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Serious Mental Illness/Serious Emotional Disturbance 2021-2025 Waiver Evaluation Plan

Final





Prepared for: **Indiana Family and Social Services Administration**

Submitted by: **The Lewin Group, Inc.**

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Indiana Family and Social Services Administration

Serious Mental Illness/Serious Emotional Disturbance 2021-2025 Waiver Evaluation Plan

Final for CMS Review

October 27, 2021*

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A. General Background Information

The Centers for Medicare & Medicaid Services (CMS) initially approved the Indiana Family and Social Services Administration's (FSSA) §1115(a) demonstration waiver for adults with serious mental illness (SMI) on December 20, 2019 for a period of January 1, 2020 through December 31, 2020. On October 26, 2020 CMS granted approval for the waiver to remains in effect for five years, from January 1, 2021 through December 31, 2025. Through this demonstration, Indiana will be allowed to receive federal financial participation for services furnished to Medicaid beneficiaries who are primarily receiving short-term treatment services for a serious mental illness (SMI) in facilities that meet the definition of an institutions for mental diseases (IMD).

A 2015 report to the Indiana General Assembly highlighted the need for expanded crisis services, access to inpatient psychiatric beds, and improved coordination for individuals transitioning from inpatient services back into the community. Specifically, the report indicated that there is a need for increased options for individuals in psychiatric crises, with survey results suggesting that Indiana residents rely heavily on general hospital emergency rooms to handle individuals in acute crisis.[1] In 2018, the FSSA received authority from the CMS to reimburse IMDs for Medicaid-eligible individuals aged 21-64 years with substance use disorders (SUDs). In 2019, Indiana sought to expand this authority to reimburse for acute inpatient stays in IMDs for individuals diagnosed with SMI.[2]

Through the §1115(a) demonstrations and waiver authorities in the Social Security Act, states can test and evaluate innovative solutions to improve quality, accessibility, and health outcomes in a budget-neutral manner. Indiana's approved §1115 waiver Specific Terms and Conditions (STCs) to implement the SMI waiver require an evaluation of this program's ability to meet its intended goals. This Evaluation Plan will guide the federally required, independent evaluation of this program, and is organized as follows:

- Section A: General Background Information
- Section B: Evaluation Questions and Hypotheses
- Section C: Methodology
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- Section E: Attachments
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[1] DMHA distributed the Psychiatric and Addiction Crisis Survey in December 2014 and January 2015. Tailored surveys went out to respondent groups including mental health and addiction providers, hospital emergency department staff, first responders, consumer and family advocates, and probation and parole officers.

[2] Reimbursement will not be extended to IMDs for residential stays; additionally, state mental health hospitals will not be classified as IMDs eligible for reimbursement under this waiver. Facilities with more than 16 beds that are certified as Private Mental Health Institution (PMHI) by the Division of Mental Health and Addiction qualify as IMDs under this waiver.

1. Demonstration Goals

In an effort to ensure a comprehensive continuum of behavioral health services, the State will monitor the new approaches and flexibilities in Indiana's Medicaid program to reimburse for acute inpatient stays in IMDs for Medicaid enrollees with SMI. Over the demonstration period (from January 1, 2021 through December 31, 2025), the State seeks to achieve several demonstration goals (**Exhibit A.1**). These goals inform the State's evaluation of the SMI demonstration and include, but are not limited to, the following:

Exhibit A.1: Indiana §1115(a) Demonstration

Name of Demonstration:
SMI/SED Amendment Request for the Healthy Indiana Plan (HIP)

Amendment Approval Date of Demonstration:
October 26, 2020

Demonstration Period: January 1, 2021 - December 31, 2025

1. Reduced utilization and length of stay in emergency departments (EDs) among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment in specialized settings;
2. Reduced preventable readmissions to acute care hospitals and residential settings;
3. Improved availability of crisis stabilization services, including services made available through call centers and mobile crisis units, intensive outpatient services, as well as services provided during acute short-term stays in residential crisis stabilization programs, psychiatric hospitals, and residential treatment settings throughout the state;
4. Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI/SED, including through increased integration of primary and behavioral health care; and
5. Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities.

The above goals address key milestones of §1115(a) demonstrations outlined in **Exhibit A.2**.

Exhibit A.2: SMI/SED Demonstration Milestones

Milestones	
Milestone 1	Ensuring quality of care in psychiatric hospitals and residential settings
Milestone 2	Improving care coordination and transitioning to community-based care
Milestone 3	Increasing access to the continuum of care, including crisis stabilization services
Milestone 4	Earlier identification and engagement in treatment, including through increased integration

2. Description of the Demonstration and Implementation Plan

In 2018, the FSSA received authority from the CMS to reimburse for inpatient and residential stays in institutions for mental diseases (IMDs) for Medicaid eligible individuals ages 21-64 with substance use disorders (SUD). In 2019, Indiana sought to expand this authority to reimburse for acute inpatient stays in IMDs for individuals diagnosed with SMI.[3] The SMI demonstration was approved by CMS on December 20, 2019 and became effective January 1, 2020. On October 26, 2020, CMS granted approval for the waiver to remain in effect for five years (January 1, 2021 through December 31, 2025).

Under this demonstration, beneficiaries have access to high-quality, evidence-based mental health treatment services. These services 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. Indiana must achieve a statewide average length of stay of no more than 30 days in inpatient treatment settings and will be continuously monitored.

Overview of Indiana's Behavioral Health System of Care

Indiana's publicly funded behavioral health (both mental health and addiction) system of care supports access to prevention, early intervention, and recovery-oriented services and supports in all 92 counties, blending federal, state and local funding streams to a provider network of agencies and individual practitioners. Indiana's FSSA and specifically its Office of Medicaid Planning and Policy (OMPP) and Division of Mental Health and Addiction (DMHA) partner to provide policy oversight and primary funding of services and supports for individuals in need of behavioral health services. OMPP includes a robust continuum of behavioral health services as a benefit to enrollees in its fee-for service and Medicaid managed care programs. DMHA leverages its block grant funding from the Substance Abuse and Mental Health Services Administration (SAMHSA) and state appropriations to complement the Medicaid service array, with a focus on serving adults with SMI, youth with SED, and individuals with SUD of any age, and who are at or below 200% of the federal poverty level (FPL). OMPP and DMHA also partner with the Department of Child Services (DCS) and the Department of Corrections (DOC) in supporting access to and oversight of behavioral services for Indiana's most vulnerable Hoosiers.

Provider Network

OMPP maintains a large network of behavioral health providers including hospitals, psychiatric residential treatment facilities (PRTF), SUD residential providers, community-based agencies, and individual practitioners. Individual practitioners are certified and/or licensed by the Indiana Professional Licensing Agency (IPLA). While IPLA is separate and independent from FSSA, both OMPP and DMHA maintain a strong collaborative relationship with the agency. DMHA is responsible for certification and licensure for SUD provider agencies, freestanding psychiatric hospitals, and community mental health centers (CMHCs). Indiana Administrative Code (IAC) outlines provider requirements that assist in assuring quality and program integrity. Addiction, residential, CMHCs, and Clubhouse providers participating within the Medicaid program must be certified/licensed by DMHA prior to provider enrollment with OMPP.

Community Mental Health Centers

There are currently 24 certified CMHCs in Indiana. DMHA is responsible for CMHC certification and requirements under the IAC and/or contracts which include responsibility for respective geographic

[3] Reimbursement will not be extended to IMDs for residential stays; additionally, state mental health hospitals will not be classified as IMDs eligible for reimbursement under this waiver. Facilities certified as PMHI by the DMHA with more than 16 beds qualify as IMDs under this waiver.

service areas to ensure statewide coverage of the continuum of behavioral health services. The CMHCs are required to provide a defined continuum of care that includes:

- Individualized treatment planning;
- Access to 24 hour-a-day crisis intervention;
- Case management;
- Outpatient services, including intensive outpatient services, substance abuse services, and treatment;
- Acute stabilization services including detoxification services;
- Residential services;
- Day treatment, partial hospitalization, or psychosocial rehabilitation;
- Family support;
- Medication evaluation and monitoring; and
- Services to prevent unnecessary and inappropriate treatment and hospitalization and the deprivation of a person's liberty.

Many of these services are part of Medicaid Rehabilitation Option (MRO) state plan services, under which an assessment confirms a need for services with an eligible diagnosis and level-of-care determination using the Child and Adolescent Needs and Strengths Assessment (CANS) or Adult Needs and Strengths Assessment (ANSA).

Current Service Continuum

Prevention/Early Intervention

Prevention/early intervention occur through the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program. These services are available to Medicaid members from birth through the month of the member's 21st birthday. Members eligible for EPSDT services may be enrolled in the Healthy Indiana Plan (HIP), Hoosier Care Connect (HCC), Hoosier Healthwise (HHW), or Traditional Medicaid. A psychosocial/behavioral assessment is required at each EPDST visit. This assessment is family-centered and may include an assessment of a child's social-emotional health, caregiver depression, as well as social risk factors. The Indiana Health Coverage Programs (IHCP) also provide coverage for annual depression screening and screening and brief intervention (SBI) services. Providers are expected to use validated, standardized tests for the depression screening. These tests include, but are not limited to, the Patient Health Questionnaire (PHQ), Beck Depression Inventory, Geriatric Depression Scale, and Edinburgh Postnatal Depression Scale (EPDS). SBI identifies and intervenes with individuals who are at risk for substance abuse related problems or injuries. SBI services use established systems, such as trauma centers, emergency departments, community clinics, and school clinics, to screen patients who are at risk for substance abuse and, if necessary, provide the patients with brief interventions or referrals to appropriate treatment.

Outpatient Mental Health Services

The IHCP covers outpatient mental health services provided by a licensed medical doctor, doctor of osteopathy, psychologist endorsed as a health service provider in psychology (HSPP), psychiatric hospitals, psychiatric wings of acute care hospitals, and outpatient mental health facilities.

Reimbursement is also available for services provided by mid-level practitioners when a physician or an HSPP supervises those services. The physician, psychiatrist, or HSPP is responsible for certifying the diagnosis and supervising the treatment plan.

Adult Mental Health Habilitation Services

Effective November 1, 2014, Indiana implemented the §1915(i) Adult Mental Health Habilitation (AMHH) services program. Indiana adopted AMHH services to provide community-based opportunities for the care of adults with SMI who may most benefit from keeping or learning skills to maintain a healthy safe lifestyle in the community. AMHH services are intended for individuals who meet all of the following core target group criteria: 1) enrolled in Medicaid; 2) aged 19 years or older; 3) reside in a setting which meets federal setting requirements for home and community-based services (HCBS); and 4) has an AMHH-eligible, DMHA-approved diagnosis.[4] Once approved by the State Evaluation Team, an eligible AMHH enrollee is able to receive an AMHH service package, according to an individualized care plan. All services covered under the AMHH program are applicable for an additional prior authorization (PA) option. This will allow additional units to be authorized above the initial listed limit. Additional units can be requested via the Data Assessment Registry Mental Health and Addiction (DARMHA) system. The State Evaluation Team (SET) will review all PA requests and approve or deny additional units requested. Initial eligibility in the program is for one year and can be extended if medical need remains. The following are the AMHH services:

- Adult day services
- Home- and Community-Based Habilitation and Support Services
- Respite care
- Therapy and behavioral support services
- Addiction counseling
- Supported community engagement services
- Care coordination
- Medication training and support

Inpatient/Acute Care

Prior authorization is required for all inpatient psychiatric admissions, rehabilitation, and substance abuse inpatient stays. Each Medicaid-eligible patient admitted to an acute psychiatric facility or unit must have an individually developed plan of care (POC). For members aged 22 years and older, a POC must be developed by the attending or staff physician. For members aged 21 years old and younger, POCs must be developed by a physician and interdisciplinary team. All POCs must be developed within 14 days of the admission date, regardless of the member's age. For a patient who becomes eligible for

[4] Indiana recently amended its AMHH SPA, which became effective April 1, 2020. The modifications are intended to make the program more accessible for members and remove administrative burden for providers. Specific changes are as follows:
- Eligibility age was changed from 35 years and older to 19 years and older;
- The required Adult Needs and Strengths Assessment (ANSA) score was changed from 4 and above to 3 and above; and
- Each AMHH service will no longer require an individual justification. Instead, an individual service package will be assigned.

Medicaid after admission to a facility, the POC must be prepared to cover all periods for which Medicaid coverage is claimed. The following components must be documented in each member's POC:

1. Treatment objectives and goals, including an integrated program of appropriate therapies, activities, and experiences designed to meet the objectives; and
2. 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 their family and community upon discharge.

The POC is developed as a result of a diagnostic evaluation that includes an examination of the medical, psychological, social, and behavioral aspects of the member's presenting problem and previous treatment interventions. The attending or staff physician reviews the POC to ensure that appropriate services are provided and that they continue to be medically necessary. The attending or staff physician also recommends necessary adjustments in the plan, as indicated by the member's overall adjustment while an inpatient. The POC must be in writing and must be part of the member's record.

State Hospitals

Indiana's six state psychiatric hospitals provide intermediate and longer-term inpatient psychiatric stays for adults who have co-occurring mental health and addiction issues; who are deaf or hearing impaired; and who have forensic involvement; as well as youth with SED. Individuals are admitted to a state hospital only after a screening by a CMHC. CMHCs are responsible for providing case management to the individual in both the hospital and their transition to the community following discharge. The state psychiatric hospitals are accredited by the Joint Commission (JC). To maintain JC accreditation, all hospitals are required to participate in a performance measurement program. This is accomplished through participation in the National Research Institute Performance Measurement System, which provides a framework within which the state psychiatric hospitals can identify and implement consistent measures of performance and outcomes.

On March 15, 2019, Indiana opened its NeuroDiagnostic Institute (NDI) and Advanced Treatment Center located on the campus of Community East Hospital in Indianapolis. Operated in partnership with Community Health Network, NDI delivers advanced evaluation and treatment for patients with the most challenging and complex neuropsychiatric illnesses and transitions them more efficiently into the most appropriate treatment settings within the community or to a state-operated inpatient system of care. The NDI is a key component of FSSA's initiative to modernize and reengineer Indiana's network of state-operated inpatient mental health facilities, including reducing lengths of stay. The NDI also serves as a teaching hospital by partnering with local universities for medical and nursing students, as well as social work and psychology interns, which affords them hands-on experience helping NDI patients in their recovery.

Telehealth

Effective March 1, 2020 and through the duration of Indiana's coronavirus disease 2019 (COVID-19) Public Health Emergency (PHE), the OMPP was authorized via executive order to expand the variety of services, providers, and modalities rendered via telehealth. This expansion included the following allowances: 1) voice-only modalities (e.g., telephones) could be utilized for telehealth purposes, 2) health care services that were allowed via telehealth were no longer limited to procedure codes on IHCP's Telemedicine Services Code Set, and 3) the set of providers who could use telehealth was no

longer limited by licensure restrictions defined under the Indiana Professional Licensing Agency (IPLA) section of Indiana Code.

Due to these changes in policy, IHCP saw an increase in the number of claims billed when using telehealth services. In 2019, there were only 63,844 paid claims for telehealth services, versus 2,673,241 claims in 2020, an increase of over 4000%. A majority of these claims were submitted by behavioral health providers, with claims for psychotherapy services making up a significant portion of health care services provided via telehealth.

As a result of this increase in access to services using telehealth, OMPP was supportive of Indiana Senate Bill 3: "Telehealth Matters," which expanded the "telemedicine" section of code under the IPLA to include an expanded list of "practitioners" able to utilize telehealth service delivery under their scope of licensure and updated the term "telemedicine" to instead the more inclusive term of "telehealth." The bill therefore allowed OMPP to keep some of the policy expansions bestowed to the agency during the PHE in relation to telehealth. The bill was signed into law April 20th, 2021 and is effective starting at the end of executive order permissions. OMPP is currently working to adopt this new legislation into permanent telehealth policy.

