DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

NOV 0 5 2019

Melisa Byrd
Senior Deputy Director and State Medicaid Director
Department of Health Care Finance
One Judiciary Square 441 4th Street NW
Washington, DC 20001

Dear Ms. Byrd:

Under section 1115(a) of the Social Security Act ("the Act"), the Secretary of Health and Human Services ("Secretary") or the Centers for Medicare & Medicaid Services (CMS), operating under the Secretary's delegated authority, may authorize a state to conduct experimental, pilot, or demonstration projects that, in the judgment of the Secretary, are likely to assist in promoting the objectives of the Medicaid program, as discussed below. Congress enacted section 1115(a) of the Act to ensure that federal requirements did not "stand in the way of experimental projects designed to test out new ideas and ways of dealing with the problems of public welfare recipients."[1] As relevant here, the Secretary (1) may, under section 1115(a)(1), waive provisions in section 1902 of the Act; and/or (2) may, under section 1115(a)(2)(A), authorize federal financial participation (FFP) for state expenditures that would not qualify for FFP under section 1903 of the Act (i.e., provide "expenditure authority"). Section 1902 of the Act lists what elements the Medicaid state plan must include, such as provisions relating to eligibility, beneficiary protections, benefits, services, and premiums. Section 1903, "Payments to States," describes expenditures that may be "matched" with federal title XIX dollars, allowable sources of non-federal share, and managed care requirements.

For the reasons discussed below, CMS hereby approves the District of Columbia's ("the District") section 1115(a) demonstration titled, "Behavioral Health Transformation" (BHT) (Project Number: 11-W-00331/3). Approval of this demonstration will enable the District to receive FFP once CMS approves implementation plans for inpatient, residential and other services provided to otherwise-eligible Medicaid beneficiaries while residing in institutions for mental diseases (IMD) for diagnoses of substance use disorder (SUD), serious mental illness (SMI) and/or serious emotional disturbance (SED). The demonstration will also allow the District to provide community-based services designed to improve behavioral health care for individuals with SUD or SMI/SED.

This is the first combined SMI/SUD application submitted to CMS since the Secretary announced the SMI/SED opportunity via State Medicaid Directors Letter (SMDL) #18-011 on November 13, 2018.

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[1] See S. Rep. No. 87-1589, at 19 (1962), as reprinted in 1962 U.S.C.C.A.N. 1943, 1961.

Objectives of the Medicaid Program

Under section 1901 of the Act, the Medicaid program provides federal funding to participating states "[f]or the purpose of enabling each state, as far as practicable under the conditions in such state, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care."

As this statutory text makes clear, a basic objective of Medicaid is to enable states to "furnish . . . medical assistance" to certain vulnerable populations (i.e., payment for certain healthcare services defined at section 1905 of the Act, the services themselves, or both). By paying these costs, the Medicaid program helps vulnerable populations afford the medical care and services they need to attain and maintain health and well-being. In addition, the Medicaid program is supposed to enable states to furnish rehabilitation and other services to vulnerable populations to help them "attain or retain capability for independence or self-care," per section 1901 of the Act.

We are committed to supporting states that seek to test policies that are likely to improve beneficiary health because we believe that promoting independence and improving health outcomes is in the best interests of the beneficiary and advances the fundamental objectives of the Medicaid program. Healthier, more engaged beneficiaries also may consume fewer medical services and have a lower risk profile, making the program more efficient and potentially reducing the program's national average annual cost per beneficiary of $7590.[2] Policies designed to improve beneficiary health that lower program costs make it more practicable for states to make improvements and investments in their Medicaid program and ensure the program's sustainability so it is available to those who need it most. In so doing, these policies can promote the objectives of the Medicaid statute.

While CMS believes that states are in the best position to design solutions that address the unique needs of their Medicaid-eligible populations, the agency has an obligation to ensure that proposed demonstration projects are likely to better enable states to serve their low-income populations, through measures designed to improve health and wellness and help individuals and families attain or retain capability for independence or self-care. Medicaid programs are complex and shaped by a diverse set of interconnected policies and components, including eligibility standards, benefit designs, reimbursement and payment policies, information technology (IT) systems, and more. Therefore, in making this determination, CMS considers the proposed demonstration as a whole.

In its consideration of the District's proposal, CMS considered whether the demonstration was likely to assist in delivering high-quality, clinically appropriate treatment to beneficiaries diagnosed with SMI/SED and/or SUD and receiving treatment while they are short-term residents in settings that qualify as IMD. CMS has determined the BHT demonstration is likely to promote these Medicaid objectives, and the waiver and expenditure authorities sought are necessary and appropriate to carry out the demonstration. Specifically, the demonstration is

[2] U.S. Department of Health and Human Services 2017 Actuarial Report on the Financial Outlook for Medicaid.

expected to assist the District in increasing identification, initiation, and engagement of Medicaid beneficiaries diagnosed with SUD and SMI/SED; increase adherence to, and retention in, SUD and SMI/SED treatment; reduce overdose deaths, particularly those due to SUD; and reduce inappropriate or preventable utilization of emergency departments and inpatient hospital settings through improved access to a continuum of care services in additional settings that, absent this demonstration, would be ineligible for payment for most Medicaid enrollees.

Extent and Scope of the Demonstration

In addition to authorizing FFP for Medicaid state plan services provided to individuals residing in IMD settings, the BHT demonstration will also provide temporary 1115 authority for the following:

- Comprehensive Psychiatric Emergency Program
- Mobile Crisis Intervention and Outreach Services
- Psychiatric Residential Crisis Stabilization Services
- Recovery Support Services
- Psychosocial Rehabilitative Services
- Trauma-Informed Services
- Services of a Licensed Behavioral Health Professional
- Transition Planning Services
- Supported Employment Services

These temporary expenditure authorities will be granted for 24 months – and provided that the District adheres to the terms of the relevant special terms and conditions (STCs). CMS will work closely with the District to facilitate the state plan amendment (SPA) approval process to the greatest extent feasible for approval of these additional SPAs. Finally, CMS is also approving the state's request to eliminate the current one dollar ($1) copayment requirement for prescriptions associated with medication assisted treatment (MAT).

Elements of the Demonstration Request CMS is Not Approving at This Time

In the application, the District requested authority to provide supported housing services for beneficiaries. CMS is continuing its review of that request but is not approving it with the attached STCs. Likewise, the District's proposed Transition Planning Services for inmates of a correctional facility are also not being approved.

Consideration of Public Comments

The federal public comment period was open from June 11, 2019 to July 11, 2019 and CMS received 17 comments related to the demonstration application. The majority of comments were supportive, and only one commenter, during the federal public comment period, expressed concerns. In comment #455525, the commenter raised several concerns regarding the District's proposal including one that stated FFP for IMDs risks diverting resources away from community-based services and undermining community integration.

Nothing in this demonstration requires that services be provided to any individual in any particular setting, nor does it limit the availability of community-based settings. In fact, the

District is expanding its community-based services, such as supported employment, available under the demonstration and will be working to promote coordinated transitions to community-based services from inpatient and institutional care. Nonetheless, the District should ensure that inpatient and residential care will supplement and coordinate with community-based care. In addition, 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.

The District also will ensure that it maintains current spending on outpatient, community-based mental health services consistent with historical spending at the local level, as outlined in STC 36(e)(iii). The remaining comments were generally predicated upon a misapprehension about the nature and scope of CMS's 1115 authority.

Other Information

CMS's approval of this demonstration is subject to the limitations specified in the enclosed authorities and STCs, which define the nature, character, and extent of federal involvement in this project. The state may deviate from the Medicaid state plan requirements only to the extent they have been specifically listed as waived or not applicable to expenditures or individuals covered by expenditure authority.

This approval is also subject to your written acknowledgement of the award and acceptance of the STCs within 30 calendar days of the date of this letter. Please send written acceptance to your project officer, Mr. Jack Nocito. Mr. Nocito is available to answer any questions concerning your section 1115(a) demonstration and may be contacted as follows:

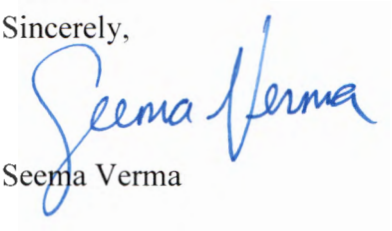
Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
Telephone: (410) 786-0199
E-mail: Jack.Nocito@cms.hhs.gov

Official communications regarding this demonstration should be simultaneously sent to Mr. Nocito and Mr. Francis McCullough, Director, Division of Medicaid Field Operations (DMFO) East, in our Regional Operations Group (ROG). Mr. McCullough's contact information is as follows:

Mr. Francis McCullough
Director, Division of Medicaid Field Operations East
Regional Operations Group
Centers for Medicare & Medicaid Services
Jacob K. Javits Federal Building
26 Federal Plaza, Room 3811
New York, NY 10278-0063
E-mail: francis.mccullough@cms.hhs.gov

If you have any questions regarding this approval, please contact Mrs. Judith Cash, Director, State Demonstrations Group, Centers for Medicaid & CHIP Services at (410) 786-9686.

Sincerely,



Seema Verma

Enclosures

CENTERS FOR MEDICARE & MEDICAID SERVICES

EXPENDITURE AUTHORITY

NUMBER: **11-W-00331/3**

TITLE: **BEHAVIORAL HEALTH TRANSFORMATION**

AWARDEE: **DISTRICT OF COLUMBIA**

Under the authority of section 1115(a)(2) of the Social Security Act ("the Act"), expenditures made by the District of Columbia ("the District") for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from January 1, 2020 through December 31, 2024, unless otherwise specified, be regarded as expenditures under the District's title XIX plan.

The Secretary of Health and Human Services has determined that the Behavioral Health Transformation demonstration, including the granting of the expenditure authorities described below, is likely to assist in promoting the objectives of title XIX of the Act.

The following expenditure authorities may only be implemented consistent with the approved Special Terms and Conditions (STCs) and shall enable the District to operate this section 1115(a) demonstration.

1. **Residential and Inpatient Treatment for Individuals with Substance Use Disorder and Serious Mental Illness.** Expenditures for Medicaid state plan services—furnished to eligible individuals who are primarily receiving short-term treatment and withdrawal management services for substance use disorder (SUD) and/or a serious mental illness (SMI) in facilities that meet the definition of an IMD.

2. **Temporary SMI/SED and/or SUD Non-State Plan Services.** Expenditures for additional SMI/(serious emotional disturbance (SED) and/or SUD services furnished during a stay in an IMD to eligible individuals who are primarily receiving treatment for the conditions described in Expenditure Authority #1 above. These services, which are not currently Medicaid state plan-approved, are authorized from January 1, 2020 through December 31, 2021 (see STC 66 for exclusions).

3. **Temporary SMI/SED and/or SUD Non-IMD Services.** Expenditures for additional SMI/SED and/or SUD or behavioral services furnished outside of an IMD setting to eligible individuals who are receiving treatment or who are assessed as needing treatment or recovery support services for the conditions described in Expenditure Authority #1 above and other behavioral health conditions as specified in STCs 20 through 35. These additional services, which are not currently Medicaid state plan-approved, are authorized from January 1, 2020 through December 31, 2021 (see STC 66 for exclusions).

