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

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

OCT 2 5 2019

Karen Kimsey
Director
Virginia Department of Medical Assistance Services
600 East Broad Street
Richmond, VA 23219

Dear Ms. Kimsey:

Under Section 1115 of the Social Security Act (the Act), the Secretary of Health and Human Services (HHS) may approve any experimental, pilot, or demonstration project that, in the judgment of the Secretary, is likely to assist in promoting the objectives of certain Act programs including Medicaid. Congress enacted section 1115 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." S. Rep. No. 87-1589, at 19 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 1943, 1961. Section 1115 of the Act allows the Secretary to waive compliance with Medicaid and Children's Health Insurance Program (CHIP) requirements of sections 1902 or 2102 of the Act, to the extent and for the period he finds necessary to carry out such demonstration project. In addition, section 1115 of the Act allows the Secretary to provide federal financial participation for demonstration costs that would not otherwise be considered as federally matchable expenditures under sections 1903 or 2107 of the Act, to the extent and for the period prescribed by the Secretary.

For the reasons discussed below, the Centers for Medicare & Medicaid Services (CMS) is approving Virginia's request for an extension of its section 1115 CHIP demonstration, entitled "Virginia Family Access to Medical Insurance Security (FAMIS) MOMS and FAMIS Select," Project Number 21-W-00058/3. Approval of this extension is granted under the authority of section 1115(a) of the Social Security Act and is based on the determination that the expenditure authority granted therein is likely to assist with promoting the objectives of title XXI of the Act by improving access to high-quality, person- centered prenatal, obstetric, and postpartum services that produce positive health outcomes for low-income women and their newborns. The demonstration also promotes positive health outcomes by providing an affordable private and employer-sponsored health insurance option for low-income families through premium assistance. This approval is effective as of the date of this letter through June 30, 2029.

Our approval of this demonstration extension is subject to the enclosed Special Terms and Conditions (STCs) and the limitations specified in the associated list of waiver and expenditure authorities and title XXI requirements made not applicable. The Commonwealth may deviate from CHIP state plan requirements only to the extent those requirements have been specifically

listed as granted expenditure authority or title XXI requirements not applicable. All CHIP requirements as expressed in law, regulation, and policy statement not expressly identified as not applicable in this letter, shall apply to this demonstration.

CMS approval of this demonstration is also conditioned on continued compliance with the enclosed set of STCs that define the nature, character, and extent of anticipated federal involvement in the demonstration project. The award is subject to your written acknowledgement of the award and acceptance of the STCs and associated authorities within 30 days of the date of this letter.

Extent and Scope of the Demonstration

Virginia's section 1115 CHIP demonstration, entitled "Virginia FAMIS MOMS and FAMIS Select," was initially approved June 30, 2005 and has been operating since August 1, 2005. The demonstration has two components. The first component is the "FAMIS MOMS" program that provides coverage to uninsured pregnant women in families with income up to and including 200 percent (plus a five percent income disregard) of the federal poverty level (FPL) who are not otherwise eligible for Medicaid. "FAMIS MOMS" also provides coverage to lawfully residing pregnant women and pregnant women with access to state employee's health benefit coverage (in accordance with the hardship exception as provided in section 2110(b)(6)(C) of the Social Security Act (the Act)); thereby aligning the Commonwealth's coverage of pregnant women with the expansion of CHIP coverage to children of state employees. FAMIS MOMS coverage is the same as that provided to pregnant women under the Medicaid state plan. Under the demonstration, Virginia is also authorized to deem infants born to FAMIS MOMS to be eligible for Medicaid or CHIP coverage, as appropriate. FAMIS MOMS beneficiaries receive health care services primarily through one of the managed care organizations (MCOs) contracted by the Commonwealth to provide Medicaid and FAMIS (CHIP state plan) benefits.

The second component is the "FAMIS *Select*" program that provides premium assistance for private or employer-sponsored insurance to uninsured children, ages 0 through 18, in families with income up to and including 200 percent (plus a five percent income disregard) of the FPL, who are eligible for direct CHIP coverage. These individuals are provided the option to receive premium assistance for private or employer-sponsored insurance and supplemental immunization benefits in lieu of receiving coverage under the CHIP state plan. However, these individuals still retain the right to elect to receive direct CHIP coverage at any time. FAMIS *Select* beneficiaries receive health care services through the private or employer-sponsored plan of choice.

Objectives of the CHIP Program

As noted above, the Secretary may approve a demonstration project under section 1115 of the Act if, in his judgment, the demonstration is likely to assist in promoting the objectives of title XXI. The purpose of CHIP is to provide funds to enable each State: (1) "to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children." Act §2101(a); and (2) "to provide pregnancy-related assistance" for "targeted low-income

pregnant women" should the state elect to do so via amendment to its State child health plan. Act §2112(a).

Section 1115 demonstration projects present an opportunity for states to experiment with reforms that go beyond just routine medical care and focus on interventions that drive better health outcomes and quality of life improvements, and that may increase beneficiaries' financial independence. Such policies may include those designed to address certain health determinants and those that encourage beneficiaries to engage in health-promoting behaviors and to strengthen engagement by beneficiaries in their personal health care plans. These tests will necessarily mean a change to the status quo. They may have associated administrative costs, particularly at the initial stage, and section 1115 acknowledges that demonstrations may "result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing." Act §1115(d)(1). But in the long term, they may create incentives and opportunities that help enable many beneficiaries to enjoy the numerous personal benefits that come with improved health and financial independence.

Section 1115 demonstration projects also provide an opportunity for states to test policies that fulfill the purposes of CHIP as stated above in accordance with sections 2101(a) and 2112(a) of the Act, while making it more practicable for states to furnish insurance coverage to a broader range of persons in need. Such measures may enable states to stretch their resources further and enhance their ability to provide medical assistance to a broader range of persons in need, including by expanding the services and populations they cover. By the same token, such measures may also preserve states' ability to continue to provide the optional services and coverage they already have in place.

Our demonstration authority under section 1115 of the Act allows us to offer states more flexibility to experiment with different ways of improving health outcomes and strengthening the financial independence of beneficiaries. Demonstration projects that seek to improve beneficiary health and financial independence improve the well-being of CHIP beneficiaries and, at the same time, allow states to maintain the long-term fiscal sustainability of their CHIP programs and to provide more medical services to more CHIP beneficiaries. Accordingly, such demonstration projects advance the objectives of CHIP.