State Strategies for Addressing Waiver Milestones

Current Oversight of Institutions for Mental Disease (IMDs)

In order to operate in the state of Indiana, all free-standing psychiatric hospitals must be licensed as a private mental health institution (PMHI) by DMHA. 440 IAC 1.5 currently requires PMHIs to be accredited by an accrediting body approved by the Division. This list only includes accrediting agencies also approved by CMS for deeming authority for Medicare requirements under 42 CFR 488.5 or 42 CFR 488.6. PMHI licensure must be renewed annually. DMHA conducts annual visits to ensure requirements are being met. In SFY 2019, all PMHI renewal site visits were unannounced. In SFY 2020, all site visits were conducted virtually due to the PHE. DMHA utilizes a site visit checklist that crosswalks with licensure requirements. The site visit checklist includes confirmation that individuals receive a physical within 24 hours of admission as well as an initial emotional, behavioral, social and legal assessment per IAC requirements. This includes screening for chronic health conditions and substance use disorders. Prior authorization is currently required for inpatient psychiatric care under both managed care and for fee for service enrollees, and, with the implementation of the State's SMI demonstration, includes IMD admissions as well. There are currently 29 freestanding psychiatric hospitals licensed in the state of Indiana with a capacity of 1,193 beds. Only 11 of the 29 PMHIs have 16 or fewer beds. DMHA is in the process of reviewing the IAC related to PMHIs with attention to quality assurance and monitoring for these providers based on the most recent cycle of onsite reviews and compliance with the goals and milestones under Indiana's current §1115 SMI waiver authority.

Improving Integration and Care Coordination, including Transitions to Community Based Care

Indiana has several initiatives, leveraging different authorities outside the §1115(a) waiver, to promote and expand care coordination and integrated delivery of behavioral health and primary care. These efforts focus on both youths with SED and adults with SMI and include cross-collaboration with Indiana's DMHA and State Department of Health (ISDH).

Indiana's Primary Care and Behavioral Health Integration

FSSA in partnership with ISDH launched an initiative in 2012 to develop a statewide strategic plan to integrate primary and behavioral health care services in Indiana. Indiana's Primary Care and Behavioral Health Integration (PCBHI) efforts include the formation of a statewide stakeholder group, formalized definition for integration for Indiana, and the original creation of five subcommittees that spearheaded research and collaboration in the following areas that support integrated care:

- Data/Technology
- Education/Training
- Funding/Reimbursement
- Health Homes/Care Coordination
- Policy Development

In addition, FSSA applied for and was awarded the SAMHSA and National Association of State Mental Health Program Directors (NASHMHPD) Transformation Transfer Initiative (TTI) Grant, which allowed Indiana to complete the following initiatives toward integration:

- Eight integration educational training events in 2013;
- Completion of a statewide integration survey;
- Cross-training opportunities for Community Health Workers (CHW) and Certified Recovery Specialists;
- Creation of an established process for state approved integrated care CHW certification; and
- Creation of established PCBHI Guiding Principles.

FSSA and ISDH established a process by which CMHCs, Federally Qualified Health Centers (FQHCs), Community Health Centers (CHCs), and Rural Health Clinics (RHCs) could become a state-certified, integrated care entity (ICE). ICE providers are required to provide care coordination that includes partnering with physicians, nurses, social workers, discharge planners, pharmacists, representatives in the education system, representatives of the legal system, representatives of the criminal justice system and others during any transition of care. The goals of this coordination include reducing unnecessary inpatient and emergency room use and increasing consumer and family members' ability to manage their own care and live safely in the community. Due to the Covid-19 pandemic, the State has to postpone this project. OMPP and DMHA are reevaluating the changes that need to be made within the Behavioral Health System in order to successfully transition from the ICE model to a health home program.

Behavioral and Primary Healthcare Coordination Service Program

Conceived under a separate §1915(i) state plan amendment, the Behavioral and Primary Healthcare Coordination (BPHC) program offers a service that consists of the coordination of health care services to manage the mental health/addiction and physical health care needs of eligible recipients. This includes logistical support, advocacy and education to assist individuals in navigating the health care system and activities that help recipients gain access necessary to manage their physical and behavioral health conditions.

BPHC service activities may include support in adhering to health regimens, scheduling and keeping medical appointments, obtaining and maintaining a primary medical provider and facilitating communication across providers. In addition, BPHC includes direct assistance in gaining access to services; coordination of care within and across systems; oversight of the entire case; linkage to appropriate services; needs-based assessment of the eligible recipient to identify service needs; development of an individualized integrated care plan (IICP); referral and related activities to help the recipient obtain needed services; monitoring and follow-up; and evaluation.

Child Mental Health Wraparound (CMHW) Services

The §1915(i) Child Mental Health Wraparound (CMHW) Services Program is authorized through Medicaid state plan authority. The §1915(i) CMHW Services are outlined in 405 IAC 5- 21.7. CMHW services provide youth with SED with intensive home and community-based wraparound services provided within a system of care (SOC) philosophy and consistent with wraparound principles. Services are intended to augment the youth's existing or recommended behavioral health treatment plan. The State's purpose for providing CMHW services is to serve eligible participants who have SED and enable them to benefit from receiving intensive wraparound services within their home and community with natural family/caregiver supports and provided sustainability of these services, which were originally offered under the CMS Community Alternatives to Psychiatric Residential Treatment Facilities (CA-PRTF) demonstration. Under the demonstration, Indiana was able to provide a quicker and more seamless transition of youth from PRTF placement as well as prevent some youth from placement within a PRTF setting. The CMHW services available to the eligible participant include wraparound facilitation, habilitation, respite care, and training and support for the unpaid caregiver. In 2020, the State incorporated auto-renewals to ensure that individuals did not lose coverage during the PHE.

Increasing Access to Continuum of Care Including Crisis Stabilization Services

On March 18, 2019, CMS approved a state plan amendment that expands crisis intervention services, intensive outpatient program services, and peer recovery services to all Indiana Medicaid programs. Previously, these services were limited to the MRO program. This change expands the potential number of providers eligible to deliver these services to Indiana enrollees. This SPA became effective July 1, 2019.

This expansion of the crisis continuum specifically began in 2014. DMHA partnered with the National Alliance on Mental Illness of Indiana (NAMI Indiana), Mental Health America of Indiana (MHAI), the Indiana Hospital Association (IHA), Key Consumer, and the Indiana Council on Community Mental Health Centers (ICCMHC) to conduct a review of Indiana's mental health and substance use crisis services. The review was in response to Indiana Senate Enrolled Act No. 248 of 2014, which mandated DMHA to conduct a psychiatric crisis intervention study ("crisis study") and report the results to the legislative council by September 2015. The crisis study included a review of psychiatric and addiction crisis services available in Indiana, a survey of professionals and individuals in Indiana who have experience with the current state of Indiana's crisis response, and a review of crisis services and models implemented by other states that could improve outcomes for individuals who experience psychiatric or addiction crises.

In Indiana's application for the Serious Mental Illness (SMI) 1115 Waiver, the State indicated interest in expanding and improving the crisis services available to members across the State. These programmatic changes were supposed to be implemented by DMHA during calendar year 2020 but due to the COVID-19 pandemic were put on hold. Prior to the PHE, the State covered many of the crisis services that the SAMHSA suggests should be included in Community-Based Mobile Crisis Units. With the passing of the

American Rescue Plan in March 2021, the State is looking into applying for the federal match opportunity related to Community-Based Mobile Crisis Response Services. In addition to establishing mobile response units, the State hopes to establish Crisis Stabilization Units (CSU). The goals for these units are to provide an alternative to crisis evaluations within emergency departments and divert admissions to inpatient psychiatric units. Currently, OMPP and DMHA are working together to develop a plan to expand crisis services as outlined in the approved SMI 2020 Evaluation Plan.

Additionally, in accordance with 440 IAC 9-2-2, all CMHCs must provide 24/7 crisis intervention services which meet the following minimum requirements:

- Operation and promotion of a toll-free or local call crisis telephone number staffed by individual(s) trained to recognize emergencies and refer calls to the appropriate clinician or program;
- When a determination is made by the crisis telephone line that a clinician needs to be involved, a trained clinician is available to reach the consumer by telephone within 15 minutes;
- When the assessment indicates a face-to-face meeting between the clinician and consumer is necessary, an accessible safe place is available within 60 minutes driving distance of any part of the CMHC's service area, with a transportation plan for consumers without their own mode of transportation to be able to access the safe place; and
- Participation in a quality assurance/quality improvement system that includes a review of individual cases and identification and resolution of systemic issues including review by supervisory or management level staff for appropriateness of disposition for each crisis case.

Some of the State's CMHCs are providing the following additional crisis services:

- Mobile crisis teams
- Assertive community treatment (ACT)
- 23-hour crisis stabilization units
- Short-term crisis residential
- Peer crisis services

Additionally, Hoosier Care Connect managed care entities (MCEs), who serve the State's aged, blind and disabled Medicaid population are contractually required to ensure the availability of behavioral health crisis intervention services 24/7.

Earlier Identification and Engagement in Treatment

Indiana has expanded coverage for mental health screening, SUD screening, and referral under Medicaid. In 2014, OMPP expanded provider types eligible for reimbursement of screening and brief intervention for SUD to include midlevel licensed individuals under the supervision of a physician, including nurse practitioners (NP), health service providers in psychology (HSPP), licensed clinical social workers (LCSW), licensed mental health counselors (LMHC), and licensed marriage and family therapists (LMFT). In October 2016, OMPP began coverage for annual depression screening. Providers are expected to use validated standardized tests for the screening. These tests include, but are not limited to, the Patient Health Questionnaire (PHQ), Beck Depression Inventory, Geriatric Depression Scale, and Edinburgh Postnatal Depression Scale (EPDS). Coverage applies to all IHCP programs under Medicaid.

The State has also focused on school-based initiatives to increase behavioral health integration. Indiana Medicaid allows enrolled school corporations reimbursement for Medicaid-covered services in an Individualized Education Program (IEP) or Individualized Family Service Plan (IFSP). Medicaid-covered IEP services include occupational, physical, speech and applied behavior analysis therapy, hearing, nursing and behavioral health evaluation and treatment services as well as IEP-required specialized transportation. In addition, CMHCs across the State work in close collaboration with Indiana schools. Currently 85% of school districts have partnerships with the CMHC in their area. Through these partnerships behavioral health staff are co-located within the schools and providing behavioral health services to youth and their families.

3. Population Groups Impacted by the Demonstration

Indiana will evaluate whether the demonstration has the intended effects on the target population. This waiver of the IMD exclusion includes all Medicaid beneficiaries aged 21-64 years, regardless of the delivery system. All enrollees will continue to receive services through their current delivery system and payment methodologies will be consistent with those approved in the Medicaid State Plan.

Demonstration Eligibility

Individuals apply for Medicaid services through the Division of Family Resources, which determines eligibility for Indiana Health Coverage Programs. If an individual is determined eligible, beneficiaries will have access to high quality, evidence-based mental health treatment services under this demonstration.

All enrollees eligible for a mandatory or optional eligibility group approved for full Medicaid coverage, and aged 21-64 years, would be eligible for acute inpatients stays in an IMD under the waiver. The eligibility groups outlined in **Exhibit A.3** below are not eligible for stays in an IMD as they receive limited Medicaid benefits only.

Exhibit A.3: Eligibility Groups Excluded from the Demonstration

Eligibility Group Name	Social Security Act & CFR Citation
Limited Services Available to Certain Aliens	42 CFR §435.139
Qualified Medicare Beneficiaries (QMB)	1902(a)(10)(E)(i) 1905(p)
Specified Low Income Medicare Beneficiaries (SLMB)	1902(a)(10)(E)(iii)
Qualified Individual (QI) Program	1902(a)(10)(E)(iv)
Qualified Disabled Working Individual (QDWI) Program	1902(a)(10)(E)(ii) 1905(s)
Family Planning	1902(a)(10)(A)(ii)(XXI)

B. Evaluation Questions and Hypotheses

The evaluation will focus on the demonstration policy goals described in **Section A**. This section provides the hypotheses and research questions (RQs) that correspond to each of the goals. Logic models, depicting the expected relationship between activities and short- and long-term outcomes, are included for each research question.

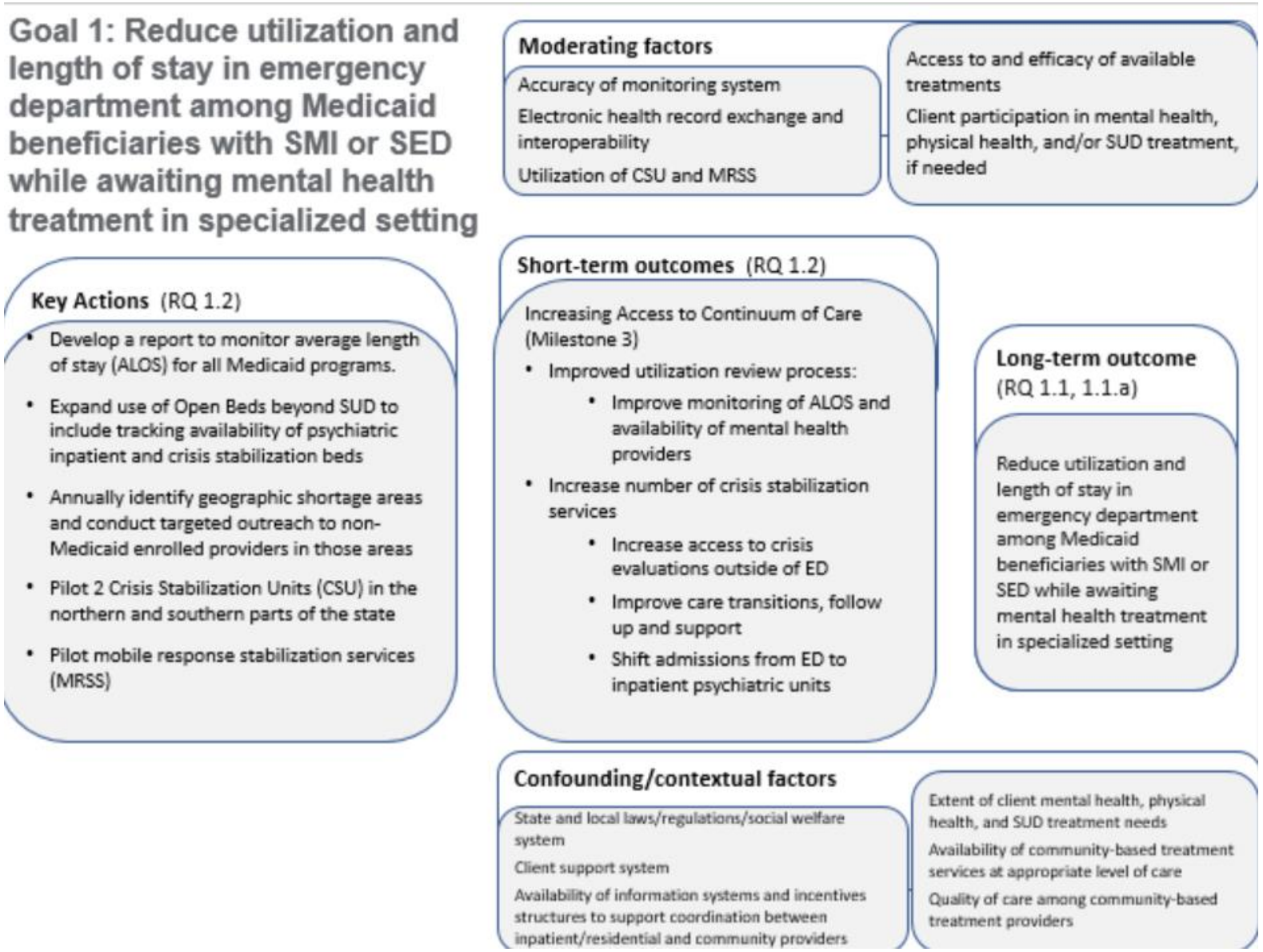
1. Goal One: Reduced utilization and length of stay in emergency departments (EDs) among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment in specialized settings

The evaluation explores the impact of expanding access to high-quality, evidence-based mental health treatment services in IMDs on utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment in specialized settings. **Exhibit B.1.a.** lists the hypothesis and research questions and **Exhibit B.1.b.** outlines the logic model corresponding to this goal.

Exhibit B.1.a.: Hypothesis and Research Questions for Goal 1

Hypotheses	Research Questions
Hypothesis 1: The SMI/SED demonstration will result in reductions in utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment.	**Primary research question 1:** Does the SMI/SED demonstration result in reductions in utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment? **Subsidiary research question 1.1:** How do the SMI/SED demonstration effects on reducing utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED vary by geographic area or beneficiary characteristics? **Subsidiary research question 1.2:** How do SMI/SED demonstration activities contribute to reductions in utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment in specialized settings?

