DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, MD 21244-1850

SMD # 17-003
RE: Strategies to Address the Opioid Epidemic

November 1, 2017

Dear State Medicaid Director:

The purpose of this letter is to announce a new direction in how the Centers for Medicare & Medicaid Services (CMS) would like to work with states on section 1115(a) demonstrations to improve access to and quality of treatment for Medicaid beneficiaries as part of a Department-wide effort to combat the ongoing opioid crisis. This revised policy will take the place of the initiative announced in the State Medicaid Directors' letter issued on July 27, 2015.

CMS is now offering a more flexible, streamlined approach to accelerate states' ability to respond to the national opioid crisis while enhancing states' monitoring and reporting of the impact of any changes implemented through these demonstrations. As the opioid crisis continues to raise alarm and highlight the need for better access to high quality, evidence-based treatment, CMS would like to partner with states to support ways to progressively improve outcomes for Medicaid beneficiaries struggling with addiction in the context of 5-year demonstrations. In addition to these efforts, CMS will ensure states take significant steps to prevent inappropriate prescribing of opioids for Medicaid beneficiaries.

The Administration's March 14, 2017, letter to the Governors, expressed interest in exploring "additional opportunities for states to provide a full continuum of care for people struggling with addiction" and in developing "a more streamlined approach for section 1115 substance abuse treatment demonstration opportunities." This letter also pointed out the need "to properly account for demographic and geographic considerations, as well as health system variables, which vary in degree from one state to the next" and offered to support state efforts "to advance the next wave of innovative solutions to Medicaid's challenges – solutions that focus on improving quality, accessibility, and outcomes in the most cost-effective manner."

In keeping with these objectives, the new initiative described in this letter is aimed at giving states flexibility to design demonstrations that improve access to high quality, clinically appropriate treatment for opioid use disorder (OUD) and other substance use disorders (SUDs) while incorporating metrics for demonstrating that outcomes for Medicaid beneficiaries are in fact improving under these demonstrations. Further, through this initiative, CMS offers states the opportunity to demonstrate how to implement best practices for improving OUD and other SUD treatment in ways that take into account the particular challenges raised by the opioid epidemic in each state. Participating states would also conduct rigorous evaluations of these

demonstrations, with CMS approval of the evaluation design. Information on states' progress and the outcomes of these demonstrations and evaluations will be made public in a timely and readily accessible manner on the Medicaid.gov website so that states can learn from these programs. This cycle of evaluation and reporting will be critical to informing our evolving response to the national opioid crisis.

Under the demonstration authority granted by section 1115 of the Social Security Act, CMS can waive certain federal requirements so that states can test new or existing ways to deliver and pay for health care services in Medicaid to the extent that the demonstration is likely to promote the objectives of the Medicaid program. Section 1115 demonstrations must be budget neutral, which means that the proposed demonstration cannot cost the federal government more than costs would be absent the demonstration.

Through this new section 1115 initiative, states will have an opportunity to receive federal financial participation (FFP) for the continuum of services to treat addiction to opioids or other substances, including services provided to Medicaid enrollees residing in residential treatment facilities. Ordinarily such residential treatment services are not eligible for federal Medicaid reimbursement due to the exclusion in the Medicaid statute of services provided to patients in institutions for mental diseases (IMDs). As part of this initiative, states should indicate how inpatient and residential care will supplement and coordinate with community-based care in a robust continuum of care in the state. CMS will closely monitor spending in these demonstrations on services in IMDs to accurately capture the costs and ensure adherence to budget neutrality requirements. CMS encourages states to maintain their current funding levels for a continuum of services, and this initiative should not reduce or divert state spending on mental health and addiction treatment services as a result of available federal funding for services in IMDs.

