claims data	
Continuity of pharmacotherapy for OUD	USC, NQF #3175, CMS SUD Monitoring Metric #22	Number of participants who have at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than seven days.	Individuals who had a diagnosis of OUD and at least one claim for an OUD medication.	Claims data	Descriptive statistics, chi-square tests

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #2: ***Does the demonstration increase the percentage of beneficiaries who initiate and engage in treatment for OUD and other SUDs?***					
Rate of Medicaid beneficiaries receiving intensive outpatient tx	CMS SUD Monitoring Metric #8	Number of unique beneficiaries who received outpatient treatment during the measurement period.	Individuals identified with a SUD diagnosis using CMS Metric #3.	Claims and enrollment data	ITS, including sensitivity analysis
Rate of Medicaid beneficiaries receiving intensive outpatient tx	CMS SUD Monitoring Metric #9	Number of unique beneficiaries who received intensive outpatient or partial hospitalization during the measurement period.	Individuals identified with a SUD diagnosis using CMS Metric #3.	Claims and enrollment data	ITS, including sensitivity analysis
Rate of Medicaid beneficiaries receiving residential treatment	CMS SUD Monitoring Metric #10	Number of unique beneficiaries who have a service for residential treatment for SUD during the measurement period.	Individuals identified with a SUD diagnosis using CMS Metric #3.	Claims and enrollment data	ITS, including sensitivity analysis
Rate of Medicaid beneficiaries receiving withdrawal management	CMS SUD Monitoring Metric #11	Number of unique beneficiaries who received withdrawal management during the measurement period.	Individuals identified with a SUD diagnosis using CMS Metric #3.	Claims and enrollment data	ITS, including sensitivity analysis
Rate of Medicaid beneficiaries receiving MAT	CMS SUD Monitoring Metric #12	Number of unique beneficiaries who received MAT during the measurement period.	Individuals identified with a SUD diagnosis using CMS Metric #3.	Claims and enrollment data	ITS, including sensitivity analysis

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #3: ***Does the demonstration decrease the rate of emergency department visits among Medicaid beneficiaries with SUD?***					
Demonstration Goal: Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.					
Evaluation Hypothesis #3: The demonstration will decrease the rate of emergency department visits among Medicaid beneficiaries with SUD since the initial demonstration period.					
Emergency department visits for SUD-related diagnoses and specifically for OUD	CMS SUD Monitoring Metric #23	The number of ED visits with a SUD diagnosis present during the measurement period.	Beneficiaries enrolled in Medicaid for at least one month (30 consecutive days) during the measurement period.	Claims and enrollment data	ITS, including sensitivity analysis
Evaluation Question #4: ***Does the demonstration decrease the rate of hospital readmissions among Medicaid beneficiaries with SUD?***					
Demonstration Goal: Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappopriate.					
Evaluation Hypothesis #4: The demonstration will decrease the rate of hospital readmissions among Medicaid beneficiaries with SUD since prior to the initial demonstration period.					
Readmissions Among Beneficiaries with SUD	CMS SUD Monitoring Metric #25	At least one acute unplanned readmission for any diagnosis within 30 days of the date of discharge from the index hospital stay.	Medicaid beneficiaries age 18 and older with a SUD diagnosis and an index stay (discharges in first 11 months of measurement year).	Claims and enrollment data	Descriptive statistics, chi-square tests
Evaluation Question #5: ***Does the demonstration increase the percentage of Medicaid beneficiaries with SUD who receive care for comorbid conditions?***					
Demonstration Goal: Improved access to care for physical health conditions among beneficiaries.					
Evaluation Hypothesis #5: The demonstration will increase the percentage of Medicaid beneficiaries who receive care for comorbid conditions since prior to the initial demonstration period.					
Access to preventive/ ambulatory health services for adult Medicaid beneficiaries with SUD	NCQA, CMS SUD Monitoring Metric #32	Number of beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period.	Number of beneficiaries with a SUD diagnosis	Claims and enrollment data	ITS, including sensitivity analysis