CENTERS FOR MEDICARE & MEDICAID SERVICES

WAIVER AUTHORITY

NUMBER: **11-W-00331/3**

TITLE: **BEHAVIORAL HEALTH TRANSFORMATION**

AWARDEE: **DISTRICT OF COLUMBIA**

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived in this list, shall apply to the demonstration.

The following waivers shall enable the District to implement the approved STC for the Behavioral Health Transformation (BHT) section 1115(a) demonstration beginning January 1, 2020 and ending December 31, 2024.

1. Amount, Duration & Scope **Section 1902(a)(10)(B)**

To enable the District to exempt beneficiaries receiving SUD treatment under this demonstration from $1 pharmacy co-payments when they are also receiving prescriptions associated with medication assisted therapy (MAT).

2. Comparability **Section 1902(a)(10), Section 1902(a)(17)**

To allow the District to apply different pharmacy cost sharing requirements for individuals described in Expenditure Authority #1 above.

CENTERS FOR MEDICARE & MEDICAID SERVICES

SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00331/3

TITLE: BEHAVIORAL HEALTH TRANSFORMATION

AWARDEE: DISTRICT OF COLUMBIA

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the "Behavioral Health Transformation" section 1115(a) Medicaid demonstration (hereinafter "demonstration" or "BHT"), to enable the District of Columbia (hereinafter "the District") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted waivers of requirements under section 1902(a) of the Social Security Act ("the Act"), and expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those waivers and expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the District's obligations to CMS related to the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted.

The STCs related to the programs for those state plan populations affected by the demonstration are effective from January 1, 2020 through December 31, 2024 unless otherwise specified.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility and Enrollment
V. Demonstration Programs and Benefits
VI. Cost Sharing
VII. Delivery System
VIII. General Reporting Requirements
IX. Monitoring
X. Evaluation of the Demonstration
XI. General Financial Requirements Under Title XIX
XII. Monitoring Budget Neutrality for the Demonstration
XIII. Schedule of Deliverables for the Demonstration Extension Period

Additional attachments have been included to provide supplementary information and guidance for specific STCs.

Attachment A: Developing the Evaluation Design
Attachment B: Preparing the Interim and Summative Evaluation Reports
Attachment C: Reserved for SMI/SED Implementation Plan (includes Financing Plan)
Attachment D: Reserved for SUD Implementation Plan
Attachment E: Reserved for SMI/SED and SUD Monitoring Protocol(s)
Attachment F: Reserved for SMI/SED and SUD Evaluation Design(s)

II. PROGRAM DESCRIPTION AND OBJECTIVES

The goal of this demonstration is for the District to maintain and enhance access to mental health services, opioid use disorder (OUD), and other substance use disorder (SUD) services; and continue delivery system improvements to provide more coordinated and comprehensive treatment for Medicaid beneficiaries with serious mental illness (SMI), serious emotional disturbance (SED), and/or SUD (hereafter collectively "SMI/SED and/or SUD"). This demonstration authorizes the District to receive federal financial participation (FFP) for delivering high-quality, clinically appropriate treatment to beneficiaries diagnosed with SMI and/or SUD and receiving treatment while they are short-term residents in settings that qualify as Institutions for Mental Diseases (IMD). This demonstration also complements the District's efforts to implement models of care that are focused on increasing supports for individuals outside of institutions, in home and community-based settings (HCBS) to improve their access to SMI/SED and/or SUD services at varied levels of intensity, and to combat OUD and other SUDs among District residents.

During the demonstration period, the District seeks to achieve the following goals:

SMI/SED Goals:

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

SUD Goals:

1. Increased rates of identification, initiation, and engagement in treatment for SUD;
2. Increased adherence to and retention in treatment;

3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of hospital 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 with SUD.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The District must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).

2. **Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The District must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the District to submit an amendment to the demonstration under STC 7. CMS will notify the District 30 business days in advance of the expected approval date of the amended STCs to allow the District to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The District must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**

    a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the District must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the District may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.

b. If mandated changes in the federal law require District legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such District legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

5. **State Plan Amendments**. The District will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The District must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the District to submit required elements of a complete amendment request as described in this STC, and failure by the District to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

   a. An explanation of the public process used by the District, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the District in the final amendment request submitted to CMS;
   b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
   c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

d. An up-to-date CHIP allotment worksheet, if necessary;
e. The District must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. Extension of the Demonstration. States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the District in accordance with the requirements of 42 CFR§431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit a phase-out plan consistent with the requirements of STC 9.

9. Demonstration Phase-Out. The District may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

a. Notification of Suspension or Termination: The District must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The District must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the District must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the District must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the District must provide a summary of the issues raised by the public during the comment period and how the District considered the comments received when developing the revised transition and phase-out plan.
b. Transition and Phase-out Plan Requirements: The District must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the District will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the District will undertake to notify affected beneficiaries, including community resources that are available.
c. Transition and Phase-out Plan Approval. The District must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
d. Transition and Phase-out Procedures: The District must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210 and 431.213. In addition, the District must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the District must maintain benefits as required in 42 CFR 431.230. In addition, the District must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP

eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the District must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).

f. Enrollment Limitation during Demonstration Phase-Out. If the District elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the District's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers are suspended by the District, FFP must limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

10. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX or title XXI. CMS will promptly notify the District in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the District an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

11. Adequacy of Infrastructure. The District will ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

12. Public Notice, Tribal Consultation, and Consultation with Interested Parties. The District must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the District must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The District must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

The District must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the District's

approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the District.

13. **Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

14. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

15. **Common Rule Exemption.** The District must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

IV. ELIGIBILITY AND ENROLLMENT

16. **Eligibility Groups Affected by the Demonstration.** Under the demonstration, there is no change to Medicaid eligibility. Standards and methodologies for eligibility remain set forth under the state plan and are subject to all applicable Medicaid laws and regulations.

V. DEMONSTRATION PROGRAMS AND BENEFITS

17. **SMI/SED and/or SUD Program Benefits.** Under this demonstration, beneficiaries will have access to high quality, evidence-based SMI/SED and/or SUD treatment and withdrawal management services. These services will range in intensity from medically supervised withdrawal management for SUDs and short-term acute care in inpatient settings for SMI to ongoing chronic care for these conditions in cost-effective community-based settings. The District will work to improve care coordination and care for co-occurring physical and behavioral health conditions. The District must achieve a statewide average length of stay of no more than 30 days in residential and inpatient treatment settings, to be monitored pursuant to the SMI/SED and SUD Monitoring Plans as outlined in STCs 36 – 38 below.

    The coverage of SMI and/or SUD treatment services during short term residential and inpatient stays in IMDs will expand the District's current SMI and/or SUD benefit package

available to all the District's Medicaid beneficiaries as outlined in Table 1 (except where prohibited in these STCs).

The District attests that the services indicated in Table 1 as being either already covered under the Medicaid state plan authority or being authorized under the terms of this demonstration.

Table 1. SMI/SED and/or SUD Benefits Coverage Authorized with Expenditure Authority

Benefit	Type	Medicaid Authority	Expenditure Authority
Outpatient services	SMI/SED and/or SUD	State plan (Individual services covered)	N/A
Intensive outpatient services	SMI/SED and/or SUD	State plan[1] (Individual services covered)	N/A
Inpatient services	SMI/SED and/or SUD	State plan (Individual services covered)	Services provided to individuals in IMDs
Residential treatment services	SMI and/or SUD	Section 1115 demonstration	Services provided to individuals residing in IMDs
Medically Supervised Withdrawal Management	SUD	State plan (Individual services covered)	Services provided to individuals in IMDs
Medication-Assisted Treatment (MAT)	SUD	State plan (individual services covered)	Services provided to individuals in IMDs
Comprehensive Psychiatric Emergency Program	SMI and/or SUD	Section 1115 demonstration	N/A
Mobile Crisis Intervention and Outreach Services	SMI/SED and/or SUD	Section 1115 demonstration	N/A
Psychiatric Residential Crisis Stabilization Services	SMI/SED	Section 1115 demonstration	Services provided to individuals in IMDs

[11] The District State Plan provides coverage for a broad array of intensive outpatient services, including assessment and diagnostic, clinical care coordination, crisis intervention, counseling, medication management, and MAT. Under the demonstration, the District is planning to more fully implement intensive outpatient services, consistent with the Implementation Plan.

Table 1. SMI/SED and/or SUD Benefits Coverage Authorized with Expenditure Authority			
Benefit	**Type**	**Medicaid Authority**	**Expenditure Authority**
Recovery Support Services	SUD	Section 1115 demonstration	Services provided to individuals in IMDs
Psychosocial Rehabilitative Services	SMI	Section 1115 demonstration	N/A
Trauma-Informed Service: Trauma Recovery and Empowerment Model (TREM)	SMI/SED and/or SUD	Section 1115 demonstration	Services provided to individuals in IMDs
Trauma-Informed Service: Trauma Systems Therapy (TST)	SED	Section 1115 demonstration	N/A
Services of a Licensed Behavioral Health Practitioner	SMI/SED and/or SUD	Section 1115 demonstration	Services provided to individuals in IMDs
Transition Planning Services	SMI/SED and/or SUD	Section 1115 demonstration	Services provided to individuals in IMDs
Supported Employment	SMI	Section 1115 demonstration	N/A
Supported Employment	SUD	Section 1115 demonstration	N/A

18. Residential SUD Treatment Services. Treatment services delivered to residents of a residential care setting, including facilities that meet the definition of an IMD, are provided to the District's Medicaid recipients with a SUD diagnosis when determined to be medically necessary and in accordance with an individualized plan of care.

a. Residential treatment services are services provided to an individual residing in a District-certified facility that has been enrolled as a Medicaid provider and assessed as delivering care consistent with ASAM or other nationally recognized, SUD-specific program standards for residential treatment facilities.
b. Residential treatment services can be provided in settings of any size.
c. The implementation date for residential treatment services is January 1, 2020.

d. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.
e. Covered services include:

i. Assessment/Diagnostic and Plan of Care Development: Includes assessment and diagnosis of the client and the development of the plan of care.
ii. Clinical Care Coordination: The initial and ongoing process of identifying, planning, coordinating, implementing, monitoring, and evaluating options and services to best meet a client's care needs.
iii. Case Management: Facilitation of implementation of the plan of care and administrative facilitation of the client's service needs, including but not limited to scheduling of appointments, assisting in completing applications, facilitating transportation, tracking appointments, and collecting information about the client's progress. Also includes coordination of linkages to vocational, housing, child care, and social services.
iv. Crisis Intervention: An immediate short-term treatment intervention, which assists a client to resolve an acute personal crisis that significantly jeopardizes the client's treatment, recovery progress, health, or safety.
v. SUD Counseling/Therapy: Individual, family, or group counseling; includes group-psychoeducation counseling.
vi. Drug Screening: Toxicology sample collection and breathalyzer and urine testing to determine and detect the use of alcohol and other drugs.
vii. Medication Management: Coordination and evaluation of medications consumed by clients, monitoring potential side effects, drug interactions, compliance with doses, and efficacy of medications.
viii. Medication Assisted Treatment: Use of pharmacotherapy and other psychosocial supports for the treatment of opioid or other substance use disorders.
ix. Withdrawal management: Treatment of acute emotional, behavioral, cognitive, or biomedical distress resulting from, or occurring with, an individual's use of alcohol or other drugs.

