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

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

State Demonstrations Group

OCT 16 2019

Nathan Checketts
Director
Utah Division of Medicaid and Health Financing
Department of Health
PO Box 143101
Salt Lake City, UT 84101

Dear Mr. Checketts:

The Centers for Medicare & Medicaid Services (CMS) has approved Utah's substance use disorder (SUD) evaluation design, which responded to CMS comments provided to the state, for the section 1115 demonstration entitled "Primary Care Network (PCN)" (Project Nos. 11-W-00145/8 and 21-W-00054/8), effective through June 30, 2022. We sincerely appreciate the state's commitment to a rigorous evaluation approach of your initiative.

CMS has added the approved SUD evaluation design to the demonstration Special Terms and Conditions (STC) as part of Attachment G. Per 42 CFR 431.424(c), the approved SUD evaluation design may now be posted to the state's Medicaid website within thirty days of CMS approval. CMS will also post the approved evaluation design as a standalone document separate from the STCs on Medicaid.gov.

Please note that an interim evaluation report, consistent with this approved evaluation design, is due to CMS one year prior to the expiration of the demonstration, or at the time of the renewal application if the state chooses to extend the demonstration. Likewise, a summative evaluation report, consistent with this approved design, is due to CMS within 18 months of the end of the demonstration period.

We look forward to our continued partnership with you and your staff on the PCN section 1115 demonstration. If you have any questions, please contact your CMS project officer, Ms. Mandy Strom. Ms. Strom can be reached by email at mandy.strom@cms.hhs.gov.

Sincerely,

[redacted]

Danielle Daly
Acting Director
Division of Demonstration
Monitoring and Evaluation

[redacted]

Andrea Casart
Director
Division of Medicaid Expansion
Demonstrations

Enclosure

cc: Richard Allen, Director, Western Regional Operations Group

UTAH 1115 PRIMARY CARE NETWORK DEMONSTRATION WAIVER

SUBSTANCE USE DISORDER EVALUATION DESIGN

Prepared by: Rodney W. Hopkins, M.S.
Kristen West, MPA

Social Research Institute
College of Social Work
THE UNIVERSITY OF UTAH

INTRODUCTION

In October 2017, the Utah Department of Health (UDOH), Division of Medicaid and Health Financing (DMHF) received a five-year extension to its 1115 Primary Care Network (PCN) Demonstration Waiver. This extension adds covered benefits and continues providing health coverage to eight vulnerable population groups, some of whom are not eligible for Medicaid under the state plan.

This proposal will both track the general performance of the 1115 waiver and evaluate demonstration impacts and outcomes. Results of the evaluation will be presented in a series of annual reports, as well as interim and final evaluation reports. This draft proposal identifies the general design and approach of the evaluation in response to the required Special Terms and Conditions (STC's).

A. GENERAL BACKGROUND INFORMATION

Utah's 1115 PCN Demonstration Waiver (hereinafter referred to as "Demonstration") is a statewide waiver that was originally approved on February 8, 2002 and implemented on July 1, 2002. Since that time, the Demonstration has been extended and amended several times to add additional benefits and Medical programs. Most recently, the Demonstration was amended and approved on October 31, 2017 with an approval period through June 30, 2022. The evaluation will cover the Demonstration approval period.

Waiver Population Groups
The Demonstration authorizes the State of Utah to administer the following medical programs and benefits:

- PCN Program (Demonstration Population I) - Provides a limited package of preventive and primary care benefits to adults age 19-64.
- Current Eligibles - Provides a slightly reduced benefit package for adults receiving Parent/Caretaker Relative (PCR) Medicaid.
- Utah's Premium Partnership Program (UPP) (Demonstration Populations III, V & VI) - Provides premium assistance to pay the individual's or family's share of monthly premium costs of employer sponsored insurance or COBRA.
- Targeted Adult Medicaid- Provides state plan Medicaid benefits to a targeted group of adults without dependent children.
- Former Foster Care Youth from Another State- Provides state plan Medicaid benefits to former foster care youth from another state up to age 26.
- Dental Benefits for Individuals who are Blind or Disabled- Provides dental benefits to individuals age 18 and older with blindness or disabilities.
- Substance Use Disorder (SUD) Residential Treatment- Allows the State to provide a broad continuum of care which includes SUD residential treatment in an Institution for Mental Disease (IMD) for all Medicaid eligible individuals.

This Evaluation Design will focus on the SUD component of the Demonstration, which provides a broad continuum of care for all Medicaid eligible individuals. This is an important Medicaid addition due to the significant impact substance use disorders have on the health and well-being of Utahans.

Prior to the approval of this demonstration, individuals who were receiving SUD residential treatment in an IMD were not eligible to receive Medicaid. SUD services provided in residential and inpatient treatment settings that qualified as an IMD, were not otherwise matchable expenditures under section 1903 of the Act. Individuals needing treatment waited months to receive residential treatment due to the low number of treatment beds available in smaller facilities. Prior to implementation of the demonstration, there were approximately 50 treatment beds available. Since implementation, approximately 490 additional treatment beds have been added Statewide. The State currently has seven SUD treatment facilities that meet the definition of a SUD IMD facility.

Substance Use Disorders in the United States

Behavioral health disorders, which include substance use and mental health disorders, affect millions of adolescents and adults in the United States and contribute heavily to the burden of disease.[1,2,3] Illicit drug use, including the misuse of prescription medications, affects the health and well-being of millions of Americans. Cardiovascular disease, stroke, cancer, infection with the human immunodeficiency virus (HIV), hepatitis, and lung disease can all be affected by drug use. Some of these effects occur when drugs are used at high doses or after prolonged use. However, other adverse effects can occur after only one or a few occasions of use.[4] Addressing the impact of substance use alone is estimated to cost Americans more than $600 billion each year.[5]

Reducing SUD and related problems is critical to Americans' mental and physical health, safety, and quality of life. SUDs occur when the recurrent use of alcohol or other drugs (or both) causes clinically significant impairment, including health problems, disability, and failure to meet major responsibilities at work, school, or home. These disorders contribute heavily to the burden of disease in the United States. Excessive substance use and SUDs are costly to our nation due to lost productivity, health care, and crime.[6, 7, 8] Approximately 23.3 million people aged 12 or older in 2016 had SUDs in the past year, including 15.6 million people with an alcohol use disorder and 7.4 million people with an illicit drug use disorder.[9]