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #6: ***Does the demonstration increase the level of access to community-based SUD treatment for Medicaid beneficiaries with SUD?***					
Demonstration Goal: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs.					
Demonstration Goal: Increased adherence to and retention in treatment.					
Demonstration Goal: Reduction in overdose deaths, particularly those due to opioids.					
Demonstration Goal: Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.					
Evaluation Hypothesis #6: The demonstration will improve access to community-based services for SUD treatment since the initial demonstration period.					
ASAM 3.x bed capacity for Medicaid beneficiaries	HMA-Burns	Total number of beds available at ASAM level 3.1 and 3.5 by providers licensed by Division of Mental Health & Addiction and registered as Medicaid providers.		FSSA-maintained report	Descriptive statistics (frequencies and percentages)
MAT prescribers in Indiana accepting Medicaid clients	HMA-Burns	Total MAT prescribers in Indiana that received payment for delivering MAT to a Medicaid beneficiary in the previous 12 months.	Total MAT prescribers in Indiana	FSSA report, claims data	Descriptive statistics (frequencies and percentages)
Authorized residential treatment days as a percentage of total requested days	HMA-Burns	Total days requested and approved by MCEs to residential treatment providers to deliver treatment to Medicaid beneficiaries.	Total days requested by residential treatment providers to deliver treatment to Medicaid beneficiaries.	MCE-submitted data	Descriptive statistics (frequencies and percentages)
Average distance travelled by Medicaid beneficiaries seeking residential treatment	HMA-Burns	Total driving miles from member's home to residential treatment provider where service is received.	Total unique member-to-provider residential treatment stays in the study period.	Claims and enrollment data	Descriptive statistics (frequencies and percentages). Results will be computed across eight regions of the state.

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #7: ***Does the demonstration improve transitions between ASAM levels of care?***					
Demonstration Goal: Increased adherence to and retention in treatment.					
Demonstration Goal: Reduction in overdose deaths, particularly those due to opioids.					
Demonstration Goal: Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.					
Evaluation Hypothesis #7: Care coordination and transitions between ASAM levels of care will improve during the demonstration period.					
Percentage of discharges from inpatient or residential treatment for SUD for Medicaid beneficiaries which were followed by a SUD treatment.	RTI, NQF #3590	Number of beneficiaries within (a) 7 and (b) 14 days who received a SUD treatment following discharge from an inpatient or residential SUD provider in a 12-month period.	Number of beneficiaries, age 18-64, with an inpatient or residential SUD stay in 12-month period.	Claims and enrollment data	Descriptive statistics (frequencies and percentages)
Percentage of discharges from inpatient or residential treatment for SUD that readmit for inpatient or residential within 180 days of initial discharge	HMA-Burns	Number of Medicaid beneficiaries an index event that readmit to inpatient hospital or residential treatment for SUD within 180 days of discharge from the index event.	Number of beneficiaries, age 18-64, with an inpatient or residential SUD stay in 12-month period.	Claims and enrollment data	Descriptive statistics (frequencies and percentages)
Rate of Medicaid beneficiaries enrolled in managed care and actively engaged in case or care management with their MCE	HMA-Burns	Number of unique beneficiaries who are actively enrolled in case or care management with their MCE. One rate will be computed for complex case management, another for care management.	Individuals identified with a SUD diagnosis using CMS Metric #3 who are enrolled with an Indiana MCE for a minimum of 90 days.	Claims and enrollment data plus MCE-submitted data	Descriptive statistics (frequencies and percentages)

Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #8: ***Does the demonstration rebalance Medicaid expenditures for SUD treatment away from institutional toward community-based care?***					
Demonstration Goal: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs.					
Demonstration Goal: Increased adherence to and retention in treatment.					
Demonstration Goal: Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.					
Evaluation Hypothesis #8: The demonstration will rebalance Medicaid expenditures for treatment of SUD more toward community-based care since the initial demonstration period.					
Per beneficiary per month costs in total and by categories of service among the SUD population	CMS-specified (SMI/SED and SUD Guidance Appendix C)	Total monthly costs for SUD beneficiaries. Categories include inpatient, outpatient, pharmacy, long term care, IMDs and other.	1. Total member months for beneficiaries with an SUD diagnosis. 2. Total member months for all enrolled beneficiaries.	Claims data	ITS, including sensitivity analysis
Per capita SUD spending	CMS SUD Monitoring Metric #28	Total monthly costs for SUD beneficiaries. Categories include residential treatment, intensive outpatient, outpatient, assessment.	1. Total member months for beneficiaries with an SUD diagnosis. 2. Total member months for all enrolled beneficiaries.	Claims data	ITS, including sensitivity analysis

SECTION IV: METHODOLOGICAL LIMITATIONS

There are inherent limitations to both the study design and its specific application to the SUD waiver evaluation. That being said, the proposed design is feasible and is a rational explanatory framework for evaluating the impact of the SUD waiver on the SUD population. Moreover, to fill gaps left by the limitations of this study design, a limited number of qualitative methods are proposed to provide a more holistic and comprehensive evaluation.

Some measures and/or sub-populations may not be meaningful for reporting and insufficient statistical power to detect a difference is a concern. For any observational studies, especially if the population size exposures and the outcomes being assessed are rare, it is difficult to find statistically significant results. It is not unexpected, therefore, that many of the outcome measure sample sizes will be too small to observe statistically significant results. HMA-Burns recommends a threshold for minimum numbers of observations. For any measures below this threshold, the expectation of statistical testing would be waived.