States should continue to adhere to existing regulations intended to ensure Medicaid beneficiaries are accessing high-quality treatment providers and to guard against fraudulent practices. Specifically, states must screen all newly enrolling providers and reevaluate existing providers pursuant to the rules in 42 CFR Part 455 Subparts B and E, ensure addiction treatment providers have entered into Medicaid provider agreements pursuant to 42 CFR 431.107, and establish rigorous program integrity protocols to safeguard against fraudulent billing and other compliance issues.

To further support this initiative, the Medicaid Innovation Accelerator Program (IAP) will continue to be available to states that would benefit from strategic design support related to improving their treatment delivery systems. The IAP provides states with access to national learning opportunities and technical expert resources, including strategic design support to states planning targeted addiction treatment delivery system reforms and developing 1115 proposals.

Background

Rates of drug overdose deaths have continued to increase rapidly over the past fifteen years, and the rise in prescription and illicit opioid abuse has been the primary driver of this increase. In 2015, the rate of drug overdose deaths was more than 2.5 times the rate in 1999 with deaths from heroin overdoses triple the rate in 2010, [1] and more recently, an influx of illicitly made fentanyl and fentanyl analogs has fueled a substantial increase in synthetic opioid overdose deaths.[2] Despite the fact that there are effective evidence-based treatments for OUD, only about one in five people who currently need treatment for this condition actually receive it.[3] Moreover, Medicaid beneficiaries tend to have higher rates of OUD than the general population, comprising about 25 percent of adults with OUD in 2015.[4] However, only about 32 percent of Medicaid beneficiaries with OUD received treatment in 2015.[5]

To improve access to OUD and other SUD treatment services for Medicaid beneficiaries, it is important to offer a variety of evidence-based services at different levels of intensity across a continuum of care since the type of treatment or level of care needed may be more or less effective depending on the individual beneficiary. Moreover, treatment needs of individual beneficiaries can greatly vary over time. States should demonstrate how they are implementing evidence-based treatment guidelines, such as those published by the American Society of Addiction Medicine (ASAM), including by covering critical levels of care including outpatient, intensive outpatient (IOP), medication assisted treatment (MAT), residential, inpatient, and medically supervised withdrawal management.

Medicaid beneficiaries who struggle with addiction to opioids or other substances have high rates of comorbid physical and mental health conditions, resulting in higher spending for general medical services.[6] Recent research has reaffirmed that most spending on individuals struggling with addiction is not on treatment for those conditions, but instead on co-morbid physical conditions.[7] Between 2010 and 2013, among adult Medicaid beneficiaries treated for a behavioral health disorder, 75 percent of spending for these individuals was for treatment of co-morbid conditions as opposed to their behavioral health condition. At least one state has found

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[1] Centers for Disease Control and Prevention (CDC), National Center for Health Statistics Data Brief*, Drug Overdose Deaths in the United States, 1999-2015* (Feb. 2017).
[2] Katz J, *Drug Deaths in America are Rising Faster than Ever,* The New York Times, June 5, 2017.
[3] Saloner B, Karthikeyan S, *National Changes in 12-Month Substance Abuse Treatment Utilization Among Individuals with 2 Opioid Use Disorders, 2004-2013*, JAMA (Oct. 13, 2015).
[4] Medicaid and CHIP Payment and Access Commission (MACPAC), *Report to Congress on Medicaid and CHIP, Chapter 2, Medicaid and the Opioid Epidemic* (June 2017).
[5] *Ibid*.
[6] Freeman E, McGuire CA, Thomas JW, Thayer DA, *Factors Affecting Costs in Medicaid Populations with Behavioral Health Disorders*, Med Care, 52: S60-66 (2014).
[7] Thorpe K, Jain S, Joski P, *Prevalence and Spending Associated with Patients Who have a Behavioral Health Disorder*, Health Affairs, 36 (1): 124-132 (2017).

significant reductions in medical costs among Medicaid beneficiaries who accessed addiction treatment compared to those who did not.[8]

