# Attachment D

# CENTERS FOR MEDICARE & MEDICAID SERVICES WAIVER LIST

NUMBER: 11-W-00001/9

TITLE: QUEST Integration Medicaid Section 1115 Demonstration

**AWARDEE:** Hawaii Department of Human Services

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in accompanying expenditure authorities, shall apply to the demonstration project effective from August 1, 2019 through July 31, 2024, unless otherwise stated. In addition, these waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs).

Under the authority of section 1115(a)(1) of the Social Security Act (the Act), the following waivers of State plan requirements contained in section 1902 of the Act are granted subject to the STCs for the QUEST Integration Medicaid Section 1115 Demonstration. These waivers shall apply to all demonstration enrollees.

## 1. Medically Needy

**Section 1902(a)(10)(C) and Section 1902(a)(17)** 

To enable the state to limit medically needy spend-down eligibility in the case of those individuals who are not aged, blind, or disabled to those individuals whose gross incomes, before any spend-down calculation, are at or below 300 percent of the federal poverty level. This is not comparable to spend-down eligibility for the aged, blind, and disabled eligibility groups, for whom there is no gross income limit.

## 2. Amount, Duration, and Scope

Section 1902(a)(10)(B)

To enable the state to offer demonstration benefits that may not be available to all categorically eligible or other individuals.

#### 3. Freedom of Choice

**Section 1902(a)(23)(A)** 

To the extent necessary to enable the state to restrict freedom of choice of provider through the use of mandatory enrollment in managed care plans for the receipt of covered services. To enable Hawaii to restrict the freedom of choice of providers to populations that could not otherwise be mandated into managed care under section 1932. No waiver of freedom of choice is authorized for family planning providers.

# CENTERS FOR MEDICARE AND MEDICAID SERVICES EXPENDITURE AUTHORITY

NUMBER: 11-W-00001/9

TITLE: QUEST Integration Medicaid Section 1115 Demonstration

**AWARDEE:** Hawaii Department of Human Services

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the state for the items identified below, which are not otherwise included as expenditures under section 1903 shall, for the period of this demonstration extension, August 1, 2019 through July 31, 2024, be regarded as expenditures under the state's title XIX plan, unless otherwise stated, but are further limited by the Special Terms and Conditions (STCs) for the QUEST Integration Section 1115 demonstration.

## For enrollees in All Components of the Demonstration:

1. **Managed Care Payments.** Expenditures to provide coverage to individuals, to the extent that such expenditures are not otherwise allowable because the individuals are enrolled in managed care delivery systems that do not meet the following requirements of section 1903(m):

Expenditures under contracts with managed care organizations (MCOs) that do not meet the requirements under section 1903(m)(2)(A)(vi) of the Act insofar as that provision requires compliance with requirements in section 1932(a)(4)(A)(ii)(I) of the Act, including as it is implemented and interpreted in 42 CFR 438.56(c)(2)(i)). With this expenditure authority, the state may restrict enrollees' right to disenroll without cause within 90 days of initial enrollment in an MCO, described in STC 36. Enrollees may disenroll for cause at any time and may disenroll without cause at least once every 12 months, as specified at section 1932(a)(4)(A)(ii)(II) of the Act, including as it is implemented and interpreted in 42 CFR 438.56(c)(2)(ii), except with respect to enrollees on rural islands who are enrolled into a single plan in the absence of a choice of plan on that particular island.

Expenditures for capitation payments to MCOs, and PIHPs, in non-rural areas that do not provide enrollees with a choice of two or more plans, as required under section 1903(m)(2)(A)(xii), section 1932(a)(3)(A) and federal regulations at 42 CFR section 438.52(a)(1).

- 2. **Quality Review of Eligibility.** Expenditures for Medicaid services that would have been disallowed under section 1903(u) of the Act based on Medicaid Eligibility Quality Control findings.
- 3. **Demonstration Expansion Eligibility.** Expenditures to provide coverage to the following demonstration expansion populations:

