New Jersey FamilyCare Opioid Use Disorder/Substance Use Disorder Demonstration Program: 10/31/2017-6/30/2022

Evaluation Plan by Rutgers Center for State Health Policy

General Background Information

Under the NJ FamilyCare 1115 Demonstration Waiver, the New Jersey Division of Medical Assistance and Health Services (DMAHS) is participating in a new initiative for addressing the opioid use disorder/substance use disorder (OUD/SUD) crisis over the period 10/31/2017-6/30/2022. The NJ FamilyCare OUD/SUD program under development will bring a full continuum of evidence-based care to beneficiaries with OUD/SUD in an effort to improve accessibility, treatment quality, and health outcomes for this population.

The Implementation Plan for New Jersey's OUD/SUD program was approved by CMS on May 17, 2018.¹ In this plan, the State details the overall **goals** of the OUD/SUD program. They are:

- 1. Increase the rates of identification, initiation and engagement in treatment for OUD and other SUDs;
- 2. Increase adherence to, and retention in, treatment for OUD and other SUDs;
- 3. Reduction in overdose deaths, particularly those due to opioids;
- 4. Reduce utilization of emergency departments and inpatient hospital settings for OUD and other SUD treatment, where the utilization is preventable or medically inappropriate;
- 5. Reduce preventable, or potentially preventable, readmission to the same or higher level of care for OUD and other SUD; and
- 6. Improve access to care for physical health conditions among beneficiaries with OUD or other SUDs.

¹ NJDHS-DMAHS (New Jersey Department of Human Services, Division of Medical Assistance and Health Services). 2018. *NJ FamilyCare Comprehensive Demonstration Implementation Protocol for the Opioid Use Disorder* (*OUD*)/Substance Use Disorder (SUD) Program. Trenton: NJDHS-DMAHS.

https://www.state.nj.us/humanservices/dmahs/home/Comprehensive_Demonstration_Implementation_Protocol _OUD-SUD_Program.pdf.

In pursuit of these goals, the Centers for Medicare and Medicaid Services (CMS) has prescribed milestones for the implementation of New Jersey's OUD/SUD program.^{2,3} These **milestones** require the State to:

- 1. Establish new benefits for access to critical levels of care for OUD/SUDs;
- Establish requirements for evidence-based, SUD-specific patient placement criteria to govern providers' assessments of beneficiaries and guide utilization management;
- Establish residential treatment provider qualifications using evidence-based, SUD program standards and require that residential treatment providers offer access to Medication Assisted Treatment (MAT), and ensure provider compliance with standards of care;
- 4. Assess provider capacity at each level of care (including MAT for OUD) and develop a plan for addressing any identified gaps;
- Implement comprehensive treatment and prevention strategies to address opioid abuse and OUD via prescribing guidelines, access to Naloxone, and an SUD Health Information Technology (IT) Plan for prescription drug monitoring;
- 6. Develop and implement policies to improve transitions between levels of care and improve care coordination between residential/inpatient facilities and community supports.

The timeframes laid out in the Waiver Special Terms and Conditions (STCs) require completion of Milestones 1-5 within 24 months of the demonstration approval on October 31, 2017. Milestone 6 is carried out over the course of the five-year demonstration period.

To allow for the flexibility and innovation needed to craft a successful OUD/SUD program, the Waiver also gives the State authority to make key service delivery changes. Due to an existing federal policy, only Medicaid members ages 18 to 20 and 65 or older were covered for both detox-rehabilitative services and short-term residential treatment (STR) in an Institution for Mental Disease (IMD). Any hospital, nursing facility, or other institution of more than 16 beds caring for individuals where the majority (over 50%) have a diagnosis of mental disease qualifies as an IMD, thus severely limiting the bed capacity in the state available for treatment of Medicaid beneficiaries with OUD/SUD aged 21-64. These individuals had to self-pay or access state funding for treatment, which entailed waiting for a bed in one of only four facilities statewide. The result was delayed treatment admission for withdrawal management services that are vital to the continuum of care in New Jersey. Subsequent to Waiver approval on October 31, 2017, gaps in the care

² CMS (Centers for Medicare & Medicaid Services). 2017. *NJ FamilyCare Comprehensive Demonstration (Project No. 11-W-00279/2)*. Baltimore: CMS. https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nj/nj-1115-request-ca.pdf.

³ CMS (Centers for Medicare & Medicaid Services). 2017. *SMD #17-003 Re: Strategies to Address the Opioid Epidemic*. Baltimore: CMS. https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf.

continuum, like the IMD exclusion, can be closed. Specifically, the State was granted waiver authority to make these **service delivery changes**⁴:

- 1. Remove the exclusion prohibiting withdrawal management or residential treatment services delivered in an Institute for Mental Disease (IMD);
- 2. Add long-term residential treatment, including treatment in an IMD, as a new level of care in the OUD/SUD service continuum;
- 3. Add peer recovery support specialist and case management programs to the benefit package for individuals with OUD/SUD;
- 4. Move to a managed care delivery system with integrated physical and behavioral health services, with gubernatorial approval, over the course of the five year demonstration under an amendment to the waiver.

These service delivery changes complement additional activities and policies enacted by the State under this initiative. These other activities are described in detail in the State's Implementation Plan. Briefly, the State will:

- Operationalize the use of American Society for Addiction Medicine (ASAM) criteria and the LOCI-3 assessment tool for SUD treatment;
- Operationalize and align the utilization management by managed care organizations and the Interim Managing Entity (IME) to ensure the appropriate level of care;
- Ensure NJ residential treatment facility (RTF) regulations and provider contracts with MCOs (managed care organizations) meet ASAM criteria for services types, hours of care, and staff credentials and establish a review process to ensure provider compliance;
- Ensure access to MAT on-site and after RTF discharge;
- Conduct a statewide capacity report and maintain provider capacity data profiles for all levels of care with a plan to address any insufficiency;
- Implement strategies under the Health IT plan to connect SUD providers to EHRs and the Prescription Drug Monitoring Program;
- Utilize and expand training and use of Naloxone to reverse overdoses; and
- Implement an Opioid Overdose Recovery program to those who have received Narcan reversal.

All together, these changes under the demonstration enable New Jersey to achieve the programmatic milestones and goals described above, Specifically, lifting the IMD exclusion (delivery change 1) increases access to critical levels of care for OUD/SUD for beneficiaries aged 21-64 who will have access to hundreds more withdrawal

⁴ NJDHS-DMAHS (New Jersey Department of Human Services, Division of Medical Assistance and Health Services). 2018. NJ FamilyCare Comprehensive Demonstration Implementation Protocol for the Opioid Use Disorder (OUD)/Substance Use Disorder (SUD) Program. Trenton: NJDHS-DMAHS.

https://www.state.nj.us/humanservices/dmahs/home/Comprehensive_Demonstration_Implementation_Protocol _OUD-SUD_Program.pdf.

management and detox beds in NJ. The addition of long-term residential (LTR) treatment (delivery change 2), peer recovery support, and case management (delivery change 3) are also new benefits expanding the continuum of care as per the first milestone. LTR treatment and peer recovery services are available to beneficiaries of all ages with OUD/SUD, and the case management benefit will be available for adults ages 18 and older.⁵ The movement towards integrated physical and behavioral health under a managed care model (delivery change 4) supports the sixth milestone of improving transitions and care coordination in OUD/SUD treatment and affects beneficiaries of all ages with OUD/SUD.⁶ Finally, all the additional activities in the State's Implementation Plan enumerated above are also intended to benefit beneficiaries with OUD/SUD of all ages.

Evaluation Questions and Hypotheses

A robust and timely independent evaluation is required as part of the Waiver Special Terms and Conditions (STCs) to determine if the State's OUD/SUD program succeeds in meeting the population health goals of the national initiative. The STCs set forth the following research question relevant to the Waiver OUD/SUD program:

What is the impact of providing substance use disorder services to Medicaid beneficiaries? Including paying for services rendered in an institution for mental disease (IMD)?

Following the evaluation design requirements also put forth in the STCs, hypotheses aligning with the overall goals of the OUD/SUD initiative will be tested to answer this research question.

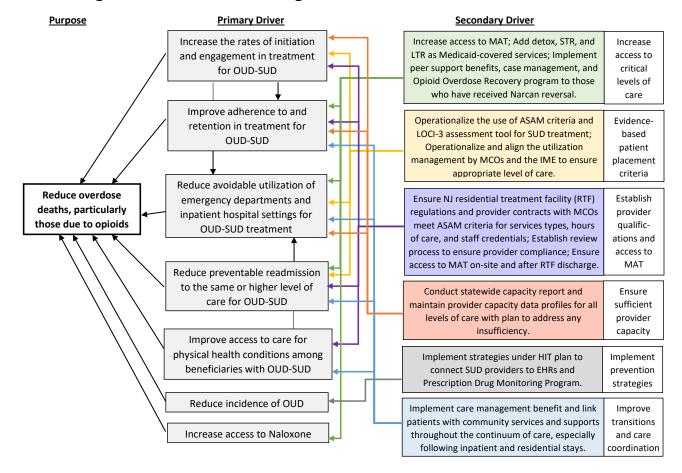
As is clear from the milestones, the primary strategy for achieving the goals under this initiative is building an effective, evidence-based delivery system for OUD-SUD treatment.⁷ Lifting the IMD exclusion allows beneficiaries aged 21-64 increased access to withdrawal management or detox services to access treatment rather than delaying treatment on a waiting list for a state-funded facility. This can increase adherence to OUD-SUD treatment and avoid overdose deaths. The addition of peer support recovery services is an evidence-based strategy to support individuals with OUD/SUD during critical transitions in care and into recovery. These and the other changes fulfilling Milestone 1 should improve adherence to and retention in OUD-SUD treatment, averting use of emergency departments and hospitals for unmet treatment needs. Similar benefits are expected from achievement of Milestone 2 establishing widespread use of evidence-

⁵ Children with behavioral health needs already receive case management services.