Among those dealing with SUDs, opioid misuse, overdose and addiction, occurs in only a subset of individuals prescribed opioid medications for pain relief. However, because many individuals take opioids, the number of Americans affected is significant. According to the Centers for Disease Control and Prevention (CDC), deaths due to prescription opioid pain medication overdose in the US have more than quadrupled from 1999 to 2011.[10] In addition to the increase in drug-related deaths, the rise in opioid prescribing has led to increases in the prevalence of opioid use disorder.[11] Other research has demonstrated that the so-called opioid epidemic has a disproportionate impact on Medicaid beneficiaries. Medicaid beneficiaries are prescribed painkillers at twice the rate of non-Medicaid patients and are at three-to-six times the risk of prescription painkillers overdose.[12, 13] North Carolina found that while the

Medicaid population represented approximately 20 percent of the overall state population, it accounted for one-third of drug overdose deaths, the majority of which were caused by prescription opioids. [14] One study from the state of Washington found that 45 percent of people who died from prescription opioid overdoses were Medicaid enrollees. [15]

Substance Use Disorders in Utah

According to the 2016 National Survey of Drug Use and Health, in Utah there were an estimated 134,764 adults in need of treatment for alcohol and/or drug dependence or abuse.[16] For youth in grades 6 through 12 in 2017 there were 11,804 in need of treatment. However, only 13,780 adults and 1,179 youth received SUD treatment services in FY 2017. [17] Of those in treatment, 46% received outpatient, 21% received intensive outpatient, 21% participated in detox, and 12% participated in residential treatment. Seventy-one percent of those in treatment were retained for 60 or more days. In 2017, Opioids were the top drug of choice at admission (32%). [18]

Utah has experienced a sharp increase in opioid related deaths since 2000. Recent data suggests that the number of deaths due to opioids peaked initially in 2007, then showed a promising decreasing trend through 2010, before increasing dramatically once more from 2011 through 2015. Emergency department encounters data over the same timeframe shows a steady increase through 2012, with a small decrease observed from 2012 to 2014. Males accounted for approximately 60% of opioid deaths in 2013, but the gap between males and females has shrunk so that by 2015 males accounted for only 54% of deaths. For emergency department encounters, the opposite has been true. In the past, females have traditionally accounted for more visits than males. However, similar to the death data, the gap between females and males has been closing. In 2014, the percentage of emergency department encounters for males and females was essentially even (50.3% vs. 49.7% for females and males, respectively). [19]

However, SUDs are preventable and treatable. The Utah State Division of Substance Abuse and Mental Health (DSAMH) has statutory oversight of substance abuse and mental health treatment services statewide through local county authority programs. SUD services are available to all Medicaid members statewide. A full continuum of SUD services becomes even more critical in an effort to address the needs of Medicaid members. [20]

B. EVALUATION QUESTIONS & HYPOTHESES

The primary goals of the waiver are to increase access, improve quality, and expand coverage to eligible Utahans. To accomplish these goals, the Demonstration includes several key activities including enrollment of new populations, quality improvement, and benefit additions or changes. This evaluation plan will describe how the University of Utah's Social Research Institute (SRI) will document the implementation of the key goals of the Demonstration, the changes associated with the waiver including the service outputs, and most importantly, the outcomes achieved over the course of the Demonstration.

Evaluation Purpose

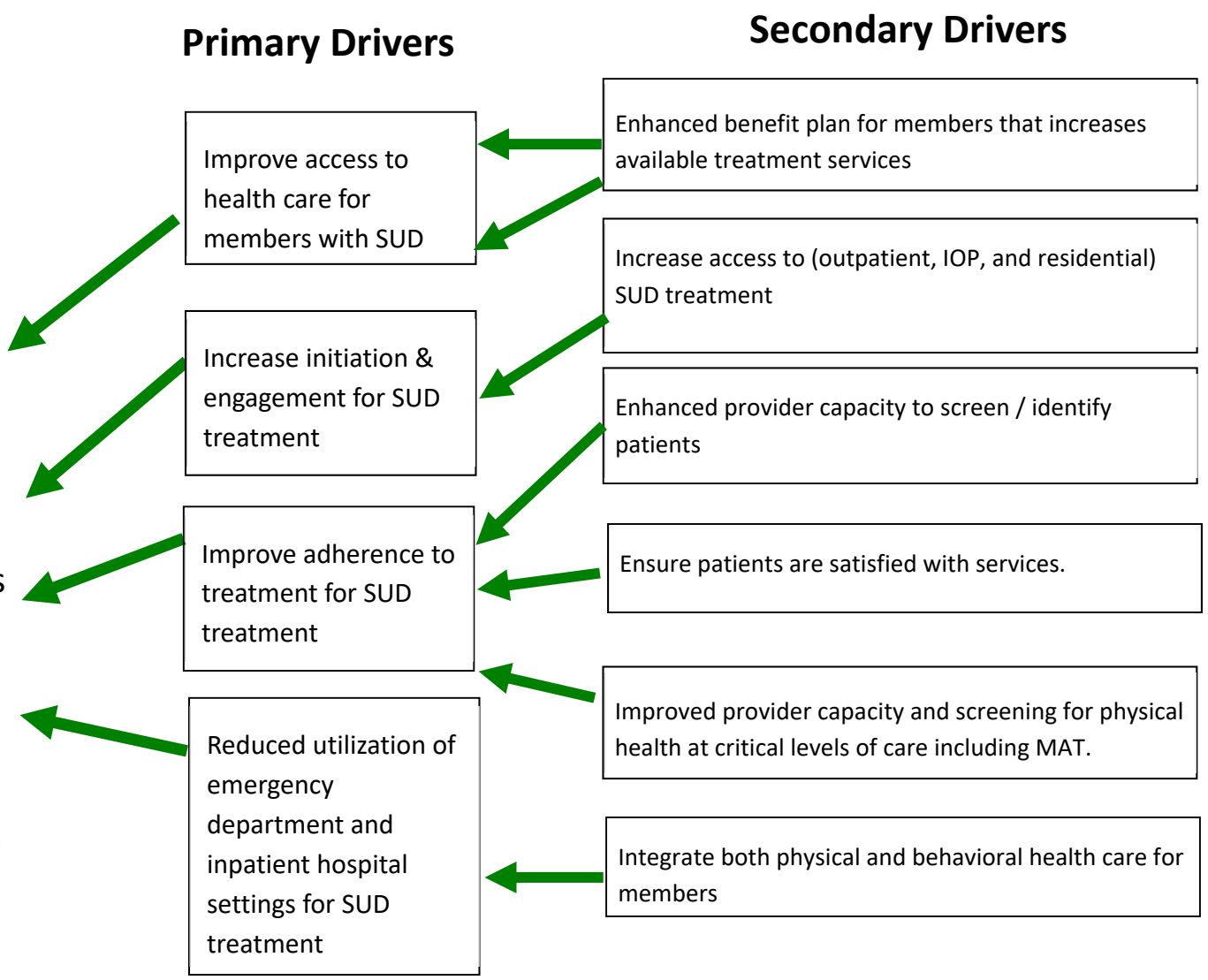
SRI will conduct an evaluation of the Utah 1115 PCN Demonstration Waiver by establishing research questions and a study design that is responsive to the hypotheses identified by UDOH. SRI will collaborate with UDOH and DSAMH to obtain the appropriate data to conduct the analysis needed to complete the required evaluation reports on an annual basis, and at each subsequent renewal or extension of the demonstration waiver. This includes an evaluation of the overall waiver and the SUD component. The SUD evaluation is addressed in this document.

