
SMD # 15-003

July 27, 2015

**Re: New Service Delivery Opportunities for
Individuals with a Substance Use Disorder**

Dear State Medicaid Director:

The purpose of this letter is to inform states of opportunities to design service delivery systems for individuals with substance use disorder (SUD), including a new opportunity for demonstration projects approved under section 1115 of the Social Security Act (Act) to ensure that a continuum of care is available to individuals with SUD. There are numerous federal authorities offering states the flexibility to implement system reforms that improve care, enhance treatment and offer recovery supports for SUD. Many states have made significant progress in achieving better outcomes for individuals with SUD through traditional Medicaid authorities. In addition, the Centers for Medicare & Medicaid Services (CMS) recently introduced the Medicaid Innovation Accelerator Program (IAP) for SUD to support participating states in improving their SUD delivery system. However, a few states may also want to consider proposing a section 1115 demonstration project in this context to undertake or complement broader SUD delivery system transformation efforts.

Section 1115 demonstration projects allow states to test innovative policy and delivery approaches that promote the objectives of the Medicaid program. States may receive federal financial participation (FFP) for costs not otherwise matchable, such as services delivered to targeted populations, in limited geographic areas, or in settings that are not otherwise covered under the Medicaid program. CMS recognizes the statutory payment exclusions for services provided to individuals who reside in specific settings may challenge states' abilities to offer a full continuum of care and effectively treat individuals with SUDs.¹ CMS supports state efforts to reform systems of care for individuals with SUD, such as by enhancing the availability of short-term acute care and recovery supports for individuals with SUD, improving care delivery, integrating behavioral and physical care, increasing provider capacity and raising quality standards. As stated, CMS is offering a new opportunity for Medicaid demonstration projects authorized under section 1115 to test Medicaid coverage of a full SUD treatment service array in the context of overall SUD service delivery system transformation, provided participating states meet specific requirements outlined below. This letter details the new demonstration opportunity, outlines our expectations of a transformed SUD service delivery system and explains how to submit an application for such a demonstration project.

¹ Cf. paragraph (B) following section 1905(a)(29) of the Act.

Background

Medicaid is playing an increasingly important role as a payer for services provided to individuals with SUD in the United States. An estimated 12 percent of adult Medicaid beneficiaries ages 18-64 have an SUD.² In addition, an estimated 15 percent of uninsured individuals who could be newly eligible for Medicaid coverage in the New Adult Group have an SUD.³ CMS is committed to helping states effectively serve these individuals and introduce benefit, practice and payment reforms through the technical assistance and coverage initiatives described below.

States have compelling reasons to provide Medicaid coverage for the identification and treatment of SUD, many of which are given urgency by the national opioid epidemic. Untreated substance use disorders are associated with increased risks for a variety of mental and physical conditions that are costly. In 2009, health insurance payers spent \$24 billion to treat SUD, of which Medicaid accounted for 21 percent of expenditures.⁴ Two of the top ten reasons for Medicaid 30-day hospital readmissions are SUD-related.⁵ Individuals with SUD and co-morbid medical conditions account for high Medicaid costs, such that \$3.3 billion was expended in one year on behalf of 575,000 beneficiaries with SUD as a secondary diagnosis.⁶ Beyond health care risk, the economic costs associated with SUD are significant. States and the federal government spend billions every year on the collateral impact associated with SUD, including criminal justice, public assistance and lost productivity costs.⁷ Alarming, the rate of fatal drug overdose in the U.S. has quadrupled between 1999 and 2010.⁸ Drug overdose has become the leading cause of injury death, causing more deaths than traffic crashes.⁹ Other problems also relate to opioid prescribing including opioid exposed pregnancies, drugged driving, and increases in Hepatitis C and in some circumstances HIV from prescription opioid injection.

As states expand Medicaid coverage to millions of new beneficiaries that may have been previously uninsured, states are also expanding access to behavioral health services including

² Substance Abuse and Mental Health Services Administration. Behavioral Health Treatment Needs Assessment Toolkit for States [online]. 2013. Retrieved from: <http://store.samhsa.gov/shin/content/SMA13-4757/SMA13-4757.pdf>, p.10.

³ Busch, S, et al (2013). Characteristics of Adults with Substance Use Disorders Expected to be Eligible for Medicaid under the ACA. *Psychiatry Services*, 64(6).