Exhibit B.1.b.: Logic Model for Goal 1



2. Goal Two: Reduced preventable readmissions to acute care hospitals and residential settings

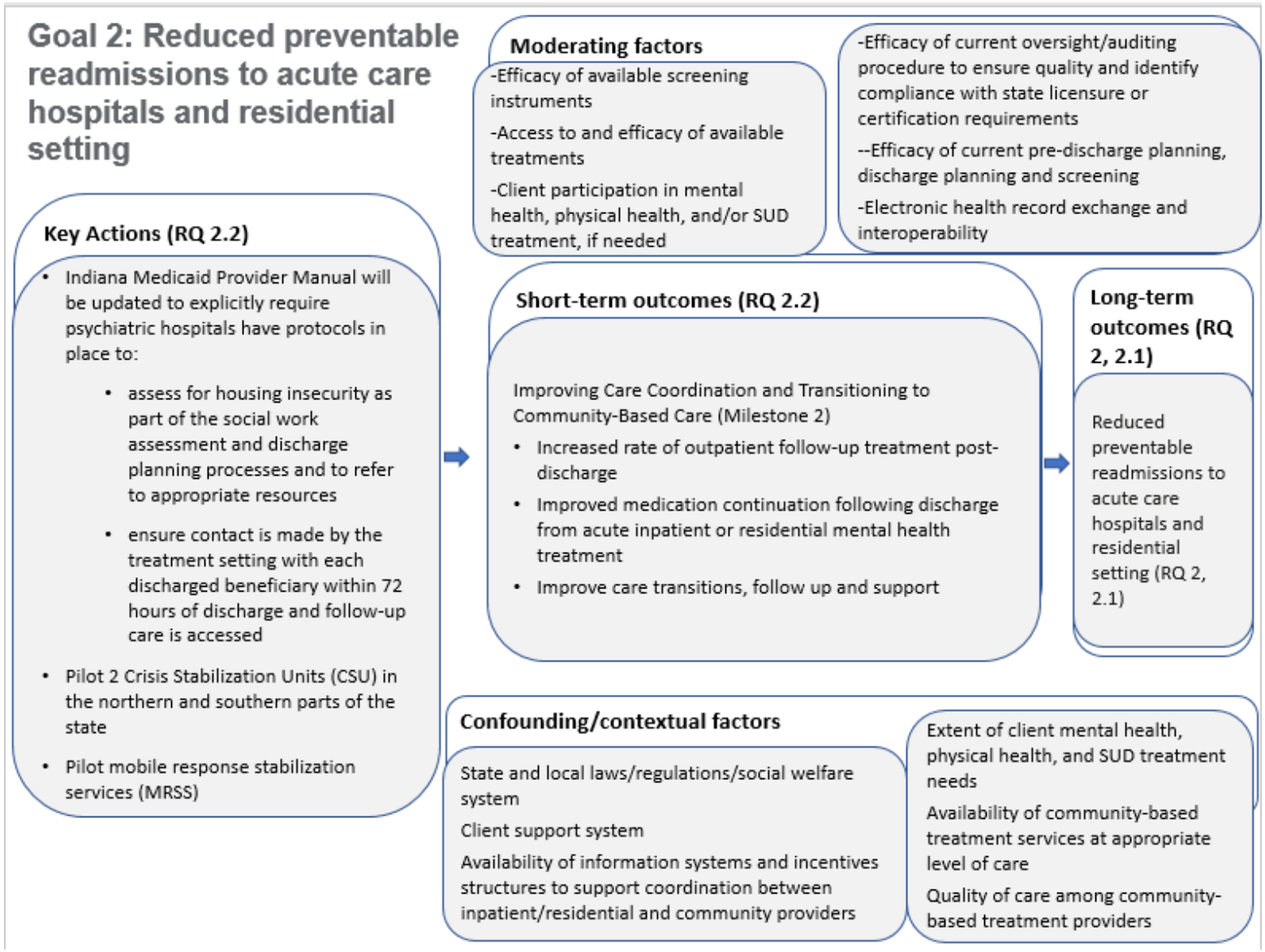
The evaluation explores the impact of expanding access to high-quality, evidence-based mental health treatment services in IMDs on reductions to preventable readmissions to acute care hospitals and residential settings. **Exhibit B.2.a.** below lists the hypothesis and research questions and **Exhibit B.2.b.** outlines the logic model corresponding to this goal.

Exhibit B.2.a.: Hypothesis and Research Questions for Goal 2[5]

Hypotheses	Research Questions
Hypothesis 2: The SMI/SED demonstration will result in reductions in preventable readmissions to acute care hospitals and residential settings.	**Primary research question 2:** Does the SMI/SED demonstration result in reductions in preventable readmissions to acute care hospitals and residential settings (including, short-term inpatient and residential admissions to both IMDs and non-IMD acute care hospitals, critical access hospitals, and residential settings)? **Subsidiary research question 2.1:** How do the SMI/SED demonstration effects on reducing preventable readmissions to acute care hospitals and residential settings vary by geographic area or beneficiary characteristics? **Subsidiary research question 2.2:** How do demonstration activities contribute to reductions in preventable readmissions to acute care hospitals and residential settings? **Subsidiary research question 2.3:** Does the SMI/SED demonstration result in increased screening and intervention for comorbid SUD and physical health conditions during acute care psychiatric hospital and residential setting stays and increased treatment for such conditions after discharge?

[5] Indiana is not including Subsidiary Research Question 2.3: "Does the SMI/SED demonstration result in increased screening and intervention for comorbid SUD and physical health conditions during acute care psychiatric hospital and residential setting stays and increased treatment for such conditions after discharge?" Calculation and monitoring of such a metric will require medical reviews be performed which would require substantial resources. As this research question is not associated with primary objective of the waiver, the State determined not to monitor and calculate this metric during time of preparation of this evaluation plan.

Exhibit B.2.b.: Logic Model for Goal 2



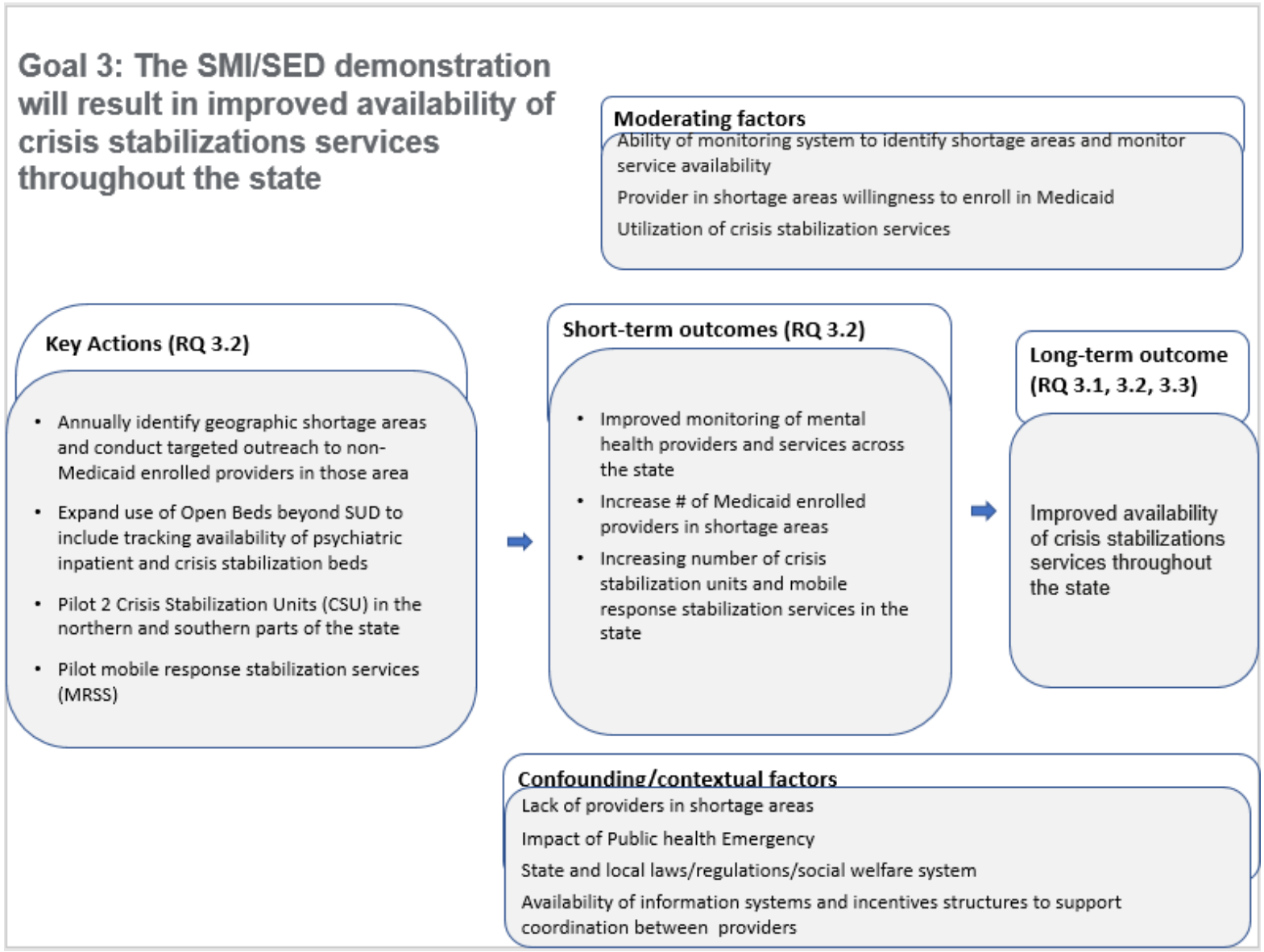
3. Goal Three: Improved availability of crisis stabilization services utilizing multiple service models to meet the unique needs across the state

Indiana will assess the availability of crisis stabilization services across the state. **Exhibit B.3.a.** below lists the hypotheses and research questions and **Exhibit B.3.b.** outlines the logic model corresponding to this goal.

Exhibit B.3.a.: Hypothesis and Research Questions for Goal 3

Hypotheses	Research Questions
Hypothesis 3: The SMI/SED demonstration will result in improved availability of crisis stabilization services throughout the state.	**Primary research question 3.1:** To what extent does the SMI/SED demonstration result in improved availability of crisis outreach and response services (including crisis call centers, mobile crisis units, crisis observation/assessment centers, and coordinated community crisis response teams) throughout the state? **Primary research question 3.2:** To what extent does the SMI/SED demonstration result in improved availability of intensive outpatient services and partial hospitalization? **Primary research question 3.3:** To what extent does the SMI/SED demonstration improve the availability of crisis stabilization services provided during acute short-term stays in each of the following: public and private psychiatric hospitals; residential treatment facilities; general hospital psychiatric units; and community-based settings (such as residential crisis stabilization programs, small inpatient units in community mental health centers, peer-run crisis respite programs, and so on)?

Exhibit B.3.b.: Logic Model for Goal 3



4. Goal Four: Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI or SED including through increased integration of primary and behavioral health care.

Indiana will assess the access to community-based services to address the chronic mental health care needs of beneficiaries with SMI or SED including through increased integration of primary and behavioral health care. **Exhibit B.4.a.** below lists the hypotheses and research questions and **Exhibit B.4.b.** outlines the logic model corresponding to this goal.

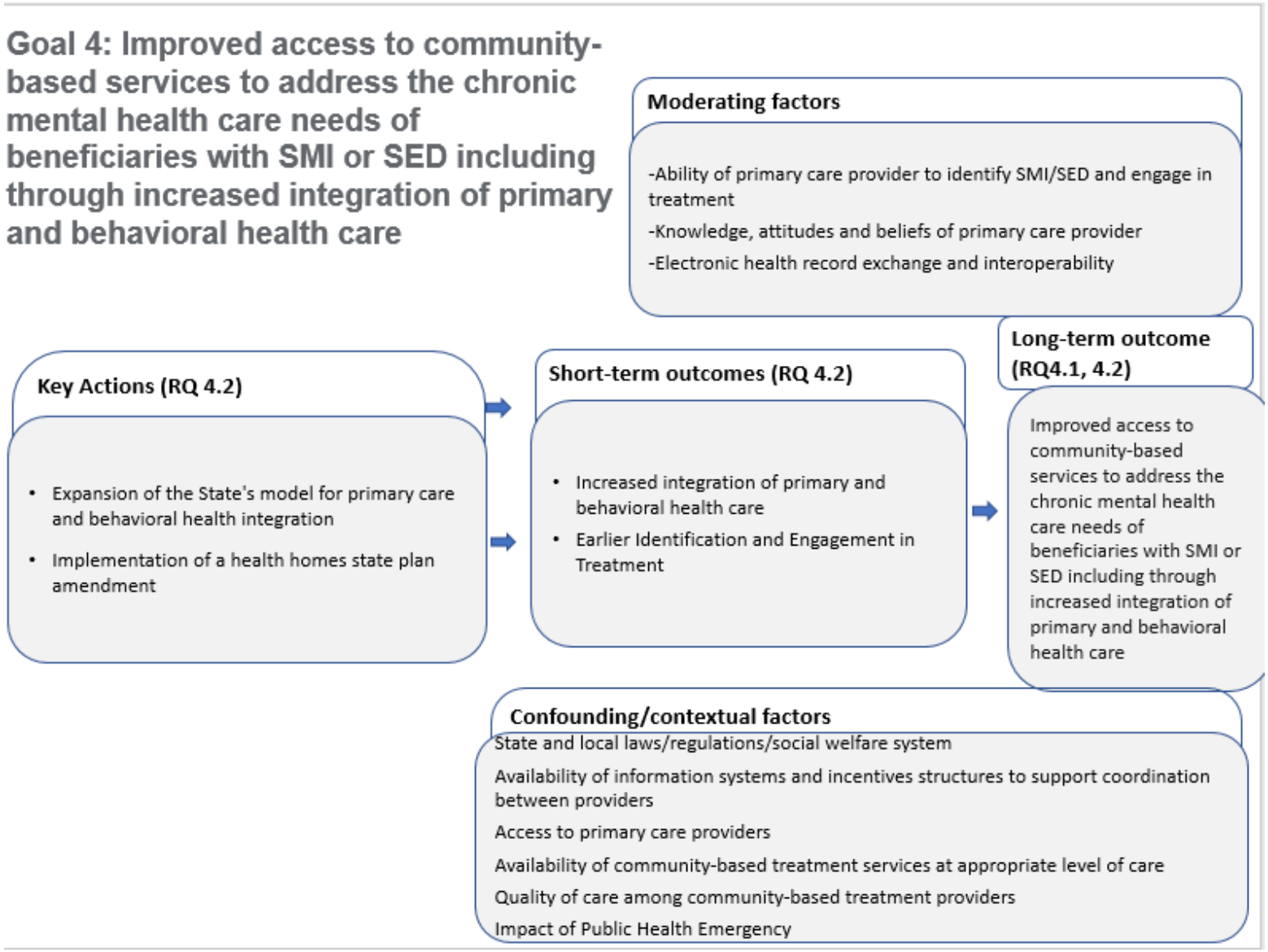
Exhibit B.4.a.: Hypothesis and Research Questions for Goal 4[6]

Hypotheses	Research Questions
Hypothesis 4: Access of beneficiaries with SMI/SED to community-based services to address their chronic mental health care needs will improve under the demonstration, including through increased integration of primary and behavioral health care.	**Primary research question 4.1:** Does the demonstration result in improved access of beneficiaries with SMI/SED to community-based services to address their chronic mental health care needs? **Subsidiary research question 4.1a:** To what extent does the demonstration result in improved availability of specific types[7] of community-based services needed to comprehensively address the chronic needs of beneficiaries with SMI/SED? **Subsidiary research question 4.1b:** To what extent does the demonstration result in improved access of SMI/SED beneficiaries to the specific types of community-based services that they need? **Primary research question 4.2:** Does the integration of primary and behavioral health care to address the chronic mental health care needs of beneficiaries with SMI/SED increase under the demonstration?

[6] Indiana is not including Subsidiary Research Question 4.1c in this Evaluation Plan: "How do the SMI/SED demonstration effects on access to community-based services vary by geographic area or beneficiary characteristics?" The provider type summaries seen in Goal 3 can address this subsidiary RQ and streamline evaluation efforts and State resources.

[7] Types of community-based services to address the chronic mental health care needs of beneficiaries with SMI/SED may include certified community behavioral health clinics, supportive housing, illness self-management, evidence-based psychotherapy, peer-support and consumer-operated services, psychosocial habilitation or rehabilitation, outreach to and engagement of those who are homeless, systematic medication management, integrated treatment for co-occurring substance use disorders and other disabilities, supported employment, education and family supports, school-based services, and trauma-informed care, among others.