⁶ Some special populations (MLTSS, DDD, and FIDE-SNP) are already receiving integrated physical and behavioral health services under managed care, but most SUD services were carved out at the time this initiative began.

⁷ NJ also has a few complementary activities aimed at reducing the incidence of OUD (e.g. prescribing guidelines and increasing utilization and functioning of prescription drug monitoring).

based, SUD-specific patient placement criteria. By matching individuals with the appropriate level of care for their diagnosis and treatment needs, adherence to treatment can be improved and readmissions to a higher level of care can be prevented. NJ is also committed to increased access to MAT and integrated care for individuals with an OUD. A fundamental addition to the continuum of care is supporting individuals as they transition between levels of care or into the community with the addition of SUD specific Care Management services. These links, and others, between the milestones and goals are shown in the following driver diagram. This diagram depicts this relationship between the service delivery changes that fulfill each milestone (secondary drivers), the care and treatment goals they are intended to impact (primary drivers), and the overall purpose of the OUD-SUD initiative, which is to reduce deaths due to drug overdose. This diagram may be modified over the course of the evaluation to reflect what is learned about the interventions that are helping to achieve desired results.⁸



Driver Diagram for NJ OUD/SUD Program

⁸ CMS-CMMI (Center for Medicare & Medicaid Services – Center for Medicare and Medicaid Innovation) 2013. *Defining and Using Aims and Drivers for Improvement: A How-To Guide*. Baltimore: U.S. Department of Health and Human Services. <u>https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf</u>.

Accordingly, the hypotheses aligning with these goals which will be addressed in the evaluation are:

<u>Hypothesis 1</u>: Rates of identification, initiation and engagement in treatment for OUD and other SUDs will increase as a result of the OUD/SUD program.

<u>Hypothesis 2</u>: Rates of adherence to, and retention in treatment for OUD and other SUDs, overall and for individuals aged 21-64, will increase as a result of the OUD/SUD program.

<u>Hypothesis 3</u>: Overdose deaths, particularly those due to opioids, will decline overall and for individuals aged 21-64 as a result of the OUD/SUD program.

<u>Hypothesis 4</u>: Utilization of emergency departments and inpatient hospital settings for OUD and other SUD treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services will decline overall (including individuals aged 21-64) as a result of the OUD/SUD program.

<u>Hypothesis 5</u>: Readmissions to the same or higher level of care where readmissions is preventable or medically inappropriate for individuals with OUD and other SUD will decline overall (including individuals aged 21-64) as a result of the OUD/SUD program

<u>Hypothesis 6</u>: Access to care for physical health conditions among beneficiaries with OUD or other SUDs will improve as a result of the OUD/SUD program

These hypotheses will be evaluated for the overall OUD/SUD program using both qualitative and quantitative methods. Select outcomes for a subset of hypotheses (e.g. 2, 3, 4 and 5) will also be separately assessed for isolating the impact of removing the IMD exclusion on beneficiaries ages 21-64. Statistical hypothesis testing will be done using, where possible, both process and outcome measures selected preferentially from nationally-recognized sources and measures sets.

Methodology

The approach to testing these hypotheses will be structured around three aims:

Aim 1: Collect information for structuring a robust analytic strategy.

Integral to assessing the effect of the policy changes is identification of the set of relevant quality metrics that will reflect potential changes in our outcomes of interest. In this stage we will examine the peer-reviewed and gray literature to identify the most relevant process and outcome measures for each hypothesis. We will consider metrics utilized during similar evaluation activities in the State and nationally. We will determine the applicability of such measures to New Jersey's OUD/SUD program and the feasibility of constructing such measures with available data. We will seek input from key stakeholders on what process and outcome measures would be of interest for understanding the impact of this initiative. Stakeholder engagement will be planned in consultation with the State. We will monitor developments and modifications in nationally-recognized quality measures in response to the opioid crisis to make use of the most current, validated

metrics that can be reliably trended over the demonstration period. We will consult the State's monitoring protocol for the OUD/SUD program, when complete, and CMS's required and optional demonstration monitoring and performance measures.^{9,10} We will also closely follow the State's implementation activities to provide context for qualitative interviewing which will both directly and indirectly address the evaluation hypotheses.

The culmination of this stage will be an inventory of independently calculated evaluation measures, measures collected from secondary sources, and qualitative interview domains pertaining to each hypothesis. A preliminary version of this, containing candidate measures thus far identified, is presented below as Table 1.¹¹ We will use a subset of these measures for our final analysis.

⁹ CMS (Centers for Medicare & Medicaid Services). 2017. *SMD #17-003 Re: Strategies to Address the Opioid Epidemic*. Baltimore: CMS. https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf.

¹⁰ CMS (Center for Medicare & Medicaid Services) 2019. *Monitoring Metrics for Section 1115 Demonstrations with SUD Policies*. Baltimore: U.S. Department of Health and Human Services. https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/sud-monitoring-metrics.pdf.

¹¹ Additional details on each candidate measure, including the specific age groups for which they are relevant, are presented in Table 2 later in this evaluation plan.

Table 1: Preliminary Inventory of Candidate OUD/SUD Program Evaluation Measures and Qualitative Interview Domains

	Quantitative		Qualitative
Process Measures	Outcome Measures	\mathbf{IMD}^4	Domains/Sample Interview Questions
	ation, initiation, and engagement in treatment for OUD/S	UD	
Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (NCQA; NQF #0004)	Identification of alcohol and other drug services: summary of the number and percentage of members with OUD and SUD who received the following chemical dependency services during the measurement period: any service, inpatient, intensive outpatient or partial hospitalization, outpatient or ambulatory MAT, ED, or telehealth (NCQA).		Access to guideline- adherent care for OUD/SUD Performance of IME What has been the experience of getting individuals who are identified as having OUD/SUD into the right level of care?
Hypothesis 2. Adherence and re	etention in OUD/SUD treatment		
Follow-up after Discharge from Emergency Department for Alcohol or Other Drug Dependence (NCQA) Continuity of Pharmacotherapy for OUD (RAND; NQF #3175) Use of peer support services following discharge from inpatient/residential stays for OUD/SUD	Percentage of beneficiaries with an SUD diagnosis including those with OUD who used the following services (multiple rates reported) ² : • Outpatient; • Intensive outpatient and partial hospitalization services; • Medication assisted treatment for OUDs and alcohol; • Residential/inpatient treatment (including average lengths of stay (LOS) in residential treatment aiming for a statewide average LOS of 30 days); and • Medically supervised withdrawal management	Х	Continuum of care; Provider availability and quality of care What have been the challenges and benefits of establishing peer support services? How has the availability of OUD/SUD services impacted treatment success?
Hypothesis 3: Overdose deaths			
Use of Opioids at High Dosage in Persons without Cancer	Mortality rate for individuals with SUD, and specifically OUD. ²	Х	What are the key interventions for averting deaths due to

(NCQA or Pharmacy Quality Alliance; NQF #2940) Use of Opioids from Multiple Providers in Persons without Cancer (NCQA; NQF #2950)	Rate of all and OUD overdose deaths (Medicaid and NJ overall) ³		overdose and how well have these been addressed in the OUD/SUD program?
Hypothesis 4: Preventable ED	and inpatient use for OUD/SUD treatment		
	Rate of Emergency department visits for SUD-related diagnoses and specifically for OUD ² Rate of Inpatient admissions for SUD and specifically OUD ²	х	How well have beneficiaries' needs for treatment been met within the OUD/SUD program?
Hypothesis 5: Fewer readmiss	th OUD/		
Transitions of Care – Patient Engagement after Hospital Discharge (NCQA) ¹	 30 day readmission rate for OUD/SUD treatment following hospitalization or residential treatment for an SUD-related diagnosis and specifically for OUD² 30 day all-cause readmission rate following hospitalization or residential treatment for an SUD-related diagnosis and specifically for OUD² 	x	How is care coordinated for people in the OUD/SUD program?
Hypothesis 6. Access to care f	or physical health among individuals with OUD/SUD		
Use of OUD/SUD case management services	PQI rate among individuals with OUD/SUD (AHRQ) ¹ Avoidable ED visits for individuals with OUD/SUD (NYU) ¹ Percentage of beneficiaries with an SUD diagnosis, and specifically those with OUD, who access preventive/ambulatory care ²		What has been the impact of case management on access to care for physical health among those with OUD/SUD?