⁴ Substance Abuse and Mental Health Services Administration. National Expenditures for Mental Health Services and Substance Abuse Treatment, 1986–2009. HHS Publication No. SMA-13-4740. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

⁵ Hines, A, et al. *Conditions With the Largest Number of Adult Hospital Readmissions by Payer, 2011*. Healthcare Cost and Utilization Project. Statistical Brief #172. Agency for Healthcare and Quality, 2014.

⁶ Bouchery, E, et al (2012). Medicaid Substance Abuse Treatment Spending: Findings Report. Retrieved from: <http://aspe.hhs.gov/daltcp/reports/2012/msaspend.shtml>.

⁷ Heroin addiction costs the US \$20 billion annually in crime, preventable medical costs and lost productivity. See University of Maryland, Baltimore County. *An Evaluation of Whether Medical Savings are Associated with Expanding Opioid Maintenance Therapy for Heroin Addiction in Baltimore City*. Center for Health Program Development and Management, 2007.

⁸ *Results from the 2010 National Survey on Drug Use and Health: Detailed Tables*. Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, September 2011, <http://www.samhsa.gov/data/nsduh/2k10NSDUH/tabs/LOTsect7pe.htm#TopOfPage>.

⁹ Centers for Disease Control and Prevention. Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. 2014. Retrieved from: <http://www.cdc.gov/injury/wisqars/fatal.html>.

covering these services in Alternative Benefit Plans as required by the Affordable Care Act. CMS has received a number of requests from states and stakeholders interested in enhancing care for individuals with SUD. Many requests center on short-term acute treatment services, including detoxification, intensive outpatient programs, and residential treatment services. However, there are other important service modalities and approaches vital to effectively treating SUD that we encourage states to provide, including screening and intervention services in a broad range of settings, integration with primary care, medication assisted treatment and recovery supports services such as peer recovery supports and recovery coaches. Providing these services will help achieve better health outcomes among individuals with SUD, helping them to lead healthier and longer lives.

Many states have already achieved notable success in improved care and lower costs for SUD services through benefit, practice and payment reform. For instance:

- Massachusetts found that monthly Medicaid expenditures were significantly less for beneficiaries receiving SUD treatment compared to diagnosed but untreated beneficiaries. Treatment included ambulatory detoxification and medication-assisted treatment services.¹⁰
- Washington found that Screening, Brief Intervention and Referral to Treatment (SBIRT) services significantly reduced healthcare costs among Medicaid beneficiaries, resulting in savings of \$250 per member per month associated with inpatient hospitalization from emergency department admissions.¹¹
- In addition, Washington tackled SUD and emergency department (ED) usage by adopting seven best practices. As a result, ED visits decreased by 9.9 percent; the number of people with frequent ED use dropped by 10.7 percent; and the number of visits resulting in narcotic prescription dropped by 24 percent. The state attributed savings of about \$34 million.¹²
- For individuals in managed care with alcohol dependence, total healthcare costs were 30 percent less for individuals receiving medication-assisted treatment than for individuals not receiving medication-assisted treatment.¹³
- Medical costs for Medicaid patients in California decreased by one-third over three years following engagement in medication-assisted treatment. This includes reduced

¹⁰ Clark, R.E., et al (2011). The Evidence Doesn't Justify Steps by State Medicaid Programs to Restrict Opioid Addiction Treatment with Buprenorphine. *Health Affairs*, 30(9), 1425-1433.

¹¹ Estee, S et al. *Medicaid Cost Outcomes*. Department of Social and Health Services, Research and Data Analysis Division. Olympia, Washington, 2006.

¹² Washington State Health Care Authority, Report to the Legislature: Emergency Department Utilization: Update on Assumed Savings from Best Practices Implementation, March 20, 2014. Retrieved from: http://www.hca.wa.gov/documents_legislative/EmergencyDeptUtilization.pdf.