Determination that the demonstration project is likely to assist in promoting CHIP's objectives

Demonstration projects under section 1115 of the Act offer a way to give states more freedom to test and evaluate innovative solutions to improve quality, accessibility, and health outcomes in a budget-neutral manner, provided that, in the judgment of the Secretary, the demonstration is likely to assist with promoting the objectives of CHIP. This extension of the Virginia FAMIS MOMS and FAMIS Select demonstration improves access to prenatal, obstetric, and postpartum services for low-income women beneficiaries and their newborns who otherwise would not have access to these services. This demonstration extension further improves access to private or employer-sponsored insurance to beneficiaries who would otherwise have difficulty affording such health insurance coverage.

The Commonwealth's evaluation data for FAMIS MOMS shows that beneficiaries who were continuously enrolled in FAMIS MOMS for at least the last 43 days of their pregnancy had

better birth outcomes than a comparison population of women who were not consistently enrolled prior to the day of delivery. Evaluation data showed that women who are continuously enrolled in the FAMIS MOMS component of the demonstration are less likely to experience early term births, have lower rates of low birthweight births, and had a lower rate of emergency department visits than the comparison group of mothers and their newborns. Although evaluation data suggest positive birth outcomes relative to the comparison population, it also indicates room for improvement in bringing birth outcomes for the FAMIS MOMS population closer to rates for all Virginia residents, and for women nationally. In addition, for this extension period, the Commonwealth intends to conduct a focused study and address previous findings that FAMIS MOMS beneficiaries were not accessing pediatric primary care visits recommended in the first 30 days following birth at the same rate as the comparison group of mothers.

Virginia encountered challenges obtaining some of the data necessary to fully conduct its evaluation of FAMIS Select. However, among the small group of FAMIS Select participants, evaluation data showed that FAMIS Select was generally a more advantageous and cost-effective option for families with larger numbers of CHIP-eligible children, and that many participating families were long-term participants enrolled in the program for longer than a year. In this extension period, CMS has updated the monitoring and evaluation sections of the STCs to better aid the Commonwealth in measuring and tracking the demonstration's impact on families participating in FAMIS Select. A new evaluation design is required post-approval, and must be approved by CMS.

Therefore, the Secretary has determined that the FAMIS MOM and FAMIS Select section 1115 demonstration is likely to assist in promoting the objectives of CHIP.

Consideration of Public Comments

Consistent with federal transparency requirements, CMS considers all public comments received during both the state and federal public comment periods when evaluating whether the demonstration project as a whole will likely assist in promoting the objectives of CHIP. CMS and Virginia received a small number of public comments about the demonstration during the respective public comment periods, which were supportive of the extension request for the demonstration.

Virginia received three public comments during its public comment period that were all in support of the continuation of the FAMIS MOMS and FAMIS Select demonstration. Two supporting comments were expressed during one of Virginia's two public hearings. The Virginia Poverty Law Center submitted a written letter of support for continuing the FAMIS MOMS and FAMIS Select demonstration. The commenters also spoke about the need to promote awareness for the FAMIS Select program in the Commonwealth's outreach efforts. In response to the public comments, Virginia expressed its appreciation for the supporting comments offered by stakeholders. Virginia also acknowledged that there is a need to promote awareness of FAMIS Select and expressed that it plans to boost local outreach efforts and will continue to explore ways to identify families and children who may benefit from the FAMIS Select program. The Tribes did not submit comments during either of the two 60-day public comment periods provided by the Commonwealth.

The federal public comment period for this extension request began May 3, 2019 and ended June 2, 2019. CMS received one comment during the federal public comment period from the American College of Obstetricians and Gynecologists (ACOG) in support of continuing the FAMIS MOMS and FAMIS Select demonstration. ACOG also asked that Virginia and CMS consider amending the demonstration to extend postpartum coverage from 60 days to 12 months postpartum to provide a more robust, longer-lasting benefit to Virginia's low-income moms. This change would first require authorization by the Virginia legislature and could not be considered as part of this extension approval.

Your project officer for this demonstration is Ms. Ticia Jones. She is available to answer any questions concerning your section 1115 demonstration and this extension. Ms. Jones's contact information is:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-01-16
7500 Security Boulevard
Baltimore, MD 21244-1850
E-mail: ticia.jones@cms.hhs.gov

Official communications regarding this demonstration should be sent simultaneously to Ms. Ticia Jones and to Ms. Sabrina Tillman-Boyd, Deputy Director, Division of Medicaid Field Operations East. Her contact information is as follows:

Sabrina Tillman-Boyd
Deputy Director
Division of Medicaid Field Operations East
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
801 Market Street
Suite 9400
Philadelphia, PA 19107-3134
Email: Sabrina.Tillman-Boyd@cms.hhs.gov

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

Sincerely,

[redacted]

Calder Lynch
Acting Director

cc: Sabrina Tillman-Boyd, Deputy Director, Division of Medicaid Field Operations East

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **21-W-00058/3**

TITLE: **Virginia FAMIS MOMS and FAMIS *Select* Section 1115 Demonstration**

AWARDEE: **Virginia Department of Medical Assistance Services**

Expenditure Authority

All requirements of the Medicaid and Children's Health Insurance Program (CHIP) not identified as not applicable in this list, shall apply to the demonstration expenditures listed below as of October 25, 2019, the date on the accompanying CMS approval letter, through June 30, 2029.

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the Commonwealth of Virginia for the items identified below (which are not otherwise included as expenditures under section 1903 or section 2107(e)(2)(A)) shall, for the period of this demonstration in accordance with the Special Terms and Conditions (STCs), be regarded as matchable expenditures under Virginia's title XXI plan:

1. **Demonstration Population I**: Expenditures for extending health insurance coverage through CHIP to uninsured pregnant women with income up to and including 200 percent (plus a five percent income disregard) of the federal poverty level (FPL), who are not otherwise Medicaid eligible. This includes those pregnant women who are lawfully residing in the United States and those with access to state employees' health benefit coverage.

   Should the Commonwealth freeze enrollment or otherwise discontinue coverage of the CHIP pregnant woman population, the title XXI expenditure authority will terminate and will not be subject to extension.

2. **Demonstration Population II:** Expenditures for extending health insurance coverage to children in families with income up to and including 200 percent (plus a five percent income disregard) of the FPL, who are eligible for Virginia's separate title XXI CHIP coverage but choose to elect a monthly premium assistance subsidy for private or employer-sponsored insurance coverage.