¹ In cases where existing, nationally-recognized quality metrics are not specific to OUD/SUD, we will calculate the metric for the OUD/SUD population. ² For metrics that are not part of established, nationally-recognized measure sets, we will adapt a related validated metric, relying as much as possible on established cohort identification and clinical definitions (e.g. in HEDIS) and/or on decisions made by the State and CMS in developing the data monitoring protocol for the OUD/SUD program.

³ Deaths due to drug overdose cannot be identified in Medicaid claims data. The rate of overdose deaths due to opioids would need to be provided by the State. Depending on data availability, trends in drug-induced deaths in NJ overall can be assessed using NJ State Health Assessment Data for comparison purposes. ⁴Measures that will also be used to look at the impact of lifting the IMD exclusion will be age-stratified: <21, 21-64, and 65.

Aim 2: Collect and assess stakeholder feedback

Stakeholder feedback is an important source of information for identifying improvements and problems during the demonstration, as well as for evaluating successes and challenges. As the OUD/SUD program is implemented, the evaluation team may attend selected meetings of established councils, committees, and workgroups involved in planning of the demonstration and/or preparing for implementation that are deemed to be relevant. We will review the activities and recommendations of the advisory committees, review meeting minutes and documents, and monitor progress on implementing the demonstration, successes, challenges, and lessons learned.

In this stage we will also conduct 10-15 targeted key informant interviews with stakeholders to assess perceptions of the policy changes, resultant process changes and their impact. Interviews will be conducted with officials from the Department of Human Services, Department of Health, as well as representatives of working groups, community partners, and provider and consumer associations to obtain viewpoints about expected benefits and unanticipated consequences for patients and families. We will attempt to enumerate and represent in our interviews stakeholders representing the various categories of providers and consumers in the state to get the fullest possible picture of how the program is affecting different groups. Our activities under Aim 1 of this evaluation plan will help inform our selection of interviewees. Initial interviewees will be identified by their participation in State-convened stakeholder forums such as the Office-Based Addictions Treatment workgroup, the Opioid Overdose Recovery Program Providers workgroup, and/or the Professional Advisory Council. If needed, we will seek recommendations from the State's technical assistance contractor responsible for convening some stakeholder meetings to assist with identifying key stakeholders from these groups and other provider and consumer associations affected by the OUD/SUD demonstration initiatives. Interview subjects may also be suggested by other interviewees or stakeholders/policymakers and/or may reach out to us upon learning of our role as the third-party evaluator of the OUD/SUD program and Comprehensive Waiver as a whole. Interview subjects will not receive incentives to participate. The timing of the interviews would depend on program implementation and complementary evaluation activities.

The interview protocol will be based on the domains noted in Table 1, which will have been informed by input from stakeholders as part of Aim 1. It will be a semi-structured guide containing key questions to ensure data collection consistency while allowing for follow-up questions and probes to elicit more in-depth responses to the primary questions. A draft interview guide is included as Attachment A to this evaluation plan.

Data from key informant interviews will be de-identified and then independently coded by two researchers to identify themes and patterns in the data using an inductive process.¹² In our analysis, we will consider emergent themes as well as unique comments, as some

¹² Thomas DR. "A General Inductive Approach for Analyzing Qualitative Evaluation Data." American Journal of Evaluation 27(2): 237-246, June 2006.

of our stakeholders may represent unique populations. We will consider stakeholder comments regarding different consumer populations (e.g., as differentiated by age, race/ethnicity, geographic location, existence/type of comorbidity, etc.), different kinds of provider organizations (e.g., different levels of service intensity, different type of clinician certification, etc.), and different kinds of information/referral organizations (e.g., contracted agencies, state advocacy groups, locally based prevention or response organizations, etc.) with respect to how system changes have affected the ability of consumers to access appropriate OUD/SUD services. We are interested in obtaining from our interviewees a picture of the processes through which consumers progress as they access OUD/SUD services—from information and referral, eligibility determination and redetermination, enrollment, receipt of services, follow-up care, and other issues that may be mentioned. If relevant interim quantitative findings are available, we will present selected findings to stakeholders to capture reactions and interpretations that will contextualize the findings.

.Aim 3: Conduct quantitative analyses of independently calculated and reported quality measures

In this stage of the evaluation, we will assess the subset of measures chosen from the candidate list (see Table 1) over the pre- and post-policy period to estimate the impact of the policies related to the OUD/SUD program. This quantitative component will involve analysis of Medicaid claims/encounter data and aggregated or summary statistics from secondary sources. The claims data provides information on patient, provider and geographic characteristics, and we will adjust for such factors while examining the policy effects on our outcomes of interest. We will not have such information for secondary metrics but will construct trends and calculate statistical significance of trends wherever possible. The analytic strategy described below, specifically the multivariate statistical analysis, is thus relevant to the claims data analysis.

We will utilize Medicaid claims and managed care encounter data over the period January 2016 to June 2022. These data are received under an agreement with the NJ Division of Medical Assistance and Health Services and contain statewide data for all Medicaid beneficiaries. Personal identifying information in compliance with guidelines for limited data sets have been removed from records before receipt. Key data elements include:

- Time of Medicaid Enrollment
- Age, Sex, and Race/Ethnicity of Recipient
- Recipient Zip Code of Residence
- Medicaid Eligibility Category
- Fee-for-Service and type Managed Care Plan indicator
- Type of encounter/service
- Type of Medicaid program/waiver category
- Facility/Provider identifiers

- Beginning and ending dates of service
- Charges, paid claims amounts and payment dates
- Principle and Secondary Diagnosis Codes
- Prescription drug information
- Hospital discharge disposition
- Place of service
- Admission type and source of admission

Monthly extracts are received and used to build static, annual analytic claims files with a minimum six month runout. The State has estimated that the majority of FFS and managed care claims are received within six months of the date of service, and this lag efficiently balances data completeness with the timely completion of analyses. If lags in billing occur for new Medicaid providers in the expanded service continuum or due to lifting the IMD exclusion, we will determine whether applying a longer runout period for claims updates (e.g. 12 months) during the implementation years of the demonstration will more accurately capture utilization and costs.

Our analytic files are validated against a real-time database guery from DMAHS on total payment amounts, total number of claims, and recipient eligibility counts for a specified period and differ by <1%. Additionally, constructed population indicators will be benchmarked against State figures for these same populations when available. Further assurances of the completeness and quality of claims data are provided by existing State processes and MCO contracting requirements. New Jersey managed care plans must submit encounter claims for all services provided to Medicaid recipients to the State. The accuracy and completeness of provider payment amounts reported on these encounter claims is assured through a number of validation checks. First, service encounters are reviewed for accuracy by New Jersey's fiscal agent before being considered final. The State implements liquidated damages on its health plans for excessive duplicate encounters and excessive denials. Further, accurate payment reporting processes are ensured by the requirement that after a defined period of time the total dollar value of encounters accepted by the State's fiscal agent must also equal 98 percent of the medical cost submitted by the plans in their financial statements. Claims for SUD services that are covered on a FFS basis are also subject to validation checks by the State's contracted billing agency.

We will utilize January 2016-September 2017 as the baseline period preceding the implementation period over October 2017-December 2019 and examine changes

between the baseline and post-policy period spanning January 2020-June 2022.¹³ For some policy changes, depending on the timing, a part of this overall implementation period may be included in the post-policy period. We will conduct descriptive analyses, calculating estimates for outcome measures on a monthly, quarterly, or annual basis over these periods and examine trends where applicable. To examine the policy impact and test the hypotheses stated above we will employ three different statistical techniques: difference-in-differences estimation, segmented regression analysis, and regression discontinuity design.

Difference-in-Differences Estimation: For estimating the effect of the OUD/SUD program overall and the removal of the IMD exclusion specifically, the evaluation will utilize a difference-in-differences (DD) estimation technique that identifies the impact of the demonstration by comparing the trend in outcomes for the program targeted (intervention) population from the pre- to the post-implementation period to that of a comparison group (where available) which is otherwise similar, but not subject to the policy effect. Such an estimation strategy is able to identify changes in outcomes that are due to program impact and distinct from secular trends. It accounts for the effect of unobserved factors, as long as their impact on one of the groups relative to the other does not change over time. The following equation illustrates the general DD specification

$$Y_{it} = \beta_0 + \beta_1(target)_i + \beta_2(post \ policy)_t + \beta_3(target_i * post \ policy_t) + \gamma X_{it} + \varepsilon_{it}$$

In the above equation, variable Y_{it} represents the outcome measure enumerated for the recipient with OUD/SUD at time t. Post policy is an indicator (0/1) variable that identifies the period the policy under examination was in effect, and target is an indicator variable for the group that is subject to the policy intervention. In this model, β_3 represents the DD estimate measuring the program impact. X_{it} is a vector of other control variables relating to the recipient, and ϵ_{it} represents the random error term.