- a. <u>Demonstration Population 1</u>. Parents and caretaker relatives who are living with an 18-year-old who would be a dependent child but for the fact that the 18-year-old has reached the age of 18, if such parents would be eligible if the child was under 18 years of age.
- b. <u>Demonstration Population 2</u>. Aged, blind, and disabled individuals in the 42 C.F.R. § 435.217 like group who are receiving home- and community- based services, with income up to and including 100 percent of the federal poverty limit using the institutional income rules, including the application of regular posteligibility rules and spousal impoverishment eligibility rules.
- c. <u>Demonstration Population 3</u>. Aged, blind, and disabled medically needy individuals receiving home-and community-based services, who would otherwise be eligible under the state plan or another QUEST Integration demonstration population only upon incurring medical expenses (spend-down liability) that is expected to exceed the amount of the QUEST Integration health plan capitation payment, subject to an enrollment fee equal to the spend down liability. Eligibility will be determined using the medically needy income standard for household size, using institutional rules for income and assets, and subject to post-eligibility treatment of income.
- d. <u>Demonstration Population 4</u>. Individuals age 19 and 20 who are receiving adoption assistance payments, foster care maintenance payments, or kinship guardianship assistance, who would not otherwise be eligible under the state plan, with the same income limit that is applied for Foster Children (19-20 years old) receiving foster care maintenance payments or under an adoption assistance agreement under the state plan.
- e. <u>Demonstration Population 5</u>. Individuals who are younger than 26, aged out of the adoption assistance program or the kinship guardianship assistance program (either Title IV-E assistance or non-Title IV-E assistance) when placed from age 16 to 18 years of age, or would otherwise be eligible under a different eligibility group but for income, and were enrolled in the State plan or waiver while receiving assistance payments.
- 4. **Home and Community-Based Services (HCBS) and Personal Care Services.**Expenditures to provide HCBS not included in the Medicaid state plan and furnished to QUEST Integration enrollees, as follows:
  - a. Expenditures for the provision of services, through QUEST or QUEST Integration health plans, that could be provided under the authority of section 1915(c) waivers, to individuals who meet an institutional level of care requirement;

- b. Expenditures for the provision of services, through QUEST or QUEST Integration health plans, to individuals who are assessed to be at risk of deteriorating to the institutional level of care, *i.e.*, the "at risk" population.
  - The state may maintain a waiting list, through a health plan, for home and community-based services (including personal care services). No waiting list is permissible for other services for QUEST Integration enrollees.
- c. The state may impose an hour or budget limit on home and community based services provided to individuals who do not meet an institutional level of care but are assessed to be at risk of deteriorating to institutional level of care (the "at risk" population), as long as such limits are sufficient to meet the assessed needs of the individual.
- 5. **Additional Benefits:** Expenditures to provide the following additional benefits.
  - a. **Specialized Behavioral Health Services:** The services listed below (and further described in Attachment E of the special terms and conditions) are available for individuals with serious mental illness (SMI), serious and persistent mental illness (SPMI), or requiring support for emotional and behavioral development (SEBD).
    - i. Supportive Employment.
    - ii. Financial management services.
  - b. Cognitive Rehabilitation Services: Services provided to cognitively impaired individuals to assess and treat communication skills, cognitive and behavioral ability and skills related to performing activities of daily living. These services may be provided by a licensed physician, psychologist, or a physical, occupational or speech therapist. Services must be medically necessary and prior approved.
  - c. **Habilitation Services.** Services to develop or improve a skill or function not maximally learned or acquired by an individual due to a disabling condition. These services may be provided by a licensed physician or physical, occupational, or speech therapist. Services must be medically necessary and prior approved.
  - d. **Community Integration Services.** Pre-tenancy and tenancy sustaining services as defined in STC 23 of the STCs are available for beneficiaries who are 18 years or older and meet the criteria specified in STC 23.
  - e. **Community Transition Services Pilot Program.** Expenditures for the Community Transition Services Pilot Program as set forth in STC 23.

All requirements of the Medicaid program expressed in law, regulation, and policy statement shall apply to the demonstration expansion populations, except those expressly identified on the waiver list or listed below as not applicable.

## Title XIX Requirements Not Applicable to Demonstration Expansion Populations

## **Cost Sharing**

Section 1902(a)(14) insofar as it incorporates 1916 and 1916A

To enable the state to charge cost sharing up to 5 percent of annual family income.

To enable the state to charge an enrollment fee to Medically Needy Aged, Blind and Disabled QUEST Integration health plan enrollees (Demonstration Population 3) whose spend-down liability is estimated to exceed the QUEST Integration health plan capitation rate, in the amount equal to the estimated spend-down amount or where applicable, the amount of patient income applied to the cost of long-term care.