¹³ Baser, O., Chalk, M. Rawson, R. et al. (2001) Alcohol treatment dependence: comprehensive healthcare costs, utilization outcomes, and pharmacotherapy persistence. *The American Journal of Managed Care*, 178(8), S222-234.

expenditures in all types of health care settings, including hospitals, emergency departments and outpatient clinics.¹⁴

CMS supports states' important efforts to improve care for individuals with SUD. Over the past several years, CMS has provided states with information and technical assistance to enhance coverage for behavioral health conditions. In July 2014, CMS released a joint Informational Bulletin in partnership with the Centers for Disease Control and Prevention, the National Institute of Health and the Substance Abuse and Mental Health Services Administration (SAMHSA) describing best practices, state-based initiatives and useful resources to help ensure proper delivery of medication assisted treatment (MAT) for SUD.¹⁵ In January 2015, CMS released a joint Informational Bulletin in partnership with SAMHSA promoting behavioral health coverage opportunities for youth with SUD.¹⁶

While progress has been made, states report challenges in achieving better care for the SUD population. States cite a lack of data analytics to accurately identify prevalence and need in the Medicaid population, too few endorsed metrics for quality measurement, a lack of resources to collect and evaluate data, variation in provider qualifications, difficulties in integrating primary and substance use disorder care, and federal payment prohibitions as barriers to providing a comprehensive benefit package and delivery system.

To address these challenges, CMS recently launched the Medicaid Innovation Accelerator Program. The Innovation Accelerator Program supports state efforts to accelerate Medicaid innovations by offering technical assistance and expert resources to states engaged in Medicaid system redesign efforts. Based on our work with states and stakeholders, CMS identified SUD as the first area of focus for the Innovation Accelerator Program. As part of a strategy to improve the care and health outcomes and reduce costs for individuals with a SUD, CMS has begun engaging states to leverage IAP resources to introduce system reforms that better identify individuals with a SUD, expand coverage for effective SUD treatment, and enhance SUD practices to effectively treat beneficiaries.

Participation in the Innovation Accelerator Program is not a requirement for introducing SUD system reforms through the Medicaid authorities discussed in this letter. However, states participating in the Innovation Accelerator Program may request and receive technical assistance to identify and address the transformational activities set forth in this letter. For more information regarding Innovation Accelerator Program opportunities for substance use disorder, please visit <http://medicaid.gov/state-resource-center/innovation-accelerator-program/reducing-substance-use-disorders/reducing-substance-use-disorders.html>. Interested states should email MedicaidIAP@cms.hhs.gov. We encourage states to leverage the Innovation Accelerator Program's supports in areas where they currently do not meet the expectations for a transformed system as described below.

¹⁴ Walter, L. et al (2006). *Medicaid Chemical Dependency Patients in a Commercial Health Plan*, Robert Wood Johnson Foundation, Princeton, New Jersey, 2006.

¹⁵ <http://www.medicaid.gov/federal-policy-guidance/downloads/cib-07-11-2014.pdf>

¹⁶ <http://medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf>

Goals for the Section 1115 Demonstration Initiative

To complement the work to date, CMS is proposing an opportunity to allow states embarking on broad and deep system transformations in the area of SUD to pursue 1115 demonstrations to improve the care and outcomes for individuals with SUD. This new initiative would be available to states that are developing comprehensive strategies to ensure a full continuum of services, focusing greater attention to integration efforts with primary care and mental health treatment, and working to deliver services that are considered promising practices or have fidelity to evidence-based models consistent with industry standards. In addition, we seek to support states that are interested in developing new payment mechanisms and performance quality initiatives. As states take the necessary steps to design and implement major transformations to systems of care for individuals with SUD, this section 1115 demonstration initiative can support these efforts by addressing some of the barriers to providing effective care to individuals. Below, CMS sets forth the goals and expectations pursuant to this new section 1115 demonstration opportunity.

The aim of this initiative is to enable states that are pursuing significant delivery system transformation efforts in the area of SUD to better identify individuals with an SUD in the Medicaid population, increase access to care for these individuals, increase provider capacity, to deliver effective treatments for SUD, and use quality metrics to evaluate the success of these interventions. The specific goals of the initiative are to:

- Promote strategies to identify individuals with substance use issues or disorders.
- Enhance clinical practices and promote clinical guidelines and decision-making tools for serving youth and adults with SUD.
- Build aftercare and recovery support services, such as recovery coaching.
- Coordinate SUD treatment with primary care and long-term care.
- Coordinate with other sources of local, state and federal funds for an efficient use of resources consistent with program objectives.
- Encourage increased use of quality and outcome measures to inform benefit design and payment models.
- Identify strategies to address prescription and illicit opioid addiction, consistent with national efforts to curb this epidemic.