We will examine the effect of the policy eliminating the IMD exclusion for SUD services utilizing the DD framework by classifying beneficiaries between ages 55-64 with OUD/SUD as the intervention group and beneficiaries between ages 65-75 with OUD/SUD as a comparison group. ¹⁴ As required in a DD framework, the comparison group did not experience a change in the policy related to IMD exclusion. It helps account for the effect of other non-IMD related policy changes, or secular changes over time that need to be factored in while examining the effect of the IMD policy change on the

¹³ The incidence of outcomes may require a quarterly or annual measurement period and these period definitions (baseline, implementation, and post-policy) will be modified accordingly to align with these measurement intervals and the policy being examined.

¹⁴ Using similar groups to mitigate unmeasured confounding from age is common in the academic literature to assess policy effects that may differentially impact such populations. See for example Chakravarty, S., Gaboda, D., DeLia, D., Cantor, J. C., & Nova, J. (2015). Impact of Medicare Part D on coverage, access, and disparities among New Jersey seniors. *Med Care Res Rev, 72*(2), 127-148. doi:10.1177/1077558714563762

treatment group. While this specification could include individuals in the intervention group who may have actually received SUD services in smaller residential facilities not subject to the IMD exclusion, or under state-only funding, this would only introduce a conservative bias into the estimate of the policy effect. Wherever possible, we will explore available data and information to account for such utilization. Depending on the policy change, we will also examine the effect of the OUD/SUD program overall on the physical health outcomes of beneficiaries having OUD/SUD within the DD framework by using individuals with behavioral health problems but without OUD/SUD as a comparison group.

We will use propensity score analysis to select Medicaid beneficiaries for the comparison groups. Such a method helps balance the covariate distribution between the intervention and comparison groups.¹⁵ An initial logistic regression models the likelihood of being in the OUD/SUD service-eligible group (this will be individuals aged 55-64) as a function of characteristics such as sex, chronic disability payment score, race/ethnicity, and enrollment history. The predicted probabilities from this model will be used to weigh observations in the comparison group that are above a threshold probability level. Incorporating such propensity score reweighting¹⁶ will generate an optimal comparison group. The same procedure will be conducted to balance covariates between beneficiaries with OUD/SUD and a comparison group of recipients with behavioral health problems but without OUD/SUD.

A crucial assumption relating to the DD approach is there are no unmeasured factors whose effect on the intervention group relative to the comparison group changes over time. This may not always be fulfilled. In that case, the unobserved factors may result in the two groups having differential trends and the computed effect size will include this difference over time. Accordingly, we will test to see whether there existed statistically significant differences in trends between the intervention and comparison group prior to policy implementation. If this difference is in the same direction as the DD estimate and of comparable magnitude, it would imply that the DD model may be overestimating the effect. Accordingly our estimate process of computing effect sizes will adjust for these differential pre-trends based on well-established methods in peer-reviewed academic publications.¹⁷

¹⁵ Austin, PC and Stuart, EA. "Moving towards best practice when using inverse probability of treatment weighting using the propensity score to estimate causal treatment effects in observational studies." Statistics in Medicine 34: 3661-3679, August 2015.

¹⁶ Nichols, A. 2007. Causal inference with observational data. Stata Journal 7: 507–541; Nichols, A. 2008. Erratum and discussion of propensity–score reweighting. The Stata Journal. 2008. Volume 8 Number 4: pp. 532-539.

¹⁷ Harman, J. S., Hall, A. G., Lemak, C. H., & Duncan, R. P. (2014). Do provider service networks result in lower expenditures compared with HMOs or primary care case management in Florida's Medicaid program? Health Serv Res, 49(3), 858-877. PMCID: PMC4231575

In order to eliminate unmeasured confounding arising from age differences, we have restricted our policy and comparison groups in the DD analyses to the narrower age categories. However, as described below, we will use segmented regression analysis to examine effects on the overall policy eligible group between ages 21 and 64.

Segmented Regression Analysis/Interrupted Time Series Modeling: We will use Segmented Regression Analysis (SRA) to examine the effect on policy groups where a comparison group may not be feasible and also to implement alternative specifications to DD models including comparison groups. The SRA model assumes that the policy effect may lead to a change in level, and also a change in the existing time trend of the metric measuring quality or any other relevant outcome of interest. The regression analysis is able to measure this change in trend or level. Potential confounding may arise from factors that determine our outcomes of interest and change at the same time as the policy implementation. However, our multivariate analysis adjusting for patient, provider and geographic factors are expected to mitigate such effects. SRA will be an additional strategy to estimate the impact of OUD/SUD policies overall on different beneficiary groups in the absence of robust comparison groups. We will conduct stratified analysis by age groups, 13-20, 21-64, and 65+ to account for difference in service provisions between individuals belonging to these three groups. The equation below illustrates the general SRA specification:¹⁸

$$Y_{it} = \beta_0 + \beta_1(time)_t + \beta_2(policy \ post)_t + \beta_3(policy \ time)_t + \gamma X_{it} + \varepsilon_{it}$$

Here, Y_{it} reflects the outcome related to the ith index event or recipient at time t. On the right hand side of the equation, time is a continuous variable indicating time in months or calendar quarters from the start of the study period. The variable policy post is an indicator (0/1) variable for the period subsequent to these policy changes under the SUD initiative. The variable policy time is a continuous variable equaling the number of months (or quarters) after the corresponding policy change. Coefficient β_0 estimates the baseline level of the outcome at the first time period, and coefficient β_1 indicates the baseline trend, i.e., the trend in the outcome prior to the first policy change. In this model, the specific effect of the SUD initiative on the overall population with OUD/SUD is given by the magnitude of β_2 that gives the change in level and β_3 that gives the change in trend of the specific outcome being examined after the SUD initiative began and we further test whether these values are statistically significant. For interpretability purposes, as in our previous waiver evaluation report¹⁹, we will further compare predicted values of outcomes

¹⁸ Wagner AK, SB Soumerai, F Zhang, and D Ross-Degnan. 2002. "Segmented Regression Analysis of Interrupted Time Series Studies in Medication Use Research." *Journal of Clinical Pharmacy and Therapeutics* 27 (4): 299–309.

¹⁹ Chakravarty, S., Lloyd, K., Farnham J., Brownlee, S., & DeLia D. (2017). Examining the Effect of the NJ Comprehensive Waiver on Access to Care, Quality, and Cost of Care: Draft Final Evaluation Report. New Brunswick, New Jersey: Rutgers Center for State Health Policy. Available at:

post-policy with counterfactual values (that simulate a scenario where the policy implementation did not occur). We will further compute whether this difference is statistically significant.

Regression Discontinuity Analysis: We will explore Regression Discontinuity Analysis (RDA) to examine the effect of the IMD exclusion policy on individuals between ages 21-64 without relying on a comparison group as an additional specification to DD and segmented regression models related to the IMD policy and an alternative in the case where a suitable propensity-matched comparison group cannot be identified. The regression discontinuity technique exploits variations in outcomes around a threshold or cut-point for a rating variable. The 'rating variable' used here for RDA analysis will be age since that will decide whether the individual who is a Medicaid beneficiary with OUD/SUD was eligible for SUD services in an IMD prior to the policy change. The 'cut point' will be age 21 as individuals became eligible for such services in IMDs. We expect to see a change in outcomes at this cut point prior to the policy implementation reflected in a discontinuity or a jump which measures the effect of the treatment on individuals near the cut point. This jump should go away after the policy implementation. RDA is appropriate in this policy setting since it satisfies important criteria namely that rating variable here which is age will not be influenced by the treatment; the cut point is exogenous to the rating variable; and nothing other than the treatment status is discontinuous in the interval analysis.20

Adjusting for Patient, Provider and Geographic Factors: Our multivariate analysis will control for patient characteristics that may affect outcomes. These include beneficiary demographics, Medicaid eligibility category, health history (including chronic illness and behavioral health co-morbidities) and information specific to the policy of interest. We will incorporate hospital fixed effects (to account for time-invariant differences across hospitals) for inpatient quality-based measures and zip code fixed effects (to account for time-invariant measures across geographic locations) for measures reflecting ambulatory care. As previously mentioned, we will utilize statistical matching techniques such as "Mahalanobis matching" or propensity score matching to create comparison cohorts of patients unaffected by policy changes for patients subject to policy effects when possible. We will estimate robust standard errors to account for non-independence of observations from clustering at the provider level.

Dose Response: Wherever applicable we will examine whether there is a "dose-response" relationship. Findings of a higher response when the "dose" of a policy change will strengthen causal inferences.

http://www.cshp.rutgers.edu/publications/examining-the-effect-of-the-nj-comprehensive-waiver-on-access-to-care-quality-and-cost-of-care-draft-final-evaluation-report.

²⁰ Jacob RT, Zhu P, Sommers MA & H Bloom. 2012. *A Practical Guide to Regression Discontinuity*. MDRC. https://www.mdrc.org/publication/practical-guide-regression-discontinuity.

Trend Analysis: When no comparison group exists and when there are no data for a prepolicy period, we will calculate trends over time and determine if a linearly increasing or decreasing trend exists.

Table 2 below summarizes the hypotheses, drivers, outcomes and analytic strategy for this evaluation, aligning measures with the regression approaches described above. All candidate outcomes presented in Table 1 are included, although our final list may differ based on what is learned in carrying out Aim 1.