# CENTERS FOR MEDICARE & MEDICAID SERVICES SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00001/9

TITLE: QUEST Integration Medicaid Section 1115 Demonstration

**AWARDEE:** Hawaii Department of Human Services

### I. PREFACE

The following are the Special Terms and Conditions (STCs) for Hawaii's QUEST Integration section 1115(a) Medicaid demonstration extension (hereinafter "demonstration"). The parties to this agreement are the Hawaii Department of Human Services (hereinafter "state") and the Centers for Medicare & Medicaid Services (CMS). CMS has granted waivers of requirements under section 1902 of the Social Security Act (Act), and expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable under section 1903 of the Act, which are separately enumerated. These STCs set forth conditions and limitations on those waivers and expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to this demonstration. These STCs are effective from August 1, 2019 through July 31, 2024, unless otherwise stated. All previously approved STCs, waivers, and expenditure authorities are superseded by the STCs set forth below.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description, Objectives, and Historical Context
- III. General Program Requirements
- IV. Eligibility for the Demonstration
- V. Enrollment
- VI. Benefits
- VII. Community Integration Services
- VIII. Delivery System
- IX. Cost Sharing
- X. General Reporting Requirements
- XI. Monitoring
- XII. Evaluation of the Demonstration
- XIII. General Financial Requirements Under Title XIX
- XIV. Monitoring Budget Neutrality for the Demonstration
- XV. Schedule of State Deliverables During the Demonstration Extension Period

In the event of a conflict between any provision of these STCs and any provision of an attachment to these STCs, the STCs must take precedence.

The following attachments have been included to provide supplemental information and guidance for specific STCs. The following attachments are incorporated as part of these STCs.

Attachment A: Developing the Evaluation Design

Attachment B: Preparing the Interim and Summative Evaluation Reports

Attachment C: Reserved for Evaluation Design

Attachment D: Home and Community-Based Services (HCBS) and Long-Term Care

Provider Guidelines and Service Definitions

Attachment E: Reserved for the Behavioral Health Services Protocol

## II. PROGRAM DESCRIPTION, OBJECTIVES, AND HISTORICAL CONTEXT

QUEST Integration is a continuation of the state's ongoing demonstration, which is funded through Title XIX, Title XXI and the state. QUEST Integration uses capitated managed care as a delivery system unless otherwise noted below. QUEST Integration provides Medicaid State Plan benefits and additional benefits (including institutional and home and community-based long-term-services and supports) based on medical necessity and clinical criteria to beneficiaries eligible under the state plan and to the demonstration populations described in STC 21.

The state of Hawaii implemented QUEST on August 1, 1994. QUEST is a statewide section 1115 demonstration project that initially provided medical, dental, and behavioral health services through competitive managed care delivery systems. The QUEST program was designed to increase access to health care and control the rate of annual increases in health care expenditures. The state combined its Medicaid program with its then General Assistance Program and its innovative state Health Insurance Program and offered benefits to citizens up to 300 percent of the federal poverty level (FPL). This program virtually closed the coverage gap in the state.

The QUEST program covered adults with incomes at or below 100 percent of the federal poverty level (FPL) and uninsured children with family incomes at or below 200 percent FPL. In addition, the QUEST-Net program provided a full Medicaid benefit for children with family incomes above 200, but not exceeding 300 percent FPL and a limited benefit package for adults with incomes at or below 300 percent FPL.

Since its implementation, CMS has renewed the QUEST demonstration six times. In 2007, the QUEST demonstration was renewed under the new name QUEST Expanded. In February 2010, CMS approved an amendment to implement the Hawaii Premium Plus program to encourage employment growth and employer sponsored health insurance in the State. In July 2010, CMS approved an amendment to eliminate the unemployment insurance eligibility requirement for the Hawaii Premium Plus program. In August 2010, CMS approved an amendment to add pneumonia vaccines as a covered immunization.

In April 2012, CMS approved an amendment which reduced the QUEST-Net and QUEST-ACE eligibility for adults with income above 133 percent of the FPL and eliminated the grandfathered group in QUEST-Net with income between 200 and 300 percent of the FPL. Hawaii also requested

to increase the benefits provided to QUEST-Net and QUEST-ACE under the demonstration; eliminate the QUEST enrollment limit for childless adults; terminate the Hawaii Premium Plus program; and allow uncompensated cost of care payments (UCC) to be paid to government-owned nursing facilities.

In December 2012, the state submitted its request to extend the QUEST demonstration under section 1115(a) of the Social Security Act for 5 years under the name QUEST Integration. This extension of the demonstration included the following program changes:

- Consolidated the 4 programs within the demonstration into a single "QUEST Integration" program;
- Transitioned the low-income childless adults and former foster care children from demonstration expansion populations to state plan populations;
- Added additional new demonstration expansion populations, including a population of former adoptive and kinship guardianship children;
- Increased the retroactive eligibility period to 10 days for the non-long term services and supports population;
- Provided additional benefits, including cognitive rehabilitation, habilitation, and certain specialized behavioral health services;
- Removed the QUEST-ACE enrollment-related benchmarks from the UCC pool; and
- Required additional evaluation on UCC costs after January 1, 2014.

This demonstration integrated the demonstration's eligibility groups and benefits within the context of the Affordable Care Act (ACA). From a benefit perspective, Hawaii provided all beneficiaries with access to the same benefits based on clinical criteria and medical necessity through capitated-managed care or through managed-fee-for-service delivery systems in certain circumstances.