Reforms

CMS expects that states interested in pursuing a section 1115 demonstration in this area will promote both systemic and practice reforms in their efforts to develop a continuum of care that effectively treats the physical, behavioral and mental dimensions of SUD. Examples of systemic changes include:

- Promoting a definition of substance use disorders as a primary, chronic disease requiring long-term treatment to achieve recovery with relapse potential.
- Aligning Medicaid benefit packages, provider requirements, reimbursement, utilization review processes, medical necessity criteria, and quality indicators with Medicare and commercial plans.

- Introducing a comprehensive continuum of care based on industry standard patient placement criteria, including withdrawal management, short-term residential treatment, intensive outpatient treatment, medication assisted treatment and aftercare supports for long-term recovery such as transportation, employment, housing, and community and peer support services.
- Adding coverage of evidence-based and promising practices shown to effectively treat youth and adults for SUD that are not available through traditional Medicaid 1905(a) authority.
- Partnering with drug courts and juvenile justice systems to ensure referrals to SUD treatment are medically appropriate and effectively managed.
- Proposing payment models to support the goals of this project, such as shared savings, and managed care.¹⁷
- Collecting and reporting data to internal and external evaluators, including CMS, to assess the impact of the proposed changes.

Examples of practice changes include:

- Enhancing strategies for primary care and specialty practitioners to better identify and treat individuals with SUD in primary care through Screening, Brief Intervention and Referral to Treatment (SBIRT).
- Developing effective care coordination models to link individuals identified with SUD to appropriate providers.
- Improving efforts to enhance coordination models between SUD providers, primary care-including FQHC's, corrections systems, schools and long-term services and supports.
- Enhancing provider competencies to deliver SUD services with fidelity to industry standard models, such as the American Society for Addiction Medicine (ASAM) Criteria.
- Ensuring accreditation for residential and other SUD providers.
- Improving care transitions when individuals receive a course of treatment with various levels of care from different providers.
- Developing networks to provide long-term recovery services and supports to individuals with SUD following acute treatment regimens.
- Enhancing provider, plan, county and state capacity to secure, maintain, and utilize 42 CFR Part 2 compliant consent to disclose and/or re-disclose records on substance abuse treatment for the purposes of care coordination, population health management, research and evaluation.
- Increasing provider adoption of Office of the National Coordinator-certified health information technology products, allowing for interoperable health information exchange.

Introducing a comprehensive continuum of care will require states to ensure access to inpatient and short-term residential levels of care to provide SUD treatment and support recovery. CMS

¹⁷ <http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/SMD-13-005.pdf>

recognizes that in some instances these levels of care are offered in facilities defined as institutions for mental diseases (IMD) at 42 CFR 435.1010. While services provided to individuals residing in IMDs are excluded as medical assistance under a state plan, states can request authority for federal financial participation (FFP) for these expenditures if their proposal for a section 1115 demonstration project meets the programmatic expectations described below.

Expectations for a Transformed System

In addition to the standard requirements for an 1115 demonstration, states submitting proposals through this initiative must meet and will be subject to program requirements specific to SUD that will be incorporated into the Standard Terms and Conditions (STCs) of the waiver. These SUD-specific program requirements will reflect the following expectations, which we believe are hallmarks of a transformed system of care for individuals with SUD. The expectations to be incorporated into a state's state plan, Alternative Benefit Plan (ABP), 1915 waivers, or 1115 demonstration proposal and resulting STCs include:

Comprehensive Evidence-based Benefit Design

States will be asked to develop a substance use disorder benefit that guarantees a full continuum of evidence-based best practices designed to address the immediate and long-term physical, mental and SUD care needs of the individual. This includes better use of evidence based practices in the SUD field, including SBIRT, withdrawal management, MAT, care coordination, and long-term recovery supports and services. This can include short-term institutional services, including short-term inpatient and short-term residential SUD services for individuals in IMDs which supplement and coordinate with, but do not supplant, community-based services and supports.

Appropriate Standards of Care

States will be asked to use established standards of care in their design of the SUD benefit package, incorporating industry-standard benchmarks for defining medical necessity criteria, covered services and provider qualifications. For example, the ASAM Criteria is a nationally accepted set of treatment criteria for SUD care. States should use the ASAM Criteria as they develop a residential or inpatient SUD service continuum, and are encouraged to adopt the ASAM Criteria for other treatment modalities and levels of care as well.