For these populations, all CHIP rules not expressly waived or identified as not applicable shall apply.

The following title XXI requirements are not applicable to the populations served under the

Virginia FAMIS MOMS and FAMIS *Select* section 1115 demonstration.

Title XXI Requirements Not Applicable to Demonstration Populations I and II.

1. General Requirements, Eligibility and Outreach — Section 2102

The Commonwealth's CHIP does not have to reflect the demonstration populations, and eligibility standards do not have to be limited by the general principles in section 2102(b) of the Act. To the extent other requirements in section 2102 of the Act duplicate Medicaid or other CHIP requirements for these or other populations, they do not apply, except that the Commonwealth must perform eligibility screening to ensure that the demonstration populations do not include individuals otherwise eligible for Medicaid.

2. Cost Sharing — Section 2103(e)

Rules governing cost sharing under section 2103(e) of the Act shall not apply to the demonstration population II to the extent necessary to enable the state to impose cost sharing in private or employer-sponsored insurance plans.

3. Cost-Sharing Exemption for American Indian/ Alaskan Native (Al/AN) Children — Section 2102(b)(3)(D) 42 CFR Section 457.535

To the extent necessary to permit the Commonwealth to impose cost sharing on AI/AN children who elect to enroll in the premium assistance program.

4. Benefit Package Requirements — Section 2103

To permit the Commonwealth to offer a benefit package that does not meet the requirements of section 2103 at 42 CFR section 457.4 10(b)(1) for the demonstration populations.

5. Federal Matching Payment and Family Coverage Limits — Section 2105

Federal matching payment in excess of the 10-percent cap for expenditures related to the demonstration population and limits on family coverage are not applicable to the demonstration population.

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER AUTHORITY

NUMBER: **21-W-00058/3**

TITLE: **Virginia FAMIS MOMS and FAMIS *Select* Section 1115 Demonstration**

AWARDEE: **Virginia Department of Medical Assistance Services**

Under the authority of section 1115(a)(1) of the Social Security Act (the Act), the following exceptions to Medicaid and CHIP requirements are granted as of October 25, 2019, the date on the accompanying CMS approval letter, through June 30, 2029:

Newborn deeming **Section 1902(a)(46) and 2102(b)(2)**

To enable the Commonwealth to consider children, who are born to pregnant women enrolled in the demonstration or eligible as targeted low-income children under the approved CHIP state plan, to have applied and been determined eligible for Medicaid or CHIP on the date of birth and remaining eligible until attaining the age of 1. This does not permit waivers of either section 1903(x) of the Act or section 2105(c) which requires States to obtain satisfactory documentary evidence of citizenship or nationality during the reasonable opportunity period for individuals in Medicaid or CHIP.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS (STCs)

DEMONSTRATION NUMBER: No. 21-W-00058/3

TITLE: FAMIS MOMS and FAMIS *Select*

AWARDEE: Virginia Department of Medical Assistance Services

I. PREFACE

The following are Special Terms and Conditions (STCs) for the Virginia FAMIS MOMS and FAMIS *Select* programs, a Children's Health Insurance Program (CHIP) section 1115 demonstration. The parties to this agreement are the Virginia Department of Medical Services (Commonwealth) and the Centers for Medicare & Medicaid Services (CMS). These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the Commonwealth's obligations to CMS during the approved demonstration period specified in these STCs. All previously approved STCs, waivers, and expenditure authorities are superseded by the STCs set forth below. These STCs are effective October 25, 2019, the date of the CMS approval letter that accompanied these STCs, through June 30, 2029.

The STCs have been arranged into the following subject areas:

II. PROGRAM DESCRIPTION AND HISTORICAL CONTEXT

Demonstration Description

Virginia's FAMIS MOMS and FAMIS *Select* demonstration has two components. The first component of the demonstration entitled, "FAMIS MOMS" provides coverage to uninsured

pregnant women in families with income up to and including 200 percent (plus a five percent income disregard) of the federal poverty level (FPL) who are not otherwise eligible for Medicaid. "FAMIS MOMS" also provides coverage to lawfully residing pregnant women and pregnant women with access to state employees' health benefit coverage (in accordance with the hardship exception as provided in section 2110(b)(6)(C) of the Social Security Act (the Act)); thereby aligning the Commonwealth's coverage of pregnant women with the expansion of CHIP coverage to children of state employees. FAMIS MOMS coverage is the same as that provided to pregnant women under the Medicaid state plan. Under the demonstration, Virginia is also authorized to deem infants born to FAMIS MOMS to be eligible for Medicaid or CHIP coverage, as appropriate, consistent with 42 CFR 435.117 and 457.360. These infants are deemed eligible on the date of birth and remain eligible until attaining the age of 1.

The second component of the demonstration entitled, the "FAMIS *Select*" program, provides premium assistance for private or employer-sponsored insurance to uninsured children, ages 0 through 18, in families with income up to and including 200 percent of the FPL, who are eligible for direct CHIP state plan coverage. These individuals are provided the option to receive premium assistance for private employer-sponsored insurance and supplemental immunization benefits in lieu of receiving coverage under the CHIP state plan. However, these individuals still retain the right to elect to receive direct CHIP coverage at any time.

Demonstration History

The Virginia FAMIS MOMS and FAMIS Select demonstration was initially approved on June 30, 2005 and implemented August 1, 2005.

FAMIS MOMS

Virginia implemented the FAMIS MOMS program incrementally beginning August 1, 2005. The intent of this demonstration program component is to provide prenatal care to uninsured women within the title XXI income range and likely to give birth to FAMIS-eligible (i.e., CHIP state plan) children. The first stage expanded eligibility to pregnant women with family income above the Medicaid limit of 133 percent of the FPL but less than or equal to 150 percent of the FPL. The second stage, implemented September 1, 2006, covered pregnant women with incomes through 166 percent of the FPL. Subsequent stages covered pregnant women through 185 percent of the FPL (July 1, 2007) and through 200 percent of the FPL (July 1, 2009). Effective July 1, 2010, CMS approved an amendment to eligibility requirements to allow enrollment of pregnant women with income below 133 percent of the FPL who do not meet eligibility requirements for full Medicaid coverage but do meet the FAMIS MOMS requirements.