CMS approved the demonstration renewal in September 2013 for the demonstration period of October 2013 through December 2018. In October 2018, CMS approved an amendment to provide community integration supportive housing services to the population described in STC 22. A temporary extension of the demonstration was approved on December 8, 2018 to extend the demonstration through June 30, 2019. A second temporary extension was issued for July 1, 2019 through July 31, 2019.

Hawaii submitted a request to extend the demonstration in September 2018 for a 5 year period beginning on August 1, 2019. The 2019 extension made the following changes to the demonstration:

- Ended Hawaii's waiver of retroactive eligibility; and
- Authorized expenditure authority for Community Transition Services Pilot program.

The objectives for the 2019-2024 demonstration approval period are:

• Improve health outcomes for Medicaid beneficiaries covered under the demonstration;

- Maintain a managed care delivery system that leads to more appropriate utilization of the health care system and a slower rate of expenditure growth; and
- Address health determinants to improve health outcomes and lower healthcare costs.

## III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Statutes. The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).
- 2. Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy. All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.
- 3. Changes in Medicaid and CHIP Law, Regulation, and Policy. The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 business 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 on Demonstration of Changes in Federal Law, Regulation, and Policy.
  - a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
  - b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.
- **5. State Plan Amendments**. The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely

- through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.
- 6. Changes Subject to the Amendment Process. Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.
- 7. Amendment Process. Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:
  - a. An explanation of the public process used by the state, 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 state in the final amendment request submitted to CMS;
  - b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
  - c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
  - d. An up-to-date CHIP allotment worksheet, if necessary;
  - e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.
- **8. Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 442 Code of Federal Regulations

(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 phase-out plan consistent with the requirements of STC 9.

- **9. Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
  - a. Notification of Suspension or Termination: The state 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 state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 13, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.
  - b. <u>Transition and Phase-out Plan Requirements:</u> The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.
  - c. <u>Transition and Phase-out Plan Approval.</u> The state 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 state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210 and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).
  - e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
  - f. <u>Enrollment Limitation during Demonstration Phase-Out.</u> If the state 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 state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.
- g. <u>Federal Financial Participation (FFP)</u>. If the project is terminated or any relevant waivers are suspended by the state, FFP must 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. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and title XXI. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.
- **11. Adequacy of Infrastructure.** The state will ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.
- **12. Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state 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 state 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 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.

- **13. Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.
- **14. Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted

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

#### IV. ELIGIBILITY FOR THE DEMONSTRATION

**16. Eligibility Groups Affected by the Demonstration.** Mandatory and optional State Plan groups derive their eligibility through the Medicaid and CHIP State plan, and are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid and CHIP State Plan, except as expressly waived under authority granted by this demonstration or as described in these STCs. Any Medicaid and CHIP State Plan Amendments to the eligibility standards and methodologies for these eligibility groups will apply to this demonstration.

The beneficiary eligibility groups described below who are made eligible for QUEST Integration by virtue of the expenditure authorities expressly granted in this demonstration are subject to Medicaid and/or CHIP laws, regulations, and policies unless otherwise specified in the not applicable expenditure authorities for this demonstration.

**QUEST Integration Medicaid and CHIP State Plan Mandatory and Optional groups** 

Mandatory State Plan Groups	
Eligibility Group Name	Qualifying Criteria
Parents or caretaker relatives	Up to and including 100% FPL
Pregnant Women	Up to and including 191% FPL
	Extended and continuous eligibility for pregnant women
Infants	Infants up to age 1, up to and including 191% FPL

Deemed newborn children
Continuous eligibility for hospitalized children
Children ages 1 through 18, up to and including 133% FPL
Continuous eligibility for hospitalized children
Up to and including 133% FPL
An adoption assistance agreement is in effect under title IV-E of the Act; or  Foster care or kinship guardianship assistance maintenance payments are being made by a State under title IV-E.
No income limit
ABD individuals who meet more restrictive requirements for Medicaid than the SSI requirements. Uses SSI payment standard.
Qualified severely impaired blind and disabled individuals under age 65
Other ABD groups as described in the State Plan
Coverage for one twelve month period due to increased earnings that would otherwise make the individual ineligible under Section 1931

1931 Extension	Coverage for four months due to receipt of child or spousal support, that would otherwise make the individual ineligible under Section 1931
Qualified Medicare beneficiaries*	Standard eligibility provisions for this population as described in the State Plan.
Specified low-income Medicare beneficiaries*	Standard eligibility provisions for this population as described in the State Plan.

<sup>\*</sup>Dual eligibles are included as those with full Medicaid benefits are served under QI health plans and QI health plans pay Part B co-payments and coordinate Medicare services.