Exhibit B.4.b.: Logic Model for Goal 4



5. Goal Five: Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities

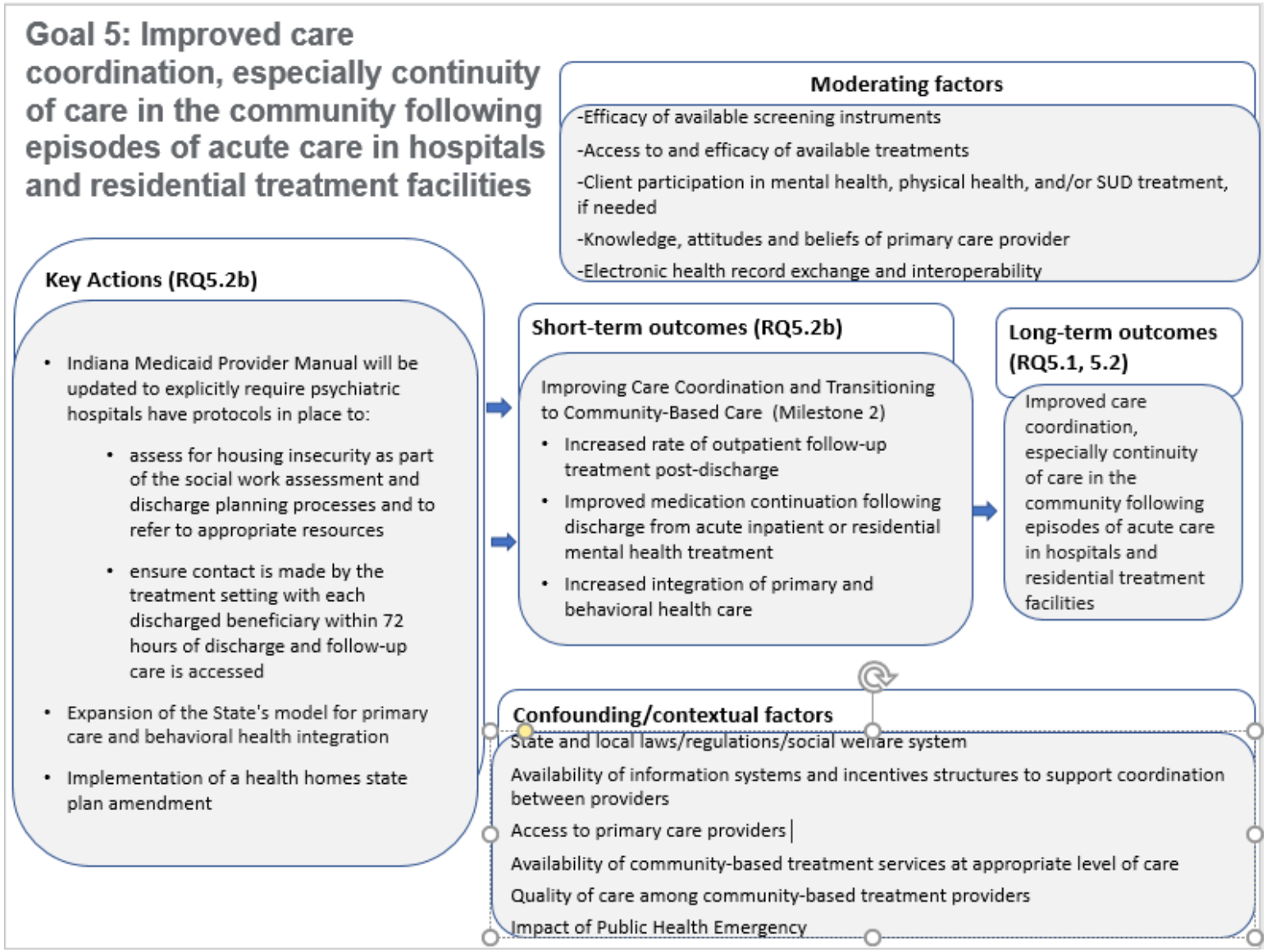
Indiana will assess care coordination for beneficiaries with SMI/SED, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities. **Exhibit B.5.a.** below lists the hypotheses and research questions and **Exhibit B.5.b.** outlines the logic model corresponding to this goal.

Exhibit B.5.a.: Hypotheses and Research Questions for Goal 5[8]

Hypotheses	Research Questions
Hypothesis 5: The SMI/SED demonstration will result in improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities.	**Primary research question 5.1:** Does the SMI/SED demonstration result in improved care coordination for beneficiaries with SMI/SED? **Primary research question 5.2:** Does the SMI/SED demonstration result in improved continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities? **Subsidiary research question 5.2b:** How do demonstration activities contribute to improved continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities?

[8] Indiana is not including Subsidiary Research Question 5.2a: "Does the SMI/SED demonstration result in improved discharge planning and outcomes regarding housing for beneficiaries transitioning out of acute psychiatric care in hospitals and residential treatment facilities?" The rationale for not addressing this question is that it is a subsidiary question (versus a primary research question), and the level of effort involved in obtaining and reviewing the facility records/facility discharge records (required for any of the CMS-recommended outcome measures) would be substantial.

Exhibit B.5.b.: Logic Model for Goal 5



C. Methodology

This section provides a summary of Indiana's evaluation design, including data sources, target populations, evaluation period, and analytic methods. This Evaluation Plan aims to provide a baseline of the demonstration through descriptive quantitative analyses and qualitative data collection and analysis to reflect all five of the program goals and to incorporate CMS' §1115(a) SMI/SED and SUD Evaluation Guidance.[9]

This Evaluation Plan covers Interim Evaluation and Summative Evaluation for SMI Demonstration (2021-2025 waiver) which will be submitted to CMS in December 2024 and June 2027 respectively. The observation period for the evaluation will be calendar years (CYs) 2018 to 2025. This period includes three years before the SMI/SED amendment took effect on January 1, 2021 through December 31, 2025.

For the Interim Evaluation, the time period is limited to fewer years (through 2023). Since we will be estimating the outcome measures based on data from the observation period, the interim evaluation will not provide conclusions about the impact of the waiver (e.g., related to health status, service use) beyond this period. The evaluation will include descriptive analyses of changes in the composition of the enrolled population, and the evaluator will consider any findings from this analysis when interpreting the results of the analyses described in the Evaluation Plan.

The evaluator will use a mixed-methods approach employing both quantitative and qualitative analyses to answer the identified research questions. Qualitative analyses will support an understanding of stakeholders' perspectives related to context, implementation, and outcomes and will identify contextual factors that help to explain outcomes. Quantitative analyses will examine changes in outcomes and estimate the impact of policy changes, as demonstration design and data permit. Quantitative and qualitative analyses will reinforce each other and contribute to understanding context, implementation, impact, and variation. Findings from evaluation activities will be summarized in key deliverables for CMS, including the Mid-Point Assessment Report, Interim Evaluation Report, and Summative Evaluation Report. Additional information on deliverables and associated timelines can be found in **Attachment E.3. Timeline and Major Milestones**.

The ongoing PHE, which began in March 2020, has continued to cause substantial changes to HIP policies, service utilization and provider availability, and will have short- and long-term impacts on Indiana's health care system. Due to the PHE, the State suspended policies regarding disenrollment of members and programmatic changes to establishing crisis services like Crisis Stabilization Units (CSU) and also expanded behavioral health telemedicine services.[10,11,12] The PHE is in effect as of this evaluation plan development and is likely to impact the evaluation of SMI/SED waiver policies. Social distancing and prioritization of health care resources are anticipated to affect utilization of a wide variety of services in 2020 and beyond, including inpatient admissions and emergency visits, demand for behavioral health care services, as well as mode of care changes such as increased use of telehealth. For example, mental health-related ED use in 2020 may be reduced due to concerns about acquiring the COVID-19 virus at the hospital; access to community-based services may be restricted due to temporary provider closures

[9] CMS. 1115 Demonstration State Monitoring & Evaluation Resources. Released and Accessed May 1, 2021 at https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html

[10] Indiana Medicaid allows telemedicine and telephone options for most health care and mental health interactions, FSSA News Release, March 19 2020, Accessed from https://www.in.gov/fssa/files/telemedicine_release_3_19_FINAL.pdf

[11] Senate Bill No. 3: Telehealth Matters, Accessed from http://iga.in.gov/legislative/2021/bills/senate/3#document-742b0b09

[12] These policies were suspended March 17, 2020. Based on State "Medicaid Policy Changes: re COVID-19" updated on July 28, 2020 and in discussion with State as of May 2021.

and/or limited hours and the use of telehealth; and initiatives to integrate physical and behavioral health and to expand crisis stabilization services may be delayed. Additionally, Medicaid enrollment is impacted due to beneficiary loss of income during the PHE, some health care providers experience financial stress due to the short-term loss of income, and there may be changes in payer mix as individuals lose employer-based coverage and Medicaid enrollment and the number of uninsured increases.

The use of data starting from 2020 to analyze the impact of the SMI/SED waiver requires careful consideration including the time frame for implementation of all waiver policies and the economic impact of COVID-19. We will consider this impact in our evaluation of the research questions, data and appropriate analytic methods during Interim and Summative Evaluation Report development.

Section F includes the analytic design tables for each goal, detailing the relevant hypotheses, research questions, data sources, outcome measures, analytic methods, and comparison group(s) (if applicable). These tables also specify the years of data to be used for individual research questions.

1. Data Sources and Collection

The evaluator will compile data from claims/encounter and enrollment data. The evaluator will also capture qualitative data via key informant interviews (i.e., State officials, MCEs, and providers). **Exhibit C.1** summarizes the data sources anticipated to be used to evaluate each goal ("X" indicates relevant sources for each goal), followed by detailed descriptions of key data sources. **Section F** provides specific information regarding how these data sources will be used in the evaluation.

Exhibit C.1: Data Sources by Goal

Type	Data Sources	Goal 1 ED Utilization and LOS	Goal 2 Preventable Readmissions	Goal 3 Crisis Stabili-zation	Goal 4 Community -based Services	Goal 5 Care Coordi-nation
Indiana– Quantitative	*1.* Member Eligibility, Application, and Enrollment Data *Note: Enrollment data will be used to select members for key informant interviews across goals.*	X	X	-	X	X
	2. Claims / Encounter Data	X	X	-	X	X
	3. State administrative data (2018-2025) collected via the Monitoring Protocol13	-	X	X	X	-

[13] Other sources of State administrative data may be leveraged as available.

Type	Data Sources	Goal 1 ED Utilization and LOS	Goal 2 Preventable Readmissions	Goal 3 Crisis Stabili-zation	Goal 4 Community -based Services	Goal 5 Care Coordi-nation
Indiana – Qualitative	1. Key Informant Interviews with Members	X	X	X	X	X
	2. Key Informant Interviews with State Officials	X	X	X	X	X
	3. Key Informant Interviews with MCEs	X	X	X	X	X
	4. Key Informant Interviews with Other Stakeholders (including consumer advocates)	X	X	X	X	X
	5. Key Informant Interviews with Providers	X	X	X	X	X

Note: We will build on the metric specifications developed for the 2020 Summative Evaluation (making any required refinements) for the 2021-2025 waiver. Metrics not developed for 2020 Evaluation will need to be created for the 2021-2025 waiver accounting for any changes to billing codes and service specifications.

Internal Data Source Descriptions – Quantitative

Current sources include:

- *Member Eligibility, Application, and Enrollment Data:* Member application and enrollment data provide information on the size, location, and socio-demographic makeup of SMI enrollees.
- *Claims / Encounter Data:* The claims records (encounter data) that the MCEs submit to the State provide information about the health care utilization patterns of SMI enrollees and identifies enrolled providers that are actively providing services.
- State Administrative Data: Program administrative data will include items such as the number of FQHCs that offer behavioral health services and the number of enrolled Medicaid providers of various types.

Other applicable data sources may be included as available and validated.

The data acquisition process will include identifying the data elements of interest (e.g., coverage information, beneficiary demographic characteristics, claims / encounter data including at least first two diagnosis codes) and appropriate data sources or data tables. Different data are captured in different systems and for appropriate interpretation and use of data, supporting data dictionaries from the data owners will be used. Enrollment and claims data from Enterprise Data Warehouse (EDW) will be used in conjunction to identify the SMI population. The population total will be benchmarked to State reports to ensure accurate identification of the target SMI population. Claims associated with individuals identified as having SMI and covered under the waiver will be used to develop utilization-based outcome measures (example ED visits in a year). Administrative data like summary information of number of crisis

call centers, mobile centers will be studied for anomalies (e.g., very large or small numbers, benchmark to published reports).

External Data Source Descriptions – Quantitative

The State will consider using external data sources as needed – specifically for any benchmark or comparison of the evaluation measures. For example, selected adult core set quality measures can be used to benchmark the research question outcome measures. Data for these measures are publicly available on CMS website.

Internal Data Source Descriptions – Qualitative

In addition to quantitative data collection and analysis, Indiana will conduct key informant interviews to capture member, State Official, MCE, provider, and other stakeholder experience and evaluate other outcomes related to each goal. Indiana will identify potential participants based on existing contacts from the 2018-2020 HIP and the 2020 SMI/SED Summative Evaluation Report, and other member and stakeholder lists. Indiana is not planning to use any monetary incentives for recruitment, and participation will not affect member enrollment status. Indiana will use findings from the key informant interviews to answer research questions in the Mid-Point and two (Interim and Summative) Evaluation reports.[14] The evaluator will conduct three rounds of key informant interviews in the spring/summer of 2023, 2024, and 2026.

Interview topics will vary from year to year and by interviewee role, although there will be continuity in the overall topic domains. As the evaluation progresses, additional topics may surface. **Exhibit C.2** describes the targeted number of interviewees and potential topics.

For each round of key informant interviews, the evaluator will work with FSSA to develop interview protocols tailored to each role. The protocols will include semi-structured questions and potential probes and last approximately 15-60 depending on the interview type. A trained interviewer will facilitate the interviews with the support of note taker who will also provide logistical support. With participant consent, interviews will be recorded and transcribed with brief summaries written up by facilitators immediately afterwards.

[14] The evaluator will also perform key informant interviews in 2021 for purposes of the 2020 Summative Evaluation Report and will leverage findings for the 2021-2025 evaluation reports.

Exhibit C.2: Summary of Indiana-Specific Qualitative Data Collection – Key Informant Interviews by Type, to be performed in 2021

Type	Potential Topics	Targeted Number of Interviewees	Approach to Selecting Participants
Member (15-minute interviews)	• Demonstration activities or their components or characteristics that stakeholders identify as most effective or hindering the effectiveness in: ○ Reducing ED visits, preventable readmissions ○ Improved availability to the range of community-based mental health services (including crisis stabilization), care coordination and continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities. ○ Reducing preventable readmissions to acute care hospitals and residential settings	25 interviews	Stratified random sample of beneficiaries
State Officials (60-minute interviews)	• Changes made to systems, processes, or policies • Demonstration activities most effective in: ○ Reducing utilization and lengths of stays in EDs ○ Reducing preventable readmissions to acute care hospitals and residential settings • Identify any obstacles as hindering the effectiveness of the demonstration in: ○ Reducing utilization and lengths of stays in EDs ○ Reducing preventable readmissions to acute care hospitals and residential settings	Two semi-structured interviews (including group interviews)	The evaluator will identify key state officials involved in the development, planning and administrative of the SMI/SED waiver.
MCEs (30–60-minute interviews)	• Demonstration activities most effective in: ○ Reducing preventable readmissions to acute care hospitals and residential settings ○ Data sharing systems, processes, or policies that staff identify as most effective for improving care coordination • Identify any obstacles as hindering the effectiveness of the demonstration in: ○ Reducing preventable readmissions to acute care hospitals and residential settings ○ Data sharing systems, processes, or policies aimed at improving care coordination	Four semi-structured interviews with representatives from the four MCEs each year	Evaluator will interview staff from each contracted MCE involved in supporting the SMI/SED waiver

Type	Potential Topics	Targeted Number of Interviewees	Approach to Selecting Participants
Providers (15–30-minute interviews – individual providers 30–60-minute interviews – provider associations	• Demonstration activities most effective in: ○ Reducing utilization and lengths of stays in EDs ○ Reducing preventable readmissions to acute care hospitals and residential settings ○ Systems, processes, or policies that staff identify as most effective for improving care coordination • Identify any obstacles as hindering the effectiveness of the demonstration in: ○ Reducing utilization and lengths of stays in EDs ○ Reducing preventable readmissions to acute care hospitals and residential settings ○ Systems, processes, or policies aimed at improving care coordination	A total of 13 provider/provider association interviews will be performed and inform all hypotheses Interviews will include provider associations and certified navigators	Evaluator will identify key provider associations serving this population (e.g., Indiana Hospital Association)
Other Stakeholders (30-60 minutes)	• Demonstration activities regarding systems, processes, or policies that staff identify as most effective for improving care coordination • Obstacles that staff identify as hindering the effectiveness of demonstration activities regarding data sharing systems, processes, or policies aimed at improving care coordination	A total of three interviews will be conducted. The interviewee will be determined based on stakeholder availability.	TBD

Data Quality and Validation

Accuracy of any data driven analyses is dependent on the quality of the underlying data used. The program evaluation will use quantitative data based primarily on state claims, enrollment and other administrative data. Qualitative analyses will be based on information collected from key informant interviews.