Moreover, many people who receive acute care for withdrawal management do not become engaged in any form of treatment following discharge.[9] Among Medicaid beneficiaries struggling with addiction (in 2008), over two-thirds (67.7 percent) did not receive any follow-up services within 14 days following an inpatient stay or residential detoxification.[10] Common consequences of not engaging in treatment are rapid readmission to an intensive care facility and increased risk of overdose as an individual's acquired tolerance is lessened by withdrawal management therapies. Engaging in treatment for addiction within 14 days of discharge from withdrawal management has been shown to reduce readmission rates.[11]

In general, a lack of availability of treatment options is often cited as an important factor in the low rate at which individuals receive treatment. In a 2013 report to Congress, SAMHSA highlighted a widespread shortage of addiction treatment providers.[12] According to one recent study, 40 percent of counties in the U.S. do not have an addiction treatment facility that provides outpatient care and accepts Medicaid.[13] This lack of treatment capacity is most prevalent in rural counties in Southern and Midwestern states and in areas with a higher proportion of racial and ethnic minorities.[14]

In recognition of these findings, CMS seeks to work with states through demonstrations authorized under the section 1115 authority described in this letter to improve Medicaid beneficiaries' access to high quality, evidence-based treatment services for addiction to opioids or other substances, ranging from acute withdrawal management to on-going chronic care for these conditions in cost-effective treatment settings while also improving care coordination and care for comorbid physical and mental health conditions.

Goals and Milestones to be addressed in State Applications and Implementation Plans

As the March 2017 letter to the Governors highlighted, we are interested in working with states "to provide a full continuum of care for people struggling with addiction," and in hearing state-

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[8] Wickizer TM, Krupski A, Stark KD, Mancuso D, et al, *The Effect of Substance Abuse Treatment on Medicaid Expenditures among General Assistance Welfare Clients in Washington State*, Milbank Quarterly 84(3): 555-576 (2006).

[9] Mark, TL, Dilonardo, JD, Chalk, M, et al, *Trends in Inpatient Detoxification Services, 1992-1997*, Journal of Substance Abuse Treatment, 23(4):253-260 (2002).

[10] Reif S, Acevedo A, Garnick DW, et al, *Reducing Behavioral Health Inpatient Readmissions for People with Substance Use Disorders: Do Follow-Up Services Matter?*, Psych Services Advance On-line, April 18, 2017.

[11] Lee MT, Horgan CM, Garnick DW, et al, *A Performance Measure for Continuity of Care After Detoxification: Relationship with Outcomes*, Journal of Substance Abuse Treatment, 47 (2), 130-139 (2014).

[12] SAMHSA*, Report to Congress on the Nation's Substance Abuse and Mental Health Workforce Issues*, Vol. 24 (Jan, 2013).

[13] Cummings JR, Wen H, Ko M, et al, *Race/Ethnicity and Geographic Access to Medicaid Substance Use Disorder Treatment Facilities in the United States*, JAMA Psychiatry, 71(2): 190-196 (Feb 2014).

[14] *Ibid.*

proposed "solutions that focus on improving quality, accessibility, and outcomes in the most cost-effective manner." This initiative offers states the flexibility to design 1115 demonstrations aimed at making significant improvements over the course of a five-year period on the following 6 goals and 6 milestones specific to addiction to opioids or other substances:

Goals:

1. Increased rates of identification, initiation, and engagement in treatment;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services;
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
6. Improved access to care for physical health conditions among beneficiaries.

Milestones:

1. Access to critical levels of care for OUD and other SUDs;
2. Widespread use of evidence-based, SUD-specific patient placement criteria;
3. Use of nationally recognized, evidence-based SUD program standards to set residential treatment provider qualifications;
4. Sufficient provider capacity at each level of care;
5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD; and
6. Improved care coordination and transitions between levels of care.

Demonstration Application

States wishing to participate in this initiative can submit a demonstration application to CMS outlining the state's strategy for achieving the goals of this demonstration opportunity, including a commitment to meeting the six milestones that are critical steps for achieving these goals over the course of the demonstration. Given the magnitude of the opioid epidemic in the U.S. and the increased focus by the Administration to combat the crisis, CMS strongly encourages states to articulate in their demonstration application how their proposal will apply evidence-based programs to meet the needs of people struggling with addiction to opioids in their state.