Driver Diagram

Aim: 1115 Demonstration Waiver SUD treatment will improve access, utilization, and health for members

Outcome Measures:

1. Increased access to SUD treatment
2. Increased utilization of SUD treatment
3. Improved health outcomes in SUD members
4. Reduce opioid-related overdose deaths
5. Slow the rate of growth of total cost of care for SUD members

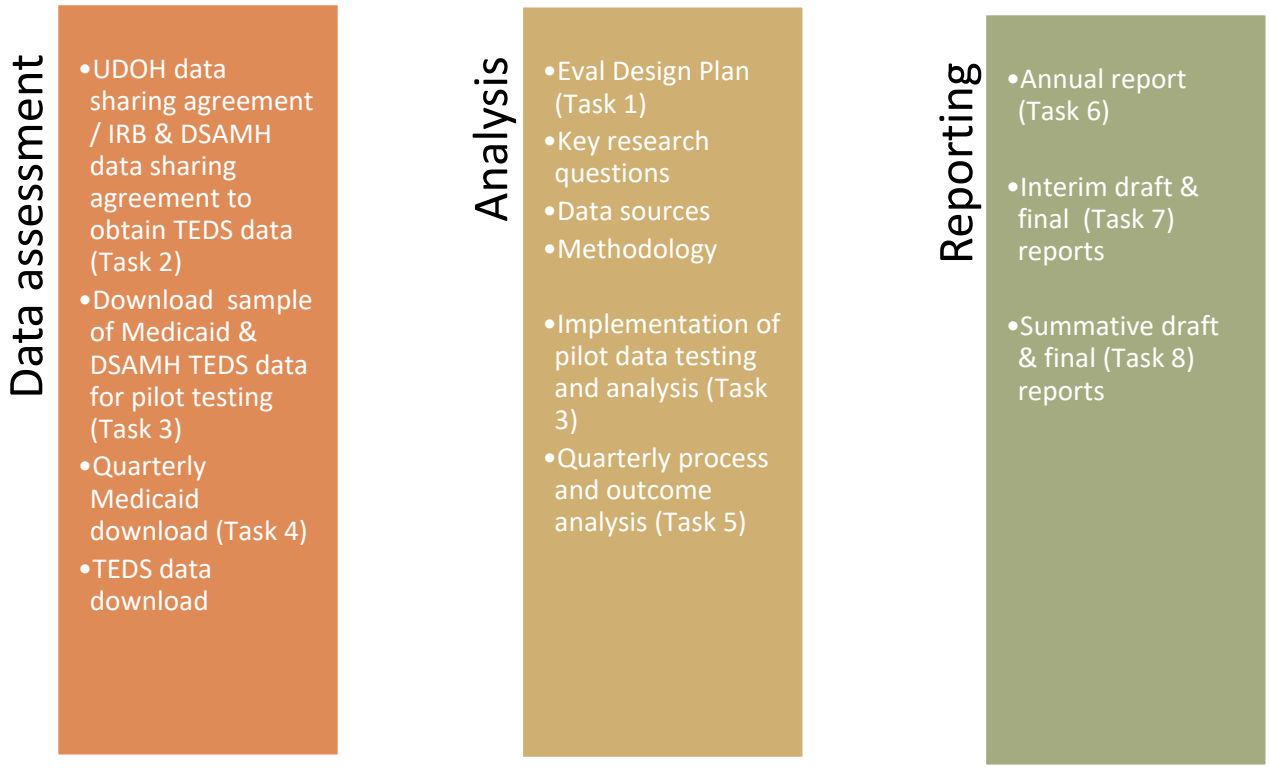


C. METHODOLOGY

Evaluation Approach

To evaluate the different components of the waiver demonstration, we envision three main phases of work: (1) data assessment and collection, (2) analysis, and (3) reporting. The last phase will include both reporting of waiver findings to UDOH in response to the STC's and also providing written summary reports for submission to the Centers for Medicare and Medicaid Services (CMS). The first key task—development of the evaluation design plan—appears at the top of Figure 1. This plan will specify the key research questions the evaluation will address for each demonstration component, as well as the primary data sources and methodologies that will be used. This plan will guide decision making at all levels of the study and drive the content of the reporting tasks.

Figure 1. Project vision



1. Evaluation Design

Due to the unique target population groups included in the Demonstration evaluation, a combination of design approaches will be implemented. First, for several of the SUD hypotheses demonstration components pre / post comparison will be conducted. Second, other SUD hypotheses will consist of a pre / post comparison where the target population will serve as its own control group. A time series design will be employed for most of the individual analysis using pre-Demonstration as a baseline and then using the first year as baseline where no pre-Demonstration data are available due to the nature of the individual target population. A quasi-experimental design (difference-in-difference, DiD) approach will be used to estimate the effect by comparing the SUD (IMD) residential treatment service expansion in Salt Lake and Utah Counties with other counties (Davis, Weber, and Washington). The use of both quantitative and qualitative data will be important to this design. Quantitative data will come from Utah Medicaid claims. Qualitative data will come from a SUD beneficiary survey.