	Optional State Plan Groups
Eligibility Group Name	Qualifying Criteria
Optional Coverage of Families and Children and the Aged, Blind, or Disabled	ABD individuals who do not receive cash assistance but meet income and resource requirements
	Individuals eligible for assistance but for being in a medical institution
	Individuals who would be eligible for Medicaid if they were in a medical institution, who are terminally ill, and who receive hospice care
	ABD individuals in domiciliary facilities or other group living arrangements
	Aged or disabled individuals with income up to and including 100% FPL
Optional targeted low- income children	Up to and including 308% FPL including for children for whom the State is claiming Title XXI funding
Certain Women Needing Treatment for Breast or Cervical Cancer	No income limit; must have been detected through NBCCEDP and not have creditable coverage

Medically Needy Non- Aged, Blind, or Disabled Children and Adults	Up to and including 300% FPL, if spend down to medically needy income standard for household size
Medically Needy Aged, Blind, or Disabled Children and Adults	Medically needy income standard for household size using SSI methodology
Foster Children	Children with non IV-E adoption assistance
Foster Children (19-20 years old)	Receiving foster care maintenance payments or under adoption assistance

# **QUEST Integration Demonstration Expansion Population Groups**

Expansion Population	
Eligibility Group Name	Qualifying Criteria
Parents or caretaker relatives with an 18-year old dependent child	Parents or caretaker relatives who (i) are living with an 18-year- old who would be a dependent child but for the fact that s/he has reached the age of 18 and (ii) would be eligible if the 18-year-old was under 18 years of age
Individuals in the 42 C.F.R. § 435.217 like group receiving HCBS	Income up to and including 100% FPL
Medically needy ABD individuals whose spend-down exceeds the plans' capitation payment	Medically needy ABD individuals whose spend-down liability is expected to exceed the health plans' monthly capitation payment
Individuals Age 19 and 20 with Adoption Assistance, Foster Care Maintenance Payments, or Kinship Guardianship Assistance	No income limit
Individuals Formerly Receiving Adoption Assistance or Kinship Guardianship Assistance	Younger than 26 years old; aged out of adoption assistance program or kinship guardianship assistance program (either Title IV-E assistance or non-Title IV-E assistance); not eligible under any other eligibility group, or would be eligible under a different eligibility group but for income; were enrolled in the state plan or waiver while receiving assistance payments

17. Post-Eligibility Treatment of Income and Resources. All individuals receiving nursing facility long-term care services must be subject to the post-eligibility treatment of income rules set forth in section 1924 and 42 CFR section 435.733. Available income after appropriate deductions, such as for a personal needs allowance, allowances for a spouse and/or family members, and incurred medical expenses, shall be the amount by which Medicaid's payment is reduced for the relevant long-term services and supports. Individuals receiving HCBS must be subject to the post-eligibility treatment of income rules

- set forth in section 1924 and 42 CFR section 435.735 if they are medically needy, with or without spend-down, or individuals who would be eligible for Medicaid if institutionalized as set forth in 42 CFR section 435.217.
- **18. Financial Responsibility/Deeming.** The state must determine eligibility using the income of household members whose income may be taken into account under the Medicaid financial responsibility and deeming rules, including institutional deeming for aged, blind, and disabled individuals.
- **19. Quality Review of Eligibility.** On March 4, 2010 CMS approved the state's MEQC plan to reflect programmatic changes as a result of the section 1115 demonstration program implementation integrating a major portion of the FFS population into Managed Care. The state shall remain relieved of any liability from disallowance for errors that exceed the 3 percent tolerance. CMS permits the state to continue with its effort to implement administrative renewal and MEQC reviews must take that policy into account.

#### V. ENROLLMENT

- **20. Spend-Down for Medically Needy Individuals**.
  - a. **Pregnant Women and Children Medically Needy State Plan Groups** are eligible upon determination of medical expenses in the month of enrollment that meet or exceed their spend-down or cost-share obligation, subject to STC 20(d). Individuals in this group whose gross income exceeds 300 percent FPL are not eligible.
  - b. Members of Aged, Blind, or Disabled Medically Needy State Plan groups whose spend-down liability is not expected to exceed the health plans' monthly capitation payment will be enrolled in a QUEST Integration health plan upon the determination of medical expenses in the month of enrollment that meet or exceed their spend-down or cost-share obligation, subject to STC 20(d).
  - c. Members of Aged, Blind, or Disabled Medically Needy State Plan groups whose spend-down liability is expected to exceed the health plans' monthly capitation payment will be eligible under the demonstration subject to STC 20(d) and an enrollment fee equal to the medically needy spend-down amount or, where applicable, the amount of patient income applied to the cost of long-term care. This group will receive all services through QUEST Integration health plans.
  - d. Medically needy individuals who are expected to incur expenses sufficient to satisfy their spend-down obligation for a retroactive period only will not be enrolled in a QUEST Integration health plan. They will receive services on a fee-for-service basis. (This category might include, for example, persons who become medically needy for a short-term retroactive period due to catastrophic injury or illness, or persons who incur high medical expenses sporadically and thus will not meet their spend-down obligations every month.)