19. Psychiatric Residential Treatment Services: Psychiatric Residential Treatment Services are intensive services offered in a non-hospital setting for individuals over the age of 21 who have been diagnosed with an SMI. All services are provided under the direction of a psychiatrist. The goal of these services is to stabilize or improve a psychiatric condition until an individual's symptoms can be managed in a community setting. The District will provide services for a targeted statewide average length of stay of thirty (30) days in inpatient and residential treatment settings, to be monitored pursuant to the SMI Implementation Plan as outlined in STCs 36 below. Reimbursement for long-term residential or inpatient stays (longer than sixty (60) days) and forensic IMD stays will not be provided under this demonstration. Total length of stay will be determined by medical necessity and reviewed by the District or its assignee for clinical appropriateness.

a. Residential treatment services are services provided to an individual residing in a District-certified facility that has been enrolled as a Medicaid provider. Residential

treatment facilities that qualify as an IMD must also be accredited in accordance with STC 36(c)(i)(B).

b. Residential treatment services can be provided in settings of any size.
c. The implementation date for residential treatment services is January 1, 2020.
d. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.
e. The components of Psychiatric Residential Treatment Services include:
    i. Assessments of the individual's social, emotional, and medical needs;
    ii. Therapeutic interventions
    iii. Psychiatric interventions
    iv. Non-hospital care in a structured 24-hour monitored environment for individuals whose mental health needs cannot be met in an outpatient setting,
    v. Comprehensive Transitional Care Coordination.
f. Provider Qualifications: Out-of-District provider psychiatric residential treatment services may be provided by a psychiatrist, APRN, physician's assistant, RN, LPN, LPC, LICSW, LMFT, psychologist, psychology associates, LGPC, LGSW, LCSW and other qualified practitioners that are authorized and licensed to provide services under District law and regulations and the state in which services are offered. For in-District providers, services must be furnished by a District-certified Psychiatric Residential Treatment Service provider. Qualified provider staff include clinicians licensed in accordance with applicable District laws and regulations operating within scope of their license, including psychiatrists, psychologists, advanced practice registered nurses (APRN), and other qualified practitioners authorized under District regulations.

20. Temporary SMI/SED and/or SUD Services. Under this demonstration, the District may also receive federal financial participation (FFP) from January 1, 2020 through December 31, 2021 for providing additional services that are detailed in Expenditure Authorities #2 and #3.

a. For the services identified in Expenditure Authorities # 2 and 3 above, the District must submit all necessary SPAs and/or 1915(i) SPA application(s) to implement these title XIX services prior to the conclusion of DY1.
b. If the District fails to submit all necessary SPAs/applications prior to commencing DY2, this expenditure authority will be withdrawn effective January 1, 2021.
    i. If the District submits a justifiable reason (via memorandum) prior to withdrawal of this expenditure authority – and contingent upon CMS approval of the submission – CMS may allow the District additional time to complete the SPA/application submission processes.
c. If CMS withdraws Expenditure Authority #2, it will notify the District, in writing, of its determination and the reasons for the withdrawal.
    i. Once received, the District may request reconsideration of CMS's decision within 30 calendar days.
d. For temporary 1915-like HCBS authorized under this demonstration and listed in Tables 2 and 3, see STCs 29-32 for additional considerations.

Temporary 1905(a) State Plan-Approvable Services STCs 21-28

21. Comprehensive Psychiatric Emergency Program (CPEP). CPEP provides 24 hours, 7 days a week emergency psychiatric assessment and treatment to individuals who present on involuntary and voluntary status through an in person, on site, multidisciplinary team comprised of attending psychiatrists, nurses, certified peer specialists, licensed professional counselors, general medical staff, licensed social workers, and credentialed CPEP staffs. The duration of treatment for Psychiatric Emergency Services is up to 72 hours.

a. Covered services include:

i. **Brief Psychiatric Crisis/Emergency Visit.** Assessment and monitoring of an individual in crisis by a psychiatrist to determine the scope of emergency services required.

ii. **Twenty-Three-Hour Psychiatric Crisis/Emergency Visit**. Assessment and monitoring of an individual in crisis by a psychiatrist and other clinical staff for up to twenty-three hours to ensure client safety when extended time is needed to assess treatment effectiveness and tolerance for crisis stabilization.

iii**. Extended Observation Psychiatric Crisis/Emergency Visit.** Evaluation and monitoring of a patient by a psychiatrist and other clinical staff when a crisis has not sufficiently resolved for safe discharge to the community. This interaction includes a mental health diagnostic assessment, and, if necessary, treatment activities including prescribing or administering medication, and evaluation and monitoring for treatment effectiveness.

b. Provider Qualifications. Services are furnished by any District-certified Comprehensive Psychiatric Emergency Program provider. Qualified provider staff include clinicians licensed in accordance with applicable District laws and regulations operating within scope of their license, including psychiatrists, psychologists, advanced practice registered nurses (APRNs), and other qualified practitioners authorized under District regulations.

22. Mobile Crisis Intervention and Outreach Services. Clinical attention or treatment provided by mobile crisis intervention and outreach staff, in the community or via telephone, to an individual experiencing a behavioral health crisis. Services are provided with the immediate goals of preventing exacerbation of the underlying condition, limiting the risk of injury to the individual or others, and connecting the individual to clinically appropriate, ongoing care.

a. The components of Mobile Crisis Intervention and Outreach Services are:
   i. Assessment and follow up;
   ii. Counseling;
   iii. Care coordination and case management.

b. **Provider Qualifications.** Services are furnished by any District-certified Comprehensive Psychiatric Emergency Program provider. Qualified provider staff include clinicians licensed in accordance with applicable District laws and regulations and operating within

the scope of their license, including psychiatrists, psychologists, advanced practice registered nurses (APRNs), and other qualified practitioners authorized under District regulations.

23. Psychiatric Residential Crisis Stabilization Services. A residential treatment alternative to psychiatric inpatient hospitalization for individuals in need of support to ameliorate psychiatric symptoms.

a. The components of Psychiatric Residential Crisis Stabilization Services include:

i. Psychiatric services, necessary to assess, treat, medicate and stabilize residents.
ii. Comprehensive nursing assessment within 24 hours of admission
iii. Monitoring of patients who pose a threat to themselves or others
iv. Stabilization and mental health services to address psychiatric, psychological, and behavioral needs
v. Development of treatment and discharge plans upon admission.
vi. Active treatment and mental health services for stabilization
vii. Individual, group counseling or other interventions as required to stabilize the person.

b. **Provider Qualifications.** Services are furnished by any District-certified psychiatric residential crisis stabilization provider. Qualified provider staff include clinicians licensed in accordance with applicable District laws and regulations and operating within the scope of their license, including psychiatrists, psychiatric nurses, licensed independent clinical social workers (LICSWs), and other qualified practitioners authorized under District regulations.

24. Recovery Support Services. Non-clinical services and supports designed to support and maintain ongoing recovery from SUD. Recovery Support Services are available to individuals with a SUD who are currently in treatment or have moved into recovery from SUD use/abuse, and individuals who have self-identified with SUD, but are assessed as not needing treatment.

a. The components of Recovery Support Services include goal-setting, case management, coaching, counseling, and other services designed to assist individuals with SUD with successful implementation of their recovery plan in either individual or group settings.

b. **Provider Qualifications.** Services are furnished by any District-certified recovery support services provider. Qualified provider staff include certified recovery coaches, certified peer specialists, and other qualified practitioners authorized under District regulations.

25. Psychosocial Rehabilitative Services. Psychosocial rehabilitative services (PRS) that use behavioral, cognitive, or supportive interventions to assist individuals with SMI to develop social networking, independent living, budgeting, self-care, and other skills that will assist them to live in the community and to prepare for securing and retaining employment.

a. The components of PRS include:
    i. Identification and management of situations and prodromal symptoms to reduce the frequency, duration, and severity of psychological relapses;
    ii. Improvement in functional competence responding to a psychiatric crisis;
    iii. Improvement in functional competence in understanding the role psychotropic medication plays in the stabilization of the members' well-being;
    iv. Increase in independent living competencies;
    v. Strengthening social and interpersonal abilities;
    vi. Increasing personal adjustment abilities to reduce dependency on professional caregivers and to enhance independence;
    vii. Increasing cognitive and adult role competency;
    viii. Identification and development of organizational support; and
    ix. Identification and development of existing natural supports for addressing personal needs.
b. **Provider Qualifications.** Services are furnished by any District-certified PRS provider. Qualified provider staff must be credentialed and meet requirements under District laws and regulations.

26. Trauma-Informed Services:

a. Trauma Recovery Empowerment Model (TREM): Trauma Recovery Empowerment Model (TREM) is a structured group therapy intervention for individuals who have survived trauma and have substance use and/or mental health conditions. TREM draws on cognitive restructuring, skills training, and psychoeducational and peer support to address recovery and healing from sexual, physical, and emotional abuse. TREM requires at least two facilitators for each group. The component services of TREM include:

    a. Therapy sessions on empowerment, self-comfort, and accurate self-monitoring as well as ways to establish safe physical and emotional boundaries.
    b. Therapy sessions on the trauma experience and its consequences. Therapy sessions on skills building, including emphases on communication style, decision-making, regulating overwhelming feelings, and establishing safer, more reciprocal relationships.
    c. **Provider Qualifications.** Services are furnished by any District-certified TREM provider. Qualified provider staff has completed District-approved TREM training and includes psychiatrists, psychologists, LICSWs, LPCs, and other qualified providers authorized under District law and regulations.

b. Trauma-Informed Service: Trauma Systems Therapy (TST) is a comprehensive, phase-based treatment program for children and adolescents who have experienced traumatic events and/or who live in environments with ongoing stress and/or traumatic reminders. TST is designed to address the complicated needs of a trauma system in which a traumatized youth who, when exposed to trauma reminders, has difficulty regulating their emotions and behavior, and their caregiver/system of care is not able to adequately protect the youth or help them manage this dysregulation. The three phases are Safety-

Focused, Regulation-Focused, and Beyond Trauma. The component services of TST include:

i. Psychotherapy,
ii. Home/community-based stabilization,
iii. Emotion regulation skills training, and
iv. Psychopharmacology.
v. **Provider Qualifications:** Services are furnished by any District-certified TST provider. Qualified provider staff has completed District-approved TST training. The multi-disciplinary treatment team includes psychiatrists, therapists, and credentialed staff practicing in accordance with District law and regulations. TST teams are supervised by licensed behavioral health practitioners, including psychiatrists, psychologists, LICSWs, or LPCs.