States' applications should also describe the state's capacity for regular reporting on progress toward meeting these milestones as well as for collecting and reporting data on performance measures. In addition, states' applications should confirm their commitment to assuring the necessary resources will be available to effectively support a robust monitoring protocol and evaluation.

Implementation Plan

Participating states will also develop implementation plans describing the various timelines and activities the state will undertake to achieve the milestones listed above. States will have the option of submitting their implementation plan as part of their application or as a post-approval protocol. Either way, FFP for services provided in IMDs will be prospective only and contingent upon CMS approval of the state's implementation plan as a part of the application or in a post-approval protocol. If a state chooses to use a post-approval protocol, the timeframe for submitting the post-approval protocol will be specified in the Special Terms and Conditions (STCs) agreement between CMS and the state. Through this 1115 opportunity states may receive federal matching funds for Medicaid-coverable services provided to individuals residing in residential treatment facilities that are not ordinarily matchable because these facilities qualify as IMDs; however, this 1115 opportunity does not allow for room and board payments in those facilities unless they qualify as inpatient facilities under section 1905(a) of the Social Security Act.

CMS will work with states through these demonstrations to establish residential treatment provider qualifications that meet nationally recognized, SUD-specific, evidence-based program standards (Milestone #3). Implementation of these program standards is identified as a critical milestone that states will address as part of these demonstrations. While states are working toward implementing nationally recognized SUD-specific program standards as provider qualifications for residential treatment facilities, the STCs will specify the provider qualifications states will use in the interim for residential treatment facilities that qualify as IMDs but would receive FFP through these demonstrations. The STCs will also describe the states' processes for ensuring those qualifications are met. Offering states the flexibility to implement the nationally recognized SUD-specific standards for residential treatment providers as the demonstration progresses will promote the objectives of the Medicaid program by encouraging more states to work with CMS on meeting the milestones and goals of these demonstrations outlined above, thus expanding rapid access to these services while, ensuring adequate quality and safety standards and incentivizing improvements in quality over time.

As a state's demonstration progresses, the state will be expected to include, in its regular section 1115 demonstration monitoring reports, information on the state's progress toward meeting the milestones identified in Table 1 in accordance with the timeframes specified in the state's implementation plan and financial data to ensure compliance with budget neutrality requirements.

Monitoring Protocol for Performance Measures Aligned with Initiative Goals

Over the course of these demonstrations, states will also include, in their regular 1115 demonstration reports, information on milestones and performance measures representing key indicators of progress toward meeting the goals for this demonstration initiative. There will be a core set of measures that all states that elect to implement this demonstration model will report on, as well as additional measures specific to particular state demonstration parameters. CMS

has been working with a contractor to identify measures for these demonstrations (see examples in Table 2 below) and will seek additional input from states. Information about the specific measures and reporting being finalized by CMS with state input will be detailed in a monitoring protocol agreed upon by CMS and the state after approval of the demonstration.

CMS will also work with participating states to develop monitoring protocols that will identify reasonable degrees of improvement on each of the agreed upon performance measures as well as specifics regarding data collection, analytic methodology, and how the states will construct baselines for each data point and performance measure against which the state's progress will be measured. If a state has not previously collected data on any of the finalized performance measures agreed to, the first year of data collected for this demonstration may be used as a baseline. CMS will also work with the states to determine the frequency of reporting on each of these milestones and performance measures. This monitoring protocol, which will be a collaborative effort between CMS and the states, can be developed after approval of the demonstration, and a timeframe for finalizing the monitoring protocol will be included in the STCs. States will submit quarterly financial data which CMS will review regularly to assure states are in compliance with the budget neutrality requirements.