#### VI. BENEFITS

- **21. QUEST Integration Benefits.** Benefits provided under authority of this demonstration are delivered through mandatory managed care (except as specified in STC 21(d), and are as follows, for all populations under the demonstration (except as otherwise provided in this STC):
  - a. **Full Medicaid State Plan.** Individuals eligible under the demonstration will receive comprehensive benefits including all services as defined in the Medicaid state plan.
  - b. **Alternative Benefit Plan:** The Affordable Care Act (ACA) New Adult Group will receive benefits provided through the state's approved alternative benefit plan (ABP) SPA.
  - c. **Managed Care Plan Change.** Beneficiaries may change managed care plans per 42 CFR 438.56(d)(2)(iv) if their residential or employment support provider is no longer available through their current plan.
  - d. **Benefits Provided to the ID/DD Population.** Medicaid eligibles with developmental disabilities will receive the full Medicaid state plan benefit package through QUEST Integration managed care plans. Case management, section 1915(c) HCBS, and ICF/ID benefits for this group will remain carved out of the capitated benefit package. All QUEST Integration health plans will be are required to coordinate the state plan benefits received by the ID/DD population with the HCBS that are provided on a fee-for-service basis from the Department of Health's (DOH) Developmental Disabilities Division.
  - e. **Behavioral Health Benefits.** All QUEST Integration plans must provide a full array of standard behavioral health benefits (including substance abuse treatment) to beneficiaries who may need such services as set forth in the Behavioral Health Services Protocol in Attachment E. The state must also provide specialized behavioral health services to beneficiaries with SMI, SPMI, or SEBD. The state must submit the Behavioral Health Services Protocol to CMS for review within 150 calendar days after approval of this demonstration extension. Failure to submit this deliverable to CMS will result in a funding deferral (STC 49). The Behavioral Health Services Protocol must include the following:
    - i. Services provided by the DOH Child and Adolescent Mental Health Division (CAMHD) to children with serious emotional behavioral disorders (SEBD).
    - ii. Services provided to adults with SMI or SPMI by the Med-QUEST division's Community Care Services (CCS) behavioral health program, or the contracted plans.
    - iii. Reimbursement methodology
    - iv. A memorandum of agreement (MOA) between each MCO and the state that reflects the current interagency agreement for behavioral health services provided by the DOH to beneficiaries.
    - v. The process(es) and protocol(s) used for referrals between MCOs and the DOH or CCS, as well as the DOH or CCS and MCOs.

- f. **Additional Benefits.** Under the demonstration, the state will provide benefits in addition to Medicaid state plan and alternative benefit plan benefits based on medical necessity and clinical criteria. These additional benefits include home and community based services (HCBS), specialized behavioral health benefits, cognitive rehabilitation benefits, and habilitation benefits, as described below.
- h. **HCBS:** QUEST Integration health plans must provide access to a comprehensive HCBS benefit package for individuals who meet institutional level of care and are able to choose to receive care at home or in the community and an expanded sub-set of HCBS services for individuals who do not meet an institutional level of care but are assessed to be at risk of deteriorating to institutional level of care (the "At Risk" population, renamed from "Personal Care-Level I/Chore" population) in order to prevent a decline in health status and maintain individuals safely in their homes and communities. The service definitions and provider types are found in Attachment D of these STCs. The amount, duration, and scope of all covered long-term care services may vary to reflect the needs of the individual in accordance with the prescribed Care Coordination Plan. The HCBS benefits that will be provided through managed care health plans include the following:

Service	Available for individuals who are assessed to be risk of deteriorating to institutional level of care	Available for individuals who meet institutional level of care ("1147 certified")
Adult day care	X*	X
Adult day health	X*	X
Assisted living facility		X
Community care foster		X
family homes		A
Counseling and training		X
Environmental accessibility adaptations		X
Home delivered meals	X*	X
Home maintenance		X
Moving assistance		X
Non-medical transportation		X
Personal assistance	X	X
Personal emergency response system	X*	X
Residential care		X
Respite care		X
Private duty nursing	X	X
Specialized case		X
management		A
Specialized medical equipment and supplies	10	X

- \* Denotes new services for the "At Risk" population under QUEST Integration.
- i. **Specialized Behavioral Health Services**: The services listed below (and further described in Attachment E of the special terms and conditions) are available for individuals with serious mental illness (SMI), serious and persistent mental illness (SPMI), or requiring support for emotional and behavioral development (SEBD).
  - i. Supportive Employment.
  - ii. Financial management services.
- j. Cognitive Rehabilitation Services: Services provided to cognitively impaired individuals to assess and treat communication skills, cognitive and behavioral ability and skills related to performing activities of daily living. These services may be provided by a licensed physician, psychologist, or a physical, occupational or speech therapist. Services must be medically necessary and prior approved.
- k. **Habilitation Services.** Services to develop or improve a skill or function not maximally learned or acquired by an individual due to a disabling condition. These services may be provided by a licensed physician or physical, occupational, or speech therapist. Services must be medically necessary and prior approved.