Table 2: Summary of Hypotheses, Drivers, Data Sources, and Analytic Approaches for Candidate OUD/SUDProgram Evaluation Measures

Driver	Measure Description	Steward/ NQF #	Numerator	Denominator	Data Source	Analytic Approach ⁷		
Research Question: (a) What is the impact of providing substance use disorder services to Medicaid beneficiaries? (b) Including paying for services rendered in an institution for mental disease (IMD)?								
	Demonstration Goal: Increase the rates of identification, initiation and engagement in treatment for OUD and other SUDs.							
result of the OUD/SUD	program.		nd engagement in treatmer					
Primary Driver(s): Incre			ation and engagement in tr					
Secondary Drivers (Use evidence- based, SUD-specific patient placement criteria; Establish evidence-based residential treatment provider qualifications; Ensure access to MAT on- site and after discharge; Ensure sufficient provider capacity at each level of care)	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment ¹	NCQA; NQF #0004	Initiation: Number who initiate treatment through an inpatient admission, outpatient visit, intensive outpatient encounter, or partial hospitalization with 14 days of the index episode start date. Engagement: Number with initiation of treatment and two or more additional services for treatment within 30 days of the initiation encounter.	Medicaid recipients age 13 or older diagnosed with a new episode of AOD dependency	Claims	RQ(a) Descriptive statistics (annual rates) and SRA to compare pre and post-policy periods		

Driver	Measure Description	Steward/ NQF #	Numerator	Denominator	Data Source	Analytic Approach ⁷
	Identification of alcohol and other drug services	NCQA	Number receiving the following chemical dependency services: Any service Inpatient Intensive outpatient or partial hospitalization Outpatient or ambulatory MAT Emergency department Telehealth	Medicaid recipients with OUD/SUD	Claims	RQ(a) Descriptive statistics (quarterly rates) and SRA to compare pre and post-policy periods
Domonotration Cool In			 Telenealth in treatment for OUD and 	athar CLIDa		
Evaluation Hypothesis: 21-64, will increase as	Rates of adherence to a result of the OUD/S	o and retent UD program	ion in treatment for OUD ar		erall and fo	r individuals aged
Secondary Drivers (Increase access to critical levels of care; Establish evidence- based residential treatment provider qualifications; Ensure access to MAT on- site and after discharge; Ensure sufficient provider capacity at each level of care)	Use of critical levels of care for OUD/SUD ^{1,2}	N/A	Number using the following services:• outpatient services• Intensive outpatient or partial hospitalization• Residential/inpat ient treatment• MAT • Withdrawal management	Medicaid recipients with OUD/SUD	Claims	RQ(a) Descriptive statistics (quarterly rates) and SRA to compare pre and post-policy periods RQ(b) Descriptive statistics (age- stratified quarterly rates); DD with near- age comparison

Driver	Measure Description	Steward/ NQF #	Numerator	Denominator	Data Source	Analytic Approach ⁷
						group and/or RD and SRA
	Average length of stay in residential treatment ^{1,2}	N/A	Days in residential treatment	Medicaid recipients receiving residential treatment	Claims	RQ (a) Descriptive statistics (quarterly averages) and SRA to compare pre and post- policy periods RQ (b) Descriptive statistics (age- stratified quarterly averages); DD with near-age comparison group and/or RD and SRA
Secondary Drivers (Increase access to critical levels of care; Establish evidence- based residential treatment provider qualifications; Ensure access to MAT on- site and after discharge; Ensure sufficient provider capacity at each level of care; Improve care coordination and	Follow-up after Discharge from Emergency Department for Alcohol or Other Drug Dependence ¹	NCQA	Number with a follow-up visit within 7 and/or 30 days of the ED visit.	ED visits by Medicaid recipients age 13 or older with a principal diagnosis of AOD abuse or dependence	Claims	RQ (a) Descriptive statistics (annual rates) and SRA to compare pre and post-policy periods RQ (b) Descriptive statistics (age- stratified annual rates); DD with near-age comparison

Driver	Measure Description	Steward/ NQF #	Numerator	Denominator	Data Source	Analytic Approach ⁷
transitions between levels of care)						group and/or RD and SRA
	Continuity of Pharmacotherapy for OUD ¹	RAND; NQF #3175	Number with at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than 7 days	Medicaid recipients age 18-64 who had a diagnosis of OUD and at least one claim for OUD medication	Claims	RQ (a) Descriptive statistics (annual rates) and SRA to compare pre and post-policy periods RQ (b) Descriptive statistics (age- stratified annual rates); DD with near-age comparison group and/or RD and SRA
Secondary Driver (Increase access to critical levels of care for OUD/SUD)	Use of peer support services following discharge from inpatient/residential stays for OUD/SUD ²	N/A	Number using peer support services after discharge	Medicaid recipients with an inpatient/reside ntial stay for OUD/SUD	Claims	RQ (a) Descriptive statistics (quarterly rates) and trend analysis
Demonstration Goal: R	educe overdose death	ns, particular	ly those due to opioids.			
	: Overdose deaths, pa		se due to opioids, will decli	ne overall and for i	ndividuals	aged 21-64 as a
Primary Driver(s): Red			-		_	
Secondary Driver (Implement comprehensive	Use of Opioids at High Dosage in Persons Without	NCQA or Pharmac y Quality	Number with opioid prescription claims where the morphine	Medicaid recipients age 18 and older	Claims	RQ (a) Descriptive statistics (annual
prevention strategies to address opioid	Cancer ¹	Alliance;	equivalent dose for 90 consecutive days or	with two or more		rates) and SRA to compare pre

Driver	Measure Description	Steward/ NQF #	Numerator	Denominator	Data Source	Analytic Approach ⁷
abuse via prescribing guidelines and monitoring)		NQF #2940	longer is greater than 120 mg	prescription claims for opioids filled on at least two separate days, for which of the sum of the days' supply is \geq 15.		and post-policy periods
	Use of Opioids from Multiple Providers in Persons without Cancer ¹	NCQA; NQF #2950	Number receiving opioid prescription claims from: 4 or more prescribers 4 or more pharmacies 4 or more prescribers <u>and</u> 4 or more pharmacies	Medicaid recipients age 18 and older with two or more prescription claims for opioids filled on at least two separate days, for which of the sum of the days' supply is \geq 15.	Claims	RQ (a) Descriptive statistics (annual rates) and SRA to compare pre and post-policy periods
OUD/SUD treatment; F treatment; Reduce pre	Reduce avoidable utiliz ventable readmission	ation of eme to the same	ment in treatment for OUD/ ergency departments and in or higher level of care for (educe incidence of OUD; Ir	npatient hospital se DUD/SUD; Improve	ettings for (access to	OUD-SUD
Secondary Driver(s) (Increase access to critical levels of care; Use evidence-based SUD-specific patient placement criteria; Establish evidence-	Mortality rate for individuals with SUD, and specifically OUD ^{2,5}	<u>00/S0D; R</u> (Number of deaths	Medicaid recipients with OUD Medicaid recipients with SUD	Claims	RQ (a) Descriptive statistics (quarterly rates) and SRA to compare pre and

Driver	Measure Description	Steward/ NQF #	Numerator	Denominator	Data Source	Analytic Approach ⁷
based residential						post-policy
treatment provider						periods
qualifications; Ensure						RQ (b)
access to MAT on-						Descriptive
site and after						statistics (age-
discharge; Ensure						stratified
sufficient provider						quarterly rates); DD with near-
capacity at each level of care; Implement						age comparison
comprehensive						group and/or RD
prevention strategies						and SRA
to address opioid	Rate of all and	N/A	Number of overdose	Medicaid	State	RQ (a)
abuse via prescribing	OUD overdose		deaths	recipients	monitor	Descriptive
guidelines and	deaths (Medicaid				ing	statistics (annual
monitoring; Improve	and NJ overall). ^{1,2}			NJ residents	data ⁶	rates) and trend
care coordination and						analysis or SRA
transitions between						RQ (b)
levels of care)						Descriptive
						statistics (age-
						stratified annual
						rates) and trend analysis or SRA
						for ages 21-64
Demonstration Goal: R	educe utilization of em	hergency dei	partments and inpatient hos	spital settings for C) UD and o	
treatment, where the u						
			ents and inpatient hospital	settings for OUD a	nd other S	SUD treatment
where the utilization is	preventable or medica	ally inapprop	riate through improved acc	ess to other contin		
			of the OUD/SUD program.			
			ency departments and inpa			
Secondary Driver(s)	Rate of emergency	N/A	Number of ED visits for:	Medicaid	Claims	RQ (a)
(Increase access to	department visits		SUD	recipients		Descriptive
critical levels of care;	for SUD-related		OUD			statistics
Use evidence-based SUD-specific patient	diagnoses and					(quarterly rates) and SRA to
SOD-specific patient						and SKA IU