27. Services of a Licensed Behavioral Health Practitioner. Outpatient behavioral health services for individuals with SMI/SED or SUD, including assessment, counseling and other treatment services, provided by licensed Psychologist, licensed Independent Clinical Social Workers, licensed Professional Counselors, and licensed Marriage and Family Therapist. Services associated with screening or treatment of Autism Spectrum disorders is not included.

a. The component services include:
   i. Assessment, diagnostic, and screening services;
   ii. Counseling and psychotherapy;
   iii. Treatment planning and care coordination; and
   iv. Psychological Testing.

b. **Provider Qualifications.** Services are furnished by licensed behavioral health practitioners. A licensed behavioral health practitioner is an individual, practicing within the scope of their professional licensure and in accordance with District law, who is authorized to diagnose or treat SMI/SED or SUD. Licensed behavioral health professionals include the following providers practicing independently, in a group practice, or in a hospital setting:
   i. Psychologist;
   ii. Licensed Independent Clinical Social Workers;
   iii. Licensed Professional Counselors; and
   iv. Licensed Marriage and Family Therapist

28. Transition Planning Services. Discharge planning and facilitation of transitions of care for individuals leaving institutional treatment settings by providers of lower levels of care. Transition planning services consist of up to eight (8) hours per individual for services provided within thirty (30) days prior to an individual being discharged.

a. The components of Transition Planning Services include:
   i. Assessment.
   ii. Development of a service plan.

iii. Care coordination and case management

b. **Provider Qualifications.**
Services are furnished by any District-certified provider qualified to provide Mental Health Rehabilitative Services, Adult Substance Abuse Rehabilitative Services, or other behavioral health services allowable under the State Plan that are authorized under District law and rulemaking to provide transition services

Temporary 1915(i)-Approvable (Supported Employment) Services STCs 29-32

29. Supported Employment for Individuals with SMI. Services available to adults with SMI for whom competitive employment has not occurred, has been interrupted, or is intermittent as a result of SMI. Vocational supports help the individual prepare for, obtain, and maintain a part-time or full-time job in a competitive employment setting, earning at least minimum wage.

a. The components of Supported Employment services include:
   i. Intake and Assessment;
   ii. Individualized work plan development;
   iii. Benefits counseling
   iv. Coordination with the individual's treatment team;
   v. Initial job development; and
   vi. Follow-along supports after job placement such as problem-solving and job coaching for the beneficiary and helping the employer with making reasonable accommodations and effective supervision strategies.

b. **Needs-Based Functional Criteria:** The supported employment services are available to individuals who meet the following health needs-based criteria:

Individual is assessed to have a behavioral health need, which is defined as at least one of the following:

a) Mental health needs, where there is a need for improvement, stabilization, or prevention of deterioration of functioning (including ability to live independently without support), resulting from the presence of a mental illness; or

b) Substance use needs, where an assessment using the American Society of Addiction Medicine (ASAM) Criteria indicates that the individual meets at least ASAM level 1.0, indicating the need for outpatient Substance Use Disorder treatment. The ASAM is a multi-dimensional assessment approach for determining an individual's need for SUD treatment; and

AND

Individual has at least one of the following risk factors:

1) Unable to sustain gainful employment for at least 90 consecutive days related to a history of a mental or substance use disorder;

2) An inability to obtain or maintain employment resulting from age or disability (physical or behavioral);

3) More than one instance of mental illness or substance use treatment in the past two years; or

4) At risk of deterioration of mental illness and/or substance use disorder, evidenced by one or more of the following:

a) Persistent or chronic risk factors such as social isolation due to a lack of family or social supports, poverty, criminal justice involvement, or homelessness;

b) Care for mental illness and/or substance use disorder requiring multiple provider types, including behavioral health, primary care, long-term services and supports; or

c) A past psychiatric history with no significant functional improvement that can be maintained without treatment and supports.

a. **Provider Qualifications:** Services are furnished by any District-certified supported employment provider. Qualified provider staff include psychiatrists, psychologists, LICSWs, licensed professional counselors, and other qualified providers that are licensed and authorized in accordance with applicable District laws and regulations and operating within the scope of their license. These qualified practitioners supervise other staff that are supported employment managers and employment specialists trained in accordance with evidence-based supported employment principles and practices, consistent with District regulations.

30. Supported Employment for Individuals with SUD. Targets adults for whom competitive employment has not occurred, has been interrupted, or is intermittent as a result of SUD. Ongoing vocational and therapeutic supports help the individual prepare for, obtain, and maintain a part-time or full-time job in a competitive employment setting, earning at least minimum wage. Job options are diverse and permanent.

a. The components of Supported Employment SUD services, include:
    i. Intake and Assessment;
    ii. Individualized work plan development;
    iii. Care coordination;
    iv. Benefits counseling;
    v. Job development and coaching; and
    vi. Follow-along supports for the beneficiary and employer. For the beneficiary, vocational supports include problem-solving and job coaching; and therapeutic supports include helping the individual manage their illness and teach strategies to help prevent symptom exacerbation that affects their employment. Supports for

the employer help with making reasonable accommodations and effective supervision strategies.

b. **Needs-Based Functional Criteria:** The supported employment services are available to individuals who meet the following health needs-based criteria:

Individual is assessed to have a behavioral health need, which is defined as at least one of the following:

a) Mental health needs, where there is a need for improvement, stabilization, or prevention of deterioration of functioning (including ability to live independently without support), resulting from the presence of a mental illness; or

b) Substance use needs, where an assessment using the American Society of Addiction Medicine (ASAM) Criteria indicates that the individual meets at least ASAM level 1.0, indicating the need for outpatient Substance Use Disorder treatment. The ASAM is a multi-dimensional assessment approach for determining an individual's need for SUD treatment; and

AND

Individual has at least one of the following risk factors:

1) Unable to sustain gainful employment for at least 90 consecutive days related to a history of a mental or substance use disorder;

2) An inability to obtain or maintain employment resulting from age or disability (physical or behavioral);

3) More than one instance of mental illness or substance use treatment in the past two years; or

4) At risk of deterioration of mental illness and/or substance use disorder, evidenced by one or more of the following:

a) Persistent or chronic risk factors such as social isolation due to a lack of family or social supports, poverty, criminal justice involvement, or homelessness;

b) Care for mental illness and/or substance use disorder requiring multiple provider types, including behavioral health, primary care, long-term services and supports; or

c) A past psychiatric history with no significant functional improvement that can be maintained without treatment and supports.

c. **Provider Qualifications:** Services are furnished by any District-certified supported employment provider. Qualified practitioners are behavioral health practitioners,

including psychiatrists, psychologists, LICSWs, licensed professional counselors, and other qualified providers that are licensed and authorized in accordance with applicable District laws and regulations and operating within the scope of their license. These qualified practitioners supervise staff that are supported employment managers and employment specialists trained in accordance with evidence-based supported employment principles and practices, consistent with District regulations.

31. Quality Improvement Strategy for 1915(c) or 1915(i)-Approvable HCBS Services Provided Through Fee-for-Service (FFS) Delivery System. The District must have an approved Quality Improvement Strategy and is required to work with CMS to develop approvable performance measures within 90 days following approval of the 1115 for the following waiver assurances (see (a) through (g) below):

a. **Administrative Authority.** A performance measure must be developed and tracked for any authority that the District's Medicaid Agency delegates to another agency, unless already captured in another performance measure.
b. **Eligibility or Level of Care Requirements**. Performance measures are required for the following:
   i. Applicants with a reasonable likelihood of needing services receive a level of care determination or an evaluation for HCBS eligibility.
   ii. The district-mandated processes for determining level of care or eligibility for HCBS are followed as documented in District materials. While performance measures for the actual provision of care or determinations of eligibility are not required to be reported, the District is expected to ensure that annual levels of care/eligibility are determined.
c. **Qualified Providers.** The District must have performance measures that track that providers meet licensure/certification standards, that non-certified providers are monitored to assure adherence to demonstration requirements, and that the District verifies that training is given to providers in accordance with the demonstration.
d. **Service Plan.** The District must demonstrate it has designed and implemented an effective system for reviewing the adequacy of service plans for HCBS participants. Performance measures are required for 1) choice of waiver services and providers; 2) service plans address all assessed needs and personal goals; and 3) services are delivered in accordance with the service plan including the type, scope, amount, duration, and frequency specified in the service plan.
e. **Health and Welfare.** The District must demonstrate it has designed and implemented an effective system for assuring HCBS participants' health and welfare. The District must have performance measures that track that on an ongoing basis it 1) identifies, addresses and seeks to prevent instances of abuse, neglect, exploitation and unexplained death; 2) an incident management system is in place that effectively resolves incidents and prevents further singular incidents to the extent possible; that District policies and procedures for the use or prohibition of restrictive interventions are followed; and, that the District establishes overall health care standards and monitors those standards based on the responsibility of the service provider as District in the approved demonstration.
f. **Financial Accountability.** For FFS, the District must demonstrate that it has designed and implemented an adequate system for ensuring financial accountability of the HCBS

program. The District must have performance measures that track that it provides evidence that claims are coded and paid for in accordance for services rendered, and that it provides evidence that rates remain consistent with the approved rate methodology throughout the five year waiver cycle. For managed care, the District must demonstrate actuarial soundness on an annual basis pursuant to 42 CFR Part 438.

g. **HCBS Settings Requirements**. The District must assure compliance with the characteristics of HCBS settings as described in the 1915(c) and 1915(i) regulations at 42 CFR 441.710 in accordance with implementation/effective dates as published in the Federal Register.

32. Quality Improvement Strategy for 1915(c) or 1915(i)-Approvable HCBS Services Provided Through Managed Care Delivery System. For services that could have been authorized to individuals under a 1915(c) waiver or under a 1915(i) HCBS District plan, the District's Quality Assessment and Performance Improvement Plan must encompass LTSS-specific measures set forth in federal managed care rules at 42 CFR 438.330 and must also reflect how the state will assess and improve performance to demonstrate compliance with applicable federal waiver assurances set forth in 42 CFR 441.301 and 441.302. The Quality Review provides a comprehensive assessment of the District's capacity to ensure adequate program oversight, detect and remediate compliance issues and evaluate the effectiveness of implemented quality improvement activities.

33. HCBS Reporting. The District will submit a report to CMS which includes evidence on the status of the HCBS quality assurances and measures that adheres to the requirements set out in the March 12, 2014, CMS Informational Bulletin, Modifications to Quality Measures and Reporting in §1915(c) Home and Community-Based Waivers set forth in 42 CFR 441.301 and 441.302. This information could be captured in the 1115 Summary Report detailed in STC 47.

34. HCBS Monitoring and Evaluation. The District must report annually the deficiencies found during the monitoring and evaluation of the HCBS demonstration requirements, an explanation of how these deficiencies have been or are being corrected, as well as the steps that have been taken to ensure that these deficiencies do not recur. The District must also report on the number of substantiated instances of abuse, neglect, exploitation and/or death, the actions taken regarding the incidents and how they were resolved. Submission is due no later than 6 months following the end of the demonstration year. This information must be included in the annual reports submitted for 1115 waivers detailed in STC 47.