Prior to developing any outcome metrics based on the enrollment, claims, administrative or other identified data, the evaluator will perform data validation. Validation of data will include obtaining data dictionaries that outline the variable names and possible values for the variables included in the data. The evaluator will develop descriptive statistics (e.g., count of beneficiaries by month and sociodemographic characteristics) for trend and outlier analyses to test if the variables have the correct values and to identify potential outliers or data anomalies. In case of identified data anomalies, the evaluator will coordinate with data stakeholders to identify strategies for data resolution or as needed account for the anomalies for program impact estimation.

The proposed qualitative data collection strategy efficiently focuses on collecting information through key informant interviews that cannot be obtained through other means. The data collection process will emphasize continual improvement and we will reflect on the data collected over initial interviews to revise protocols and select participants for subsequent rounds of data collection. The evaluator will leverage best practices from experience conducting data collection for other large-scale evaluations to train team members in interviewing and note-taking techniques to ensure consistency.

2. Target and Comparison Populations

The target population for analyses encompasses all Medicaid beneficiaries covered by an IHCP program aged 21-64 years with SMI regardless of their delivery system (e.g., managed care or fee-for-service). The SMI population is identified through four diagnosis codes in the primary or secondary diagnosis position (F20.xx [Schizophrenia and sub codes up to 2 places], F25.xx [Schizoaffective Disorder and sub codes up to two places], F31.xx [Bipolar and all sub codes up to 2 places], F33.xx [Major depression Recurrent and all sub codes up to two places]). Individuals not included in this target population are outlined in **Exhibit A.3**. IHCP programs include HIP members who are low-income, non-disabled adults ages 19 to 64; other adults eligible for Medicaid in Indiana include individuals who are 65 and older, blind, or disabled and who are also not eligible for Medicare, or low-income adults who can receive home and community-based services or who are in nursing homes and other facilities.

During the development of strategies for comparative analyses, both within-state and other-state comparison groups who are similar to HIP members but not subject to the policies being evaluated were considered. Ideally, a comparison group used to evaluate the impact of program implementation is a population with similar demographics but without comparable program or policy changes.

CMS' guidance outlined several possible comparison groups[15] (like similar beneficiaries in states without SMI/SED 1115 waivers, states without SMI/SED 1115, similar non-Medicaid beneficiaries, population prior to demonstration). Some of the suggested comparison groups are not feasible or ideal for this evaluation due to specific aspects of Indiana SMI waiver, specifically:

- The State includes all Medicaid beneficiaries with SMI and thus limits the availability of appropriate within-state comparison groups.
- SMI/SED Waiver Demonstration does not involve random assignment and the State has not staged policy implementation based on beneficiary characteristics.
- Requesting claims data directly from other states will be challenging given that other states have limited resources available for such an exchange, and also often have concerns related to how their results are publicized and expressed.
- While CMS' T-MSIS contains Medicaid claims data from other states, the availability, access, and timeliness of relevant claims data for states appropriate for comparisons to Indiana for purposes of this waiver would need to be further explored. Accessing, processing, and interpreting this data will be time-consuming and potentially challenging given variances in Medicaid programs and related billing and payment requirements. T-MSIS data has not been available in a timely manner for analytic purposes until recently.
- Indiana does not have an All-Payer Claims Database (APCD) that contains claims for hospital and community-based services for non-Medicaid beneficiaries with SMI/SED diagnoses.
- Some non-claims-based data sources will not be available in a timely manner. For example, using the measures in the CMS Adult Core Set to compare Indiana to other states may not be possible to the timing of the release of measure results.

For these reasons, depending on the research question, Indiana's Evaluation Plan uses population prior to Demonstration. The evaluator will develop quasi-experimental analyses (e.g., ITS) when adequate

[15] https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/smi-sed-eval-guide-appendix-a.pdf.

data are available before and after policy implementation. For such analyses, the SMI population post-policy implementation is the target while the member population prior to policy implementation is the comparison group. As necessary, the evaluator will explain in the Interim and Summative Evaluation Reports why regression discontinuity designs using factors like age, medical frailty was not used.

3. Analytic Methods

Indiana will use a use a mixed-methods approach employing both quantitative and qualitative analyses to answer the research questions in this evaluation. Qualitative analyses will support an understanding of stakeholders' perspectives related to context, implementation, and outcomes and will identify contextual factors that help to explain outcomes. Quantitative analyses will examine changes in outcomes and estimate the impact of policy changes, as demonstration design and data permit. Quantitative and qualitative analyses will reinforce each other and contribute to understanding context, implementation, impact, and variation.

Qualitative Analyses*:* Qualitative data collected through key informant interviews will be analyzed using thematic analysis, a systematic data coding and analysis process during which information is categorized with codes developed iteratively to reflect themes or patterns within the data. In general, the evaluation team will first analyze the data from each individual interview and then analyze data across all of the interviews as well as meaningful sub-groups. Indiana will use findings from the key informant interviews to answer research questions in the Mid-Point and two (Interim and Summative) Evaluation reports.

Quantitative Descriptive and Trend Analyses: Descriptive statistics (e.g., total, average, median, maximum, proportion) will be calculated to develop an understanding of characteristics of members participating in the SMI/SED waiver program (across time where necessary) as well as for observational inference on trends in outcomes of interest. The descriptive statistics will include information like the number of members, number of ED visits, proportion of beneficiaries who use certain services and so on by characteristics of interest (e.g., age, gender, race, health condition [e.g., depression, diabetes], region). To identify underlying trends, seasonal patterns and outliers, in addition to the descriptive statistics, the evaluator will also leverage data visualizations (e.g., line chart showing disenrollment rate over time, clustered bar chart showing beneficiary composition over time).

Where applicable and feasible, appropriate statistical tests (e.g., Chi-Square test for independence) will be used to test for differences between beneficiaries covered by SMI/SED waiver and comparison groups (e.g., non-SMI/SED waiver members included in the coverage) or to test for differences between subgroups of interest. These tests will use, as appropriate, regression-based adjustments to control for changes in member characteristics to estimate changes in measures of interest across time. The descriptive statistics along with related statistical analyses (test for difference or regression adjustments as appropriate) will be used to analyze impact of the waiver program.

Cross-Sectional Analyses: Where feasible, cross-sectional models will be used to assess associations and compare risk-adjusted outcomes for SMI beneficiaries to comparison beneficiaries (non-SMI/SED beneficiaries included in the coverage). The evaluator will conduct standard power calculations to ensure adequacy of sample sizes in available data for model development. A variety of parametric models and techniques to estimate the models are available. We will use the outcome variable characteristics, for example type (e.g., categorical or continuous) and distribution (e.g., normal, skewed), to determine the model specifications (e.g., logistic, linear, log-linear). Models will include beneficiary and geographic-level covariates to control for differences between the groups of interest. The covariates

will include demographic characteristics, income level, health status, regional characteristics, and other factors that are relevant and available within the data sources used. ***Given the lack of appropriate comparison groups (as discussed above), the evaluator does not anticipate utilizing cross-sectional analyses***.

Quantitative Impact Analyses: Because the implementation of Indiana's policy changes did not involve a randomized control design, the evaluation will use quasi-experimental approaches to estimate the impact of policy changes. For some research questions, CMS guidance indicates that states should consider a difference in differences (DiD) approach. DiD is a regression technique that measures the impact of the model by comparing changes in risk-adjusted outcomes for the target population to changes in outcomes in a comparison group, between the baseline and intervention periods. Standard power calculations would be necessary to assess adequacy of sample size in available data for model development. If this approach is used, the evaluator would ensure model specifications are appropriate for the outcome variable (e.g., logit for dichotomous outcomes) of interest. Models would include beneficiary and geographic-level covariates to control for differences between the groups of interest. The covariates would include demographic characteristics, income level, health status, regional characteristics, and other variables that are relevant and available in the data sources used. The validity of the DiD approach relies on the assumption that intervention and comparison groups were on parallel trends in the baseline. As such, it would be necessary to perform tests for parallel trends in the baseline period for key outcomes using statistical testing and visual trend analysis. ***The evaluator does not anticipate utilizing such analytics for due to limitation of availability of appropriate comparison groups (as discussed above)***.

As the intervention is at the population level and multiple years of data (before and after the policy change) are available, the evaluator proposes leveraging another quasi-experimental method called ITS. The ITS analysis (or a pre/post design) assesses change in an outcome of interest (e.g., readmission rate) after the policy change compared to the expected trend if there were no policy change. To strengthen this analysis, the evaluator will consider the method (e.g., extended time series, controlled segmented regression, propensity score based weighted) appropriate for the outcome of interest and control for possible confounders. For example, a segmented regression model with indicator variables to identify pre/post implementation time-period (like below) can be used in instances where an outcome variable has a linear trend: y

$$y_{it} = \beta_0 + \beta_1 T_t + \beta_2 P_t + \beta_3 PT_t + X_{it} + \varepsilon_{it}$$

where

- y_{it} = measure of interest for beneficiary 'i' at time 't'
- β_0 represents the baseline level
- β_1 represents the trend coefficient pre-intervention, T_t indicates time from first baseline period
- β_2 is the coefficient for the change in level of outcome post intervention, P_t indicates program implementation indicator
- β_3 indicates the slope change following intervention (or program start), PT_t indicates post implementation period (2021 and later)
- X_{it} state or program beneficiary characteristics
- ε = error term for variability not captured by the model

The model specifications will be dependent on the outcome of interest as well as any other confounding factors (or presence of autocorrelation) that might need to be considered. Since the SMI demonstration began in January 2020 (first waiver), the baseline period for the model is prior to the implementation of any waiver policies (2018 – 2019). The first year of the demonstration (2020) overlapped with onset of the COVID-19 pandemic. A separate indicator variable for the 2020 time-period will likely aide capture information on changes that were caused by reasons other than the demonstration. Prior to implementing these analyses, the evaluator would evaluate pre-implementation trends and assess comparability over time. CMS guidance indicates reviewers will consider such an approach when credible comparison groups are not available. This approach will require multiple years of baseline data (e.g., 2018-2019) to enable an estimate of the baseline trend before the implementation of the waiver amendment and is best employed over longer time spans. Additionally, prior to regression model estimation, the evaluator will perform any needed checks for multicollinearity among the independent variables (e.g., beneficiary characteristics) of interest.

Subgroup Analysis: These analyses will be part of descriptive, cross-sectional, and quantitative impact analyses as listed in **Section F**. The evaluator will determine the type and number of subgroup analyses by appropriateness for the research question, and as data and sample sizes allow. ITS or DiD analysis will produce estimates of the average impact of a policy change. However, the impact may vary by beneficiary subgroups (e.g., by older and younger members, by length of enrollment, by income, by region within state). To inform the selection of characteristics that will define subgroups, information gathered through interviews as well as through the descriptive analysis will be considered. The key informant interviews will provide perspective on potential subgroups for analysis, e.g., differences in care between geographic areas, historically marginalized populations, and individuals receiving services through the Medicaid Rehabilitation Option. The evaluator will use Medicaid administrative and enrollment data to identify these populations (e.g., based on zip code of residence, reported race/ethnicity, dual eligibility, receiving Medicaid Rehabilitation Option services via fee-for-service) for analysis. We will first test whether subgroups are adequately balanced across key characteristics. If necessary, we will use matching methods to develop subgroup-specific comparison groups, to balance intervention and comparison groups in observed characteristics. The ability to look at subgroups and differentiated effects is ultimately limited by the number of beneficiaries in each group and the variability in the data. Lewin will weigh the value of testing for differences among subgroups against having adequate sample size and power to do so precisely.

Implications of the COVID-19 pandemic: Onset of COVID-19 PHE coincides with implementation of the first year of SMI waiver – resulting in complexity in parsing out the effect of the pandemic and implementation of new policies on outcomes of interest (e.g., utilization of ED visits, readmission, follow-up provider visits). The pandemic affects program enrollment, beneficiary behavior (related to varied factors like service utilization, mental health and substance use), and provider behavior and has also affected how the waiver policies were implemented. Program impact estimation will thereby need to address these confounding effects. Some commonly adapted approaches are inclusion of time period indicators (e.g., pre-2020, first year of SMI waiver / COVID (2020), post-2020), covariates capturing COVID-19 severity in regression models, developing beneficiary-level sub-group analyses that control for

individual level factors including socio-economic status and health factors. A beneficiary level analysis will typically include a regression like:

$$y_{it} = \beta_0 + \beta_1 T_t + \beta_{41} P1_t + \beta_{42} P_t + \beta_2 P_t + \beta_3 PT_t + X_{it} + Z_t$$

where:

- y_{it} = beneficiary level measure of interest at time 't'
- β_0 represents the baseline level
- β_1 is the trend coefficient pre-intervention, T_t indicates time from first baseline period
- β_2 is the coefficient for the change in level of outcome post intervention, P_t indicates program implementation indicator
- β_3 indicates the slope change following intervention (or program start), PT_t indicates post implementation period
- X_{it} beneficiary characteristics at time 't'
- Z_t regional or economic factors (e.g. prevalence of COVID-19) at time 't'
- β_{42} is the coefficient for the change in level of outcome and β_{42} indicates the change in trend of the outcome after implementation of demonstration in 2020

COVID-19 has had varying impact – especially among racial and ethnic minorities, individuals with low income, and access to care.[16] The evaluator will develop sensitivity analyses by performing sub-group analyses by identified population sub-cohort (e.g., race, ethnicity, dual eligible status, geographic location) to provide valid program estimates.

[16] Accessed on 02/21/2022 from: https://www.milbank.org/wp-content/uploads/2021/06/Issue_Brief_COVID-19.pdf and https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf

D. Methodological Limitations

Exhibit D.1 describes the known limitations of the evaluation and anticipated approaches to minimizing those limitations and/or acknowledges where limitations might preclude casual inferences about the effects of demonstration policies. **Section C** contained information on limitations regarding identification of comparison groups and the potential impacts of the COVID-19 PHE on the use of data from 2020 and onwards for evaluation purposes. The Interim and Summative Evaluation Reports will describe in detail the limitations of the evaluation, which may include data and methodological challenges and other limitations identified during the evaluation process that are not described below. These reports will acknowledge approaches taken by the independent evaluator and necessary modifications made to the Evaluation Plan to address these challenges and limitations.

Exhibit D.1: Summary of Methodological Limitations and Approach to Minimizing Limitations

Area	Issue	Description	Anticipated Approaches to Minimizing Limitations
Overall issues	Impact of COVID-19	The ongoing COVID-19 PHE, which began in March 2020, is anticipated to cause substantial changes to: • Service utilization • Medicaid enrollment • Provider networks	• Use and inclusion of data from CY 2020 and onwards to analyze impact of policies will require careful analyses and be dependent on multiple factors including the period for reinstatement of policies, any long-term changes to service delivery (e.g., telehealth), and COVID-19's economic impact. • Provide context for interpretation of results.
	Quality of provider contact information for key informant interviews	Reliability of provider contact information made completing provider key informant interviews challenging. For example, provider email addresses and phone numbers listed in the MCE provider list often provided only generic office email addresses.	• Obtain support from key provider associations to identify providers for key informant interview purposes. • Use interviews with key provider associations in lieu of individual providers as necessary.
	Impact of changes in population over time	Changes in the SMI case mix over time may have an impact on a variety of areas of this evaluation, including service utilization, member enrollment, and access to services.	• Provide context for interpretation of results.

E. Attachments

The following attachments appear in this section:

- Exhibit E.1: Organizational Conflict of Interest
- Exhibit E.2: Evaluation Budget-Total Costs
- Exhibit E.3: Evaluation Budget-Deliverables by State Fiscal Year
- Exhibit E.4: Timeline and Milestones

Attachment E.1. Summary of Independent Evaluator Approach

Due to the COVID-19 PHE issued in Indiana, and the impact of COVID-19 on the State's budget, an independent evaluator was not procured in time for the initial Evaluation Design submission. However, Indiana has selected an independent evaluator and is in the process of finalizing a contract. The State is committed to securing an independent evaluator in a timely fashion to work through iterations of this Plan with CMS. Indiana will ensure that there are no conflicts of interest to report as stated in Section XVI, Paragraph 1 of CMS's STCs for this Waiver Evaluation.