The specific evaluation questions to be addressed are based on the following criteria:
1) Potential for improvement, consistent with the key goals of the Demonstration;
2) Potential for measurement, including (where possible and relevant) baseline measures that can help to isolate the effects of Demonstration initiatives and activities over time; and
3) Potential to coordinate with the UDOH's ongoing performance evaluation and monitoring efforts.
Once research questions are selected to address the Demonstration's major program goals and activities, specific variables and measures will then be identified to correspond to each research question. Finally, a process for identifying data sources that are most appropriate and efficient in answering each of the evaluation questions will be identified. The evaluation team will use all available data sources. The timing of data collection periods will vary depending on the data source, and on the specific Demonstration activity.

2. Target and Comparison Populations

The target population includes any Medicaid beneficiary with a substance abuse disorder (SUD) diagnosis. Several comparison population groups will be used in this evaluation. The first will be comprised of the target population, which will serve as its own comparison group longitudinally, where the research question will compare service utilization differences across the demonstration period. The second group that will be used as a comparison population for some of the SUD components will be members who previously received SUD treatment services in counties without access to an IMD. A difference-in-difference (DiD) approach will be used to estimate the effect by comparing the SUD (IMD) residential treatment service expansion in Salt Lake and Utah Counties with counties (Davis, Weber, and Washington) where there was no residential expansion. At the present time, these three counties have elected not to establish an IMD residential facility. Table 1 below summarizes the residential population and those that have received SUD treatment in the counties through publicly funded treatment programs. The source of these data is DSAMH Treatment Episode DataSet (TEDS). These five counties will be included in the DiD design comparison.

Table 1: Summary of target populations in SUD DiD design counties in Utah.

Counties w / IMD Expansion	County Population	# of clients served	Percent of Admissions in Outpatient / IOP/ Residential / Detox		
			2016	2017	2018
Salt Lake	1,152,633	7,497	36/21/10/33	35/19/13/33	30/17/17/36
Utah	622,213	1,229	29/29/27/15	29/29/28/14	33/27/21/18
Counties w / No Expansion					
Davis	351,713	1,548	55/31/14/0	58/29/13/0	75/19/6/0
Washington	171,700	596	44/35/21/0	48/31/21/0	53/28/19/0
Weber	256,359	1,757	81/14/5/0	77/18/5/0	73/22/5/0

The third comparison population will include patients in publicly funded treatment programs receiving substance services who complete annual MSHIP survey which will serve as a comparison group for the consumer survey that will be administered to SUD beneficiaries.

3. Evaluation Period

The SUD waiver evaluation components will use pre-demonstration data from January 2016 to October 2017 to understand trends in treatment services and for state-level benchmarking of treatment outcomes. The State is aware that many measures with an established measure steward require reporting according to calendar year. This includes:

- Initiation and Engagement of Alcohol and Other Drug Dependence Treatment;
- Continuity of Pharmacotherapy for OUD; and
- Follow-up after Emergency department visit for alcohol and other drug abuse or dependence

For these measures, the State will use a pre-post approach. Calendar year 2016 will serve as the pre-demonstration year. Calendar year 2017 will be reported and observed for trend, however it will be a partial-demonstration year due to the demonstration begin date of November 1, 2017. Calendar year 2018 will serve as the first full post-demonstration year.

The 1st year of the waiver will serve as the baseline using a post-only approach for some State-created measures as noted in Table 2 below. The post-only approach will be used due to the lack of a national benchmark in these measures that may inform the State on relevant performance. Data to be used for the evaluation will span the entire Demonstration period (11/1/2017 – 6/30/2022) for the targeted population groups and for the comparison groups identified.

4. Evaluation Measures

The measures to be used in the SUD evaluation include nationally standardized data collection protocols such as NFQ #0004, Initiation and Engagement of Alcohol and Other Drug Dependence Treatment, Continuity of Pharmacotherapy for OUD (NQF #3175), and qualitative data from a beneficiary survey that focuses on health care satisfaction, access, and quality. The specific measures are listed in Table 2 below.

5. Data Sources

The State will use four data sources to conduct the evaluation plan. First, UDOH's Medicaid HIPAA transaction set consisting of all Utah claims and encounters data. Data from this source is available prior to the November 2017 waiver approval and throughout the demonstration. Second, the DSAMH TEDS Admission and Discharge record is an electronic client data file that includes data from all publicly funded SUD treatment service providers in Utah. This data file includes required standardized variables that are submitted to the Substance Abuse and Mental Health Administration (SAMHSA) for its State Outcomes Measurement and Management System (SOMMS) as well as variables that are required for the National Outcome Measures (NOMS). The file includes more than 100 variables ranging from most current diagnosis (ASAM levels), Drug Court Submissions, referral sources, waiting time to enter treatment, to criminogenic risk level. TEDS data is also available prior to the waiver and annually moving forward. Third, the State will conduct a SUD beneficiary survey annually. Fourth, the State's Vital Records dataset will be used to identify overdose deaths.

6. Analytic Methods

A combination of quantitative statistical methods will be used for the analysis. Specific measures will be utilized for each demonstration as detailed in Table 2. While the Demonstration seeks to increase service provision and promote quality care, observed changes may be attributed to the Demonstration itself and/or external factors, including other State- or national-level policy or market changes or trends. For each Demonstration activity, a conceptual framework will be developed depicting how specific Demonstration goals, tasks, activities, and outcomes are causally connected to serve as the basis for the evaluation methodology. Methods chosen will attempt to account for any known or possible external influences and their potential interactions with the Demonstration's goals and activities. The evaluation will seek to isolate the effects of the Demonstration on the observed outcomes in several ways:

First, the evaluation will incorporate baseline measures and account for trends for each of the selected variables included in the evaluation. Medicaid data for each of the targeted variables and measures will be analyzed annually so that outcome measures and variables can be monitored on a regular basis. The hypotheses in Table 2 involving the DiD design compare SUD residential expansion counties with SUD residential services in non-expansion counties.