Driver	Measure Description	Steward/ NQF #	Numerator	Denominator	Data Source	Analytic Approach ⁷
placement criteria; Ensure sufficient provider capacity at each level of care; Improve care coordination and transitions between levels of care)	specifically for OUD ^{1,2}					compare pre and post-policy periods RQ (b) Descriptive statistics (age- stratified quarterly rates); DD with near- age comparison group and/or RD and SRA
	Rate of Inpatient admissions for SUD and specifically OUD ^{1,2}	N/A	Number of IP visits for: • SUD • OUD	Medicaid recipients	Claims	RQ (a) Descriptive statistics (quarterly rates) and SRA to compare pre and post-policy periods RQ (b) Descriptive statistics (age- stratified quarterly rates); DD with near- age comparison group and/or RD and SRA
Demonstration Goal: R other SUD.	educe preventable, or	potentially p	preventable readmission to	the same or higher	r level of c	
			ner level of care where read I decline overall and for ind			

Driver	Measure Description	Steward/ NQF #	Numerator	Denominator	Data Source	Analytic Approach ⁷
Primary Driver(s): Red		nission to the	e same or higher level of ca	are for OUD/SUD		
Secondary Driver(s) (Improve care coordination and transitions between levels of care	Transitions of Care – Patient Engagement after Hospital Discharge	NCQA	Number with documentation of patient engagement (e.g. office visits, visits to home, telehealth) within 30 days of discharge	Inpatient discharges by Medicaid recipients age 18 and older with OUD/SUD	Claims	RQ (a) Descriptive statistics (annual rates) and DD with BH comparison group and/or SRA
Secondary Driver(s) (Increase access to critical levels of care; Use evidence-based, SUD-specific patient placement criteria; Establish evidence- based residential treatment provider qualifications; Ensure access to MAT on- site and after	30 day readmission rate for OUD/SUD treatment following hospitalization or residential treatment for an SUD-related diagnosis and specifically for OUD ²	N/A	Number of readmissions for OUD/SUD treatment.	Inpatient/reside ntial treatment discharges for SUD, and separately for OUD, ⁴ by Medicaid recipients age 18 and older	Claims	RQ (a) Descriptive statistics (annual rates) and SRA to compare pre and post-policy periods RQ (b) Descriptive statistics (age- stratified annual rates); DD with near-age comparison group and/or RD and SRA
discharge; Improve care coordination and transitions between levels of care	30 day all-cause readmission rate following hospitalization or residential treatment for an SUD-related diagnosis and		Number of readmissions	Inpatient/reside ntial treatment discharges for SUD, and separately for OUD, ⁴ by Medicaid	Claims	RQ (a) Descriptive statistics (annual rates) and DD with BH comparison group and/or SRA to compare

Driver	Measure Description	Steward/ NQF #	Numerator	Denominator	Data Source	Analytic Approach ⁷
	specifically for OUD ²			recipients age 18 and older		pre and post- policy periods RQ (b) Descriptive statistics (age- stratified annual rates); DD with near-age comparison group and/or RD and SRA
Evaluation Hypothesis: a result of the OUD/SU	Access to care for ph D program.	ysical health	health conditions among la conditions among la conditions among benefice	ciaries with OUD or	other SUE	
Secondary Driver(s) (Improve care coordination and transitions between levels of care)	Use of OUD/SUD case management services ²	N/A	Number using case management services	Medicaid recipients age 18 and older with OUD/SUD	Claims	RQ (a) Descriptive statistics (quarterly rates) and trend analysis
Secondary Driver(s) (Establish evidence- based residential treatment provider qualifications; Improve care	PQI rate among individuals with OUD/SUD (AHRQ)	AHRQ	Number of hospitalizations for ambulatory care sensitive conditions	Medicaid recipients age 18 and older with OUD/SUD	Claims	RQ (a) Descriptive statistics (quarterly rates) and DD with BH comparison group and/or SRA
coordination and transitions between levels of care)	Avoidable ED visits for individuals with OUD/SUD	NYU ³	Number of avoidable ED visits	Medicaid recipients with OUD/SUD	Claims	RQ (a) Descriptive statistics (quarterly rates) and DD with BH

				Source	Approach ⁷
					comparison group and/or SRA
ss to entive/ Ilatory care ^{1,2}	N/A	Number who access preventive/ambulatory health services	Medicaid recipients with OUD Medicaid recipients with SUD	Claims	RQ (a) Descriptive statistics (quarterly rates) and DD with BH comparison group and/or SRA

AOD=Alcohol or other drug, MAT=Medication Assisted Treatment; RQ=Research Question; DD=Difference-in-differences; RD=Regression Discontinuity; SRA=Segmented Regression Analysis; BH=Behavioral Health

¹Exact or very similar to a 1115 SUD Demonstration Monitoring Metric

²This metric is not part of any established, nationally-recognized measure sets. Where possible, we will adapt a related validated metric, relying as much as possible on established cohort identification and clinical definitions (e.g. in HEDIS) and/or on decisions made by the State and CMS in developing the data monitoring protocol for OUD/SUD program.

³ <u>https://wagner.nyu.edu/faculty/billings/nyued-background;</u> This measure is being used to assess avoidable ED use for physical health conditions among individuals with OUD/SUD. The fact that visits due to mental health, alcohol use, and substance abuse are not classified by this algorithm does not affect the utility of this measure for examining physical health outcomes consistent with Hypothesis 6. The measure "Rate of emergency department visits for SUD-related diagnoses and specifically for OUD" under Hypothesis 4 will address ED use for mental health, alcohol use, and substance abuse.

⁴Readmission rates among those with OUD specifically will be calculated only if sample size is sufficient

⁵Disenrollment due to death is in the Medicaid claims data; however, we lack mortality information on individuals who disenroll from Medicaid for any other reason.

⁶Analysis will depend on timeliness, quality, and frequency of reporting of data from the State. Examination of the impact of lifting the IMD exclusion is only possible if age-stratified data are available.

⁷Measurement periods for descriptive analyses may change depending on the incidence of the outcome, alignment with the State's monitoring protocol, or as required by measure steward specifications.

Aim 4: Analyze costs associated with the OUD-SUD Demonstration

A required evaluation objective is to analyze patterns and trends in Medicaid costs associated with the OUD-SUD demonstration to determine whether it results in higher, lower, or neutral health care spending. Attachment A to CMS's SUD Evaluation Design Technical Assistance Document²¹ provides detailed guidance for conducting this cost analysis, and we will follow this recommended protocol as closely as possible. This will include calculating the total cost of care for Medicaid recipients with SUD as well as components related specifically to SUD treatment, non-SUD treatment and other potential drivers of total cost (inpatient, non-emergency outpatient, emergency outpatient, pharmacy, and long-term care). All necessary cost information is present in the Medicaid claims database available to us with the exception that some SUD treatment costs may have come from non-Medicaid sources, such as SAMHSA block grants or state funds.

Within the applicable framework (e.g. difference-in-difference, interrupted time series), we will use a generalized linear model with a gamma distribution and log linkage to model the impact of the demonstration policies on costs.^{22,23} The time period covered in this analysis will be January 2016 through June 2022. We will use a person-quarter as the unit of analysis and a repeated cross-sectional design which does not require minimum enrollment durations for inclusion in the analysis, although we may control for enrollment duration in our models. We agree with CMS's guidance that this approach is better than a cohort analysis due to suspected Medicaid eligibility churning by the population with SUD.

Our analysis will be conducted in light of the following considerations.

• The default application of a six month runout to our Medicaid claims and encounter database may not fully capture costs if lags in billing occur for new Medicaid providers in the expanded service continuum or due to lifting the IMD exclusion. We will consult with the State to determine whether applying a longer runout period for claims updates (e.g. 12 months) during the implementation years of the demonstration will more accurately capture costs. If this is

²¹ CMS (Center for Medicare & Medicaid Services) *2019. Substance Use Disorder (SUD) Section 1115 Demonstration Evaluation Design – Technical Assistance*. Baltimore: U.S. Department of Health and Human Services. <u>https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/sud-evaluation-design-tech-assistance.pdf</u>

²² Chakravarty, S., & Cantor, J. C. (2016). Informing the Design and Evaluation of Superuser Care Management Initiatives: Accounting for Regression-to-the-Mean. *Med Care*, 54(9), 860-867. doi:10.1097/MLR.00000000000568

²³ Dusetzina, S. B., Huskamp, H. A., Winn, A. N., Basch, E., & Keating, N. L. (2018). Out-of-Pocket and Health Care Spending Changes for Patients Using Orally Administered Anticancer Therapy After Adoption of State Parity Laws. *JAMA Oncol*, 4(6), e173598. doi:10.1001/jamaoncol.2017.3598

necessary, we may need to truncate the study period of our cost analysis by six months.