The data reported by the state will inform a mid-point assessment between years two and three of the demonstration during which CMS will evaluate whether states are making sufficient progress toward meeting the milestones and performance measure targets. In addition to its ongoing monitoring of budget neutrality compliance, CMS will also assess whether states are on track to meet the budget neutrality requirements as part of this mid-point assessment. States at risk of not meeting these targets will submit modifications to their implementation plans, which shall be subject to CMS approval. CMS may require states to provide corrective action plans if a state fails to meet the required annual triggers indicating that waiver spending is diverting from the expected trajectory under the budget neutrality requirements. In addition, FFP for services in IMDs may be withheld if states are not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in Table 1 and the required performance measures in the monitoring protocol agreed upon by the state and CMS. States must be in full compliance with the budget neutrality requirement at the end of the demonstration period or CMS will recover the difference. In addition, achievement of the milestones and performance measure targets will be taken into consideration by CMS if a state were to request an extension of their demonstration.

States will also be required to conduct independent and robust interim and final evaluations that will draw on the data collected for the milestones and performance measures, as well as other data and information needed to support the evaluation that will describe the effectiveness and impact of the demonstration using quantitative and qualitative outcomes. An evaluation design will be developed by the state, with technical assistance from CMS, to be finalized within nine months of the demonstration approval. The evaluation design will include detailed analytic plans, data development, collection, and reporting details and will be subject to CMS approval. States that fail to submit an acceptable and timely evaluation design as well as any required

monitoring, expenditure or other evaluation reporting, are subject to a $5 million deferral per item. The interim evaluation will be required one year before expiration of the demonstration or when the state submits a proposal to renew the demonstration. The final evaluations will be due eighteen months after the demonstration period ends.

Public Availability of Data on State Progress toward Meeting Milestones and Performance Measure Targets as well as Evaluation Reports

CMS will regularly post information on the Medicaid.gov website regarding the states' progress in meeting the agreed upon milestones and performance measure targets. In addition, states' regular 1115 reports, as well as their evaluation reports, will be posted, as required by section 1115 transparency rules.

Table 1: Milestones for 1115 Demonstrations Addressing Opioids and Other Substances

Milestones	Specifications and Proposed Timeframes
1. Access to Critical Levels of Care for OUD and other SUDs	1. Coverage of a) outpatient, b) intensive outpatient services, c) medication assisted treatment (medications as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state), d) intensive levels of care in residential and inpatient settings, and e) medically supervised withdrawal management Proposed Timeframe: Within 12 to 24 months of demonstration approval
2. Use of Evidence-based, SUD-specific Patient Placement Criteria	1. Implementation of requirement that providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools, e.g., the ASAM Criteria, or other patient placement assessment tools that reflect evidence-based clinical treatment guidelines Proposed Timeframe: Within 12 to 24 months of demonstration approval 2. Implementation of a utilization management approach such that a) beneficiaries have access to SUD services at the appropriate level of care, b) interventions are appropriate for the diagnosis and level of care, and c) there is an independent process for reviewing placement in residential treatment settings. Proposed Timeframe: Within 24 months of demonstration approval

Milestones	**Specifications and Proposed Timeframes**
3. Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities	1. Implementation of residential treatment provider qualifications in licensure requirements, policy manuals, managed care contracts, or other guidance. Qualification should meet program standards in the ASAM Criteria, or other nationally recognized, evidence-based SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings Proposed Timeframe: Within 12 to 24 months of demonstration approval 2. Implementation of state process for reviewing residential treatment providers to assure compliance with these standards Proposed Timeframe: Within 24 months of demonstration approval 3. Requirement that residential treatment facilities offer MAT on-site or facilitate access off-site Proposed Timeframe: Within 12 to 24 months of demonstration approval
4. Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD	1. Completion of assessment of the availability of providers enrolled in Medicaid and accepting new patients in the critical levels of care throughout the state (or at least in participating regions of the state) including those that offer MAT. Proposed Timeframe: Within 12 months of demonstration approval
5. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD	1. Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse Proposed Timeframe: Over the course of the demonstration 2. Expanded coverage of, and access to, naloxone for overdose reversal Proposed Timeframe: Over the course of the demonstration 3. Implementation of strategies to increase utilization and improve functionality, of prescription drug monitoring programs