During the period January 1, 2014 through November 30, 2014, this demonstration component was phased-out because the Virginia General Assembly adopted an amendment to the Commonwealth's biennial budget directing the Commonwealth to phase-out and eliminate the FAMIS MOMS program when health insurance coverage under the Federally Facilitated Marketplace (FFM) became available on January 1, 2014. New applications for FAMIS MOMS coverage were not accepted after December 31, 2013. However, women enrolled in FAMIS MOMS on or prior to December 31, 2013 retained eligibility for the duration of their coverage

period. Any application received for pregnancy coverage beginning January 1, 2014 through November 30, 2014, was screened for Medicaid under pregnant women eligibility and for CHIP. If the applicant was ineligible for Medicaid or CHIP, the application was transferred to the FFM. Beginning on December 1, 2014, enrollment was reopened and new applications accepted for uninsured pregnant women with income up to and including 200 percent of the FPL. This income eligibility threshold aligns with children's coverage levels under the CHIP state plan.

On April 3, 2015, CMS approved a demonstration amendment to add coverage for dental services to the FAMIS MOMS program component, consistent with the addition of these benefits for pregnant women under Medicaid. This demonstration amendment also allowed eligibility to be expanded to include pregnant women with access to subsidized health insurance through state employee benefits.

The title XXI goals and objectives of the FAMIS MOMS program is as follows:

- Facilitate access to prenatal, obstetric, and postpartum care for a vulnerable population that does not otherwise qualify for public insurance;
- Improve selected birth outcomes of FAMIS MOMS participants and their newborns; and,
- Facilitate access to recommended pediatric primary care for newborns of FAMIS MOMS participants.

FAMIS Select

Virginia implemented the FAMIS Select program beginning August 1, 2005. FAMIS Select replaced Virginia's former employer-sponsored health insurance program and provides an alternative for families with children enrolled in FAMIS (i.e., the CHIP state plan) and who have access to private or employer-sponsored coverage. The Commonwealth provides a set monthly premium assistance subsidy for health insurance coverage for children with family income up to 200 percent of the FPL who are eligible for direct coverage in FAMIS. All children are first enrolled in FAMIS. Parents may then choose the premium assistance subsidy in lieu of direct FAMIS coverage for their child(ren). Premium assistance payments are paid directly to the family based on verified payroll withholding amounts; with the maximum subsidy not to exceed a family's total share of the total monthly premium.

Parents that choose FAMIS Select are responsible for all cost-sharing associated with the private or employer-sponsored plan. Virginia does not wrap benefits with the exception of immunizations if the family's chosen plan does not provide such coverage.

The title XXI goals and objectives of the FAMIS Select program is as follows:

- Facilitate access to affordable private and employer-sponsored health insurance for low-income families through premium assistance;
- Ensure that access to and use of health care services available to children participating in FAMIS Select is comparable to that of children participating in FAMIS; and,
- Assure the aggregate cost-effectiveness of the FAMIS Select program.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The Commonwealth must comply with 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 Affordable Care Act (Section 1557).

2. **Compliance with CHIP Law, Regulation, and Policy.** All requirements of CHIP expressed in 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), must apply to the demonstration.

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The Commonwealth must, within the timeframes specified in law, regulation, or policy statement, come into compliance with any changes in federal 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 state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

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

    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 Commonwealth must adopt, subject to CMS approval, a modified allotment neutrality agreement for the demonstration as necessary to comply with such change. The modified allotment neutrality agreement will be effective upon the implementation of the change. Further, the Commonwealth reserves the right to seek an amendment to the demonstration (as per STC 7) as a result of the change in FFP.

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

5. **State Plan Amendments.** The Commonwealth will not be required to submit title XIX or title XXI state plan amendments 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 may be required, except as otherwise noted in these STCs. In all such instances, the Medicaid and CHIP state plans governs.

6. **Changes Subject to the Amendment Process**. Changes related to demonstration features, such as eligibility, enrollment, enrollee rights, benefits, beneficiary rights, delivery systems, cost-sharing, sources of non-federal share of funding, allotment 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 Commonwealth must not implement or begin operational changes to these elements without prior approval by CMS of the amendment to the demonstration. In certain instances, companion amendments to the Medicaid or CHIP state plan may be required as well. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or service-based expenditures, will be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7, 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 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 failure by the Commonwealth to submit required elements of a viable amendment request as specified in this STC and submission of required deliverables specified in these STCs in accordance with the deadlines specified herein. Amendment requests must include, but are not limited to, the following:

    a. *Demonstration Amendment Summary and Objectives.* The Commonwealth must provide a detailed description of the amendment, including what Virginia intends to demonstrate via this amendment as well as the impact on beneficiaries, with sufficient supporting documentation, the objective of the change and desired outcomes including a conforming title XIX and/or title XXI state plan amendment, if necessary;

    b. *Allotment Neutrality Worksheet.* The Commonwealth must provide an up-to-date CHIP (title XXI funding) allotment neutrality worksheet that identifies the impact of the proposed amendment on the Commonwealth's available title XXI allotment;

    c. *Waiver and Expenditure Authorities.* The Commonwealth must provide a list of waivers and expenditure authorities that are being requested or terminated, along with the programmatic description of why these waivers and expenditure authorities are being requested for the amendment;

d. *Evaluation.* The Commonwealth 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; and,

e. *Public Notice.* An explanation of the public process used by Virginia, consistent with the requirements of STC 13. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the Commonwealth in the final amendment request submitted to CMS.

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 state 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 Commonwealth may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

a. *Notification of Suspension or Termination.* The Commonwealth 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 Commonwealth must submit its 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 Commonwealth must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the Commonwealth must conduct tribal consultation in accordance with STC 13. Once the 30-day public comment period has ended, the Commonwealth must provide a summary of each public comment received, the Commonwealth's response to the comment, and how the Commonwealth considered the comments received when developing the revised transition and phase-out plan.

b. *Transition and Phase-out Plan Requirements.* The Commonwealth must minimally include in its phase-out plan the process by which it will notify affected beneficiaries; the content of said beneficiary notices (including information on the beneficiary's appeal rights); the process by which the Commonwealth will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries; the process by which the Commonwealth will ensure ongoing coverage for eligible beneficiaries; and undertake any community outreach

activities to notify affected beneficiaries (including any community resources that are available).

c. *Transition and Phase-out Plan Approval:* The Commonwealth 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 Commonwealth must comply with applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, and 431.213. In addition, the state must assure all applicable and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the Commonwealth must maintain benefits as required in 431.230. In addition, the Commonwealth 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 the 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 Commonwealth 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 per 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 Commonwealth 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 Commonwealth's obligation to determine Medicaid or CHIP eligibility in accordance with the approved Medicaid or CHIP state plans.

g. *Federal financial participation (FFP).* If the demonstration project is terminated or any relevant waivers suspended by the state, FFP shall be 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. Close-out Report. Within 120 calendar days after the end of the demonstration (i.e., upon expiration or early termination), the Commonwealth must submit a draft Close-out Report to CMS for comments.