In order to receive approval for a section 1115 demonstration under this opportunity, states must implement a process to assess and demonstrate that residential providers meet ASAM Criteria prior to participating in the Medicaid program under the demonstration and rendering services to beneficiaries. In addition, the assessment for all SUD services, level of care and length of stay recommendations must be performed by an independent third party that has the necessary competencies to use ASAM Patient Placement Criteria. Specifically, an entity other than the rendering provider will use the ASAM Criteria to perform a multidimensional assessment of beneficiaries, place beneficiaries at appropriate levels of care, and make recommendations for length of service.

States seeking to transform their SUD systems are encouraged to develop additional strategies adopted by health systems to ensure quality and consistent practices. One of the paths toward

this goal may be accreditation of their providers. Currently, some SUD providers are accredited by national organizations (e.g. the Joint Commission and the Commission on Accreditation of Rehabilitation Facilities).

Strong Network Development Plan

States will be asked to develop a network development and resource plan to ensure there is a sufficient network of knowledgeable providers in each of the levels of care recognized by ASAM and recovery support services. In addition, the state should have the resources to ensure that providers have the ability to deliver services consistent with the ASAM Criteria and provide evidence based SUD practices. The network should be sufficiently robust so that access can be assured in the event that some providers stop participating in Medicaid, are suspended or terminated.

Care Coordination Design

Coordination of care design is integral to SUD delivery reform. This entails developing processes to ensure seamless transitions and information sharing between levels and settings of care (withdrawal management, short-term inpatient, short-term residential, partial hospitalization, outpatient, post-discharge, recovery services and supports), as well as a collaboration between types of health care (primary, mental health , pharmacological, and long-term supports and services). CMS encourages states to test how to best achieve care transitions across the care continuum, including aftercare and recovery support services CMS encourages states to support electronic health information exchange, including the use of ONC-certified health IT products, to improve care coordination consistent with federal health privacy (HIPAA) and confidentiality (42 CFR Part 2) requirements.

Integration of Physical Health and SUD

State should have a clear approach for coordinating physical health and behavioral health services which could include the use of:

- Section 2703 health homes
- Integrated care models
- Accountable care organizations
- Primary care medical homes

States must specify a timeframe for integrating physical and behavioral health care for the population of individuals with SUD or a subpopulation, including committing to an approach within twelve months after 1115 SUD demonstration approval, producing a concept design within eighteen months after demonstration approval, and implementing within two years after demonstration approval.

Program Integrity Safeguards

As states strengthen their SUD benefit package, expand their Medicaid eligibility criteria and receive enhanced FMAP levels for expansion populations, the Medicaid program faces greater levels of risk of fraud and abuse. To be effective stewards of taxpayers' dollars, CMS and states must ensure there are rigorous program integrity protocols in place to safeguard against fraudulent billing. At a minimum, this should include conducting risk-based screening of all newly enrolling providers, as well as revalidating existing providers (including ordering and

referring practitioners) pursuant to provider screening rules at 42 CFR Part 455 Subpart E and accompanying guidance, ensuring SUD providers have entered into Medicaid provider agreements pursuant to 42 CFR 431.107, and ensuring that there is a process the state has put into place to address billing and other compliance issues.

Benefit Management

The provision of more clinically intensive services (including short-term inpatient and short-term residential treatment) must be managed with regular utilization review processes to ensure that these services are medically necessary. For example, these can include prior authorization, targeted post-payment claims review and billing system edits to deny claims beyond a time span, among others. States are encouraged to use capitated and managed fee-for-service approaches for their benefit management strategy. States that propose to introduce financial or treatment limitations must demonstrate compliance with the Mental Health Parity and Addiction Equity Act (MHPAEA).

Community Integration

In January 2014, CMS issued regulations regarding our Home and Community Based Services programs.¹⁸ Those regulations set forth requirements regarding person-centered planning and the characteristics of home and community based settings. States should include how they will incorporate these requirements in their service planning and service delivery efforts, including adherence to the settings requirements, where applicable.