In order to ensure an independent evaluation, the evaluation process will be independent of any process involving program policy making, management, or activity implementation of the waiver demonstration. The State's responsibility towards an independent evaluation is the assurance of quality data to the evaluator, support in understanding program context of any data anomalies, and identifying the program components that are important for the evaluation.

CMS recommended inclusion of cost analysis to understand how the demonstration affected health care spending. Analyses developed by State's actuary, Milliman Inc., will be included for this portion of the evaluation.

Exhibit E.1: Organizational Conflict of Interest

Indiana Department of Administration
Healthy Indiana Plan 1115 Waiver Evaluation

Professional Services Contract #00000000000000000000051455

Organizational Conflict of Interest Disclosure

The Lewin Group, Inc. ("Lewin") is performing Professional Services Contract #00000000000000000000051455 entitled, "Serious Mental Illness ("SMI") and Serious Emotional Disturbance ("SED") Waiver Evaluation Services" ("Contract"), for the Indiana Department of Administration, Indiana Family and Social Services Administration ("FSSA").

In accordance with the Centers for Medicare and Medicaid ("CMS") Special Terms and Conditions ("STC") 11-W-00296/5 (as extended through December 31, 2030), Attachment A-Developing the Evaluation Design, Section F-Conflict of Interest, FSSA is required to assure CMS that it will obtain an Independent Evaluator which will "conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest." These types of COIs are normally referred to as Organizational Conflicts of Interest ("OCI"). Accordingly, what follows in this OCI disclosure ("Disclosure") is an explanation of why Lewin's performance as the SMIE/SED Waiver Evaluation Contractor under the Contract does not create an actual or potential OCI. This Disclosure is organized to describe; 1) Lewin's relevant corporate affiliates and, 2) Lewin's OCI analysis.

I. Lewin's Affiliate Interests

Lewin is part of UnitedHealth Group, Incorporated ("UHG"), a diversified health and well-being company dedicated to improving the health care system in the United States. UHG is organized into six businesses. Three of those businesses — UnitedHealthcare Community & State, UnitedHealthcare Medicare & Retirement and UnitedHealthcare Employer & Individual — provide network-based health care benefits and related services under the "UnitedHealthcare" brand. The other three businesses operate under the "Optum" brand and include OptumHealth, OptumRx, and OptumInsight. Amongst its services, the Optum businesses offer a large variety of services that include but are not limited to third party administration of specialty benefits, pharmacy benefit management, disease and care management, direct care delivery, consulting, health technology and innovation support to government agencies and external third party insurers and health plans as well as to UnitedHealthcare plans. Although UHG provides certain shared services across the enterprise, Optum and UnitedHealthcare operate as separate businesses with separate operational structures and separately reported financial results. For more information, please see www.unitedhealthgroup.com and www.optum.com.

In conducting a current OCI analysis, Lewin identified three (3) affiliated businesses relevant for discussion, and are as follows:

- *UnitedHealthcare Community and State ("UHC C&S"): UHC* C&S is one of the nation's largest health benefits companies dedicated to providing diversified solutions to states that care for the economically disadvantaged, the medically underserved and those without employer-funded health care coverage. C&S Managed Care Organizations ("MCOs") contract with networks of participating providers and facilities to serve more than 5 million beneficiaries covered under Medicaid (Title 19), CHIP (the Title 21, Children's Health Insurance Program), Dually Eligible (Medicaid-Medicare enrollees), Long Term Care and Children with Special Care Needs (a Title V Program) and other federal and state health care programs. UHC C&S is also a government programs Administrative Services Organization where it acts in the capacity of an administrator on a non-risk basis. C&S participates in Medicaid programs throughout the country. Presently, UHC C&S is not an MCO in the State of Indiana. However, UHC C&S is intending to bid on FSSA Request for Proposal RFP #22-68152 Risk-Based Managed Care Services for Medicaid Beneficiaries (Hoosier Healthwise and Healthy Indiana Plan Programs) (hereby referred to as the "RFP") for which proposals are due August 9, 2021.

- *MedExpress:* MedExpress, which is part of OptumHealth, includes primary and urgent care centers in multiple states that provide walk-in neighborhood care, wellness and prevention service. MedExpress currently provides services to eligible Indiana Medicaid recipients in seven (7) locations throughout the State which include Anderson, Bloomington, Indianapolis, Kokomo, Lafayette, and Muncie.

- *OptumRx:* OptumRx is one of the three largest pharmacy benefit managers and specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. OptumRx provides full-service pharmacy benefits management services, including mail order and specialty pharmacy benefits, and a synchronized pharmacy care experience that combines member engagement with health data and analytics. Its additional services include claims processing, retail network contracting, rebate contracting and management, and clinical programs, such as step therapy, formulary management and disease/drug therapy management programs. OptumRx serves customers in multiple markets and government programs, including commercial, managed care, Medicaid, Medicare, labor and trust, workers compensation and others. OptumRx is presently under contract with FSSA to provide pharmacy benefit management services for the Indiana Health Coverage Program.

II. Lewin's OCI Analysis

For the purpose of this OCI Analysis, Lewin refers to the Federal Acquisition Regulation Part 9.5 which defines three types of conflicts. Upon review, Lewin is not aware of any facts or circumstances that would create an actual or potential OCI. To the extent that an OCI may be perceived to exist, Lewin will explain how the OCI is avoided, neutralized, or mitigated. These conclusions are based on the following:

A. Biased Ground Rules

A Biased Ground Rules OCI arises where a company, as part of its performance of a government contract, sets the ground rules for a later government procurement by, for example, writing the statement of work or the specifications. The primary concern is that the company could create an unfair competitive advantage by biasing the competition in favor of itself or its affiliate. Neither Lewin nor any of its affiliates developed or assisted FSSA in the procurement of the Contract. Accordingly, no Biased Ground Rules OCI exists.

B. Impaired Objectivity

An Impaired Objectivity OCI commonly occurs when a company's work under one government contract could require the company to evaluate the work that company itself or its affiliates performed under a separate government contract. The primary concern is that the company's ability to render impartial advice to the government could be impaired, where that advice involves the use of subjective judgment, and where the advice could affect the economic interests of the company as broadly construed.

Lewin has not identified any situation while performing work as the contracted Independent Evaluator under the Contract would create an actual or potential Impaired Objectivity OCI. Where it might be perceived that the risk of a potential OCI might exist, Lewin will explain why that perceived risk would not become an actual or potential OCI.

Lewin's OCI analysis determined that primary purpose of proposed evaluation is to determine the impact of HIP with regard to eligible Indiana Medicaid recipients and their access to health care services, utilization of those services, and health outcomes. Lewin's OCI analysis concluded that Optum's MedExpress and OptumRx affiliates do not present any risk of an Impaired Objectivity OCI in the conduct of this evaluation. Lewin also established that should its UHC C&S affiliate be awarded a future role as a Managed Care Entity ("MCE") it might be perceived that Lewin would conduct the HIP evaluation in such a manner that could financially and/or contractually benefit UHC C&S. However, after conducting a thorough review of the facts surrounding the scope of Lewin's evaluation support to FSSA, it was determined that no such OCI risk would be created for the following reasons:

- *The Objective Focus of the Evaluation:* The evaluation of the HIP is to support FSSA's continuous effort to assure Indiana Medicaid recipients are receiving the best possible health care as defined by CMS' Triple Aim for better access to care, better health care outcomes, and reduced cost to beneficiaries. At no time

during the course of the evaluation will Lewin be required to evaluate the performance of any HIP MCE including its UCH C&S affiliate as an awarded MCE under the RFP.

- *Lewin's Significant Limitations to Exercise Subjective Judgment:* Lewin will execute all evaluation tasks under an FSSA/CMS-approved evaluation design in accordance with evaluation guidance set forth in CMS STC 11-W-00296/5. Data for the evaluation data is collected from FSSA-directed sources to include statewide Medicaid member surveys, focus groups, key informant interviews, and prescribed data sets from the Indiana Medicaid Management Information System ("MMIS"). Data sets required by Lewin for analysis from state MCOs are provided to Lewin directly from state staff members. Any recommended changes to the evaluation design made by Lewin must go through a review by FSSA and its stakeholders and must be approved by CMS. Combined, these FSSA/CMS mandated requirements and parameters, significantly restricts Lewin from exercising subjective judgment. Furthermore, there is no nexus between the outcomes of Lewin's evaluation of this demonstration and the financial interests of Lewin or any of its affiliates providing healthcare services to Indiana Medicaid recipients. As such, no Impaired Objectivity OCI exists.

- *Transparency:* FSSA will have complete oversight of Lewin's in-progress work and through the review of required evaluation deliverables. Additionally, FSSA has final approval of all Lewin's work with CMS being the ultimate approver.

Given these facts and circumstances as they have been presented above, Lewin's ability to perform its HIP evaluation work will not create any risk of an actual or potential Impaired Objectivity OCI should UHC C&S serve FSSA as an MCE under the RFP.

C. Unequal Access to Information

An Unequal Access to Information OCI exists where a company has access to non-public information as part of its performance of a government contract and that information may provide the company with an unfair competitive advantage in a later competition for a government contract.

In the performance of the Contract, Lewin has access to non-public and confidential information such as claims and benefit data from Indiana MCOs. If this information was inadvertently accessed by Lewin's UHC C&S affiliate it could conceivably generate an unfair competitive advantage under the current RFP and future MCE bid opportunities. However, any such OCI concerns are unfounded because Lewin understands and complies with its obligation to handle non-public and confidential information in accordance with applicable laws, regulations, and contract requirements. As a result, in the regular course if its business, Lewin has implemented measures that would prospectively prevent any Unequal Access to Information OCI from occurring and that includes the following:

- *Information and Security Firewalls:* Lewin has established effective firewalls to prevent unauthorized use or disclosure of protected information and to guard against the risk of even inadvertent disclosure of such information. These firewalls provide an information disclosure barrier between Lewin and other business units and employees of UHG, including without limitation MedExpress, OptumRx, and UHC C&S. All protected program information in electronic form will be maintained on a secure, password-protected server that is dedicated to Lewin. Electronic documents or data files containing protected information area accessible only to Lewin employees on a need to know basis.

- *Separate Staffing:* The personnel that Lewin uses for the Contract are separate and distinct from the staff used by Lewin's MedExpress, OptumRx, and C&S affiliates. There is no overlap of staffing in this regard between the very separate businesses.

- *Information Security Policies and Procedures:* Lewin has implemented numerous policies and procedures regarding the way employees are to handle and disclose confidential information. This includes, a "need-to-know" policy, which provides that individual employees have access to the minimal amount of confidential information necessary to perform his or her work on the specific project to which the employee

is assigned. Furthermore, Lewin employees are annually trained on the firewall and its policies and have a continuing obligation to report suspected violations of the policy, including any suspected violations of the information firewall. This obligation is emphasized as part of their training on the enterprise Code of Conduct. The policy identifies the company hotline and other means through which they may make such a report (anonymously, if desired). Employees are advised that violations could result in consequences such as termination of employment.

- *Contract Requirements:* In accordance with Section 12 of the Contract (Confidentiality, Security and Privacy of Personal Information), Lewin is required to abide by HIPAA Rules as such Rules apply to Business Associates.

IV. Conclusion

For all the foregoing reasons, Lewin's continued performance of the Contract does not create an actual or potential OCI nor adversely affect or impact FSSA. Lewin understands that there is a continuing obligation to provide assurance to FSSA that no OCIs arise in the course of performing the work. In the event there is a change in facts that would give rise to an actual or significant, potential OCI, Lewin will promptly disclose the circumstances to FSSA, along with a mitigation plan, and Lewin will not proceed with performing the conflicted work until a mutually acceptable mitigation plan is in place.

Attachment E.2. Evaluation Budget

The budget for the Independent Evaluation from the awarded evaluator contract is included below. Oversight and support of this contract and provision of data to the evaluator on behalf of the state are considered to be encompassed in general program administrative costs and are not reported in this document. The state will leverage its existing contract with Milliman Inc. for the required cost analysis.

Exhibit E.2: Evaluation Budget-Total Costs

	State Fiscal Year	Dates	Total Required Work
Base Contract	2021	7/1/20 to6/30/21	$ 44,820
	2022	7/1/21 to 6/30/22	
	2023	7/1/22 to 6/30/23	$ 158,828
	2024	7/1/23 to 6/30/24	$ 368,019
	2025	7/1/24 to 6/30/25	$ 629,620
	2026	7/1/25 to 6/30/26	$ 291,962
	2027	7/1/26 to 6/30/27	$ 623,970
	2028	7/1/27 to 6/30/28	$ 149,459
		Contract Total:	$ 2,266,679

Exhibit E.3: Evaluation Budget-Deliverables by State Fiscal Year

Deliverable	SFY 2021	SFY 2022	SFY 2023	SFY 2024	SFY 2025	SFY 2026	SFY 2027	SFY 2028
Task 1: Project Management	$3,645		$42,510	$40,177	$24,601	$25,368	$26,135	
Task 2: Develop FSSA's Evaluation Plan for the 2021-2025 waiver	$41,175		$2,866					
Task 3: Conduct Key Informant Interviews			$113,452	$117,176		$121,192		
Task 4: Develop Mid-Point Assessment Report				$210,666	$23,406			
Task 5: Develop Interim Evaluation Report for 2021-2025 Waiver					$581,612	$145,403		

Deliverable	SFY 2021	SFY 2022	SFY 2023	SFY 2024	SFY 2025	SFY 2026	SFY 2027	SFY 2028
Task 6: Develop Summative Evaluation Report for 2021-2025 Waiver							$597,836	$149,459
Total	**$44,820**	**$ 0**	**$158,828**	**$368,019**	**$629,620**	**$291,962**	**$623,970**	**$149,459**

Attachment E.3. Timeline and Major Milestones

This section describes the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones and deliverables, including both interim and summative evaluations.

Mid-Point Assessment

The Mid-Point Assessment is designed to summarize progress towards meeting the SMI/SED milestones and identify related risks. Consistent with Section XI.6 of the STC, the Mid-Point Assessment will contain a description of the methodologies used for examining progress and assessing risk, the limitations of the methodologies, the evaluator's determinations regarding progress towards key milestones, and any recommendations. As required by CMS, this report will include the following elements (STC Sections 5 and 6):

- An examination of progress toward meeting each milestone and timeframe approved in the SMI/SED Implementation Plan, the SMI/SED Financing Plan, and toward meeting the targets for performance measures as approved in the SMI/SED Monitoring Protocol
- A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date
- 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
- For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the State's SMI/SED or SMI/SED Financing Plan or to pertinent factors that the State can influence that will support improvement
- An assessment of whether the State is on track to meet the budget neutrality
- An assessment if the State is meeting the STC requirement of a 30 day or less average length of stay (ALOS). If the State cannot show that it is meeting a 30 day or less ALOS requirement within one standard deviation at the Mid-Point Assessment, the State may only claim Federal financial participation (FFP) for stays up to 45 days until such time that the State can demonstrate that it is meeting a 30 day or less ALOS requirement.

The Mid-Point Assessment will also include findings from key informant interviews with stakeholders, including, but not limited to: representatives of MCEs, SMI/SED providers, members and other key partners.

The major activities associated with the development of the Mid-Point Assessment are:

- **Conduct key informant interviews** – The evaluator will use findings from key informant interviews conducted in 2021 and 2023.
- **Request and review data and key resources** – The evaluator will develop an information/data request, including FSSA monitoring reports and other program documentation. The evaluator assumes that the FSSA monitoring reports will inform the quantitative aspects of the evaluation and that primary data collection or calculation of metrics identified in the monitoring protocol will not be necessary.
- **Develop Mid-Point Assessment outline** – The evaluator will develop an outline for the Mid-

Point Assessment for review and comment by FSSA. This outline will help provide a common understanding of the content to be included within each of the sections of the assessment.

- **Develop draft and final Mid-Point Assessment Reports** – The evaluator will use FSSA's monitoring reports (based on the CMS-approved monitoring protocol), the results of the 2020 Summative Evaluation Report, and themes from key informant interviews (2021, 2023) to develop the draft Mid-Point Assessment Report.
- **Responding to CMS Feedback** – The evaluator will support FSSA in responding to feedback from CMS on the Mid-Point Assessment report.
- **CMS briefing** – The evaluator will support FSSA in briefing the Mid-Point Assessment findings to CMS. This briefing will be delivered virtually or in-person, as requested by CMS.