35. HCBS Beneficiary Protections. The District will demonstrate compliance with the following HCBS beneficiary protections.

a. **Person-Centered Planning**. The District assures there is a person-centered service plan for each individual determined to be eligible for HCBS. The person-centered service plan is developed using a person-centered service planning process in accordance with 42 CFR 441.301(c)(1), and the written person-centered service plan meets federal requirements at 42 CFR 441.301(c)(2). The person-centered service plan is reviewed, and revised upon

reassessment of functional need as required by 42 CFR 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

b. **Conflict of Interest.** The entity that authorizes the services must be external to the agency or agencies that provide the HCB supported employment services. Appropriate separation of assessment, treatment planning and service provision functions must be incorporated into the District's conflict of interest policies.

c. **Additional HCBS Beneficiary Protections**.

   i. Each beneficiary eligible for long term services and supports will have informed choice on their option to self-direct LTSS, have a designated representative direct LTSS on their behalf, or select traditional agency-based service delivery. Both level of care assessment and person-centered service planning personnel will receive training on these options. (for use in MLTSS programs with self-direction)

   ii. The District, either directly or through its MCO contracts must ensure that participants' engagement and community participation is supported to the fullest extent desired by each participant.

   iii. Beneficiaries may change managed care plans if their residential or employment support provider is no longer available through their current plan.

36. SMI/SED Implementation Plan.

a. The District must submit the SMI/SED Implementation Plan within 90 calendar days after approval of the demonstration for CMS review and comment. The District must submit the revised SMI/SED Implementation Plan within sixty (60) calendar days after receipt of CMS's comments. The District may not claim FFP for services provided in IMDs to beneficiaries with a primary diagnosis of SMI/SED until CMS has approved the SMI/SED Implementation Plan and the SMI/SED Financing Plan described in STC 37(e). After approval of the applicable implementation plans required by this STCs, FFP will be available prospectively, not retrospectively.

b. Once approved, the SMI/SED Implementation Plan will be incorporated into the STCs as Attachment C, and once incorporated, may be altered only with CMS approval. Failure to submit an SMI/SED Implementation Plan will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SMI/SED program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the District and CMS will result in a funding deferral as described in STC 44.

c. At a minimum, the SMI/SED Implementation Plan must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:

   i. **Ensuring Quality of Care in Psychiatric Hospitals and Residential Settings.**

      A. Participating hospitals must be licensed or approved as meeting standards for licensing established by the agency of the state or locality responsible for

licensing hospitals prior to the state claiming FFP for services provided to beneficiaries residing in a hospital that meets the definition of an IMD. In addition, hospitals must be in compliance with the conditions of participation set forth in 42 CFR Part 482 and be either: a) certified by the state agency as being in compliance with those conditions through a state agency survey, or b) deemed status to participate in Medicare as a hospital through accreditation by a national accrediting organization whose psychiatric hospital accreditation program or acute hospital accreditation program has been approved by CMS.

B. Participating residential treatment providers must be licensed, or otherwise authorized, by the state to primarily provide treatment for mental illnesses. They must also be accredited by a nationally recognized accreditation entity prior to the state claiming FFP for services provided to beneficiaries residing in a residential facility that meets the definition of an IMD.
C. Establishment of an oversight and auditing process that includes unannounced visits for ensuring participating psychiatric hospitals and residential treatment settings meet District licensure or certification requirements as well as a national accrediting entity's accreditation requirements;
D. Use of a utilization review entity (for example, a managed care organization or administrative service organization) to ensure beneficiaries have access to the appropriate levels and types of care and to provide oversight to ensure lengths of stay are limited to what is medically necessary and only those who have a clinical need to receive treatment in psychiatric hospitals and residential treatment settings are receiving treatment in those facilities;
E. Establishment of a process for ensuring that participating psychiatric hospitals and residential treatment settings meet federal program integrity requirements and establishment of a District process to conduct risk-based screening of all newly enrolling providers, as well as revalidating existing providers (specifically, under existing regulations, the District must screen all newly enrolling providers and reevaluate existing providers pursuant to the rules in 42 CFR Part 455 Subparts B and E, ensure treatment providers have entered into Medicaid provider agreements pursuant to 42 CFR 431.407, and establish rigorous program integrity protocols to safeguard against fraudulent billing and other compliance issues);
F. Implementation of a District requirement that participating psychiatric hospitals and residential treatment settings screen enrollees for co-morbid physical health conditions and substance use disorders (SUDs) and demonstrate the capacity to address co-morbid physical health conditions during short-term stays in residential or inpatient treatment settings (e.g., with on-site staff, telemedicine, and/or partnerships with local physical health providers).

ii. **Improving Care Coordination and Transitions to Community-Based Care.**

A. Implementation of a process to ensure that psychiatric hospitals and residential treatment facilities provide intensive pre-discharge, care coordination services to help beneficiaries transition out of those settings into appropriate community-based outpatient services, including requirements that community-based providers participate in transition efforts (e.g., by allowing initial services with a

community-based provider while a beneficiary is still residing in these settings and/or by hiring peer support specialists to help beneficiaries make connections with available community-based providers, including, where applicable, plans for employment);

B. Implementation of a process to assess the housing situation of a beneficiary transitioning to the community from psychiatric hospitals and residential treatment settings and to connect beneficiaries who are homeless or who have unsuitable or unstable housing with community providers that coordinate housing services, where available;
C. Implementation of a requirement that psychiatric hospitals and residential treatment settings have protocols in place to ensure contact is made by the treatment setting with each discharged beneficiary within 72 hours of discharge and to ensure follow-up care is accessed by individuals after leaving those facilities by contacting the individuals directly and by contacting the community-based provider they were referred to;
D. Implementation of strategies to prevent or decrease the length of stay in emergency departments among beneficiaries with SMI or SED (e.g., through the use of peers and psychiatric consultants in EDs to help with discharge and referral to treatment providers);
E. Implementation of strategies to develop and enhance interoperability and data sharing between physical, SUD, and mental health providers, with the goal of enhancing coordination so that disparate providers may better share clinical information to improve health outcomes for beneficiaries with SMI or SED.

iii. **Increasing Access to Continuum of Care Including Crisis Stabilization Services.**

A. Establishment of a process to annually assess the availability of mental health services throughout the District, particularly crisis stabilization services, and updates on steps taken to increase availability;
B. Commitment to implementation of the SMI/SED financing plan described in STC 36(e);
C. Implementation of strategies to improve the District's capacity to track the availability of inpatient and crisis stabilization beds to help connect individuals in need with that level of care as soon as possible;
D. Implementation of a requirement that providers, plans, and utilization review entities use an evidence-based, publicly available patient assessment tool, preferably endorsed by a mental health provider association (e.g., LOCUS or CASII) to determine appropriate level of care and length of stay.

iv. **Earlier Identification and Engagement in Treatment Including Through Increased Integration**

A. Implementation of strategies for identifying and engaging individuals, particularly adolescents and young adults, with SMI/SED in treatment sooner, including through supported employment and supported education programs;

B. Increasing integration of behavioral health care in non-specialty care settings, including schools and primary care practices, to improve identification of SMI/SED conditions sooner and improve awareness of and linkages to specialty treatment providers;
C. Establishment of specialized settings and services, including crisis stabilization services, focused on the needs of young people experiencing SMI or SED.

d. **SMI/SED Health IT Plan:** Implementation of the milestones and metrics as detailed in Attachment C.

e. **SMI/SED Financing Plan.** As part of the SMI/SED implementation plan referred to in STC 36(c), the District must submit, within 90 calendar days after approval of the demonstration, a financing plan that will be approved by CMS. Once approved, the Financing Plan will be incorporated into the STCs as part of the implementation plan in Attachment C and, once incorporated, may only be altered with CMS approval. Failure to submit an SMI/SED Financing Plan will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SMI/SED program under this demonstration. Components of the financing plan must include:

i. A plan to increase the availability of non-hospital, non-residential crisis stabilization services, including but not limited to the following: services made available through crisis call centers, mobile crisis units, coordinated community response services that includes law enforcement and other first responders, and observation/assessment centers; and
ii. A plan to increase availability of ongoing community-based services such as intensive outpatient services, assertive community treatment, and services delivered in integrated care settings;
iii. A plan to ensure the on-going maintenance of effort (MOE) on funding outpatient community-based services to ensure that resources are not disproportionately drawn into increasing access to treatment in inpatient and residential settings at the expense of community-based services.

37. SUD Implementation Plan.

a. The District must submit the SUD Implementation Plan within ninety (90) calendar days after approval of this demonstration for CMS review and comment. The District must submit the revised SUD Implementation Plan within sixty (60) calendar days after receipt of CMS's comments. The District may not claim FFP for services provided in IMDs to beneficiaries who are primarily receiving SUD treatment and withdrawal management services until CMS has approved the SUD Implementation Plan. Once approved, the SUD Implementation Plan will be incorporated into the STCs as Attachment D and, once incorporated, may be altered only with CMS approval. After approval of the applicable implementation plans required by these STCs, FFP will be available prospectively, not retrospectively.

b. Failure to submit a SUD Implementation Plan will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SUD program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the District and CMS will result in a funding deferral as described in STC 43.
c. At a minimum, the SUD Implementation Plan must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:

i. **Access to Critical Levels of Care for SUDs:** Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of SUD demonstration approval;
ii. **Use of Evidence-based SUD-specific Patient Placement Criteria:** Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of demonstration approval;
iii. **Patient Placement:** Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of demonstration approval;
iv. **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities:** Currently, residential treatment service providers must be a licensed organization, pursuant to the residential service provider qualifications described in Chapter 63 (Mental Health) of Subtitle A of Title 22 (Health) of the District Code of Municipal Regulations (DCMR) and Certification Standards for Substance Use Disorder Treatment and Recovery Providers and related District rulemaking in the DCMR. The District must establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
v. **Standards of Care:** Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
vi. **Standards of Care:** Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of demonstration approval;

vii. **Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for SUD/OUD:** An assessment of the availability of providers in the critical levels of care throughout the District, or in the regions of the District participating under this demonstration, including those that offer MAT within 12 months of demonstration approval;

viii. **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/OUD:** Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;

ix. **Improved Care Coordination and Transitions between levels of care:** Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of demonstration approval.

x. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in Attachment D.

d. **SMI/SED and/or SUD Health Information Technology Plan ("Health IT Plan(s)").** The SMI/SED and/or SUD Health IT plan applies to all states where the Health IT functionalities are expected to impact beneficiaries within the demonstration. As outlined in SMDL #18-011 and #17-003, respectively, states must submit to CMS the applicable Health IT Plan(s), to be included as a section(s) of the associated Implementation Plan(s) to develop infrastructure and capabilities consistent with the requirements outlined in each demonstration-type (SMI/SED and/or SUD).

The Health IT Plan(s) must detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SMI/SED and/or SUD goals of the demonstration. The plan(s) will also be used to identify areas of health IT ecosystem improvement. The Plan(s) must include implementation milestones and projected dates for achieving them (see Attachments C and D), and must be aligned with the District's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the District's Behavioral Health (BH) IT Health Plan.

i. The District must include in its Monitoring Protocol (see STC 38) an approach to monitoring its SMI/SED and/or SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.

ii. The District must monitor progress, each DY, on the implementation of its SMI/SED and/or SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Report (see STC 47).

iii. As applicable, the District should advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation

Specifications' (ISA)[2] in developing and implementing the District's SMI/SED and/or SUD Health IT policies and in all related applicable District procurements (e.g., including managed care contracts) that are associated with this demonstration.

iv. Where there are opportunities at the District- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the District should use the federally-recognized standards, barring another compelling District interest.

v. Where there are opportunities at the District- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the District should use the federally-recognized ISA standards, barring no other compelling District interest.