Second, the evaluation will use known state benchmarks for publicly funded SUD treatment annually to measure Demonstration outcomes related to domains of consumer experience with treatment services. Specifically, those seven domains are: Satisfaction, Access, Quality, Participation, Outcomes, Social Connectedness, and Functioning.[21] These variables are collected by the DSAMH annually among publicly funded SUD service providers. This DSAMH data cannot be linked to specific Medicaid enrollees, therefore, the waiver evaluation will conduct its own SUD beneficiary survey. The Utah MHSIP data collected during State fiscal year 2020-2022 will be used as a state benchmark for comparison to the SUD beneficiary survey results. Since the MHSIP survey has demonstrated modest correlations in magnitude in the predicted directions, with greater patient satisfaction being associated

with lower symptoms and more positive outcomes,[22] the same questions will be used in the Demonstration survey. This data will be analyzed with descriptive statistics such as frequencies, percentages, and t-tests.

Table 2: Summary of Demonstration Populations, Hypotheses, Evaluation Questions, Data Sources, and Analytic Approaches.

Evaluation Question: Does the demonstration increase access to and utilization of SUD treatment services?						
Demonstration Goal: Increased rates of identification, initiation, and engagement in treatment for SUDs. **Evaluation Hypothesis: The demonstration will increase the percentage of members who are referred and engage in treatment for SUDs.**						
Driver	Measure Description	Steward	Numerator	Denominator	Evaluation Period	Analytic Approach /Target or Comparison Population
Primary Driver *(Increase the rates of initiation and engagement in treatment for SUDs)*	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment	NQF #0004	Initiation: number of patients who began initiation of treatment through an inpatient admission, outpatient visits, intensive outpatient encounter or partial hospitalization within 14 days of the index episode start date	Patients who were diagnosed with a new episode of alcohol or drug dependency during the first 10 and ½ months of the measurement year	Calendar years 2016(Pre) 2017(Interim) 2018-2022(Post)	**Descriptive statistics** (frequencies and percentages); Linear regression. **Comparison population**. SUD expansion (IMD) in Salt Lake and Utah Counties compared to Davis, Washington, and Weber Counties (DiD design). Control variables for age and gender will be used.
			Engagement: Initiation of treatment and two or more inpatient admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations with any alcohol or drug diagnosis within 30 days after the date of the initiation encounter	Patients who were diagnosed with a new episode of alcohol or drug dependency during the first 10 and ½ months of the measurement year		

Secondary Drivers *(Enhance provider and plan capabilities to screen/identify patients for engagement and intervention; Improve community knowledge of available treatment and services)*	Community knowledge of available treatment and services	University of Utah / SRI	Beneficiary survey Adult SUD consumer satisfaction survey		State fiscal year 2020-2022	**Descriptive statistics** (Frequencies and percentages); t-test. **Target population**: SUD members. **Comparison population**. Patients in publicly funded programs receiving SUD services who complete annual MSHIP survey.
Demonstration Goal: Increased adherence to and retention in treatment for SUDs. **Evaluation Hypothesis: The demonstration will increase the percentage of members who adhere to treatment of SUDs.**						
Primary Drivers *(Increase the rates of initiation and engagement in treatment for OUD and SUDs; Improve adherence to treatment for SUDs)*	Continuity of Pharmacotherapy for OUD	NQF #3175	Number of members who have at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than seven days	Members who had a diagnosis of OUD and at least one claim for an OUD medication	Calendar years 2016(Pre) 2017(Interim) 2018-2022(Post)	**Descriptive statistics** (Frequencies and percentages); Linear regression. **Target population:** SUD members receiving MAT
	Percentage of members with a SUD diagnosis including those with OUD who used services per month	N/A	Number of members who receive a service during the measurement period by service type	Number of members	First year of waiver is baseline compared to years 2 through 5 of the waiver.	

Secondary Drivers *(Increase access to outpatient, intensive outpatient, and residential treatment for SUD; Improve care coordination and transitions between levels of care)*	Length of engagement in treatment	NBHQF Goal 1	Number of members completing 4th treatment session within 30 days	Number of members receiving treatment	First year of waiver is baseline compared to years 2 through 5 of the waiver.	**Comparison population**. SUD expansion (IMD) in Salt Lake and Utah Counties compared to Davis, Washington, and Weber Counties (DiD design). Control variables for age and gender will be used.
Secondary Driver *(Ensure patients are satisfied with services)*	Patient experience of care	University of Utah / SRI	Adult SUD beneficiary satisfaction survey		State fiscal year 2020-2022	**Descriptive statistics** (Frequencies and percentages); t-test. **Target population:** SUD members. **Comparison population**. Patients in publicly funded programs receiving SUD services who complete annual MSHIP survey.
Demonstration Goal: Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services. **Evaluation Hypothesis: The demonstration will decrease the rate of emergency department and inpatient visits within the beneficiary population for SUD.**						

Primary Drivers *(Reduced utilization of emergency department and inpatient hospital settings for SUD treatment)*	Follow-up after emergency department visit for alcohol and other drug abuse or dependence	NQF 2605	An outpatient visit, intensive outpatient encounter or partial hospitalization with any provider with a primary diagnosis of alcohol or other drug dependence within 7/30 days after emergency department discharge	Members treated and discharged from an emergency department with a primary diagnosis of alcohol or other drug dependence in the measurement year/1000 member months	Calendar years 2016(Pre) 2017(Interim) 2018-2022(Post)	**Descriptive statistics** (frequencies and percentages); Linear regression. **Target population**: SUD members with OUD diagnosis. **Comparison population** SUD expansion (IMD) in Salt Lake and Utah Counties compared to Davis, Washington, and Weber Counties (DiD design). Control variables for age and gender will be used.
	Inpatient admissions for SUD and specifically OUD	N/A	Number of members with an inpatient admission for SUD and specifically for OUD	Total number of members/1000 member months	First year of waiver is baseline compared to years 2 through 5 of the waiver.	
Evaluation Question: Do members receiving SUD services experience improved health outcomes?						
Demonstration Goal: Improved access to care for co-morbid physical health conditions commonly associated with SUD among members. **Evaluation Hypothesis: The demonstration will increase the percentage of members with SUD who experience care for comorbid conditions.**						
Primary Drivers *(Improve access to care for co-morbid physical health conditions among beneficiaries with SUD)*	Number of routine office visits by people with SUD	N/A	Number of members with an SUD diagnosis, and specifically those with OUD, who access physical health care.	Total number of members	First year of waiver is baseline compared to years 2 through 5 of the waiver.	**Descriptive statistics** (frequencies and percentages); Linear regression. **Target population**: SUD members with OUD diagnosis. **Comparison population** SUD expansion (IMD) in Salt Lake and Utah Counties compared to Davis, Washington, and Weber Counties (DiD design). Control variables for age and gender will be used.