While CMS may prefer comparator group from another state, in the last two years, the proliferation of the SUD demonstrations across the country renders few comparable states to Indiana. Moreover, this would require significantly more resources and cooperation with another state on sharing data. Therefore, HMA-Burns recommends using statistical tests comparing the pre- and post-waiver period to test hypotheses in the absence of a control group.

Another limitation is the length of time of the evaluation period. In some cases, the time period may be insufficient to observe descriptive or statically significant differences in outcomes in the SUD population. Therefore, it is expected that not all outcomes included in the study will show a demonstrable change descriptively, although we do expect some process measures to show a change during this time frame.

Moreover, with any study focused on the SUD population and potentially rare outcome measures, such as overdose rates, insufficient statistical power to detect a difference is a concern. For any observational studies, especially if the exposures and the outcomes being assessed are rare, it is difficult to find statistically significant results. It is not unexpected, therefore, that many of the outcome measure sample sizes will be too small to observe statistically significant results.

Related to the issues mentioned above, many of the outcome measures are multi-dimensional and influenced by social determinants of health. While changes under the waiver related to access to care may be one dimension of various outcomes of interest, and may contribute to improvements, it may be difficult to achieve statistically significant findings in the absence of data on other contributing dimensions, like social determinants of health such as housing, employment, and previous incarcerations.

SECTION V: SPECIAL METHODOLOGICAL CONSIDERATIONS

The proposed Evaluation Design Plan provides more than adequate rigor in the observational study design, especially when considering the range of supplemental evaluation methods proposed for inclusion. As described in Section IV, the study mitigates known limitations to the extent feasible drawing upon the range of options to fill gaps in the observational study design.

An important special consideration in Indiana is the fact this Indiana will be the first state undertaking a SUD demonstration renewal evaluation. Although other State Medicaid Agencies may have implemented more sophisticated SUD service delivery systems even prior to their own waiver demonstration approval, there may be less demonstrable changes in some measures between Indiana's second SUD demonstration and its first demonstration when compared to the State's first SUD demonstration period and pre-demonstration period.

Also, observed changes in outcome measures in the current waiver period will be difficult, if not impossible, to attribute to one specific demonstration component or activities outside the demonstration itself but occurring simultaneously (e.g., activities supported through federal grants) given the interrelationship of the components themselves. For many outcome measures, changes in the post-waiver period will be difficult, if not impossible, to attribute to coinciding related activities resulting from the combination of waiver, planning grant, and other activities occurring in the state. Therefore, it will be important to use statistical tests of significance so that findings are properly put into context.

Lastly, the evaluators recognize that the utilization patterns that will occur relatively early in this demonstration period will be severely disrupted due to public health emergency. The predictability of future utilization patterns remains uncertain as of the date of this document. The evaluators are prepared to work with CMS in the event that guidance is provided to states for all waiver evaluations as to options that CMS will offer with respect to how to account for the acute period of the pandemic. The initial plan for handling the effects of the public health emergency are addressed in Section III. Methodology.

ATTACHMENT A: INDEPENDENT EVALUATOR

Process

Burns & Associates, a division of Health Management Associates, (HMA-Burns) submitted a proposal to the Family and Social Services Administration to be to conduct the evaluation of Indiana's SUD demonstration waiver renewal. The proposal was developed based upon the criteria set forth in the waiver demonstration's Special Terms and Conditions as approved by the Centers for Medicare and Medicaid Services.

The FSSA has the authority to pursue this engagement through an existing contract with HMA that is effective from July 1, 2021 through June 30, 2025. HMA-Burns provided a proposed budget to complete all activities required for the waiver evaluation, but the current contract for this engagement ends June 30, 2025.

Vendor Qualifications

The team at HMA-Burns that will conduct this evaluation has also completed evaluation and monitoring work for Indiana's first SUD waiver demonstration. That work is ongoing, including the development of the Summative Evaluation. The HMA-Burns team joined Health Management Associates effective September 1, 2020 when HMA acquired Burns & Associates.

Burns & Associates (B&A) was founded in 2006. Its team works almost exclusively with state Medicaid agencies or related social services agencies in state government. During its 14-year history, B&A worked with 33 state agencies in 26 states. The HMA-Burns team proposed to complete this evaluation is also currently conducting the evaluation of the State of Delaware's SUD demonstration, the State of Delaware's Section 1115 Diamond State Health Plan Waiver demonstration, and the State of Colorado's Section 1115 Adult Prenatal Coverage in Child Health Plan Plus (CHP+) demonstration.