A. The SMI/SED Health IT Plan must describe the District's current and future capabilities to support providers implementing or expanding Health IT functionality for:
    1. Referrals,
    2. Electronic Care Plans and Medical Records.
    3. Consent.
    4. Interoperability in Assessment Data.
    5. Telehealth.
    6. Alerting/Analytics.
    7. Identity Management.

B. Components of the SUD Health IT Plan include:

    1. The SUD Health IT Plan must describe the District's goals, each DY, to enhance the District's prescription drug monitoring program (PDMP).[3]
    2. The SUD Health IT Plan must address how the District's PDMP will enhance ease of use for prescribers and other District and federal stakeholders.[4] This must also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the District will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.
    3. The SUD Health IT Plan will, as applicable, describe the District's capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the SUD Health

[2] Available at: https://www.healthit.gov/isa/section-iii-standards-and-implementation-specifications-services

[3] Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the "opioid" epidemic and facilitate a nimble and targeted response.

[4] *Ibid.*

IT Plan must describe current and future capabilities regarding PDMP queries—and the District's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The District will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.

4. The SUD Health IT Plan will describe how the activities described in (1), (2) and (3) above will support broader District and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.[5]
5. In developing the SUD Health IT Plan, states should use the following resources.

    - States may use federal resources available on Health IT.Gov (https://www.healthit.gov/topic/behavioral-health) including but not limited to "Behavioral Health and Physical Health Integration" and "Section 34: Opioid Epidemic and Health IT" (https://www.healthit.gov/playbook/health-information-exchange/).
    - States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.
    - States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

38. SMI/SED and SUD Monitoring Protocol(s). The District must submit a Monitoring Protocol for the SMI/SED and SUD programs authorized by this demonstration within 150 calendar days after approval of the implementation plan. The Monitoring Protocol Template must be developed in cooperation with CMS and is subject to CMS approval. The state must submit the revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS' comments. Once approved, the SMI/SED and SUD Monitoring Protocol will be incorporated into the STCs, as Attachment E. Progress on the performance measures identified in the Monitoring Protocol must be reported via the quarterly and annual monitoring reports. Components of the Monitoring Protocol include:

a. An assurance of the District's commitment and ability to report information relevant to each of the program implementation areas listed in STC 36(c) and STC 37(c), reporting relevant information to the District's SMI/SED financing plan described in Attachment

[5] Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017; 66.

C, and reporting relevant information to the District's Health IT plans described in STC 37(d);

b. A description of the methods of data collection and timeframes for reporting on the District's progress on required measures as part of the general reporting requirements described in Section VIII of the demonstration; and
c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by District data, and targets will be benchmarked against performance in best practice settings.

39. Evaluation. The SMI/SED Evaluation and SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections VIII (General Reporting Requirements) and X (Evaluation of the Demonstration) of these STCs.

40. Availability of FFP for the SMI/SED Services. FFP is only available for services provided to beneficiaries during short term stays for acute care in IMDs. The state may claim FFP for stays up to 60 days as long as it shows at its midpoint assessment that it is meeting the requirement of a 30 day or less average length of stay (ALOS). Stays in IMDs that exceed 60 days are not eligible for FFP under this demonstration. If the District cannot show that it is meeting the 30 day or less ALOS requirement within one standard deviation at the mid-point assessment, the state may only claim FFP for stays up to 45 days until such time that the state can demonstrate that it is meeting the 30 day or less ALOS requirement. The District assures that it will provide coverage for stays that exceed 60 days—or 45 days, as relevant—with other sources of funding if it is determined that a longer length of stay is medically necessary for an individual beneficiary.

VI. COST SHARING

41. Cost Sharing. The demonstration removes $1 co-payment cost sharing requirements now in effect under the State Plan for individuals receiving services under the demonstration who are also using prescription medications associated with MAT. Otherwise, cost sharing imposed upon individuals enrolled in the demonstration is consistent with the provisions of the approved state plan.

VII. DELIVERY SYSTEM

42. Delivery System. The District's SMI/SED and/or SUD Medicaid delivery system is divided, with overlapping authority, primarily among the District and its Medicaid MCOs. The District has authority over Medicaid's reimbursement of clinic services, hospitals, and outpatient services. MCOs contract with a behavioral health provider network providing low-acuity behavioral health services. Services and supports for individuals with SMI/SED/SUD are carved out of MCO contracts and delivered through FFS by providers operating under the oversight of the District.

Medicaid MCOs manage their own network of behavioral health service providers who offer lower level, non-rehabilitative behavioral health services. MCOs also provide inpatient, emergency, pharmacy, and psychiatric residential treatment facility (PRTF) services. MCOs

are subject to State Plan requirements and accountable to the District through the MCO contract and oversight.

For the District's residents with a diagnosis of SMI/SED, the Medicaid program (via Mental Health Rehabilitation services) provides an array of mental health services and supports. In 2011, Medicaid-covered SUD services administered by the District expanded with the implementation of the ASARS program. The District contracts with 57 providers of mental health services, 33 providers of substance use services, and 10 providers of both mental health and substance use services. The District also operates adult and child clinics that provide urgent care and crisis emergency services and provides homeless outreach and treatment services.

Under the demonstration, the Behavioral Health Transformation will continue to operate as approved in Section 1932(a) state plan authority for managed care and concurrent 1915(b) demonstration and section 1115(a) demonstrations.

VIII. GENERAL REPORTING REQUIREMENTS

43. Deferral of FFP for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The District does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the District materially failed to comply with the terms of this agreement.

The following process will be used: 1) Thirty (30) days after the deliverable was due if the District has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) Thirty days after CMS has notified the District in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

a. CMS will issue a written notification to the District providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
b. For each deliverable, the District may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the District's anticipated date of submission. Should CMS agree to the District's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the District as an interim step before applying the deferral, if the District proposes a corrective action plan in the District's written extension request.

c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the District fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the District.
d. If the CMS deferral process has been initiated for District non-compliance with the terms of this agreement with respect to required deliverable(s), and the District submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released.
e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a District's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

44. Deferral of FFP for Insufficient Progress toward Milestones. Up to $5,000,000 in FFP for services in IMDs may be deferred if the District is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in the Implementation Plan and the required performance measures in the Monitoring Plan agreed upon by the District and CMS. Once CMS determines the District has not made adequate progress, up to $5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made. The District is expected to meet the milestones by the end of the first two years of the SMI/SED demonstration.

45. Submission of Post-Approval Deliverables. The District must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

46. Compliance with Federal Systems Updates. As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the District will work with CMS to:
a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the District; and
c. Submit deliverables to the appropriate system as directed by CMS.

IX. MONITORING

47. Monitoring Reports. The District must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Report. The Quarterly Monitoring Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Monitoring

Report is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates. The operational updates will focus on progress toward meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; updates on the District's SMI/SED financing plan and maintenance of effort described in STC 36(e); legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
b. Performance Metrics. The performance metrics will provide data to demonstrate how the District is progressing towards meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.
c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The District must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the District must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.
d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the District shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.
e. SMI Health IT and/or SUD Health IT. The District will include a summary of progress made in regards to SMI/SED and/or SUD Health IT requirements outlined in STC 37(d).
f. SMI/SED Financing Plan Updates. The District will include an update on its SMI/SED Financing plan as outlined in STC 36(e).

48. SMI/SED and/or SUD Mid-Point Assessment. The District must conduct an independent mid-point assessment by January 1, 2022. In the design, planning and conduction of the mid-point assessment, the District must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of managed care organizations (MCO), SMI/SED and/or SUD treatment providers, beneficiaries, and other key partners.

The District must require that the assessor provide a report to the District that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The District must provide a copy of the report to CMS no later than 60 days after January 1, 2022. The District must brief CMS on the report.

For milestones and measure targets at medium to high risk of not being achieved, the District must submit to CMS modifications to the SMI/SED Implementation Plan and/or the SUD Implementation Plan, the SMI/SED Financing Plan, and the SMI/SED Monitoring Protocol and/or SUD Monitoring Plan for ameliorating these risks. Modifications to the applicable Implementation, Financing, and Monitoring Protocol are subject to CMS approval.

Elements of the mid-point assessment include:

a. An examination of progress toward meeting each milestone and timeframe approved in the SMI/SED and/or the SUD Implementation Plans, the SMI/SED Financing Plan, and toward meeting the targets for performance measures as approved in the SMI/SED Monitoring Protocol and/or SUD Monitoring Protocol;
b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;
c. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets;
d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the District's SMI/SED or SUD Implementation Plans or SMI/SED Financing Plan or to pertinent factors that the District can influence that will support improvement; and
e. An assessment of whether the District is on track to meet the budget neutrality requirements.

49. Corrective Action. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the District to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

50. Close-Out Report. Within 120 calendar days after the expiration of the demonstration, the District must submit a Draft Close-Out Report to CMS for comments.

a. The draft close-out report must comply with the most current guidance from CMS.

b. The District will present to and participate in a discussion with CMS on the close-out report.
c. The District must take into consideration CMS' comments for incorporation into the final close-out report.
d. The final close-out report is due to CMS no later than thirty (30) calendar days after receipt of CMS' comments.
e. A delay in submitting the draft or final version of the close-out report may subject the District to penalties described in STC 43.

51. Monitoring Calls. CMS will convene periodic conference calls with the District.

a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, enrollment and access, budget neutrality, and progress on evaluation activities.
b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
c. The District and CMS will jointly develop the agenda for the calls.

52. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the District must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) days prior to the date of the planned public forum, the District must publish the date, time and location of the forum in a prominent location on its website. The District must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the District must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

X. EVALUATION OF THE DEMONSTRATION

53. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the District must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The District must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The District may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 43.

54. Independent Evaluator. Upon approval of the demonstration, the District must begin to arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The District must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the District may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

55. Draft Evaluation Design. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs.

The District must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the approval of the demonstration. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable.

The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):

a. All applicable Evaluation Design guidance, including guidance about SMI/SED and SUD. Hypotheses applicable to the demonstration as a whole, and to all key policies referenced above, will include (but will not be limited to) the effects of the demonstration on health outcomes; the financial impact of the demonstration (for example, such as an assessment of medical debt and uncompensated care costs).
b. Attachment A (Developing the Evaluation Design) of these STCs, technical assistance for developing SUD Evaluation Designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a Draft Evaluation Design.

56. Evaluation Budget. A budget for the evaluations must be provided with the draft Evaluation Designs. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluations such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the designs are not sufficiently developed, or if the estimates appear to be excessive.

57. Evaluation Design Approval and Updates. The District must submit the revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the documents will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the District will publish the approved Evaluation Design to the District's website within thirty (30) calendar days of CMS approval.

The District must implement the evaluation designs and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the evaluation designs, if the District wishes to make changes, the District must submit a revised evaluation design to CMS for approval.