Evaluation Question: Are rates of opioid-related overdose deaths impacted by the demonstration?						
Demonstration Goal: Reduction in overdose deaths, particularly those due to opioids. Evaluation Hypothesis: The demonstration will decrease the rate of overdose deaths due to opioids.						
Primary Driver *(Reduce opioid-related opioid overdose deaths)*	Rate of overdose deaths, specifically overdose deaths due to any opioid	UDOH	Number of overdose deaths per month and per year	Number of members/1000	First year of waiver is baseline compared to years 2 through 5 of the waiver.	**Descriptive statistics** (Frequencies and percentages); t-test. **Target population:** SUD members. **Comparison population**. State General Population.

D. METHODOLOGICAL LIMITATIONS

The first potential limitation is ensuring each individual analysis is based on unduplicated data. SRI staff will work closely with Utah Medicaid data personnel and DSAMH to ensure the data used for final analysis is as accurate as possible and that error in matching the TEDS Admission and Discharge data set to Medicaid claims data has been minimized to avoid duplication. There are also limitations of conducting a time series analysis without a comparison group. For example, data collected at different times are not mutually independent, which means a single chance event may affect all later data points. As a result, the true pattern or trend underlying time series data can be difficult to discern.

E. ATTACHMENTS

A. Independent Evaluator

The Social Research Institute (SRI) will conduct all activities related to this proposal to fulfill the evaluation requirements of Utah's 1115 PCN Waiver with specific emphasis on conducting data analysis to ensure timely reporting. SRI was established in 1982 as the research arm of the College of Social Work. Its goal is to be responsive to the needs of community, state, national and international service systems and the people these systems serve. Through collaborative efforts, SRI facilitates innovative research, training and demonstration projects. SRI provides technical assistance and research services in the following functional areas: conducting quantitative and qualitative research; designing and administering surveys; analyzing and reporting data analysis; designing and conducting needs assessments of public health and social service problems and service systems; planning and implementing service delivery programs; evaluating program and policy impacts; training in research methods and data analysis; providing technical assistance.

SRI staff are experienced in complying with state and federal laws regarding protecting human subjects and assuring confidentiality of data. SRI will complete the required IRB applications for this project including any data sharing agreements that may be necessary. SRI staff comply with generally accepted procedures to safeguard data by ensuring all data is stored on password protected and encrypted computers. Specifically, we use two-factor authentication (2FA) verification as an extra layer of security. All data collection and analysis SRI is responsible for will be based on the agreed upon data collection plan and in accordance with HIPAA-compliant data management systems available to University of Utah researchers.

Data Security and Storage

SRI will store UDOH's Medicaid (HIPPA transaction set) in the University's REDCap application. REDCap is a secure database with the ability to create web-accessible forms, continuous auditing, and a flexible reporting system. Controls within REDCap allow researchers to specify differential levels of data access to individuals involved with a REDCap project, including restrictions to HIPAA-sensitive

identifiers. REDCap is located on a secure, 21 CFR Part11 compliant server farm within the Center for High Performance Computing (CHPC) at University of Utah. Data are backed up every hour with the hourly backups being incorporated into the regular backup-recovery data process (nightly, weekly, and monthly), which includes off-site storage. Routine data recovery and disaster recovery plans are in place for all research data. During analysis, de - identified data may be maintained on University of Utah-encrypted computers or hard-drives in compliance with University policy.

Independent Evaluator Selection Process

SRI staff have contracted with the Utah Department of Human Services, Division of Child and Family Services (DCFS) to evaluation their IV-E waiver demonstration project for the past 4 years. Simultaneously, SRI also served as the independent evaluator for the State of Idaho's IV-E waiver demonstration for two years. Within the past year, key research staff from DCFS who were familiar with the work performed by SRI staff changed jobs and now work for UDOH Office of Health Care Statistics. As result, when UDOH was trying to locate an independent evaluator a referral was provided and several preliminary meetings and discussions were held. This led to SRI developing a proposal for UDOH to conduct the Demonstration evaluation.

The research team will consist of Rodney W. Hopkins, M.S., Research Assistant Professor, Kristen West, MPA., Senior Research Analyst, and Jennifer Zenger, BA, Project Administrator.

Mr. Hopkins in an Assistant Research Professor and has 25 years' experience in conducting program evaluations for local, state, and federal agencies. He has an M.S. and will be the project lead, with responsibility for evaluation design and implementation, data collection, and reporting. He will be .45 FTE.

Kristen West, MPA (.25 FTE) is a Senior Research Analyst with experience conducting multi-year program evaluations for DCFS and JJS. She has expertise with a variety of statistical software programs to analyze data including multi-level regression models, linear regression, and descriptive statistics (SPSS and R). She also has experience developing and data visualization dashboards. Jennifer Zenger (.05 FTE) is SRI's Project Administrator and has 25 years' experience in budgeting, accounts payable, and working with state and federal agencies. She will be responsible for contract setup, monitoring, and accounting services.

An interdepartmental consortium has been established between SRI and the University of Utah's Department of Economics and the Department of Family and Consumer Studies. The Department of Economics, Economic Evaluation Unit led by Department Chair, Norm Waitzman, Ph.D., (.03 FTE) a Health Economist who has extensive health care utilization and cost analysis experience will lead this effort. The other principal researcher is Jaewhan Kim, Ph.D. (.21 FTE) a Health Economist and Statistician with a broad background in health care utilization and cost analysis, statistical design and data analysis including cohort studies and cross-sectional studies. He currently co-directs the Health Economics Core, Center for Clinical & Transitional Science (CCTS) at the University of Utah School of Medicine. He has expertise in analyzing claims databases for health care utilization and costs and has worked on multiple federal studies of health care utilization using diverse claims data such as Medicare,

Medicare-SEER, Medicaid, MarketScan, PHARMetrics, University of Utah Health Plan's claims data and Utah's All Payers Claims Database (APCD). He was one of the original l developers of the APCD, published the first paper with Utah's APCD data, and has worked collaboratively with other researchers to successfully conduct more than 20 studies using the APCD. They will also be supported by a to-be-named Graduate Research Assistant (1.0 FTE).