Milestones	Specifications and Proposed Timeframes
	Proposed Timeframe: Over the course of the demonstration
6. Improved Care Coordination and Transitions between Levels of Care	1. Implementation of policies to ensure residential and inpatient facilities link beneficiaries, especially those with OUD, with community-based services and supports following stays in these facilities. Proposed Timeframe: Within 12 to 24 months of demonstration approval

Table 2: Demonstration Performance Measures

Demonstration/SUD Goals	Performance Measures
Increased Rates of Identification, Initiation and Engagement in Treatment	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (National Committee for Quality Assurance; NQF #0004)* #
Improved Adherence to Treatment	1. Continuity of Pharmacotherapy for OUD (RAND; NQF #3175) 2. Follow-up after Discharge from Emergency Department for Mental Health or Alcohol or Other Drug Dependence (National Committee for Quality Assurance; NQF #2605)*# 3. Percentage of beneficiaries with an SUD diagnosis including those with OUD who used the following services per month (multiple rates reported): • Outpatient; • Intensive outpatient services; • Medication assisted treatment for OUDs and alcohol; • Residential treatment (including average lengths of stay (LOS) in residential treatment aiming for a statewide average LOS of 30 days); and • Medically supervised withdrawal management
Reduction in Overdose Deaths Particularly Those Due to Opioids	1. Use of Opioids at High Dosage in Persons Without Cancer (Pharmacy Quality Alliance; NQF # 2940)*

Demonstration/SUD Goals	Performance Measures
	2. Number of overdose deaths/ 1,000 Medicaid beneficiaries/month and specifically overdose deaths due to any opioid 3. Number of overdose deaths, and specifically deaths due to overdose of any opioid, among Medicaid beneficiaries in the reporting year
Reduced Utilization of Emergency Department and Inpatient Hospital Settings	1. Emergency department visits for SUD-related diagnoses and specifically for OUD /1,000 member months[#] 2. Inpatient admissions for SUD and specifically OUD among Medicaid beneficiaries/1,000 member months[#] 3. Baseline and periodic updates on spending on beneficiaries in residential treatment and outpatient settings for SUD treatment and on inpatient and emergency room services for beneficiaries with SUD diagnoses including spending on physical health conditions commonly associated with SUDs
Fewer Readmissions to the Same or Higher Level of Care for	30 day readmission rate following hospitalization for an SUD-related diagnosis[#] and specifically for OUD
Improved Access to Care for Co-morbid Physical Health Conditions among Beneficiaries	Percentage of beneficiaries with an SUD diagnosis, and specifically those with OUD, who access physical health care.

* Denotes measures that are part of the Medicaid Adult Core Set of Measures.
[#] Denotes measures that states with preexisting SUD 1115 demonstrations are already required to report on.

CMS will publish a technical specifications manual for a small set of required "core measures" as well as optional measures from which states can choose. CMS will also provide technical assistance to states in the collection and reporting of measures required for the demonstration.

Submission Process for Section 1115 Demonstration Projects

States should follow the usual process for submitting 1115 demonstration proposals as outlined in the federal section 1115 demonstration project transparency regulations at 42 CFR 431.412

and 42 CFR 431.408. As explained in these regulations, states should submit an application that includes the following information:

- A comprehensive description of the demonstration, including the state's strategies for addressing the goals and milestones discussed above for this demonstration initiative (see request below);
- A comprehensive plan to address opioid abuse, including aggressive preventive measures and strategies to improve access to treatment and recovery support services for Medicaid beneficiaries and an assessment of how this demonstration will complement and not supplant state activities called for or supported by other federal authorities and funding streams;
- A description of the proposed health care delivery system, eligibility requirements, benefit coverage and cost sharing (premiums, copayments, and deductibles) required of individuals who will be impacted by the demonstration, to the extent such provisions would vary from the State's current program features and the requirements of the Social Security Act;
- A list of the waivers and expenditure authorities that the state believes to be necessary to authorize the demonstration;
- An estimate of annual aggregate expenditures by population group impacted by the demonstration, including development of baseline cost data for these populations. Specifically, CMS requests that states' fiscal analysis demonstrate how the proposed changes will be budget neutral, i.e., will not increase federal Medicaid spending. CMS will work closely with states to determine the feasibility of their budget neutrality models and suggest changes as necessary;
- Enrollment data including historical SUD coverage and projected coverage over the life of the demonstration, of each category of beneficiary whose health care coverage is impacted by the demonstration;
- Written documentation of the state's compliance with the public notice requirements at 42 CFR 431.408, with a report of the issues raised by the public during the comment period and how the state considered those comments when developing the final demonstration application submitted to CMS;
- The research hypotheses that are related to the demonstration's proposed changes, goals, and objectives, and a general plan for testing the hypotheses including, if feasible, the identification of appropriate evaluation indicators, and
- Implementation Plan (if being submitted at the time of application).

CMS requests that these Section 1115 demonstration proposals describe, in as much detail as possible the state's strategy for improving access to and quality of addiction treatment through the proposed demonstration and how the state's proposed demonstration will further the goals of the initiative described above. The application should include a description of the activities the state plans to undertake to address the milestones specified in Table 1, and to report on the milestone markers and performance measures. If it is not feasible to include in the application a detailed implementation plan specifying how and when the state proposes to meet the milestone

markers in Table 1, the state should propose a date by which an implementation plan will be submitted by the state, this date will be included in the STCs. As a reminder, FFP for services in IMDs will not be available through the demonstration until the implementation plan/protocol is approved by CMS, at which time FFP will be available only prospectively. In addition, the state should indicate what data sources and resources it proposes to use for reporting on performance measures. CMS will work with states to develop a detailed monitoring protocol for these data points and performance measures after the application is received from the state.

After states develop 1115 demonstration proposals that include the information listed above, states must follow the minimum 30-day public notice and comment procedures outlined in 42 CFR 431.408, to allow opportunity for public input on the application prior to submission to CMS. This includes consultation with Indian tribes and Indian health providers (to the extent there are Indian tribes and Indian health providers located within geographic boundaries of the state) to solicit advice from the Indian health providers on ensuring access for American Indian and Alaska Native (AI/AN) individuals to the services that are part of the demonstration and that these services meet the unique and cultural needs of AI/AN individuals.

CMS is available to provide technical assistance to states on how to meet federal transparency requirements as well as to preview states' draft 1115 proposals and public notice documentation to help ensure states successfully meet federal requirements.

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

Judith Cash
Acting Director
State Demonstrations Group
Centers for Medicare & Medicaid Services
Center for Medicaid & CHIP Services
Mail Stop: S2-26-12
7500 Security Boulevard
Baltimore, MD 21244-1850

As required by 42 CFR 431.416, when states submit section 1115 proposals to CMS we will send written notice within 15 days of receipt to the state on whether its application met all federal transparency requirements and is determined complete for purposes of initiating CMS' review and the federal 30-day public notice and comment process.

CMS hopes states will use this opportunity to improve addiction treatment for Medicaid beneficiaries. Questions regarding this guidance may be directed to Kirsten Beronio, Senior Behavioral Health Policy Advisor, Disabled and Elderly Health Programs Group, at Kirsten.Beronio@cms.hhs.gov. We look forward to continuing our work together on these important issues.

Sincerely,

/s/

Brian Neale
Director

cc:
National Association of Medicaid Directors

National Academy for State Health Policy

National Governors Association

American Public Human Services Association

Association of State and Territorial Health Officials

Council of State Governments

National Conference of State Legislatures

Academy Health

National Association of State Alcohol and Drug Abuse Directors