58. Evaluation Questions and Hypotheses. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the District intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

59. Interim Evaluation Report. The District must submit an Interim Evaluation Report for each evaluation design, as applicable, and for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Reports should be posted to the District's website with the application for public comment.

a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved evaluation design.
b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
c. If the District is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the District made changes to the demonstration in its application for renewal, the research questions and hypotheses and a description of how the design was adapted should be included. If the District is not requesting a renewal for the demonstration, the Interim Evaluation Report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
d. The District must submit the final Interim Evaluation Report sixty (60) calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the District's website.
e. The Interim Evaluation Report must comply with Attachment B of these STCs.

60. Summative Evaluation Report. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs. The District must submit the draft Summative Evaluation Report for the demonstration's current approval period within eighteen (18) months of the

end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

a. Unless otherwise agreed upon in writing by CMS, the District must submit the final Summative Evaluation Report within sixty (60) calendar days of receiving comments from CMS on the draft.
b. The final Summative Evaluation Report must be posted to the District's Medicaid website within thirty (30) calendar days of approval by CMS.

61. Corrective Action Plan Related to Evaluation. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the District to submit a corrective action plan to CMS for approval. These discussions may also occur as part of a renewal process when associated with the District's Interim Evaluation Report. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

62. District Presentations for CMS. CMS reserves the right to request that the District present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.

63. Public Access. The District shall post the final documents (e.g., Monitoring Reports, Close-out Report, the approved Evaluation Design, Interim Evaluation Reports, and Summative Evaluation Reports) on the District's website within thirty (30) calendar days of approval by CMS.

64. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the District, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment on or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to District or local government officials.

XI. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

65. Allowable Expenditures. This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.[6]

[6] For a description of CMS's current policies related to budget neutrality for Medicaid demonstration projects authorized under section 1115(a) of the Act, see State Medicaid Director Letter #18-009.

66. Unallowable Expenditures. In addition to the other unallowable costs and caveats already outlined in these STCs, the District may not receive FFP under any expenditure authority approved under this demonstration for any of the following: Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

a. Costs for services provided in a nursing facility as defined in section 1919 of the Act that qualifies as an IMD.
b. Costs for services provided to individuals who are involuntarily residing in a psychiatric hospital or residential treatment facility by operation of criminal law.
c. Costs for services provided to beneficiaries under age 21 residing in an IMD unless the IMD meets the requirements for the "inpatient psychiatric services for individuals under age 21" benefit under 42 CFR 440.160, 441 Subpart D, and 483 Subpart G.

67. Standard Medicaid Funding Process. The standard Medicaid funding process will be used for this demonstration. The District will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The District will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and District and local administration costs (ADM). CMS shall make federal funds available based upon the District's estimate, as approved by CMS. Within thirty (30) days after the end of each quarter, the District shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the District, and include the reconciling adjustment in the finalization of the grant award to the District.

68. Extent of Federal Financial Participation for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the budget neutrality expenditure limits described in section XI:

a. Administrative costs, including those associated with the administration of the demonstration;
b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

69. Sources of Non-Federal Share. The District certifies that its match for the non-federal share of funds for this demonstration are District/local monies. The District further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

a. The District acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time. The District agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.
b. The District acknowledges that any amendments that impact the financial status of the demonstration must require the District to provide information to CMS regarding all sources of the non-federal share of funding.

70. Certification of Funding Conditions. The District must certify that the following conditions for non-federal share of demonstration expenditures are met:

a. Units of government, including governmentally operated health care providers, may certify that District or local monies have been expended as the non-federal share of funds under the demonstration.
b. To the extent the District utilizes certified public expenditures (CPE) as the funding mechanism for the District share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the District would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
c. To the extent the District utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the District the amount of such District or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the District share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the District's claim for federal match.
d. The District may use intergovernmental transfers (IGT) to the extent that such funds are derived from District or local monies and are transferred by units of government within the District. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and District and/or local government to return and/or redirect to the District any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care

provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

71. Program Integrity. The District must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The District must also ensure that the District and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.

72. Medicaid Eligibility Groups. Medicaid Eligibility Groups (MEG) are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The Master MEG Chart table provides a master list of MEGs defined for this demonstration.

Table 4. Master MEG Chart

MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
SUD IMD Services MCO	Hypo 1	X		X	Medicaid beneficiaries diagnosed with an SUD in managed care.
SUD IMD Services FFS	Hypo 1	X		X	Medicaid beneficiaries diagnosed with an SUD in fee-for-service.
SMI IMD Services MCO	Hypo 1	X		X	Medicaid beneficiaries diagnosed with an SMI in managed care
SMI IMD Services FFS	Hypo 1	X		X	Medicaid beneficiaries diagnosed with an SMI in fee-for-service.
Non-State Plan Services MEG	Hypo 2	X		X	Temporary authority for services detailed in Expenditure Authority #2.
Non-IMD Services MEG	Hypo 3	X		X	Temporary authority for services detailed in Expenditure Authority #3.

73. Reporting Expenditures and Member Months. The District must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00331/3). Separate

reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the District also must report member months of eligibility for specified MEGs.

a. Cost Settlements. The District will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.

b. Premiums and Cost Sharing Collected by the District. The District will report any premium contributions collected by the District from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by DY on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the District's compliance with the budget neutrality limits.

c. Pharmacy Rebates. Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The District will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.

d. Administrative Costs. The District will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the Master MEG Chart table, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

e. Member Months. As part of the Quarterly and Annual Monitoring Reports described in section IX, the District must report the actual number of “eligible member months” for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term “eligible member months” refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member

months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The District must submit a statement accompanying the annual report certifying the accuracy of this information.

f. Budget Neutrality Specifications Manual. The District will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the District will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the District's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the District compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 5. MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
SUD IMD Services MCO	Medicaid beneficiaries diagnosed with an SUD in managed care.	See STC 66	Follow CMS-64.9 Base Category of Service Definitions	Date of service	MAP	Y	1/1/20	12/31/24
SUD IMD Services FFS	Medicaid beneficiaries diagnosed with an SUD in fee-for-service.	See STC 66	Follow CMS-64.9 Base Category of Service Definitions	Date of service	MAP	Y	1/1/20	12/31/24
SMI IMD Services MCO	Medicaid beneficiaries diagnosed with an SMI/SED in managed care	See STC 66	Follow CMS-64.9 Base Category of Service Definitions	Date of service	MAP	Y	1/1/20	12/31/24
SMI IMD Services FFS	Medicaid beneficiaries diagnosed with an SMI/SED in fee-for-service.	See STC 66	Follow CMS-64.9 Base Category of Service Definitions	Date of service	MAP	Y	1/1/20	12/31/24

Table 5. MEG Detail for Expenditure and Member Month Reporting								
Non-State Plan Services MEG	Temporary authority for services described in Expenditure Authority #2.	See STC 66	Follow CMS-64.9 Base Category of Service Definitions	Date of service	MAP	Y	1/1/20	12/31/24
Non-IMD Services MEG	Temporary authority for services described in Expenditure Authority #.	See STC 66	Follow CMS-64.9 Base Category of Service Definitions	Date of service	MAP	Y	1/1/20	12/31/24

74. Demonstration Years. Demonstration Years (DY) for this demonstration are defined in the Demonstration Years table below.

Table 6 Demonstration Years		
Demonstration Year 1	January 1, 2020 to December 31, 2020	12 months
Demonstration Year 2	January 1, 2021 to December 31, 2021	12 months
Demonstration Year 3	January 1, 2022 to December 31, 2022	12 months
Demonstration Year 4	January 1, 2023 to December 31, 2023	12 months
Demonstration Year 5	January 1, 2024 to December 31, 2024	12 months

75. Budget Neutrality Monitoring Tool. The District must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing demonstration's actual expenditures to the budget neutrality expenditure limits described in section XII. CMS will provide technical assistance, upon request.[7]

[7] 42 CFR §431.420(a)(2) provides that states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and §431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS's current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and in states agree to use the tool as a condition of demonstration approval.

76. Claiming Period. The District will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the District made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the District will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

77. Future Adjustments to Budget Neutrality. CMS reserves the right to adjust the budget neutrality expenditure limit:

a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments, CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the District must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The District agrees that if mandated changes in the federal law require District legislation, the changes shall take effect on the day such District legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.
c. The District certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the District's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, District, and local statutes, regulations, and policies, and that the data are correct to the best of the District's knowledge and belief. The data supplied by the District to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

XII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

78. Limit on Title XIX Funding. The District will be subject to limits on the amount of federal Medicaid funding the District may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the District would likely have received in the absence of the demonstration. The limit may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS's assessment of the District's compliance with these tests

will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the District on the CMS-64 that pertain to the demonstration.

79. Risk. The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If a per capita method is used, the District is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the District at risk for changing economic conditions; however, by placing the District at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the District accepts risk for both enrollment and per capita costs.

80. Calculation of the Budget Neutrality Limits and How They Are Applied. To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the District may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

81. Main Budget Neutrality Test. This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.

82. Hypothetical Budget Neutrality. When expenditure authority is provided for coverage of populations or services that the District could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be "hypothetical;" that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS' current view that states should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality

Tests, which subject hypothetical expenditures to pre-determined limits to which the District and CMS agree, and that CMS approves, as a part of this demonstration approval. If the District's WW hypothetical spending exceeds the supplemental test's expenditure limit, the District agrees (as a condition of CMS approval) to offset that excess spending by refunding the FFP to CMS.

a. **Hypothetical Budget Neutrality Test 1: SMI/SED and/or SUD Services (see Expenditure Authority #1).** The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

b. **Hypothetical Budget Neutrality Test 2: SMI/SED and/or SUD Non-State Plan Services (see Expenditure Authority #2).** The table below identifies the MEG that is used for Hypothetical Budget Neutrality Test 2. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

c. **Hypothetical Budget Neutrality Test 3: SMI/SED and/or SUD Non-IMD Services (see Expenditure Authority #3).** The table below identifies the MEG that is used for Hypothetical Budget Neutrality Test 3. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

Table 7. Hypothetical Budget Neutrality Tests

MEG	PC or Agg*	WOW Only, WW Only, or Both	BASE YEAR [2018]	TREND	DY 1	DY 2	DY 3	DY 4	DY 5
SUD IMD	PC	Both	$1,605	4.3%	$1,728	$1,802	$1,880	$1,961	$2,045

Services MCO									
SUD IMD Services FFS	PC	Both	$2,331	4.3%	$2,510	$2,618	$2,730	$2,848	$2,970
SMI IMD Services MCO	PC	Both	$10,226	4.3%	$11,008	$11,481	$11,975	$12,490	$13,027
SMI IMD Services FFS	PC	Both	$7,719	4.3%	$8,309	$8,666	$9,039	$9,427	$9,833
Non-State Plan Services MEG	PC	Both	$480.06	4.3%	$517	$539	$562	$586	$612
Non-IMD Services MEG	PC	Both	$215	4.3%	$231	$241	$252	$262	$274

83. Composite Federal Share. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the District on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Main or Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

84. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from January 1, 2020 to December 31, 2024. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