Interim Evaluation Report for 2021-2025 waiver

Indiana will develop the 2021-2025 Interim Evaluation Report per requirements outlined in Appendix B of the STCs, and according to the approved final evaluation plan. As such, it will include the following sections:

- Executive summary
- General background information
- Evaluation questions and hypotheses
- Methodology
- Methodological limitations
- Results
- Conclusions
- Interpretations, policy implications and interactions with other state initiatives
- Lessons learned and recommendations
- Attachment(s), including the approved evaluation design

The main activities in the development of the Interim Evaluation Report are as follows:

- **Collect quantitative data** – The evaluator will develop and submit an information/data request based on the data sources, described in Attachment F, to FSSA and will coordinate with FSSA data team members to receive and process the data.
- **Prepare collected data for analysis** – the evaluator will leverage the data dictionaries and information shared by State data team to develop data intake and processing. Additionally, data preparation will include development of basic summaries (e.g., count of beneficiaries by year and age group. The evaluator will develop multiple analytical tables (e.g., yearly count of utilization, yearly enrollment data containing beneficiary characteristics) for use across quantitative analyses.
- **Conduct quantitative analyses** – The evaluator will conduct the quantitative analyses outlined in the **Methodology Section**.

- **Collect qualitative data and conduct qualitative analysis** – The evaluator will incorporate findings from key informant interviews.
- **Develop Report outline** – The evaluator will develop an outline for the Interim report for review and comment by FSSA. This outline will help provide a common understanding of the content to be included within each of the sections of the report.
- **Develop Draft Evaluation Report** – The evaluator will use the quantitative and qualitative analyses described above to develop the draft Interim Evaluation Report for public comment. The evaluator will review public comments and adjust the draft report in consultation with FSSA, as appropriate. FSSA will submit the report to CMS by December 31, 2024.
- **Respond to CMS feedback** – Indiana review CMS feedback on the draft 2021-2025 Interim Evaluation Report, revise as appropriate and necessary and submit the final report to CMS

Develop Summative Evaluation Report for 2021-2025 waiver

The 2021-2025 Summative Evaluation Report will be based on the requirements outlined in Appendix B of the STCs, and according to the approved Evaluation Plan. As such, it will include the following sections:

- Executive summary
- General background information
- Evaluation questions and hypotheses
- Methodology
- Methodological limitations
- Results
- Conclusions
- Interpretations, policy implications and interactions with other state initiatives
- Lessons learned and recommendations
- Attachment(s), including the approved evaluation design

This report will reflect additional key informant interviews and quantitative data analyses that reflect the full waiver time period (as described in the Methods section). The main activities in the development of the Summative Evaluation Report will be similar to those described above (development of Interim Evaluation Report) including:

- Data request (enrollment, claims / encounters, administrative)
- 2021-2025 Summative Evaluation Report outline
- Draft 2021-2025 Summative Evaluation Report for FSSA review
- Revised 2021-2025 Summative Evaluation Report for public comment
- 2021-2025 Summative Evaluation Report for CMS Review
- Final 2021-2025 Summative Evaluation Report

Exhibit E.4: Timeline and Milestones

		State Fiscal Year:	2021				2022				2023				2024				2025				2026				2027				2028
		Calendar Year:	CY 2021				CY 2022				CY 2023				CY 2024				CY 2025				CY 2026				CY 2027				
Task	Activity/Deliverable		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
1	**Conduct Project Management and Monitoring Activities**																														
2	**Develop Evaluation Plan**																														
	Draft Evaluation Plan																														
	Submit to CMS																														
	Respond to CMS feedback, Final Report																														
3	**Perform Key Informant Interviews**																														
4	**Develop Mid-Point Assessment Report**																														
	Outline																														
	Data request																														
	Draft Report																														
	Revised Report for submission to CMS																														
	Respond to CMS feedback, Final Report																														
5	**Develop 2021-2025 Interim Evaluation Report**																														
	Outline																														
	Data request																														
	Draft Report																														
	Revised Report for public comment																														
	Revised Report for submission to CMS																														
	Respond to CMS feedback, Final Report																														
6	**Develop 2021-2025 Summative Evaluation Report**																														
	Outline																														
	Data request																														
	Draft Report																														
	Revised Report for public comment																														
	Revised Report for submission to CMS																														
	Respond to CMS feedback, Final Report																														

F. Analytic Tables

The tables include research questions, outcome measures and time specification for the interim and summative report. Assumption: all measures will be used for both Interim and Summative Evaluation Reports. To study trends over time and develop observational analyses, outcome measures will be calculated for a 12-month time-period (calendar year). All regression-based analyses (e.g., ITS) will use beneficiary level data. Depending on the research question, other time frame (e.g., quarterly, monthly) will be considered for analysis.

Goal 1: Reduced utilization and length of stay in emergency departments among Medicaid beneficiaries with SMI or SED while awaiting mental health treatment in specialized settings

Exhibit F.1: Goal 1

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.1: The SMI/ SED demonstrations will result in reductions in utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment.	**Primary RQ 1.1:** Does the SMI/SED demonstration result in reductions in utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment?[17]	• Number of all-cause ED visits per 1,000 beneficiary-months among adult Medicaid beneficiaries aged 18 and older who met the eligibility criteria of beneficiaries with SMI • (Denominator = total months of enrollment for beneficiaries aged 18 and older and had SMI diagnosis, Numerator = total number of all cause ED visits for beneficiaries included in Denominator) *Measure steward, endorsement (benchmark): Milestone 2 monitoring metric* *SMI/SED demonstration monitoring metric #3 All-Cause Emergency Department (ED) Utilization Rate for Medicaid Beneficiaries who may Benefit From Integrated Physical and Behavioral Health Care (PMH-20).*[18]	• Claims/encounter data (2018-2025) • Enrollment data (2018-2025)	Descriptive quantitative analysis of trends over time during the demonstration Interrupted time series analysis	n.a.

[17] The research questions were drafted to align with CMS guidance (https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/smi-sed-eval-guide-appendix-a.pdf). For each research question, the State identified one outcome measure for the evaluation. For this research question, the State is assessing impact of program based on reduced number of ED visits.

[18] Based on Technical Specifications and Resource Manual, this measure is defined as the number of all-cause ED visits per 1,000 beneficiary months among adult Medicaid beneficiaries aged 18 and older who meet the eligibility criteria of beneficiaries with SMI in a year. The Technical Specifications and Resource Manual is available at: https://www.medicaid.gov/resources-for-states/innovation-accelerator-program/functional-areas/quality-measurement/physical-and-mental-health-integration-quality-measures/index.html

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.1, continued	Subsidiary RQ 1.1: How do the SMI/SED demonstration effects on reducing utilization and lengths of stays in EDs among Medicaid beneficiaries with SMI/SED vary by geographic area or beneficiary characteristics?	• Number of all-cause ED visits per 1,000 beneficiary-months among adult Medicaid beneficiaries aged 18 and older who met the eligibility criteria of beneficiaries with SMI (Refer to Primary RQ 1.1 for measure calculation) *Measure steward, endorsement (benchmark): Milestone 2 monitoring metric #3*	• Claims/encounter data (2018-2025) • Enrollment data (2018-2025)	Descriptive quantitative analysis of trends over time during the demonstration Interrupted time series analysis	n.a.
H.1, continued	Subsidiary RQ 1.2: How do SMI/SED demonstration activities contribute to reductions in utilization and length of stay in EDs among Medicaid beneficiaries with SMI/SED while awaiting mental health treatment in specialized settings?	• Demonstration activities or their components or characteristics that stakeholders identify as most effective in reducing utilization and lengths of stays in EDs among Medicaid beneficiaries with SMI or SED • Obstacles that stakeholders identify as hindering the effectiveness of the demonstration in reducing utilization and lengths of stays in EDs	Key informant interviews with members, MCEs, State staff and ED providers	Descriptive qualitative analysis of demonstration activities most effective, and obstacles that stakeholders identify, in reducing utilization and lengths of stays in EDs	n.a.

Goal 2: Reduced preventable readmissions to acute care hospitals and residential settings

Exhibit F.2: Goal 2,[19] Hypothesis 2

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.2: The SMI/SED demonstration will result in reductions in preventable readmissions to acute care hospitals and residential settings.	**Primary RQ 2:** Does the SMI/SED demonstration result in reductions in preventable readmissions to acute care hospitals and residential settings (including, short-term inpatient and residential admissions to both IMDs and non-IMD acute-care hospitals, critical access hospitals, and residential settings)?	Number of thirty-day, all-cause unplanned readmissions (acute care hospitals and residential settings) following psychiatric hospitalization (Study population = all beneficiaries aged 18 and older and had SMI diagnosis having psychiatric hospitalization, measure calculation = Among beneficiaries included in study population number of admission, for any reason, to acute care hospital (including Critical Access Hospitals) or residential care that occurs within 3-30 days after the discharge date from a psychiatric hospitalization) (Benchmark to State published NQF #2860 measure - *SMI/SED demonstration monitoring metrics#4. Metric #4 is30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility (IPF))*[20]	• Claims/encounter data (2018-2025) • Enrollment data (2018-2025) • Adult Core Set (for NQF #2860)	Descriptive quantitative analysis of trends over time during the demonstration Interrupted time series analysis	n.a.

[19] Indiana is not including Subsidiary Research Question 2.3: "Does the SMI/SED demonstration result in increased screening and intervention for comorbid SUD and physical health conditions during acute care psychiatric hospital and residential setting stays and increased treatment for such conditions after discharge?" Calculation and monitoring of such a metric will require medical reviews be performed which would require substantial resources. As this research question is not associated with primary objective of the waiver, the State determined not to monitor and calculate this metric during time of preparation of this evaluation plan.

[20] This measure is based on the 30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility (IPF) in the IPFQR program. The program manual for IPFQR is available at: https://qualitynet.org/files/5df7a5ca62faad001ffd7a87?filename=FY20_IPFQR_CBM_Sp ecs.pdf.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.2, continued	**Subsidiary RQ 2.1:** How do the SMI/SED demonstration effects on reducing preventable readmissions to acute care hospitals and residential settings vary by geographic area or beneficiary characteristics?	Number of thirty-day, all-cause unplanned readmissions following psychiatric hospitalization (Refer to Primary RQ 2 for measure calculation) (Benchmark to State published NQF #2860 measure - *SMI/SED demonstration monitoring metrics #4. Metric #4 is 30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility (IPF)*	• Claims/encounter data (2018-2025) • Enrollment data (2018-2025) • Adult Core Set (for NQF #2860)	Descriptive quantitative analysis of trends over time during the demonstration Interrupted time series analysis	n.a.
H.2, continued	**Subsidiary RQ 2.2:** How do demonstration activities contribute to reductions in preventable readmissions to acute-care hospitals and residential settings?	• Demonstration activities or their components or characteristics that stakeholders identify as most effective in reducing preventable readmissions to acute care hospitals and residential settings • Obstacles that stakeholders identify as hindering the effectiveness of the demonstration in reducing preventable readmissions to acute care hospitals and residential settings	Key informant interviews with members, State staff, MCEs, providers, and other stakeholders (including consumer advocates)	Qualitative analysis to identify themes associated with the effectiveness of demonstration activities for reducing preventable readmissions to acute care hospitals and residential settings	n.a.

Goal 3: The SMI/SED demonstration will result in improved availability of crisis stabilization services throughout the state

Exhibit F.6: Goal 3

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.3: The SMI/SED demonstration will result in improved availability of crisis stabilization services throughout the state.	**Primary RQ 3.1:** To what extent does the SMI/SED demonstration result in improved availability of crisis outreach and response services (including crisis call centers, mobile crisis units, crisis observation/assessment centers, and coordinated community crisis response teams) throughout the state?	• Number of crisis call centers • Number of mobile crisis units • Number of crisis observation/assessment centers • Number of coordinated community crisis response teams	State administrative data (2018-2025)[21] collected via the Quarterly Monitoring Reports submitted to CMS. These data are updated annually in the Q1 report.	Descriptive quantitative analysis of trends over time during the demonstration	Baseline assessment at the start of the demonstration
	Primary RQ 3.2: To what extent does the SMI/SED demonstration result in improved availability of intensive outpatient services and partial hospitalization?	Number of intensive outpatient and partial hospitalization providers *Note: The metric is based on State Availability Assessment. The Assessment gets submitted annually by May 30 as part of the monitoring report. The Assessment is point in time and performed on Feb 1 of that year.*	State administrative data (2018-2025) collected via the Quarterly Monitoring Reports submitted to CMS. These data are updated annually in the Q1 report.	Descriptive quantitative analysis of trends over time during the demonstration Lookback time period for trend will depend on available data	Baseline assessment at the start of the demonstration

[21] Once CMS publishes monitoring reports, they can be found here: https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/81641

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.3, continued	**Primary RQ 3.2:** To what extent does the SMI/SED demonstration result in improved availability of intensive outpatient services and partial hospitalization?	• Demonstration activities or their components or characteristics that stakeholders identify as most effective in improved availability of intensive outpatient services and partial hospitalization • Obstacles that stakeholders identify as hindering the effectiveness of the demonstration in improved availability of intensive outpatient services and partial hospitalization	Key informant interviews with members, State staff, MCEs, providers, and other stakeholders (including consumer advocates)	Qualitative analysis to identify themes associated with the effectiveness of demonstration activities for improved availability of intensive outpatient services and partial hospitalization	n.a.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.3, continued	**Primary RQ 3.3:** To what extent does the SMI/SED demonstration improve the availability of crisis stabilization services provided during acute short-term stays in each of the following: public and private psychiatric hospitals; residential treatment facilities; general hospital psychiatric units; and community-based settings (such as residential crisis stabilization programs, small inpatient units in community mental health centers, peer-run crisis respite programs, and so on)?	Number of: • Intensive outpatient and partial hospitalization providers • Psychiatric hospitals • Residential mental health treatment facilities and beds • Medicaid-enrolled psychiatric units in acute care and critical access hospitals • Licensed psychiatric hospital and psychiatric unit beds • Community Mental Health Centers	State administrative data (2018-2025) collected via the Quarterly Monitoring Reports submitted to CMS. These data are updated annually in the Q1 report.	Descriptive quantitative analysis of trends over time during the demonstration Lookback time period for trend will depend on available data	Baseline assessment at the start of the demonstration

Goal 4: Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI or SED including through increased integration of primary and behavioral health care

Exhibit F.7: Goal 4[22]

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.4: Access of beneficiaries with SMI/SED to community-based services to address their chronic mental health care needs will improve under the demonstration, including through increased integration of primary and behavioral health care.	**Primary RQ 4.1:** Does the demonstration result in improved access of beneficiaries with SMI/SED to community-based services to address their chronic mental health care needs?	Proportion of beneficiaries with SMI/SED who use mental-health-related (1) outpatient, rehabilitation, and targeted case management services; (2) home and community-based services; and (3) long-term services and supports (Denominator = total number of beneficiaries aged 18 and older and having SMI diagnosis and meeting Medicaid coverage eligibility, Numerator = number of beneficiaries included in denominator and using specific services) *Measure steward for (1): Milestone 3 monitoring metric for outpatient* *mental health services utilization (metric # 15) divided by Milestone 4 monitoring* *metric for count of beneficiaries with SMI/SED (metric #21)* (Benchmark to State published monitoring metrics) *SMI/SED demonstration monitoring Metric SMI/SED demonstration monitoring metric #15: Mental Health Services Utilization – Outpatient, #21: Count of Beneficiaries With SMI/SED (monthly)*	• Enrollment data (2018-2025) • Claims/encounter data (2018-2025) ○ Institutional ○ Non-institutional ○ Pharmacy	Descriptive quantitative analysis of trends over time during the demonstration Interrupted time series analysis	n.a.