Strategies to Address Prescription Drug Abuse

The Centers for Disease Control and Prevention has classified prescription drug abuse as an epidemic. In 2011 the Administration published its Prescription Drug Abuse Prevention Plan, which outlined four pillars, education, monitoring, safe storage and disposal, and enforcement.¹⁹ These were geared towards preventing non-medical prescription drug use and the consequences of the opioid epidemic and augmented the interagency efforts outlined in the National Drug Control Strategy concerning supply and demand reduction and consequence prevention. While there has been a marked decrease in the use of some illegal drugs like cocaine, data from the National Survey on Drug Use and Health show that nearly one-third of people aged 12 and over whom used drugs for the first time in 2009 began by using a prescription drug non-medically.²⁰ From 1999 to 2013, the rate for drug poisoning deaths involving opioid analgesics nearly quadrupled.²¹

¹⁸ Centers for Medicaid and CHIP Services. *Final Rule – CMS 2249-F – 1915(i) State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, Setting Requirements for Community First Choice, and CMS 2296-F 1915(c) Home and Community-Based Services Waivers*. [2014]. Retrieved from: <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-01-10-14.pdf>.

¹⁹ Office of National Drug Control Policy. *Epidemic: Responding to America's Prescription Drug Abuse Crisis*. [2011]. Retrieved from: https://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf.

²⁰ National Survey on Drug Use and Health. Retrieved From: <http://www.samhsa.gov/data/population-data-nsduh>

²¹ Centers for Disease Control and Prevention. *QuickStats: Rates of Deaths from Drug Poisoning and Drug Poisoning Involving Opioid Analgesics — United States, 1999–2013*. MMWR Weekly. Retrieved from: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a10.htm>.

There are a variety of strategies that states and payers have put into place to address prescription drug abuse. These include issuing prescribing guidelines, introducing claims edits for equivalent opioid and concomitant benzodiazepine prescriptions, utilizing Prescription Drug Monitoring Programs (PDMPs), and supporting Electronic Prescribing of Controlled Substances (EPCS). CMS encourages states to promote and improve the use of PDMPs and to encourage adoption of EPCS. We are requesting that states develop and implement proven strategies to address prescription drug abuse at the state, plan, patient, pharmacy and provider level.

Strategies to Address Opioid Use Disorder

The abuse of and addiction to opioids is a serious and challenging public health problem. While the rate for drug-poisoning death involving opioid analgesics has leveled in the most recent years, the rate for deaths involving heroin nearly tripled between 2010 and 2013.²²

On March 26, 2015, the U.S. Department of Health and Human Services announced a targeted initiative to decrease opioid overdoses, decrease overall overdose mortality, and decrease the prevalence of opioid use disorder. The Secretary's initiative targets three priority areas to combat opioid abuse:

- Opioid prescribing practices to reduce opioid use disorders and overdose
- Expanded use and distribution of naloxone
- Expansion of MAT to reduce opioid use disorders and overdose.

These three interventions align with the goal of this 1115 demonstration opportunity and reflect the expectations of a transformed system of care for individuals with SUD outlined in this letter. As described above, states should develop and issue opioid prescribing guidelines in concert with other interventions to address prescription drug abuse. States should expand the coverage of and access to naloxone in Medicaid, and should work in partnership with relevant social services and law enforcement agencies to design and deploy naloxone distribution strategies. States should also consider developing a robust benefit package and enhance clinical practices for MAT and other services to treat opioid addiction.

Services for Adolescents and Youth with an SUD

States will ensure that benefits are covered, services are available and access is timely for the youth and adolescent population with SUD. Pursuant to the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit, states are required to provide all 1905(a) coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid beneficiaries under the age of 21. Please visit <http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-01-26-2015.pdf> for more information on Medicaid coverage for behavioral health services for youth with SUD.

²² Centers for Disease Control and Prevention. *Drug-poisoning Deaths Involving Heroin: United States, 2000-2013*. National Center for Health Statistics Data Brief #190 [2015]. Retrieved from: <http://www.cdc.gov/nchs/data/databriefs/db190.pdf>.

Reporting of Quality Measures

A critical component of evaluating the efforts that states undertake to transform care for individuals with SUD will rely on a state's ability to track quality measures. States will be required to report certain current quality measures as part of this demonstration project.