For Indiana's initial SUD demonstration, the HMA-Burns team developed the approved Evaluation Design Plan, produced the Interim Evaluation, and conducted the MidPoint Assessment. For the Delaware and Colorado waivers, the team has delivered Evaluation Design Plans and work is underway related to activities defined in these evaluation design plans.

Prior to the acquisition by HMA, the HMA-Burns team on this Indiana engagement conduced independent assessments of Indiana's 1915(b) waiver for Hoosier Care Connect and served as the External Quality Review Organization (EQRO) for Indiana from 2007 to 2020. The team wrote an External Quality Review (EQR) report each year during this period. The reports were all submitted to CMS. HMA-Burns team members also conducted independent evaluations for state agencies in Minnesota, New York, and Oklahoma.

Assuring Independence

HMA-Burns attests to having no conflicts to perform the tasks needed to serve as an independent evaluator on this engagement. HMA-Burns' Principal Investigator is prepared to deliver a signed attestation to this effect upon request.

ATTACHMENT B: EVALUATION BUDGET

The total budget for this Evaluation Design is $1,045,000. The distribution of hours and cost for each deliverable is shown in the exhibit below. All costs are built into the hourly rates for the staff conducting the work, including travel and other overhead costs.

Labor Category	Evaluation Design	Mid-Point Assessment	Interim Evaluation	Summative Evaluation	Total
Principal Investigator	120	180	280	320	**900**
Onsite Reviewers and Stakeholder Interviewers	60	220	320	430	**1,030**
Statistician	5	120	400	500	**1,025**
SAS Programmer	0	30	144	206	**380**
Data Analyst	30	80	120	180	**410**
All Labor Categories	**215**	**630**	**1,264**	**1,636**	**3,745**

Deliverable Cost	**$65,000**	**$180,000**	**$350,000**	**$450,000**	**$1,045,000**

ATTACHMENT C: TIMELINE AND MILESTONES

The HMA-Burns team was required to submit a work plan, including major tasks and milestones, to complete the scope of work requested by the State of Indiana related to its SUD demonstration waiver evaluation for activities completed through the available contracting period ending June 30, 2025. In an effort to show the complete level of effort that would be proposed to complete all deliverables, HMA-Burns is showing a work plan that covers the entire evaluation period. A summary of the work plan is shown on the next page. Tasks are further detailed out by sub-task and available upon request. Tasks are scheduled out by calendar quarter.

FINAL VERSION

Evaluation Design Plan for Indiana's 1115 Substance Use Disorder Waiver, Jan. 2021 – Dec. 2025

		CY 2021				CY 2022				CY 2023				CY 2024				CY 2025				CY 2026			
Major Task		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
A	**Ongoing Tasks to Support Engagement**																								
A.1	Monthly project mgmt/status mtg with FSSA																								
A.2	Read in, validate, and incorporate claims data																								
A.3	Read in, validate, and incorporate enrollment data																								
B	**Develop Evaluation Design Document**																								
B.1	Create draft Evaluation Design to submit to CMS																								
B.2	Finalize Evaluation Design based on CMS feedback																								
C	**Prepare Mid-Point Assessment**																								
C.1	Conduct focus study on member access to services																								
C.2	Conduct focus study on service auth requests																								
C.3	Conduct focus study on transitions to care																								
C.4	Conduct focus study on care coordination																								
C.5	Conduct interviews with beneficiaries																								
C.6	Conduct interviews with service providers																								
C.7	Conduct interviews with managed care entities																								
C.8	Submit draft Mid-Point Assessment to FSSA																								
C.9	Submit Mid-Point Assessment to CMS																								
D	**Prepare Interim Evaluation**																								
D.1	Compile data measures for all subpopulations																								
D.2	Perform statistical tests on results, if applicable																								
D.3	Assess FSSA status against SUD Implementation Plan																								
D.4	Submit draft Interim Evaluation to FSSA																								
D.5	Submit Interim Evaluation to CMS																								
E	**Prepare Summative Evaluation**																								
E.1	Conduct member access focus study, Round 2																								
E.2	Conduct service auth focus study, Round 2																								
E.3	Conduct transitions focus study, Round 2																								
E.4	Conduct care coordination focus study, Round 2																								
E.5	Conduct Round 2 interviews with beneficiaries																								
E.6	Conduct Round 2 interviews with service providers																								
E.7	Conduct Round 2 interviews with MCEs																								
E.8	Compile data measures for all subpopulations																								
E.9	Perform statistical tests on results, if applicable																								
E.10	Submit draft Summative Evaluation to FSSA																								
E.11	Submit Summative Evaluation to CMS																								