[22] Indiana is not including Subsidiary Research Question 4.1c: "How do the SMI/SED demonstration effects on access to community-based services vary by geographic area or beneficiary characteristics?" in this Evaluation Plan. The outcome measures from Goal 3, the summaries of provider types, address this question. Furthermore, this Evaluation Plan is limited to one year of the demonstration and because this is a subsidiary research question.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.4, continued	**Subsidiary RQ 4.1a:** To what extent does the demonstration result in improved availability of community-based services needed to comprehensively address the chronic mental health needs of beneficiaries with SMI/SED?	Number of Medicaid-enrolled: • Community mental health centers • Psychiatrists and other mental health practitioners authorized to prescribe • Mental health practitioners (other than psychiatrists) who are certified and licensed by the state to independently treat mental illness • Federally qualified health centers (FQHCs) that offer behavioral health services	State administrative data (2018-2025) collected via the Quarterly Monitoring Reports submitted to CMS. These data are updated annually in the Q1 report.	Descriptive quantitative analysis of trends over time during the demonstration Level of granularity of analysis and lookback time period for trend will depend on available data	Baseline assessment at the start of the demonstration
H.4, continued	**Primary RQ 4.2:** Does the integration of primary and behavioral health care to address the chronic mental health care needs of beneficiaries with SMI/SED improve under the demonstration?	• Demonstration activities or their components or characteristics that stakeholders identify as most effective in the integration of primary and behavioral health care to address the chronic mental health care needs of beneficiaries with SMI/SED • Obstacles that stakeholders identify as hindering the effectiveness of the demonstration in the integration of primary and behavioral health care to address the chronic mental health care needs of beneficiaries with SMI/SED	Key informant interviews with members, State staff, MCEs, ED providers, and other stakeholders (including consumer advocates)	Qualitative analysis to identify themes associated with the effectiveness of demonstration activities for the integration of primary and behavioral health care to address the chronic mental health care needs of beneficiaries with SMI/SED	n.a.

Goal 5: Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities

Exhibit F.9: Goal 5[23]

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.5: The SMI/SED demonstration will result in improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities.	**Primary RQ 5.1:** Does the SMI/SED demonstration result in improved care coordination for beneficiaries with SMI/SED?	Percentage of discharges for patients aged 18 and older who had a visit to the ED with a primary diagnosis of mental health or alcohol or other drug dependence during the measurement year AND who had a follow-up visit with any provider with a corresponding primary diagnosis of mental health or alcohol or other drug dependence within 7 and 30 days of discharge (Denominator = total number discharges for beneficiaries aged 18 and older and having SMI diagnosis and a primary diagnosis of mental health or alcohol or other drug dependence, meeting Medicaid coverage eligibility and had ED visit, Numerator = number of discharges in denominator that had a follow-up visit with provider within 7 and 30 days of discharge) (*Benchmark to Milestone 2 monitoring metric, NCQA, NQF #0576 (adapted)* *SMI/SED demonstration monitoring metric* ***#8 (NQF #0576 adapted): Follow-up After Hospitalization for Mental Illness: Age 18 and older***	• Enrollment data (2018-2025) • Claims/ encounter data (2018-2025) ○ Institutional ○ Non-institutional ○ Pharmacy • Adult Core Set (for NQF #0576)	Descriptive quantitative analysis of trends over time during the demonstration[24] Interrupted time series analysis	n.a.

[23] Indiana is not including Subsidiary Research Question 5.2a: "Does the SMI/SED demonstration result in improved discharge planning and outcomes regarding housing for beneficiaries transitioning out of acute psychiatric care in hospitals and residential treatment facilities?" This is because this Evaluation Plan is limited to one year of analysis and the level of effort involved in obtaining and reviewing facility records, and facility discharge records, is substantial especially considering Indiana's budget and the impact of COVID-19.

[24] This measure is part of the CMS Adult Core Set. The developed measure can be used to compare against other states using State report to CMS. Differences in results will not necessarily be due to impact of SMI waiver. The evaluation team will consider feasibility of the comparison during analysis process.)

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.5, continued	**Primary RQ 5.1:** Does the SMI/SED demonstration result in improved care coordination for beneficiaries with SMI/SED?	• Changes made through the demonstration to data-sharing systems, processes, or policies • Demonstration activities regarding data-sharing systems, processes, or policies that staff identify as most effective for improving care coordination • Obstacles that staff identify as hindering the effectiveness of demonstration activities regarding data sharing systems, processes, or policies aimed at improving care coordination	• Key informant interviews with members, State staff, MCEs, providers, and other stakeholders (including consumer advocates)	Qualitative analysis to identify themes associated with the effectiveness of demonstration activities to improve data sharing systems, processes, and policies to support care coordination	n.a.
H.5, continued	**Primary RQ 5.2:** Does the SMI/SED demonstration result in improved continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities?	• Demonstration activities or their components or characteristics that stakeholders identify as most effective in improving continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities • Obstacles that stakeholders identify as hindering the effectiveness of the demonstration in improving continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities.	• Key informant interviews with members, State staff, MCEs, providers, and other stakeholders (including consumer advocates)	Qualitative analysis to identify themes associated with the effectiveness of demonstration activities for improving continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities	n.a.

Hypothesis	Research Question	Outcome Measure(s)	Data Sources	Analytic Approach	Comparison Strategy
H.5, continued	**Subsidiary RQ 5.2b:** How do demonstration activities contribute to improved continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities?	• Demonstration activities or their components or characteristics that stakeholders identify as most effective in improving continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities • Obstacles that stakeholders identify as hindering the effectiveness of the demonstration in improving continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities.	• Key informant interviews with members, State staff, MCEs, providers, and other stakeholders (including consumer advocates)	Qualitative analysis to identify themes associated with the effectiveness of demonstration activities for improving continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities	n.a.

G. Impact of Demonstration on Health Care Spending

The State's actuary, Milliman, Inc. will be performing the cost analyses required as part of evaluation reports for Section 1115 demonstrations for individuals with SMI/SED or SUD. This analysis will follow the structure outlined in Appendix C of related CMS guidance.[25]

This analysis will assess how the demonstration impacts health care spending (increase, decrease or remain unchanged). Even though total costs might remain unchanged or even increase with the implementation of the demonstration as new services become available to Medicaid members, certain costs might decrease (such as emergency department visits). This is ascertained by modeling the impact of the demonstration on different types of costs.

The analysis will be conducted using costs expressed in dollars per beneficiary per month (PBPM). In Indiana, individuals with SMI diagnoses receive services through both the fee-for-service (FFS) and managed care (MC) delivery systems; therefore, this analysis will utilize the following types of claims:

- FFS claims for those receiving services on a FFS basis. This also includes FFS claims paid for members enrolled in managed care, where the services are currently or were previously carved out of the managed care capitation payments during the pre- and post-demonstration; or
- MC encounter claims (indicating the amount paid to providers as recorded by Managed Care Entities (MCEs)) as submitted to the fiscal agent and deduplicated by Milliman.

Both FFS claims and MC encounters will be summarized from the Enterprise Data Warehouse (EDW) with data provided by the fiscal agent, Gainwell, and maintained by Optum.

Administrative costs associated with SMI 1115 demonstration will also be included and will be provided to Milliman by the State.

The following three levels of cost analysis will be conducted as recommended in the CMS guidance:

1. The first level focuses on the total costs for SMI beneficiaries by adding up all the claim costs and administrative costs.
2. The second level of analysis focuses on identifying cost drivers by splitting the total costs into components based on the presence of SMI/SED diagnosis and the setting for the SMI services (IMD or other).
3. The third level of analysis strives to identify cost drivers for the SMI population by stratifying the total costs into the component for different type of care (based on T-MSIS mapping). Outpatient services are further stratified into ED services and non-ED services as ED services represent an area of potential saving given better service access to those with SMI diagnosis.

The state will utilize the interrupted time series analysis (ITS) approach. The preferred difference-in-difference analysis (DiD) has not been selected, due to the absence of a valid comparison group.

The cost analysis will be performed using the steps described below.

[25] https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/smi-sed-sud-cost-appendix-c.pdf

STEP 1 – Beneficiary Pool Identification

Starting two years prior to the demonstration (January 1, 2018), we will identify beneficiary-months (member IDs and the month and year) for all SMI/SED treatment events. SMI/SED treatment events will be identified by the diagnosis or provider type/provider specialty combination on the claim or encounter.

- Any diagnosis on the claim that meets the following SMI criteria
    - F20.xx (Schizophrenia and sub codes up to 2 places)
    - F25.xx (Schizoaffective Disorder and sub codes up to two places)
    - F31.xx (Bipolar and all sub codes up to 2 places)
    - F33.xx (Major depression Recurrent and all sub codes up to two places)
- The following provider type/provider specialty combination on the claim

Provider Type	Provider Specialty
01-Hospital	011-Psych Facility (IMDs)
11-Behavioral Health Provider	110-Outpatient Mental Health Clinic 111-CMHC 114-Health Service Provider in Psych (HSPP) 115-Adult Mental Health & Habilitation Provider 613-MRO Clubhouse 616-Licensed Psychologist 617-Licensed Independent Practice School Psychologist 618-Licensed Clinical Social Worker 619-Licensed Marriage & Family Therapist 620-Licensed Mental Health Counselor 621-Licensed Clinical Addiction Counselor

The analytic file will include an observation (beneficiary-month) for each month of service containing an SMI/SED treatment event for the beneficiary as well as up to 11 beneficiary-months following each identified event, as long as the beneficiary remains enrolled in Medicaid. If there are no subsequent claims with SMI/SED treatment events, the beneficiary may be dropped from the exposure after the initial 12 months of observation. However, if another SMI/SED treatment event occurs before the observation period is over, the observation period will be extended for up to another 11 months after the subsequent event, or through the last month of Medicaid eligibility, whichever comes first.

STEP 2 – Demographic Information

For each beneficiary-month we will collect the following demographic information:

- Age
- Gender
- Race
- Dual status
- County
- Condition (stratified by the four diagnosis categories)

STEP 3 – Create the Analytic File

For each beneficiary-month identified in the Step 1 above, we will collect all the beneficiary's Medicaid costs incurred during the month, and stratify the costs based on the 10 categories specified in Table C.1 of the CMS guidance:

1. Total costs
2. Total federal costs
3. SMI IMD costs
4. Other SMI costs
5. Non-SMI costs
6. Outpatient costs, non-ED
7. Outpatient costs, ED
8. Inpatient costs
9. Pharmacy costs
10. Long-term care costs

IMD costs will be identified using billing provider IDs for facilities identified by the state as an IMD provider (consistent with IDs being used for the quarterly monitoring of the 1115 demonstration). Stratification by category of service will be performed consistent with T-MSIS mapping.

STEP 4 – Regression Indicators

We will use indicator variables to mark time periods prior to the beginning of the demonstration (2018 and 2019), the first year of the demonstration (2020), and demonstration time periods after the implementation period (2021 and later). Since the implementation corresponds to the onset of the COVID-19 pandemic, separately collecting information for 2020 may help to account for changes that were caused by reasons other than the demonstration.

We will add the following indicators:

- Impl – 0 for the period through December 2019, prior to implementing the SMI/SED 1115 waiver, 1 starting in January 2020
- Demo – 0 through the first year of the SMI/SED demo (December 2020), 1 starting with the current demonstration as of January 2021

Indiana is not planning on using a comparison group, so there is no need for the treatment group indicator.

STEP 5 – Data Validation

To verify that month-to-month variation is within expected bounds, we will calculate average costs for each of the 10 service categories and summarize mean costs for each calendar quarter and service category in the format of Table C.2 (without a comparison group) from the CMS guidance. Means will be graphed for visual inspection of trends, and to check for data errors.

We plan to summarize monthly data by quarters as this is the count variable utilized in the regression in the next step. However, we will do testing and graphing on a monthly basis.

STEP 6 – Regression Analysis

As indicated above, we will utilize ITS to understand the impact of the demonstration on health spending as it is well suited for the interventions being evaluated here26. This time series will be run separately for each of the 10 types of costs listed in Step 3 as specified in the CMS guidance on page C.9.

We will implement ITS using the following regression model:

$$Cost_{it} = \beta_0 + \beta_1 * time_t + \beta_2 * impl_t + \beta_3 * time_t * impl_t + \beta_4 * demo_t + \beta_5 * time_t * demo_t + \beta_i * Controls_{it} + \varepsilon_{it}$$

Where:

- Cost– expenditures being evaluated (quarterly expenditures for each beneficiary)
- i – individual beneficiary
- t – indexes time (quarter as indicated in Step 5)
- impl – binary indicator for implementation of the SMI/SED 1115 as of January 2020, as described in Step 4
- demo – binary indicator for a year after implementation period (starting January 2021) as described in Step 4
- Controls – covariates (demographic characteristics defined in Step 2)
- β_0 – estimates the baseline level of the cost at time 0
- β_1 – estimates the change in the costs during the baseline period (baseline trend)
- β_2 – estimates the change in the costs immediately after the implementation of the SMI/SED demonstration as of January 2020
- β_3 – estimates the change in the trend after the implementation of the SMI/SED demonstration as of January 2020
- β_4 – estimates the change in the costs immediately after the initial year of the demonstration, starting January 2021
- β_5 – estimates the change in the trend after the initial year of the demonstration, starting January 2021
- ε – error terms that represents random variability not explained by the model

We are interested in the PBPM cost trends demonstrated by the ITS. If the average marginal effect of the interaction terms ($\beta_3 * time_t * impl_t$ and $\beta_5 * time_t * demo_{t)}$ is a positive dollar amount, then the costs in the post-demonstration and post-implementation periods are higher than the costs in the pre-demonstration period. However, if the interaction terms are negative, then post-demonstration and

[26] James Lopez Bernal, Steven Cummins, Antonio Gasparrini; Interrupted time series regression for the evaluation of public health interventions: a tutorial, International Journal of Epidemiology, Volume 46, Issue 1, 1 February 2017, Pages 348–355, https://doi.org/10.1093/ije/dyw098

post-implementation costs are lower than pre-demonstration costs. We will also assess whether the effect is statistically significant from zero.

Challenges and limitations

Seasonality

Errors for quarters separated by multiples of 12 months can be examined to detect seasonal correlation. If seasonality is detected, a term could be introduced in the regression model to reduce the potentially confounding effect of seasonality.

Additional autocorrelation of error terms

Linear regression assumes that errors are independent. If errors are found to not be independent, steps would need to be taken to correct for that. A plot of residuals will be inspected, and the Durbin-Watson statistic will be examined for serial autocorrelation of the error terms. Durbin-Watson reported statistic is between 0 and 4, where 2 indicates no correlation, with values under 1 or over 3 indicating a positive or negative correlation, respectively. If autocorrelation of the error terms is detected, an autoregressive regression model, such as Cochrane-Orcutt model or auto-regressive integrated moving average (ARIMA) model will be used instead of the linear regression.

Heteroscedasticity check

Linear regression assumes that the variance in the error terms over time is constant. Heteroscedasticity occurs when the variance for all observations in the data is not the same. To test for the heteroscedasticity, we will examine the plot of error terms against predicted cost values. If the points are not symmetrically distributed around a horizontal line, then the data may be nonlinear, and transformation of the dependent variable will need to take place. This will be accomplished by logging/or deflating.

Heterogeneity check

Heterogeneity in a dataset occurs when there is a high variability in the underlying data characteristics. For the cost analysis, we will examine the difference between the FFS claims and encounter data for MC enrolled members to understand if there is variability in reimbursement levels or treatment patterns. The existence of this variability can increase the noise and possibly understate the impact of the demonstration. In order to understand the impact of heterogeneity of the underlying claims, the cost analysis could be performed separately for those receiving services through FFS or MC delivery systems to understand if these populations were impacted differently by the demonstration.

Multicollinearity check

Multicollinearity in the regression model occurs when the independent variables of the model are highly correlated. This correlation in the independent variables will cause the model results to be unstable and have significant fluctuations making it harder to interpret the results of the cost analysis. This can also cause overfitting of the model. There are bivariate correlation checks that can be performed, such as looking for correlation between Age and Dual Status or Age and condition. Another method that can be applied is Variance Inflation Factor (VIF) for each independent variable. If the value of VIF is higher than 10, then a high correlation exists with other independent variables. If multicollinearity is identified between the independent variables, we would perform cost analysis using one demographic variable at a time.

Impact of the COVID-19 pandemic

Pandemic onset corresponded closely with the implementation of the SMI 1115 waiver demonstration as of January 2020. Given the close timing, the impact of COVID-19 on service utilization and outcomes could be conflated with the impact of the demonstration. As described in Step 4 above, the addition of the implementation period indicator may help us separate the effect of the pandemic on the cost of the members, since the impact of the pandemic on service utilization and treatment was heaviest during CY 2020, while the impact of the demonstration is expected to be more sustained. We will examine the data after December 2020 and, if necessary, add another indicator or extend the period for the initial implementation indicator, in order the isolate the cost impact created by the pandemic and not the demonstration itself.

STEP 7 – Reporting Results of the Cost Analysis

The results for the marginal effects and standard errors will be reported utilizing a format similar to that illustrated in Table C.4 of the CMS guidance. CMS has offered to provide future assistance on best presentation of the results.