Specifically, states will be required to report the relevant quality measures from the Medicaid Adult and Children's Core Sets for individuals with SUD, including the Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (NQF #0004).²³ States submitting proposals under this opportunity will also be required to report the SUB-3 Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and the SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge (NQF #1664) measures. States are encouraged to use the Follow-up after Discharge from the Emergency Department for Mental Health or Alcohol or Other Drug Dependence (NQF #2605) measure in their evaluation design. States are also encouraged to include the Pharmacy Quality Alliance opioid performance measures in their design for evaluating efforts to reduce prescription opioid drug abuse.²⁴

CMS is interested in evaluating the effectiveness of the services delivered through this demonstration initiative in terms of health outcomes, health care costs and service utilization. To that end, we ask that states to assess the impact of providing SUD services on:

- Readmission rates to the same level of care or higher;
- Emergency department utilization; and
- Inpatient hospital utilization.

Proposals should also include a framework to evaluate successful care transitions to outpatient care, including hand-offs between levels of care within the SUD care continuum as well as linkages with primary care upon discharge. For example, states may consider adapting and modifying the Timely Transmission of Transition Record (NQF #0648) or Transition Record With Specified Elements Received by Discharged Patients (NQF #0647) measures for appropriate application to SUD services.

States may also propose other quality or process measures they currently use or may be asked to use measures that become available for this population. The data collected and reported by states participating in this demonstrative initiative will contribute to setting an initial baseline and establishing a national benchmark for these vital behavioral health services.

Collaboration With Single State Agency for Substance Abuse

Achieving the goals of this system transformation initiative will take the combined efforts of stakeholders across the health care system. The state Medicaid agency will need to apply for changes to the approved state plan or for demonstration projects to implement this initiative. In doing so, state Medicaid agencies should coordinate with the state's substance use disorder

²³ These measures can be found at <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/downloads/2015-adult-core-set.pdf> and <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/downloads/2015-child-core-set.pdf>.

²⁴ These measures can be found at http://pqaalliance.org/images/uploads/files/Memo_NewMeasures_Opioids_Final.pdf.

authority on the concept design for the system transformation. These authorities can provide valuable data sets, such as block grant encounter information, which may inform the concept design and may be integral to data analytics and evaluation strategies. As a condition for approval of any demonstration authority to implement this initiative, state Medicaid agencies are required to collaborate and coordinate funding with the state substance use disorder authority in their efforts to transform their SUD system. State Medicaid agencies should also work and partner with relevant local, state and federal social services agencies to ensure the overall welfare of beneficiaries is provided for so they are positioned to respond to treatment successfully.

Medicaid Authorities Including Section 1115 Demonstrations

Many traditional (non-demonstration) Medicaid authorities provide states the flexibilities necessary to implement desired coverage and delivery reforms. These include options for coverage under section 1905(a) of the Act and Alternative Benefit Plan authorities under section 1937 of the Act, health home programs with enhanced federal matching for the first 8 quarters under section 1945 of the Act, managed care options under sections 1915(b) and 1932 of the Act, and coverage of home and community-based services under sections 1915(c), (i) and (k) of the Act. States seeking to transform their SUD systems may consider these other authorities in lieu of or in addition to 1115 demonstration projects. Please visit <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/downloads/pathways-2-9-15.pdf> for more information on pursuing SUD system transformation efforts through these and other pathways.

Section 1115 demonstrations may be designed to provide more effective treatment of SUD by extending coverage for services in inpatient and/or residential settings that are within the definition of IMDs at 42 CFR 435.1010. To the extent that a demonstration initiative is consistent with the expectations for a transformed SUD treatment system, CMS would specifically allow FFP for costs not otherwise matchable to provide coverage for services furnished to individuals residing in IMDs for short-term acute SUD treatment. Short-term acute SUD treatment may occur in inpatient settings and/or residential settings.

Inpatient services are described by the ASAM Criteria as occurring in Level 4.0 settings, which are medically managed services. Inpatient services are provided, monitored and observed by licensed physician and nursing staff when the acute biomedical, emotional, behavioral and cognitive problems are so severe that they require inpatient treatment or primary medical and nursing care. For short-term inpatient treatment for individuals with SUD in settings that meet the definition of an IMD, stays have been proposed to be limited to fifteen (15) days.

Residential services are provided in in ASAM Level 3.1, 3.3, 3.5 and 3.7 settings, which are clinically managed and medically monitored services typically provided in freestanding, appropriately licensed facilities or residential treatment facilities without acute medical care capacity. For short-term residential SUD treatment in settings that meet the definition of an IMD, stays will be limited to an average length of stay of thirty (30) days.