85. Mid-Course Correction. If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the District to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Table 8. Hypothetical Budget Neutrality Test Mid-Course Correction Calculations		
	Cumulative Target Definition	**Percentage**
DY1	Cumulative budget neutrality limit plus:	2.0 percent
DY1 through DY2	Cumulative budget neutrality limit plus:	1.5 percent
DY1 through DY3	Cumulative budget neutrality limit plus:	1.0 percent
DY1 through DY4	Cumulative budget neutrality limit plus:	0.5 percent
DY1 through DY5	Cumulative budget neutrality limit plus:	0.0 percent

Table 9. Schedule of Deliverables		
Date	**Deliverable**	**STC**
30 calendar days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 calendar days after SUD program approval date	SUD Implementation Plan	STC 37(c)
60 calendar days after receiving CMS feedback	Draft SUD Implementation Plan	STC 37(c)
150 calendar days after SUD implementation plan approval date	Draft SUD Monitoring Protocol	STC 37
60 calendar days after receiving CMS feedback	Revised SUD Monitoring Protocol	STC 37
180 calendar days after demonstration approval date	Draft Evaluation Design	STC 55
60 Calendar days after receiving CMS feedback	Revised Evaluation Design	STC 55
30 calendar days after CMS Approval	Approved Evaluation Design published to state's website	STC 55
June 30, 2023, or with renewal application	Draft Interim Evaluation Report	STC 59(c)
60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 59(d)
Within 18 months after June 30, 2024	Draft Summative Evaluation Report	STC 60
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 60(a)-(b)
Monthly Deliverables	Monitoring Call	STC 51
Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4th quarter, beginning November 2019.	Quarterly Monitoring Reports, including implementation updates	STC 47
	Quarterly Expenditure Reports	STC 47(c)
Annual Deliverables - Due 90 calendar days after end of each 4th quarter	Annual Reports	STC 47

ATTACHMENT A
Developing the Evaluation Design

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform both Congress and CMS about Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both District and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Designs

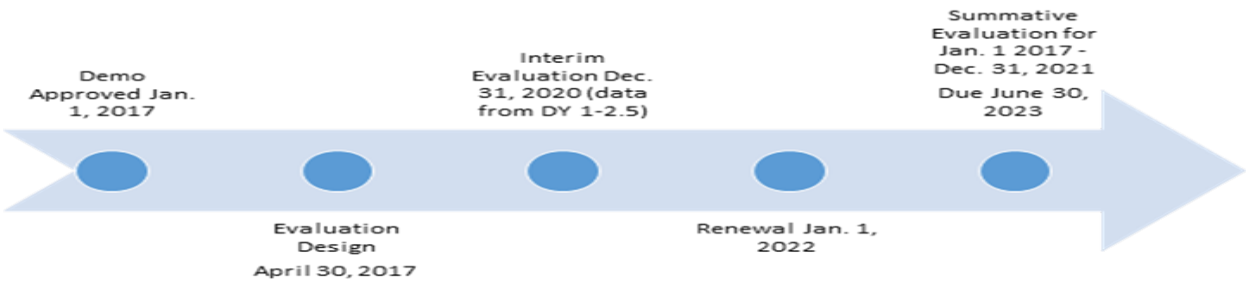
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals**.**

The format for the Evaluation Design is as follows:

A. General Background Information;
B. Evaluation Questions and Hypotheses;
C. Methodology;
D. Methodological Limitations;
E. Attachments.

Submission Timelines

There is a specified timeline for the District's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline). In addition, the District should be aware that section 1115 evaluation documents are public records. The District is required to publish the Evaluation Design to the District's website within thirty (30) days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of All Evaluation Designs
The Evaluation Design sets the stage for the Interim and Summative Evaluation Reports. It is important that the Evaluation Design explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology (and limitations) for the evaluation. A copy of the District's Driver Diagram (described in more detail in paragraph B2 below) should be included with an explanation of the depicted information.

A. General Background Information – In this section, the District should include basic information about the demonstration, such as:

1. The issue/s that the District is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the District selected this course of action to address the issue/s (e.g., a narrative on why the District submitted an 1115 demonstration proposal).

2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.

3. A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration.

4. For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

5. Describe the population groups impacted by the demonstration.

B. Evaluation Questions and Hypotheses – In this section, the District should:

1. Describe how the District's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.

2. Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf.

3. Identify the District's hypotheses about the outcomes of the demonstration.

4. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.

5. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the District is to describe in detail the proposed research methodology.

The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

1. Evaluation Design – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?

2. Target and Comparison Populations – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

3. Evaluation Period – Describe the time periods for which data will be included.

4. Evaluation Measures – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:

    a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
    b. Qualitative analysis methods may be used, and must be described in detail.
    c. Benchmarking and comparisons to national and District standards, should be used, where appropriate.
    d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
    e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
    f. Among considerations in selecting the metrics shall be opportunities identified by the District for improving quality of care and health outcomes, and controlling cost of care.

5. Data Sources – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources. If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).

6. Analytic Methods – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
    a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the District might want to articulate the analytic methods for each research question and measure.
    b. Explain how the District will isolate the effects of the demonstration (from other initiatives occurring in the District at the same time) through the use of comparison groups.
    c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
    d. The application of sensitivity analyses, as appropriate, should be considered.

7. Other Additions – The District may provide any other information pertinent to the Evaluation

Design of the demonstration.

Table A. Example Design Table for the Evaluation of the Demonstration

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
Hypothesis 1				
Research question 1a	-Measure 1 -Measure 2 -Measure 3	-Sample e.g. All attributed Medicaid beneficiaries -Beneficiaries with diabetes diagnosis	-Medicaid fee-for-service and encounter claims records	-Interrupted time series
Research question 1b	-Measure 1 -Measure 2 -Measure 3 -Measure 4	-sample, e.g., PPS patients who meet survey selection requirements (used services within the last 6 months)	-Patient survey	Descriptive statistics
Hypothesis 2				
Research question 2a	-Measure 1 -Measure 2	-Sample, e.g., PPS administrators	-Key informants	Qualitative analysis of interview material

D. Methodological Limitations – This section provides detailed information on the limitations of the evaluation. This could include the design, the data sources or collection process, or analytic methods. The District should also identify any efforts to minimize the limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the District would like CMS to take into consideration in its review. For example:

1. When the District demonstration is:

    a. Long-standing, non-complex, unchanged, or
    b. Has previously been rigorously evaluated and found to be successful, or
    c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)

2. When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:

    a. Operating smoothly without administrative changes; and
    b. No or minimal appeals and grievances; and
    c. No District issues with CMS-64 reporting or budget neutrality; and

d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

1. Independent Evaluator. This includes a discussion of the District's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the District will assure no conflict of interest. Explain how the District will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include "No Conflict of Interest" signed by the independent evaluator.

2. Evaluation Budget. A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

3. Timeline and Major Milestones. Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(2)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

ATTACHMENT B
Preparing the Interim and Summative Evaluation Reports

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provide important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both District and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single District or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the District's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Guidance

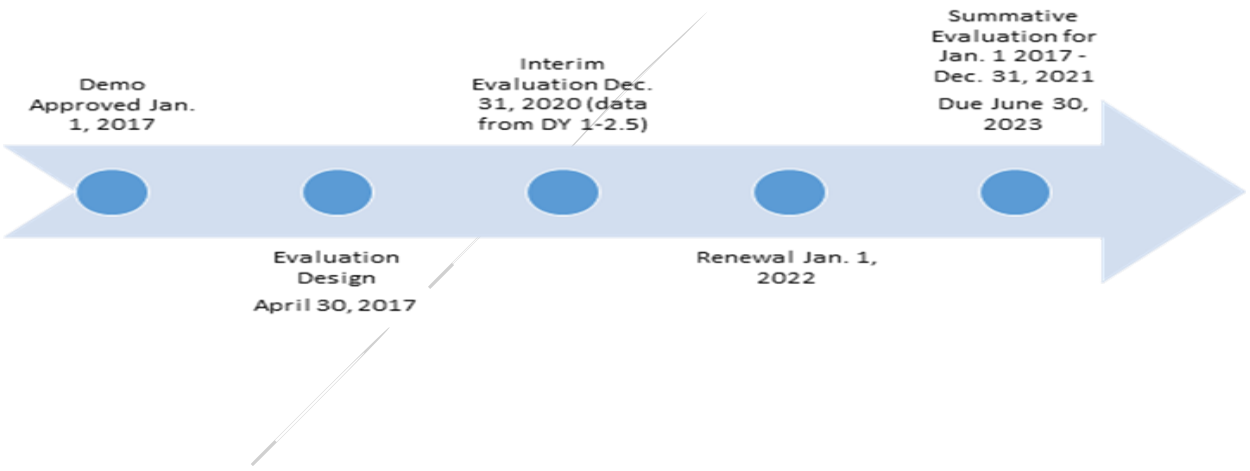
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the District's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Guidance is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

The format for the Interim and Summative Evaluation reports is as follows:

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other District Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

Submission Timelines

There is a specified timeline for the District's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the District should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the District is required to publish to the District's website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS, pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



Required Core Components of Interim and Summative Evaluation Reports
The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the District's Driver Diagram (described in the Evaluation Design guidance) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the District would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the District's submission must include:

A. Executive Summary – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

B. General Background Information about the Demonstration – In this section, the District should include basic information about the demonstration, such as:

1. The issues that the District is trying to address with its section 1115 demonstration and/or expenditure authorities, how the District became aware of the issue, the potential magnitude of the issue, and why the District selected this course of action to address the issues.
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
3. A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
4. For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the District and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
5. Describe the population groups impacted by the demonstration.

C. Evaluation Questions and Hypotheses – In this section, the District should:

1. Describe how the District's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
2. Identify the District's hypotheses about the outcomes of the demonstration;
    a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
    b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and

c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

D. Methodology – In this section, the District is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design.
The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an interim evaluation.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. Evaluation Design – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?
2. Target and Comparison Populations – Describe the target and comparison populations; include inclusion and exclusion criteria.
3. Evaluation Period – Describe the time periods for which data will be collected
4. Evaluation Measures – What measures are used to evaluate the demonstration, and who are the measure stewards?
5. Data Sources – Explain where the data will be obtained, and efforts to validate and clean the data.
6. Analytic methods – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. Other Additions – The District may provide any other information pertinent to the evaluation of the demonstration.

E. Methodological Limitations - This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

F. Results – In this section, the District presents and uses the quantitative and qualitative data to show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

G. Conclusions – In this section, the District will present the conclusions about the evaluation results.

1. In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
2. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
   a. If the District did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

H. Interpretations, Policy Implications and Interactions with Other District Initiatives – In this section, the District will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the District's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the District with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the District and national levels.

I. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1. What lessons were learned as a result of the demonstration?
2. What would you recommend to other states which may be interested in implementing a similar approach?

J. Attachment - Evaluation Design: Provide the CMS-approved Evaluation Design

ATTACHMENT C
Reserved for SMI/SED Implementation & Financing Plan

ATTACHMENT D
Reserved for SUD Implementation Plan

ATTACHMENT E
Reserved for SMI/SED and SUD Monitoring Protocol(s)

ATTACHMENT F
Reserved for SMI/SED and SUD Evaluation Design(s)