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

b. The state will present to and participate in a discussion with CMS on the Close-out report.

c. The state 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 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 state to penalties described in STC 26.

11. **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 waivers or expenditure authorities would no longer be in the public interest or promote the objectives of titles XIX and/or XXI. CMS will promptly notify the Commonwealth in writing of the determination and the reasons for the withdrawal, together with the effective date, and must afford the Commonwealth 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 authorities, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling participants.

12. **Adequacy of Infrastructure.** The Commonwealth must 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.

13. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The Commonwealth 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 Commonwealth must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The Commonwealth 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 Commonwealth 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 state's approved Medicaid or CHIP state plan, when any program changes to the

demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state

14. **Federal financial participation (FFP).** No federal matching for expenditures for this demonstration, including administrative and medical assistance expenditures, will be available until the effective date identified in the CMS demonstration approval letter that accompanied these STCs.

15. **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, managed care organizations (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.

16. **Common Rule Exemption.** The Commonwealth 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 or 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(b)(5).

IV. ELIGIBILITY AND ENROLLMENT

17. **Eligibility Groups Affected By the Demonstration.** There are two populations eligible under this demonstration:

    a. **FAMIS MOMS.** Coverage is provided to uninsured pregnant women in families with income up to and including 200 percent of the FPL who are not eligible for Medicaid, including those women lawfully residing in the United States. FAMIS MOMS coverage is also provided to pregnant women with access to state employee's health benefit coverage (in accordance with the hardship exception as provided in section 2110(b)(6)(C) of the Act), thereby aligning with the Commonwealth's coverage of pregnant women with the expansion of CHIP coverage to children of state employees. FAMIS MOMS coverage is the same as that provided to pregnant women under the Medicaid state plan. Pregnant women are eligible for the duration of their pregnancy and for 60 days after the pregnancy ends; and any remaining days in the month in which the 60th day falls.

Under the demonstration, Virginia is also authorized to deem infants born to FAMIS MOMS to be eligible for Medicaid or CHIP coverage, as appropriate, consistent with 42 CFR 435.117 and 457.360. These infants are deemed eligible on the date of birth and remain eligible until attaining the age of 1.

b. **FAMIS *Select* Premium Assistance.** Children eligible for and enrolled in Virginia's separate CHIP program, may elect to enroll in FAMIS *Select* and receive CHIP premium assistance payments to purchase private or employer sponsored health insurance coverage. Such enrollment is voluntary and based on informed choice regarding all implications of choosing premium assistance in lieu of direct CHIP state plan coverage, including the possibility of reduced benefits and increased cost-sharing, and that the CHIP cost-sharing limit of five percent on annual, aggregate cost sharing will not apply.

The Commonwealth will ensure that enrollees are annually notified that they may choose direct CHIP state plan coverage at any time. The Commonwealth will inform families that all age-appropriate immunizations in accordance with the recommendations of the Advisory Committee on Immunization Practices (ACIP) are covered by CHIP if their private or employer sponsored health insurance coverage does not provide for such immunizations. Families will continue to be told that this coverage is a factor to consider in choosing premium assistance in lieu of direct CHIP state plan coverage. The Commonwealth shall provide information as to where children may receive immunizations, well-baby, and well-child services in the event these services are not covered in the private or employer-sponsored health plan in which they are enrolled. In the case where title XXI eligibles are enrolled in private or employer-sponsored health insurance that does not include immunizations, the Commonwealth has an established mechanism in effect to reimburse providers for the cost of immunizations.

18. **Screening for Medicaid.** Applicants for the demonstration will continue to be screened for Medicaid eligibility. Demonstration applicants eligible for Medicaid will be enrolled in Medicaid and receive the full Medicaid benefit package.

19. **Enrollment Limits.** There is no enrollment cap for FAMIS MOMS and FAMIS *Select*. Enrollment in an individual or employer-sponsored plan is voluntary and the child may continue to elect to switch to direct CHIP state plan coverage at any time.

20. **Applicability of title XXI Maintenance of Effort to Demonstration Populations.** The maintenance of effort provision at section 2105(d)(3)(A) of the Act applies to title XXI eligible children enrolled in FAMIS *Select*. This provision requires that, with certain exceptions, as a condition of receiving federal financial participation for Medicaid, states must maintain CHIP "eligibility standards, methodologies, and procedures" for children that are no more restrictive than those in effect on March 23, 2010. See STCs 49 and 50 related to title XXI funding limits and shortfalls.

Section 2105(d)(3) of the Act is not applicable to pregnant women enrolled under the

FAMIS MOMS component of the demonstration.

V. BENEFITS

21. Demonstration Benefits. There are two distinct benefit packages offered under this demonstration:

a. **FAMIS MOMS** – Women enrolled in FAMIS MOMS receive the same package of benefits as provided to pregnant women covered by Virginia's Medicaid program. The benefit package includes comprehensive health and dental benefits, including orthodontics (orthodontics benefit is limited to women under the age of 21). All dental services must be received through the Commonwealth's contracted ***Smiles for Children*** service provider.

If changes are made in the benefit package, the Commonwealth must submit the proposed change to CMS for review and approval, as outlined in STC 7, before modifications can be implemented by the Commonwealth.

b. **FAMIS *Select* Premium Assistance**. For families with CHIP eligible children who choose to receive premium assistance for private or employer-sponsored health insurance coverage, benefits are limited to premium assistance subsidies and immunizations as described in STC 17.b.

22. Cost Effectiveness. Consistent with 2105(c)(3) of the Social Security Act, cost-effectiveness for the purchase of employer-sponsored insurance shall be determined relative to the amount of expenditures (determined on an individual or aggregate basis) under the state child health plan, including administrative expenditures, that the state would have made to provide comparable coverage to the targeted low-income child or family involved (as applicable).