#### VII. COMMUNITY INTEGRATION SERVICES

### 22. Community Integration Services (CIS).

- a. Eligibility Criteria. These eligibility criteria apply to all CIS benefits described in this STC.
  - i. Individual meets at least one of the following health needs-based criteria and is expected to benefit from community integration services:
    - 1. Individual assessed to have a behavioral health need which is defined as one or both of the following criteria:
    - 2. Mental health need, where there is a need for improvement, stabilization, or prevention of deterioration of functioning (including ability to live independently without support) resulting from the presence of a serious mental illness; and/or
    - 3. Substance use need, where an assessment using American Society of Addiction Medicine (ASAM) criteria indicates that the individual meets at least ASAM level 2.1 indicating the need for outpatient day treatment for Substance Use Disorder (SUD) treatment.
    - 4. Individual assessed to have a complex physical health need, which is defined as a long continuing or indefinite physical condition requiring improvement, stabilization, or prevention of deterioration of functioning (including the ability to live independently without support).
  - ii. Including STC 22(a)(i), the individual must have at least one of the following risk factors:
    - 1. Homelessness, defined as lacking a fixed, regular, and adequate nighttime residence, meaning:
      - a. Has a primary nighttime residence that is a public or private place not designed for or ordinarily used as a regular sleeping accommodation for

- human beings, including a car, park, abandoned building, bus or train station, airport, or camping ground; or
- b. Living in a supervised publicly or privately operated shelter designated to provide temporary living arrangements (including congregate shelters, transitional housing, and hotels and motels paid for by charitable organizations or by federal, state, or local government programs for low income individuals).
- 2. At risk of homelessness, defined as an individual who shall lose their primary nighttime residence:
  - a. There is notification in writing that their residence will be lost within 21 days of the date of application for assistance;
  - b. No subsequent residence has been identified; and
  - c. Does not have sufficient resources or support networks, e.g., family, friends, faith-based or other social networks, immediately available to prevent them from moving to or living in a place not meant for human habitation, a safe haven, or an emergency shelter; or
  - d. History of frequent and/or lengthy stays in a nursing facility
  - e. Frequent is defined as more than one contact in the past 12 months.
  - f. Lengthy is defined as 60 or more consecutive days within an institutional care facility.
- iii. The state must require that the MCO determine all enrollee's eligibility for the CIS Programs based on the eligibility criteria set forth in STC 22. Once an enrollee is determined eligible to participate in the CIS Program, the state must require that the MCO seek consent from the enrollee to participate in the CIS Program and the enrollee will have the option to opt-out at any time from the CIS Program. An eligible enrollee must have the option to re-enroll in the program at any time following the enrollee's voluntary disenrollment, after being reassessed for eligibility. Enrollees who do not opt-out will remain enrolled in the CIS Program until they no longer meet the eligibility criteria or do not require the applicable services to address an unmet need as determined in the eligibility reassessment. Eligibility reassessments must take place at least quarterly.
- iv. Enrollees determined ineligible must have the opportunity to request to have their eligibility status be reassessed when there is an indication the enrollee's health status or social risk factors have changed. Upon a determination of ineligibility, the state must require that the MCO communicate to the enrollee the process to request a reassessment and provide a right to appeal the determination of ineligibility. The process for such an appeal must comply with the requirements in 42 C.F.R. §§ 438.400 through 438.24 for an adverse benefit determination. Eligibility reassessments will consist of utilizing the same tools previously used to evaluate the enrollee in the initial assessment.
- b. Determinations. The state must require the MCOs to use an assessment tool using standardized questions to screen possibly eligible enrollees to determine whether they meet the eligibility criteria to receive Community Integration Services. The state must require that each MCO determines the services to be provided and will review the plan of care with the enrollee after the assessment is complete.
- c. CIS Benefits. These services are furnished only to the extent it is reasonable and

necessary as clearly identified through an enrollee's care plan and the enrollee is unable to meet such expense or when the services cannot be obtained from other sources. This Program is voluntary for beneficiaries.