- Identification of the population of Medicaid recipients with OUD/SUD is dependent on service utilization. We are limited by service utilization appearing in our claims database, which does not include utilization occurring at non-Medicaid providers. This could lead to under-identification of Medicaid recipients with OUD/SUD, particularly in the pre-policy period before certain services became available under the demonstration. For instance, a detoxification visit with a diagnosis of alcohol or other drug dependence can qualify a recipient as having SUD. Due to the restriction on accessing detoxification in IMDs for those 21-64 prior to the demonstration, we are less likely to observe this qualifying utilization in our Medicaid claims database in the pre-policy period for recipients in this age group. We will conduct a sensitivity analysis, ignoring utilization of demonstration-impacted services in identification of our OUD/SUD population.
- Data on SUD treatment costs not paid through Medicaid are not available for this analysis. Trends in SUD treatment costs will need to be interpreted with this limitation in mind. We will consult with the State to quantify the costs over time not included in our analysis to qualitatively assess the extent of any cost shifting.
- Nearly all Medicaid recipients in New Jersey (~95%) are in managed care. Behavioral health services, including treatment for SUD, are carved out of the capitated managed care arrangement except for some special populations, but are being gradually shifted to managed care as part of this waiver demonstration. Therefore, these services will show up on a mix of fee-for-service and encounter claims in our database over the study period. Both types of claims include payment amounts and therefore, we will not need to use shadow pricing or alternative methods to capture costs related to inpatient, ED, or outpatient utilization for either acute or behavioral health care.
- The demonstration in NJ was not implemented in stages based on characteristics
 of Medicaid recipients, nor was it phased in for certain geographic regions of the
 State before others. When examining cost components that are not SUDspecific, it may be feasible to use Medicaid recipients with behavioral health
 conditions, but not SUD, as a comparison group in difference-in-difference
 models. Because we cannot exploit a staggered rollout to identify a comparison
 group when modeling cost components for SUD treatment enabling a differencein-differences estimation, alternative specifications for these cost analyses (e.g.
 interrupted time series) will need to be used as described in Attachment A to
 CMS's SUD Evaluation Design Technical Assistance Document.

Methodological Limitations

Qualitative

Qualitative analyses based on key informant interviews are limited by the representativeness of the interviewees and by the generally smaller number of people interviewed as compared with a broader survey; however, the richness of the information and ability to ask follow-up questions makes this approach worthwhile. We will strive to ensure the representativeness of interviewees while respecting the voluntary nature of participation by allotting sufficient lead time when scheduling interviews and a long enough recruitment period to find alternate interviewees representing key viewpoints in the event of cancellations/refusals.

Quantitative

We propose to examine several outcomes specifically for the population with OUD that may require a minimal sample size to ensure accuracy of estimates. This is more likely to limit reporting of outcomes that are based on an index event, such as hospital discharge (followed by a readmission or outpatient physician visit), as opposed to being measured for every member of the population. This, and reporting of all rates over a measurement period, are subject to achieving minimum cell sizes.

To conduct difference-in-differences (DD) analyses, we have proposed a comparison group for examining the impact of removing the IMD exclusion on individuals ages 21-64 and for examining the impact of demonstration policies overall on physical health outcomes using individuals with behavioral health conditions, but without substance use disorder. As mentioned above, there may be limitations associated with such comparison groups, and we have proposed alternative modeling strategies (e.g. regression discontinuity and segmented regression analysis) to be used in such cases. An additional requirement of the DD approach is ensuring there are no significant differences in trends between the intervention and comparison group prior to policy implementation. As mentioned above, we will test for such differential pre-trends and adjust our estimate accordingly if necessary.

There are further limitations related to the use of the difference-in-difference framework for evaluating the impact of lifting the IMD exclusion. The proposed comparison group of elderly adults age 65-75 is more likely than the younger Medicaid beneficiaries in our intervention population to be Medicaid-Medicare dual eligibles. This requires consideration of the completeness of utilization reporting in the Medicaid claims data for services where Medicare is the primary payer. An undercount of utilization for dual eligibles could only impact our difference-in-differences estimates if there was a reporting/policy change between the pre- and post-periods. Similarly, dual eligibles could be exclusively subject to other concurrent policy changes that will need to be accounted for when utilizing them as a comparison group. This latter consideration is often relevant to many comparison groups and we will examine and account for any policy changes that may differentially impact the comparison group. Additionally, there may be sample size limitations posed by use of an age-restricted intervention group. If prevalence of OUD/SUD in the 55-64 age group is too low, we will expand the treatment group age inclusion criterion iteratively to 45-64 and 35-64 carry out a difference-in-difference model. While this may increase the variation in age across treatment and comparison groups, our controlling for age and comorbid conditions will largely account for such differences. Also, certain outcomes, such as use of critical levels of care for OUD/SUD, may lack sufficient sample if utilization of services is too low in this age group. For most outcomes, assuming sufficient prevalence of OUD-SUD among 55-64 year olds, low utilization of IMDs will not limit our findings since access to, not use, of IMDs is the relevant policy change that we are examining, and this access is experienced by all members of the population ages 55-64 due to the Demonstration. Further we expect that differential access any time over the study period will impact the rates of different outcomes of interest that are not infrequent, such as ED visits. Nevertheless, triangulating DD results with those from alternative specifications such as regression discontinuity and segmented-regression analysis, which makes use of the full intervention population age 21-64 and avoids the comparison group limitations mentioned above, will be very important for evaluating this policy change.

Sometimes outcome data relating to a pre-policy baseline period are not available if reported data is collected only after policy implementation. Our examination of the impact of this initiative on overdose deaths relies on data collected by the State and will depend on the timeliness, quality, and frequency of that data reporting, as well as whether it is available by age. If no pre-policy data are available, we will assess time trends in the post-policy period and assess changes in outcomes over time.

As noted for the cost analysis, identification of the population of Medicaid recipients with OUD/SUD is dependent on service utilization. We are limited by service utilization appearing in our claims database, which does not include utilization occurring at non-Medicaid providers. This could lead to under-identification of Medicaid recipients with OUD/SUD, particularly in the pre-policy period before certain services became available under the demonstration. We have proposed sensitivity tests to assess the impact this has on our findings. Also, some OUD/SUD treatment costs may be absent from our claims database, and the amounts may vary over time due to cost shifting. We will consider how this, and all such limitations, may impact our conclusions about the causal impact of the demonstration policies.

Timelines and Deliverables

An interim and summative evaluation report for New Jersey's OUD/SUD program will be prepared as standalone reports, distinct from the evaluation reports for the other components of the Waiver. These reports will follow the preparation instructions described in Attachment L of the STCs.

Demonstration Period: 10/31/17 to 6/30/2022

Project Period: 1/1/2019-12/31/2023

Stakeholder Report

OUD/SUD Program Stakeholders Interview: 7/30/2022

Interim and Final Evaluation Reports

Draft Interim Evaluation Report: 6/30/2021

Draft Final Evaluation Report: 9/30/2023

Finals reports due 60 days after receiving CMS comments on Draft Evaluation.

Allocations of effort over the study period are reflected in the Budget, which is Attachment B to this evaluation plan.

Attachments

Attachment A – Draft Interview Guide

Attachment B - Budget

Attachment C – About Rutgers Center for State Health Policy

Conflict of interest declarations from all personnel are required by Rutgers University as part of the project initiation process. If requested, copies of these declarations may be submitted to DMAHS prior to project initiation.

ATTACHMENT A

INTERVIEW QUESTIONS for OUD/SUD Initiative

Evaluation of the NJ FamilyCare Comprehensive Waiver Demonstration

NOTE: Individuals interviewed will be stakeholders involved in the administration and implementation of the OUD/SUD initiative or professionals working with populations impacted by the OUD/SUD initiative. Informed consent will be administered prior to interview.

Thank you for agreeing to talk with us about the OUD/SUD initiative. We are talking with a variety of stakeholders about this initiative in order to provide information for our evaluation of the behavioral health reforms related to care and treatment of OUD/SUD for Medicaid beneficiaries under the Medicaid Comprehensive Waiver. We would like to ask you about the successes and challenges of this program. If you do not know the information or would prefer not to answer a question, feel free to let us know.

- 1. What improvements in access to guideline-adherent care for OUD/SUD, if any, occurred due to the OUD/SUD initiative?
- 2. What has been the experience of getting individuals who are identified as having OUD/SUD into the right level of care?
- 3. How is care coordinated for people in the OUD/SUD program?
- 4. What have been the challenges and benefits of establishing peer support services?
- 5. How has the availability of OUD/SUD services impacted treatment success?
- 6. What are the key interventions for averting deaths due to overdose and how well have these been addressed in the OUD/SUD program?
- 7. How well have beneficiaries' needs for treatment been met within the OUD/SUD program?
- 8. What has been the impact of case management on access to care for physical health among those with OUD/SUD?
- 9. What are your observations about the performance of the Interim Managing Entity under the OUD/SUD initiative?
- 10. Have there been any unanticipated negative consequences of the OUD/SUD initiative?
- 11. Thank you for your time. We would like to interview a broad spectrum of individuals or organizations that were involved in the planning and implementation of the OUD/SUD initiative. Who do you think we should consider interviewing?