23. Minimum Essential Coverage (MEC). In accordance with CMS' February 12, 2016 correspondence to the Virginia Department of Medicaid Assistance Services' Director, Cynthia Jones, the Commonwealth's benefit package provided to uninsured pregnant women and newborn children under the FAMIS MOMS component of the demonstration is equivalent to CHIP state plan coverage. Accordingly, CMS has determined coverage provided to these women and children under this demonstration is recognized as MEC.

CMS also concluded that the Commonwealth's coverage provided under the FAMIS Select component of the demonstration does not meet the comprehensive criteria for MEC. The FAMIS Select program does not provide premium assistance enrollees with wrap-around services or cost-sharing assistance that is comparable to CHIP state plan out-of-pocket limits, thus, this is a lesser benefit than coverage afforded to children who are eligible for CHIP state plan coverage. Accordingly, CMS has determined that the coverage provided to these children under the FAMIS Select demonstration component is not recognized as MEC.

VI. COST SHARING

24. Cost Sharing. The cost-sharing requirements for this demonstration are outlined below:

a. **FAMIS MOMS -** The cost-sharing requirements for the FAMIS MOMS component of the demonstration are consistent with those described in the Medicaid state plan. There are no monthly premiums or enrollment fees associated with participation in the demonstration.

Co-payments for services received by FAMIS MOMS are identical to co-payments required of pregnant women covered by Medicaid. By policy, there are no co-payments required for pregnancy related services or for medical conditions that may complicate the pregnancy, including dental services. Also, it is a contractual requirement that Managed Care Organization (MCO) not charge pregnant women co-payments for any services. Therefore, the only co-payments that may be charged to a pregnant woman receiving services through Medicaid or FAMIS MOMS would be for non-pregnancy related services delivered through fee-for-service.

b. **FAMIS *Select* Premium Assistance**. For families with CHIP eligible children who choose to receive premium assistance for private or employer-sponsored insurance and supplemental immunization benefits in lieu of receiving coverage under the CHIP state plan, cost-sharing requirements will continue to be set by their private or employer-sponsored insurance plan.

VII. DELIVERY SYSTEM

25. Demonstration Delivery System. The demonstration delivery system varies by population as described below:

a. **FAMIS MOMS -** Health care services are delivered primarily through one of the MCOs contracted by DMAS to provide Medicaid and FAMIS benefits. Initially, benefits are provided on a fee-for-service basis until the pregnant woman is enrolled in an MCO. Dental services are provided by the contracted ***Smiles for Children*** service provider.

b. **FAMIS *Select* Premium Assistance**. For families who select premium assistance, health care services are delivered through the private or employer-sponsored plan of choice.

VIII. GENERAL REPORTING REQUIREMENTS

26. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in an amount up to

$1,000,000 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 Commonwealth does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The following process will be used: 1) Thirty days after the deliverable was due if the state 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 Commonwealth in writing that the deliverable was not accepted for being insufficient, or 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 state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).

b. For each deliverable, the Commonwealth 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 Commonwealth's anticipated date of submission. Should CMS agree to the Commonwealth's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the Commonwealth as an interim step before applying the deferral, if the Commonwealth proposes a corrective action plan in the state's written extension request.

c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the Commonwealth 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 Commonwealth.

d. If the CMS deferral process has been initiated for the Commonwealth's non-compliance with the terms of this agreement with respect to required deliverable(s), and the state 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.

As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, the Commonwealth'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.

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

28. **Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional section 1115 demonstration reporting and analytics functions, the state 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 section 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the Commonwealth; and,

    c. Submit deliverables to the appropriate system as directed by CMS.

IX. MONITORING

29. **Monitoring Reports.** The Commonwealth must submit one Semi-Annual Report and one compiled Annual Report each demonstration year. The Semi-Annual Reports are due no later than 60 calendar days following the end of each six month period (i.e., September – February semi-annual report will be due by April 29 each year). The compiled Annual Report is due no later than 90 calendar days following the end of the demonstration year (i.e., the September – June compiled annual report will be due by September 28 each year). 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 must 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; 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 conducted in accordance with required by 42 CFR 431.420(c) regarding the progress of the demonstration.

b. Performance Metrics. The performance metrics will provide data to demonstrate how the state 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 requiring 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. Allotment Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The Commonwealth must provide an updated allotment neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring allotment neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected allotment neutrality data upon request. In addition, the Commonwealth must report quarterly expenditures associated with the populations affected by this demonstration on the Form CMS-21. No later than six months after the end of each demonstration year, or as soon thereafter as data are available, the Commonwealth will calculate and report to CMS annual demonstration expenditures for the completed year. 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 Commonwealth shall include a summary of the progress of evaluation activities, including rapid cycle evaluation assessments, key milestones accomplished, and any challenges encountered and how they were addressed.

30. Corrective Action. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of CHIP, CMS reserves the right to require the Commonwealth to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waiver or expenditure authorities as outlined in STC 11.

31. Monitoring Calls. CMS and the Commonwealth will hold monitoring calls no later than 60 calendar days after submission of the Monitoring Reports described in STC 29 to discuss the program update provided in the reports and any issues associated with the continued operation of the demonstration. The purpose of these calls is to discuss 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, allotment

neutrality, and progress on evaluation activities. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration. The Commonwealth and CMS will jointly develop the agenda for the calls.

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

X. EVALUATION OF THE DEMONSTRATION

33. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the Commonwealth 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 Commonwealth 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 Commonwealth may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 26.

34. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The Commonwealth must submit, for CMS comment and approval, a draft evaluation design with implementation timeline, no later than 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 also include a proposal for rapid cycle evaluation and should specify for the rapid cycle evaluation report, what hypotheses and research questions will be addressed. The draft Evaluation Design must be developed in accordance with the following CMS guidance provided in Attachment A (Developing the Evaluation Design) and any applicable CMS-provided evaluation design guidance.

Failure to comply with this STC may result in a deferral being issued as outlined in STC 26.

35. **Evaluation Budget.** A budget for the evaluation must 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 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.

36. **Evaluation Design Approval and Updates.** The Commonwealth must submit the revised draft Evaluation Design within 60 calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the Commonwealth will publish the approved Evaluation Design on the Commonwealth's website within 30 calendar days of CMS approval. The Commonwealth must implement the evaluation designs and submit a description of its evaluation implementation process in each of the Monitoring Reports, including any required rapid cycle assessments specified in these STCs. Once CMS approves the evaluation design, if the Commonwealth wishes to make changes, the Commonwealth must submit a revised evaluation design to CMS for approval.