Conflict of interest document attached.

B. Evaluation Budget

The initially proposed budget (3/2018) of projected costs for the 1115 Demonstration evaluation are detailed below. Costs include all personnel (salary + benefits), study related costs (mileage), and university indirect (reduced from 49.9% to 14.8% state rate). Year 1 budget begins April 1, 2018 and ends June 30, 2018. Year 2-5 are based on the state fiscal year. An additional 90-day period has also been included, during which SRI will complete the Year 5 Annual Report, Waiver Final Report, and SUD Final Report.

Table 1. Proposed budget

Salaries	ABA	FTE	SALARY	BENEFITS	YEAR I	YEAR II	YEAR III	YEAR IV	YEAR V	90-DAY	
Faculty											
Matt Davis	$102,000	5%	$ 5,100	$ 2,059	$ 1,785	$ 7,283	$ 7,428	$ 7,577	$ 7,729	$ 1,971	
Rod Hopkins	$ 91,997	15%	$ 13,800	$ 5,877	$ 4,919	$ 20,170	$ 20,471	$ 20,880	$ 21,298	$ 5,431	
			$ 18,900	$ 7,936	$ 6,704	$ 27,453	$ 27,899	$ 28,457	$ 29,027	$ 7,402	
Staff											
Kristen West	$ 57,222	15%	$ 8,583	$ 3,433	$ 3,004	$ 12,257	$ 12,502	$ 12,752	$ 13,007	$ 3,318	
Jennifer Zenger	$ 85,435	5%	$ 4,272	$ 1,709	$ 1,495	$ 6,100	$ 6,222	$ 6,347	$ 6,473	$ 1,650	
			$ 12,855	$ 5,142	$ 4,499	$ 18,357	$ 18,724	$ 19,099	$ 19,481	$ 4,968	
Total Staff					$4,499	$18,357	$ 18,724	$ 19,099	$ 19,481	$ 4,968	
Total Faculty Salaries					$6,704	$27,453	$ 27,899	$ 28,457	$ 29,027	$ 7,402	
Total Fringe Benefits					added in above	added in above	added in above	added in above	added in above		
Travel (1 trip per month to UDOH & DSAMH)					$65	$250	$250	$250	$ 250	$ 65	
Total Direct					**$11,268**	**$46,060**	**$ 46,874**	**$ 47,806**	**$ 48,757**	**$ 12,435**	
Indirect (F&A) Cost				*14.80%*	**$1,668**	**$ 6,817**	**$ 6,937**	**$ 7,075**	**$ 7,216**	**$ 1,840**	
Grand Total					**$12,936**	**$52,877**	**$ 53,811**	**$ 54,881**	**$ 55,973**	**$ 14,275**	**$244,754**

Budget Narrative

Rodney Hopkins, M.S., Assistant Research Professor will be the lead on this project and will be responsible for day-to-day activities. He will work (.15 FTE) closely with UDOH and DSAMH staff to ensure appropriate data is available to answer the research questions and execute the data analysis and

reporting. Dr. Davis (.05 FTE) will bring his considerable experience with quantitative analysis to this project. Kristen West, MPA, Senior Research Analyst (.15 FTE) will assist with data analysis and reporting, including data visualization. Jennifer Zenger (.05 FT) is SRI's Project Administrator. She oversees contract monitoring and the budget.

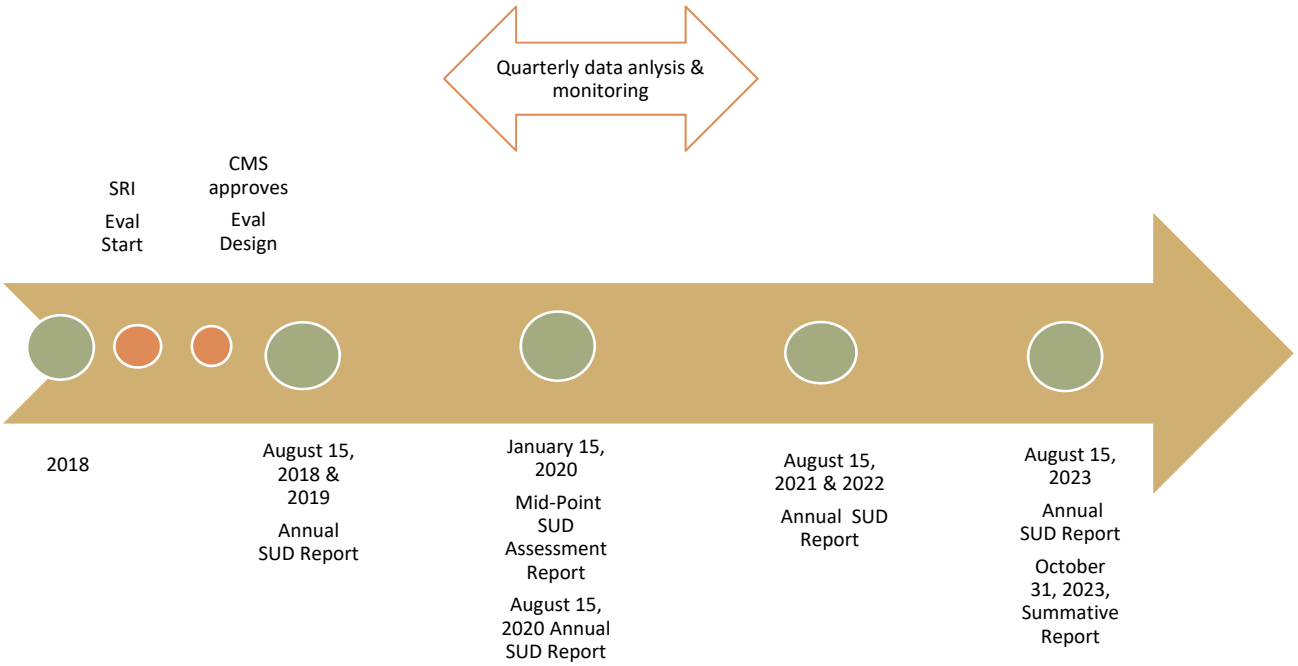
A strength this team brings to the project will be its ability to conduct a thorough and accurate data analysis and provide a professional report that will address each component of the waiver demonstration. Salaries calculated include a 2% increase as of July 1 of each year. University of Utah benefits are calculated at 40%. Year 1 is only a 6-month budget (April 1, 2018 – Sept. 30, 2018).