ATTACHMENT B: BUDGET FOR OUD/SUD EVALUATION

RUTGERS, THE STATE UNIVERSITY INSTITUTE FOR HEALTH, HEALTH CARE POLICY & AGING RESEARCH CENTER FOR STATE HEALTH POLICY

Project Title: Medicaid Waiver Evaluation Principal Investigator: Sujoy Chakravarty Sponsor: State of New Jersey - Department of Human Services Project Dates: 01/01/2019 - 12/31/2023

	% salary	Period 1 01/01/19 06/30/19		Period 2 07/01/19 06/30/20		Period 3 07/01/20 06/30/21		Period 4 07/01/21 06/30/22		Period 5 07/01/22 06/30/23		Period 6 07/01/23 12/31/23	Cumulative 01/01/19 12/31/23
Personnel:													
PI: Chakravarty, Sujoy - Asst Research Professor CY (A)	5.0%	2,836	5.0%	5,933	5.0%	6,041	5.0%	6,246	5.0%	6,433	5.0%	3,301	30,790
Lloyd, Kristen - Research Analyst Spvr CY (A)	20.0%	8,924	20.0%	18,669	20.0%	19,009	20.0%	19,654	20.0%	20,244	20.0%	10,386	96,886
Nova, Jose - Research Analyst CY (A)	5.0%	2,317	5.0%	4,847	5.0%	4,935	5.0%	5,103	5.0%	5,256	5.0%	2,696	25,154
Farnham, Jennifer - Research Analyst CY (A)	10.0%	3,972	10.0%	8,309	10.0%	8,460	10.0%	8,747	10.0%	9,010		4,622	43,120
Lontok, Oliver - Research Analyst CY (A)	10.0%	4,035	10.0%	8,440	10.0%	8,594	10.0%	8,886	10.0%	9,152	10.0%	4,695	43,802
TBN - CY (A) Bram	0.0%	0	0.0%	0	5.0%	3,341	5.0%	3,455	5.0%	3,558	5.0%	1,825	12,179
Subtotal Personnel		22,084		46,198		50,380		52,091		53,653		27,525	251,931
Fringe Benefits:													
Fringe Benefits FY18 - 50.53% (A); 7.65% (B)		11,159		23,344	- •	25,457		26,322		27,111		13,907	127,300
Subtotal Personnel & Fringe Benefits		33,243		69,542		75,837		78,413		80,764		41,432	379,231
Travel:													
Project Travel - Meetings in Trenton <u>\$30</u> per trip X 2 people	8	240	8	240	8	240	8	240	8	240	8	240	1,440
Conference Travel		0		0		0		0		0		0	0
Subtotal Travel		240		240		240		240		240		240	1,440
Other Direct Costs:													
Net Data Core		0		12,376		11,732		10,508		9,390		4,196	48,202
Project Supplies - <u>\$25</u> /month	0	0	0	0	0	0	0	0	0	0	0	0	0
Computer Supplies (including software & licensing) - <u>\$30</u> /month	0	0	0	0	0	0	0	0	0	0	0	0	0
Duplicating - Copy & Print - <u>\$25</u> /month	6	150	12	300	12	300	12	300	12	300	6	150	1,500
Postage - <u>\$10</u> /month	0	0	0	0	0	0	0	0	0	0	0	0	0
Telecommunications - <u>\$23.50</u> /month	0	0	0	0	0	0	0	0	0	0	0	0	0
Transcription Services	0	0	0	0	0	0	0	0	0	0	- ⁰	0	0
Subtotal Other Direct Costs		150		12,676		12,032		10,808		9,690		4,346	49,702
Total Direct Costs		33,633		82,458		88,109		89,461		90,694		46,018	430,373
Indirect Costs:													
F&A - 10% TDC		3,363		8,246	- •	8,811		8,946		9,069		4,602	43,037
Total Costs		36,996		90,704	. .	96,920		98,407		99,763		50,620	473,410

PERSONNEL EXPENSES

Sujoy Chakravarty, Ph.D. will serve as Principal Investigator for the project. Dr. Chakravarty is an Assistant Research Professor at the Center. Dr. Chakravarty will have primary responsibility for ensuring that this work is completed in a timely fashion and within budget, conceptualizing and implementing the data analysis plan, providing statistical and methodological expertise, and directing the data analysis and reporting. He will provide **5% effort** averaged over the course of this project.

Kristen Lloyd, M.P.H. Senior Research Scientist, will act as Project Manager for this study. Following up on their collaboration on the first Medicaid Waiver evaluation, Ms. Lloyd will assist Dr. Chakravarty in developing and implementing the project protocol, perform data analysis, and provide ongoing tracking and monitoring of evaluation activities. She will also analyze findings and assist in report writing. Ms. Lloyd will provide **20% effort** over the course of this project.

Jose Nova, M.S. Assistant Director for Data Analysis, will manage the Medicaid claims database and perform specific data assembly and analysis tasks. He will provide **5% effort** over the project period.

Jennifer Farnham, M.S. Senior Research Analyst, will assist in conducting interviews to gather and analyze feedback on the OUD/SUD initiative. She will provide **10% effort** averaged over the course of this project.

Oliver Lontok, M.D., M.P.H., Senior Research Manager will manage all IRB requirements necessary for carrying out the project. He will also be responsible for assuring that all activities are in compliance with the agreements executed with the Division of Medical Assistance & Health Services. Dr. Lontok will contribute **10% effort** over the project period.

Bram Poquette, M.L.I.S., Editorial Media Specialist will provide assistance with information resources and publication support. He will contribute **3% effort** averaged over the project period.

Fringe Benefits

Fringe benefits for full-time faculty and staff are estimated to be charged at a rate of 50.53%. The total fringe benefits requested calculate to \$127,300 for this project.

Total Salary & Wages for the project with fringe benefits - \$379,231

NON-PERSONNEL EXPENSES

Office Operations:

We are requesting a total of \$48,202 to support technology, data, and equipment expenses. This line item includes the pro rata share of Institute-wide expenses related to computing equipment depreciation and maintenance contracts, software licenses, and other data-system related expenses. We are requesting \$1,500 for basic office operations, such as duplicating services/supplies that relate to this project.

Travel:

We are requesting support in the amount of \$1,440 for the project period. This is for several trips per year to meetings located in Trenton and Hamilton @ \$0.540 per mile for round trip plus parking expenses.

INDIRECT COSTS

Facilities and Administrative Costs:

Indirect costs are calculated as 10 percent of total direct costs (for this project, all costs listed above are included in the total direct cost base). We are requesting \$43,037 for this line item.

The total requested budget is \$473,410.

ATTACHMENT C

About the Rutgers Center for State Health Policy

The Rutgers Center for State Health Policy (CSHP) provides impartial policy analysis, research, training, facilitation, and consultation on important state health policy issues. The Center combines Rutgers University's traditional academic strengths in public health, health services research, and social science with applied research and policy analysis initiatives. The Center's signature areas of research include Access and Coverage, Health and Long-Term Care Workforce, Health System Performance Improvement, Long-Term Services and Supports, and Population Health.

Currently, CSHP houses data from the Medicaid Management Information System, which includes Medicaid/CHIP enrollment, claims, and managed care encounter records from 2011 to present. CSHP has been an analytic partner working with Medicaid, using these data to inform program and policy strategy and for evaluation of Medicaid initiatives such as the Comprehensive Waiver Demonstration (2012-2017) and ACO Demonstration programs.

Following is a summary of the qualifications of key faculty and staff at CSHP assigned to evaluation of the OUD/SUD Program:

Sujoy Chakravarty, Ph.D. Assistant Research Professor and Health Economist at the Rutgers Center for State Health Policy; Dr. Chakravarty led the evaluation of the 2012-2017 NJ Medicaid 1115 Comprehensive Waiver Demonstration that included analyses of the MLTSS and DSRIP programs among other reforms. Dr. Chakravarty has considerable expertise in Medicaid policies and their potential effects on healthcare services and outcomes and is an expert in policy evaluation design and analysis strategies. The waiver evaluation involved examining the effect of several simultaneous policy changes relating to eligibility, financing and population health management for specific waiver populations by analyzing Medicaid fee-for-service claims and managed care encounter data. He has published several papers and reports utilizing econometric techniques such as panel data estimation and difference-in-differences modelling to examine provider services, healthcare utilization, prescription coverage, and racial and ethnic disparities in access.

Kristen Lloyd, M.P.H Senior Research Scientist at the Rutgers Center for State Health Policy has been a research analyst at CSHP since 2009. Ms. Lloyd was project manager and lead analyst for the evaluation of the 2012-2017 NJ Medicaid 1115 Comprehensive Waiver Demonstration. She has training in epidemiology and statistics and extensive experience in the implementation of econometric techniques for policy evaluation using New Jersey's Medicaid claims and encounter database and complex survey data. She possesses high-level expertise in the areas of programming and statistical modeling.

Jennifer Farnham, M.S. Senior Research Analyst at the Rutgers Center for State Health Policy has been a research analyst at CSHP since 2005, where she has contributed to

ATTACHMENT C

About the Rutgers Center for State Health Policy

numerous health systems research projects. Her experience includes policy analysis, analysis of census and hospitalization data, survey research, interviewing, and program and policy evaluation. She played a key role in conducting of stakeholder interviews and qualitative analysis for the MLTSS and DSRIP programs during the evaluation of the 2012-2017 New Jersey's Comprehensive Medicaid waiver.

Jose Nova, M.S. Assistant Director of Data Management is an experienced analyst with in-depth knowledge of analysis of large datasets including NJ Medicaid and other administrative data as well as possesses high-level statistical expertise, including in the areas of programming and modeling. Nova serves as a senior analyst and maintains familiarity with the NJ Medicaid and other datasets, providing advanced and specialized data analyses on various Center projects.