    Failure to comply with this STC may result in a deferral being issued as outlined in STC 26.

37. **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 state intends to test. Each demonstration component should have at least one evaluation question and hypotheses. 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' Core Set of Health Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by the National Quality Forum (NQF).

38. **Interim Evaluation Report.** The Commonwealth must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for extension, the Evaluation Report should be posted to the Commonwealth'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 any 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. The Commonwealth must provide a draft Interim Evaluation Report for the corresponding years, no longer than one year after completion of the measurement period, as follows. The state must submit a final Interim Evaluation Report for each measurement period 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the documents to the Commonwealth's website.
    i. An Interim Evaluation Report for the period of June 2019 through June 2021 will be due by no later than June 30, 2022.
    ii. An Interim Evaluation Report for the period of July 2021 – June 2024 will be due by no later than June 30, 2025.
    iii. An Interim Evaluation Report for the period of July 2024 – June 2027 will be due by no later than June 30, 2028.

d. If the Commonwealth is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted. If the Commonwealth made changes to the demonstration in its application for extension, the research questions and hypotheses, and how the design was adapted should be included. If the Commonwealth is not requesting a demonstration extension, an Interim Evaluation report is due one year prior to the end of the demonstration. For demonstration phase-out prior to the expiration of this demonstration 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.

e. The Commonwealth must submit the final Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the Commonwealth's website.

f. The Interim Evaluation Report must comply with attachment B (Preparing the Evaluation Report) of these STCs.

39. Evaluation Outcomes. CMS may exercise its rights as described in STC 11 to not reauthorize any demonstration program authority for which there are no evaluation findings to support the conclusion that the state is making progress in achieving the goals of the demonstration program component in accordance with the CMS approved evaluation design for the demonstration. If CMS makes such determination, the Commonwealth must submit a phase-out plan for that demonstration component in accordance with STC 9.

40. **Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with attachment B (Preparing the Evaluation Report) of these STCs. The Commonwealth must submit a draft Summative Evaluation Report for the demonstration approval period specified in these STCs within 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 Commonwealth shall submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.

    b. The final Summative Evaluation Report must be posted to the Commonwealth's website within 30 calendar days of approval by CMS.

41. **State Presentations for CMS.** CMS reserves the right to request that the Commonwealth present and participate in a discussion with CMS on the Evaluation Design, the interim evaluation, and/or the summative evaluation.

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

43. **Additional Publications and Presentations.** For a period of 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 Commonwealth, contractor, or any other third party directly connected to the demonstration over which the Commonwealth has control. 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 business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

XI. GENERAL FINANCIAL REQUIREMENTS

This project is approved for title XXI expenditures applicable to services rendered during the demonstration period. This section describes the general financial requirements for these expenditures.

44. **Extent of Federal Financial Participation (FFP) for the Demonstration**. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP only for the medical assistance services and premium assistance payments as described in STC 21 and associated administrative expenditures. CMS

will provide FFP at the applicable federal matching rate for the demonstration as outlined below, subject to the Commonwealth's title XXI allotment limit:

a. Administrative costs, including those associated with the administration of the demonstration.

b. Net expenditures and prior period adjustments of the Medicaid or CHIP program that are paid in accordance with the approved state plans.

c. Medical Assistance expenditures made under section 1115 demonstration authority, including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability or CMS payment adjustments.

45. Sources of Non-Federal Share. The Commonwealth must certify that the matching non-federal share of funds for the demonstration are state/local monies. The Commonwealth further certifies that such funds shall not be used as the 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. CMS may review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.

b. Any amendments that impact the financial status of the program shall require the state to provide information to CMS regarding all sources of the non-federal share of funding.

c. The Commonwealth assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provisions, as well as the approved Medicaid or CHIP state plan.

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

i. Units of government, including governmentally operated health care providers, may certify that state or local tax dollars have been expended as the non-federal share of funds under the demonstration.

ii. To the extent the Commonwealth utilizes certified public expenditures (CPEs) as the funding mechanism for title XXI (or under section 1115 authority) payments, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of

the process by which the Commonwealth would identify those costs eligible under title XXI (or under section 1115 authority) for purposes of certifying public expenditures.

iii. To the extent the Commonwealth utilizes CPEs as the funding mechanism to claim federal match for payments under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the Commonwealth the amount of such tax revenue (state or local) used to satisfy demonstration expenditures. The entities that incurred the cost must also provide cost documentation to support the Commonwealth's claim for federal match.

e. The Commonwealth may use intergovernmental transfers to the extent that such funds are derived from state or local tax revenues and are transferred by units of government within the Commonwealth. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XXI payments.

f. Under all circumstances, health care providers must retain 100 percent of the reimbursement amounts claimed by the Commonwealth as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect any portion of Medicaid or CHIP payments. This confirmation of Medicaid/CHIP 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, and business relationships with governments that are unrelated to Medicaid or CHIP, and in which there is no connection to Medicaid or CHIP payments) are not considered returning and/or redirecting a Medicaid or CHIP payment.

XII. MONITORING ALLOTMENT NEUTRALITY

46. Reporting Expenditures Subject to the Title XXI Allotment Neutrality Agreement. The following describes the reporting of expenditures subject to the allotment neutrality agreement for this demonstration:

a. Tracking Expenditures: In order to track expenditures under this demonstration, the Commonwealth must report demonstration expenditures through the Medicaid and State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-21 reporting instructions as outlined in section 2115 of the State Medicaid Manual.

b. Use of Waiver Forms: Title XXI demonstration expenditures will continue to be reported on separate Forms CMS-21 Waiver and/or CMS-21P Waiver, identified by the demonstration project number assigned by CMS (including project number

extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made). The Commonwealth must submit separate forms CMS-21 Waiver and/or CMS-21P Waiver for each demonstration population (i.e., FAMIS MOMS and FAMIS Select).

c. Premiums: Premium contributions under the demonstration shall be reported to CMS on Form CMS-21 Waiver, line 29, in order to assure that the demonstration is properly credited with premium collections.

d. Claiming Period: All claims for expenditures related to the demonstration (including any cost settlements) must be made within two years after the calendar quarter in which the Commonwealth made the expenditures. Furthermore, all claims for services during the demonstration period (including cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the Commonwealth must continue to identify separately, on the Form CMS-21 Waiver, net expenditures related to dates of service during the operation of the demonstration.