Local travel will be needed for SRI faculty and staff to attend meetings with UDOH and DSAMH staff. We anticipate one meeting per month.

UDOH state agency to state agency indirect costs calculated at 14.8%.

C. Timeline and Major Milestones

Figure 2. Waiver Evaluation Timeline



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Utah SUD Demonstration Cost Analysis

Utah Department of Health (UDOH) will conduct a cost analysis of the Substance Use Disorder (SUD) Demonstration that became effective in November 2017. The cost analysis will provide an objective measure of this important demonstration outcome. UDOH will include cost analysis reports as part of both interim and final evaluation reports.

Costs

UDOH will conduct three levels of cost analyses

Level of analysis	Type of costs	Data components (source)
Total costs	Total costs	Claims and managed care capitation payments (Data Warehouse)[1]
	Total federal costs	Federal Financial Participation (FFP) for total costs[2]
SUD cost drivers	SUD-IMD	Claims and encounters[3] with IMD procedure code with SUD diagnosis (Data Warehouse)[4]
	SUD-other	Claims and encounters with SUD diagnosis and/or procedure code (Data Warehouse)
	Non-SUD	Claims and encounters without SUD diagnosis or procedure code (Data Warehouse)
Type of source of care cost drivers	Outpatient costs – non ED	Outpatient hospital claims and encounters as defined by T-MSIS OT specifications, excluding ED (Data Warehouse)
	Outpatient costs – ED	ED claims and encounters (Data Warehouse)
	Inpatient costs	Inpatient hospital claims and encounters as defined by T-MSIS IP specifications (Data Warehouse)
	Pharmacy costs	Pharmacy claims and encounters as defined by T-MSIS RX specifications (Data Warehouse)
	Long-term care costs	Long-term claims and encounters as defined by T-MSIS LT specifications (Data Warehouse)

[1] UDOH will not include administrative costs. There has not been a staff hiring nor has there been a vendor added for the exclusive purpose of servicing the SUD demonstration

[2] State and program-specific FFP will be used including those expenses eligible for enhanced federal share.

[3] UDOH will use the managed care payment amount to assign costs to encounters paid by managed care entities.

[4] SUD-IMD services were not paid by UDOH in the pre-demonstration period. SUD-IMD costs will not exist in the pre-demonstration period of this cost analysis.

Population of interest

UDOH will identify beneficiaries based on claims and encounters with a SUD diagnosis and/or procedure code. The SUD diagnosis and procedure codes will be identified using the Adult Core Set Value Set Directory. Pharmacy claims and encounters with a dispensed drug for Medication Assisted Treatment (MAT) will also be used to identify the population of interest. Once a beneficiary has been identified, they will remain in the population of interest until 11 months pass without another qualifying SUD claim or encounter. Populations participating in the SUD demonstration include state plan populations, the Targeted Adult Medicaid demonstration population, and the Current Eligibles demonstration population.

Scope

Utah will use two pre-demonstration years beginning November 2015 and ending October 2017. Utah's SUD demonstration was approved for November 9, 2017 until June 30, 2022. For the purpose of this analysis, Utah will consider the entire month of November 2017 to be post-demonstration.

Challenges

Utah does not have a valid comparison population for this analysis. Utah's SUD demonstration was implemented state-wide on the same date to all state plan populations and two 1115 demonstration populations. Only the 1115 demonstration population Primary Care Network (PCN) is excluded from the SUD demonstration population benefits, however they are excluded from all behavioral health benefits. For this reason, PCN does not represent a valid comparison group. Utah will not be able to provide a comparison population in order to complete the preferred difference-in-difference analysis.

Method

UDOH will conduct an interrupted time series analysis to estimate the linear effects of the SUD demonstration. Utah will use the model provided in the SUD Technical Assistance (February 22, 2018).

$$Costs = \beta 0 + \beta 1*TIME + \beta 2*POST + \beta 3*(TIME*POST) + Bi* CONTROLS + \varepsilon$$

Where:

TIME is a count variable that starts with the first quarter pre-demonstration period data and ends with the last quarter of post-demonstration period data.

POST is the indicator variable that equals 1 if the month occurred on or after demonstration start date.

CONTROLS are covariates as follows:

Control	**Possible Values**
Age	Beneficiary's age (in years) on the first day of the month.
Gender	Male/Female
Race	White; Asian/Pacific Islander; American Indian/Alaskan Native; Black; or Other/missing.
Dual Medicare-Medicaid enrollment	Yes/No
Delivery system	Managed care plan or fee-for-service

Demonstration Population	Identification of special 1115 populations: Targeted Adult Medicaid[5]; Current Eligibles; or State Plan Eligibility (Non-Waiver).

UDOH will conduct both a logit model for estimating zero-cost months and a generalized linear model [GLM] for estimating non-zero cost months. The GLM model will use log costs to account for costs that are not normally distributed.

Deliverable

The interrupted time series results will be presented in the format suggested within the SUD technical assistance. Additionally, UDOH will provide the marginal effects and standard error terms.

Interrupted Time Series results	Total costs	Total federal costs	SUD-IMD	SUD-other	Non-SUD	Outpatient non-ED	Outpatient ED	Inpatient	Pharmacy	Long-term care
Logit										
Demonstration period										
Time (continuous)										
Demonstration period * time (continuous)										
Covariates										
Constant										
GLM										
Demonstration period										
Time (continuous)										
Demonstration period * time (continuous)										
Covariates										
Constant										

[5] The Targeted Adult Medicaid demonstration population was approved effective November 1, 2017. It consists of adults, without dependent children, age 19-64, who meet defined criteria including being chronically homeless, justice involved, and/or needing substance use disorder or mental health treatment. This population has no pre-SUD-demonstration experience. Because they are a unique population with complex behavioral health needs, it is important to separately identify them as a covariate.