CMS remains committed to the underlying rationale of ensuring integrated and community-based care provided in right settings, so such inpatient and residential care should supplement

and coordinate with community-based care and be clinically appropriate. CMS encourages states continue to maintain its current funding commitment and levels to a continuum of community services consistent with SAMHSA's maintenance of effort requirements for its Substance Abuse Prevention and Treatment Block Grant, regardless of increased federal contributions. This SUD initiative should not reduce or divert state spending on mental and substance use disorder service as a result of available federal funding for services in IMDs.

In addition to promoting the objectives of the Medicaid program and improving care for low-income individuals, section 1115 demonstrations must be budget neutral. This means that the proposed demonstration cannot cost the federal government more than it would absent the demonstration. CMS will work closely with states in their efforts to determine the feasibility of their budget neutrality model while they are developing their conceptual demonstration project design.

Submission Process for Section 1115 Demonstration Projects

States should follow the usual process for submitting 1115 demonstration projects proposals. CMS requests that the proposal address each of the expectations set forth in this guidance. Generally, states must provide at least the information listed below:

- A demonstration program description, and goals and objectives that will be implemented under the demonstration project.
- The description of the proposed health care delivery system and benefit coverage.
- An estimate of the expected increase or decrease in annual aggregate expenditures by population group impacted by the demonstration. If available, include historic data for these populations.
- An estimate of historic coverage and enrollment data (as appropriate), and estimated projections expected over the term of the demonstration, for each category of beneficiary whose health care coverage is impacted by the demonstration.
- Other demonstration program features that require flexibilities within the Medicaid and CHIP programs.
- The types of waivers and expenditure authorities that the State believes to be necessary to authorize the demonstration.
- The research hypothesis or hypotheses that are related to the demonstration's proposed changes, goals, and objectives, a plan for testing the hypotheses in the context of an evaluation, and, if a quantitative evaluation design is feasible, the identification of appropriate evaluation indicators.

Section 1115 demonstration applications may be submitted electronically to 1115DemoRequests@cms.hhs.gov or by mail to:

Eliot Fishman
Centers for Medicare & Medicaid Services
Center for Medicaid & CHIP Services
Mail Stop: S2-01-16
7500 Security Boulevard
Baltimore, MD 21244-1850

Public Input

The Affordable Care Act required the Secretary to set forth transparency and public notice procedures for experimental, pilot, and demonstration projects approved under section 1115 of the Social Security Act that increase the public availability of information about Medicaid and CHIP demonstration applications and approved demonstration projects and promote public input as states develop and the federal government reviews these demonstrations. CMS issued a final regulation on February 27, 2012, outlining the new regulatory requirements for initial section 1115 demonstration applications and extension requests, public notice procedures, and reporting and evaluation requirements. The rule can be found at <http://www.gpo.gov/fdsys/pkg/FR-2012-02-27/pdf/2012-4354.pdf>.

The high rates of alcohol and substance use disorder, mental health disorders, suicide and behavior-related chronic diseases in American Indian and Alaska Native (AI/AN) communities are well documented. AI/ANs are significantly more likely to report past-year alcohol and substance use disorders than any other race.²⁵ As required by the transparency regulations cited above, states with Indian tribes and Indian health providers must consult with the tribes and solicit advice from the Indian health providers to assure access to these services is available and meets the unique and cultural needs of AI/AN individuals. In addition, states must solicit advice from the Indian health providers in the state as required by 1902(a)(73) of the Social Security Act. We encourage states to work collaboratively with the Indian health providers in the state to assure inclusion of providers that have the expertise to address the unique cultural needs of AI/AN.

We hope this information will be helpful. Questions regarding this guidance may be directed to Mr. John O'Brien, Senior Policy Advisor, Disabled and Elderly Health Program Group (John.O'Brien3@cms.hhs.gov), or Mr. Eliot Fishman, Director, State Demonstrations Group (Eliot.Fishman@cms.hhs.gov). We look forward to continuing our work together.

Sincerely

/s/

Vikki Wachino
Director

cc:

National Association of Medicaid Directors

National Academy for State Health Policy

²⁵ Indian Health Service. *Behavioral Health*. [2015]. Retrieved from: http://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/factsheets/BehavioralHealth.pdf.

National Governors Association

American Public Human Services Association

Association of State and Territorial Health Officials

Council of State Governments