47. Standard CHIP Funding Process. The standard CHIP funding process will continue to be used during the demonstration. Virginia will continue to estimate matchable CHIP expenditures on the quarterly Form CMS-21B. On a separate CMS-21B, the Commonwealth shall provide updated estimates of expenditures for the demonstration populations. CMS will make federal funds available based upon the Commonwealth's estimate, as approved by CMS. Within 30 days after the end of each quarter, the Commonwealth must submit the Form CMS-21 quarterly CHIP expenditure report. CMS will reconcile expenditures reported on the Form CMS-21 with federal funding previously made available to the Commonwealth, and include the reconciling adjustment in the finalization of the grant award to the Commonwealth.

48. Title XXI Administrative Costs. Administrative costs will not be included in the allotment neutrality limit, but the Commonwealth must separately track and report additional administrative costs that are directly attributable to the demonstration, using Forms CMS-64.10 Waiver and/or 64.10P Waiver, with waiver name "ADM".

Total expenditures for outreach and other reasonable costs to administer the title XXI state plan and this demonstration that are applied against the Commonwealth's title XXI allotment may not exceed ten percent of total title XXI net expenditures.

49. Limit on Title XXI Funding. Virginia will be subject to a limit on the amount of federal title XXI funding that the Commonwealth may receive on current eligible CHIP state plan populations and the demonstration populations described in STC 17 during the demonstration period. Federal title XXI funds for the Commonwealth's CHIP program (i.e., the approved title XXI state plan and this demonstration) are restricted to the Commonwealth's available allotment and reallocated funds. Title XXI funds (i.e., the allotment or reallocated funds) must first be used to fully fund

costs associated with CHIP state plan populations. Demonstration expenditures are limited to remaining funds.

50. Exhaustion of Title XXI Funds. If the Commonwealth exhausts the available title XXI federal funds in a federal fiscal year during the period of the demonstration, the Commonwealth must continue to provide coverage to the approved title XXI state plan separate child health program population and the demonstration populations described in STC 17 with Commonwealth funds.

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 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 state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Designs

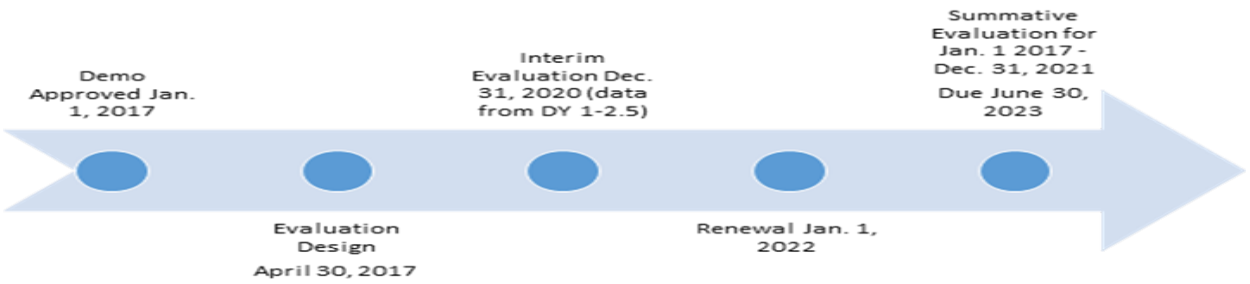
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

The format for the Evaluation Design is as follows:

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

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within 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 state's Driver Diagram (or logic model) (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 state should include basic information about the demonstration, such as:

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

1) Describe how the state'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 state's hypotheses about the outcomes of the demonstration:
   a. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
   b. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state 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 state 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 state 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 state might want to articulate the analytic methods for each research question and measure.
   b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state 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 state 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 state 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 state would like CMS to take into consideration in its review.

E. Special Methodological Considerations – CMS recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. Examples of considerations include:

1) When the state 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 state issues with CMS 64 reporting or budget neutrality; and
d. No Corrective Action Plans (CAP) for the demonstration.

F. Attachments

1) **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.

2) **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)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

Attachment B:
Preparing the Evaluation Report

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 state and federal governments need 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. With the following kind of information, states and CMS are best poised to inform and shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances. When submitting an application for renewal, the interim evaluation report should be posted on the state'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 Attachment

Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state'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 Attachment 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.

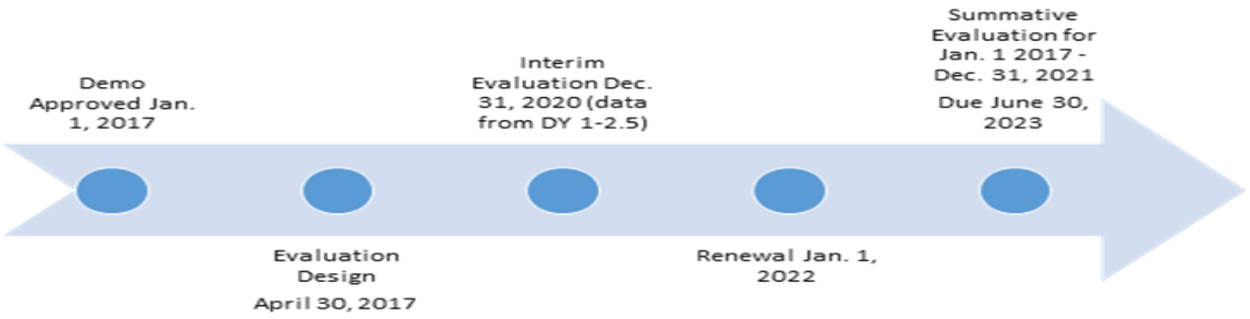
The format for the Interim and Summative Evaluation reports is as follows:

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 State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

Submission Timelines

There is a specified timeline for the state'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 state 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 state is required to publish the evaluation design and reports to the state's website within 30 days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



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 state's Driver Diagram (described in the Evaluation Design Attachment) 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 state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state'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 state should include basic information about the demonstration, such as:

i. The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
ii. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
iii. 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;
iv. 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 state 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.
v. Describe the population groups impacted by the demonstration.

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

1) Describe how the state'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 state'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 state 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 state 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 state 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 state 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 state 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 State Initiatives – In this section, the state 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 state'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 state 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 state 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

1) Evaluation Design: Provide the CMS-approved Evaluation Design

ATTACHMENT C

DEMONSTRATION EVALUATION PLAN *[RESERVED FOR APPROVAL]*

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