# i. Pre-Tenancy Supports:

- 1. Conducting a functional needs assessment identifying the beneficiary's preferences related to housing (e.g., type, location, living alone or with someone else, identifying a roommate, accommodations needed, or other important preferences) and needs for support to maintain community integration (including what type of setting works best for the individual); providing assistance in budgeting for housing and living expenses;
- 2. Assisting beneficiaries with connecting to social services to help with finding and applying for housing necessary to support the individual in meeting their medical care needs.
- 3. Developing an individualized plan based upon the functional needs assessment as part of the overall person centered plan. Identifying and establishing short and long-term measurable goal(s), and establishing how goals will be achieved and how concerns will be addressed.
- 4. Participating in person-centered plan meetings at redetermination and/or revision plan meetings, as needed.
- 5. Providing supports and interventions per the person-centered plan.

# ii. Tenancy Sustaining Services:

- 1. Service planning support and participating in person-centered plan meetings at redetermination and/or revision plan meetings, as needed.
- 2. Coordinating and linking the recipient to services and service providers including primary care and health homes; substance use treatment providers; mental health providers; medical, vision, nutritional and dental providers; vocational, education, employment and volunteer supports; hospitals and emergency rooms; probation and parole; crisis services; end of life planning; and other support groups and natural supports.
- 3. Entitlement assistance including assisting beneficiaries in obtaining documentation, navigating and monitoring application process, and coordinating with the entitlement agency.
- 4. Assistance in accessing supports to preserve the most independent living such as individual and family counseling, support groups, and natural supports.
- 5. Providing supports to assist the beneficiary in the development of independent living skills, such as skills coaching, financial counseling, and anger management.
- 6. Providing supports to assist the beneficiary in communicating with the landlord and/or property manager regarding the participant's disability (if authorized and appropriate), detailing accommodations needed, and addressing components of emergency procedures involving the landlord and/or property manager.
- 7. Coordinating with the beneficiary to review, update and modify housing support and crisis plan on a regular basis to reflect current needs and address existing or recurring housing retention barriers.
- 8. Connecting the beneficiary to training and resources that will assist the individual in being a good tenant and lease compliance, including ongoing support with activities related to household management.

- d. **Requirements for CIS Program.** The following requirements apply to the CIS Program:
  - i. <u>MCO Responsibilities</u>. The state must require the MCO to develop an enrollee care plan for each enrollee in the CIS Program. The state must require the MCO to also do the following:
    - 1. Screen Medicaid managed care beneficiaries to identify those who are eligible for receiving services through this program.
    - 2. Obtain consent for enrollment in the program.
    - 3. Determine and authorize the specified services that are necessary and appropriate for beneficiaries.
    - 4. Work in collaboration with providers to track the provision of services.
    - 5. Participation in "learning communities" to ensure that MCOs and providers are sharing and adopting best practices throughout the duration of the five-year demonstration period.
    - 6. Track and report the services provided to beneficiaries, ensuring accountability for service delivery and payment, monitoring against fixed allotments.
    - 7. Conduct periodic audits of payments to verify accurate reporting and spending. These audits must include verification that services reported are actually received by beneficiaries.
- e. **Program Integrity**. The state must maintain program integrity standards in the program, including:
  - 1. Quarterly accounting on delivered services
    - i. Encounter data must include:
      - a. Beneficiary name and Medicaid identification number
      - b. Provider organization name
      - c. Description of services(s) rendered
      - d. Date(s) and/or duration of services(s) delivery
      - e. Number of unit(s) of services(s) delivered
      - f. Cost of services(s) delivered
      - g. Service indicator (reason for service delivery)
    - ii. MCO Role. MCOs must report the following to the state on a quarterly basis:
      - a. Number of enrollees who receive each CIS service.
      - b. Total costs for each CIS service.
- f. **Audit Process**. The state must require the MCOs to ensure Medicaid payments are for services covered under this program that were actually provided and properly billed and documented by the providers through the following processes:
  - 1. Encounter Data Analysis
    - i. As part of their general Medicaid program integrity requirements, the state must require that MCOs analyze claims submitted by providers to ensure that they: (1) accurately and appropriately represent the delivery of authorized services, and (2) identify irregularities, discrepancies, or outliers requiring further investigation.
    - ii. To the extent that MCOs identify irregularities, the state must require MCOs to refer those irregularities to their Special Investigations Unit for follow-up and report them to the state's Program Integrity Division.

- 2. Visit Verification Procedures
  - i. In accordance with the state's Medicaid program integrity requirements, the state must require the MCOs regularly validate services, including those delivered through the pilots, that were rendered as provided and properly billed and documented by pilot providers through conducting visit verification procedures on a random sample of claims/invoices. Verification procedures may include:
    - a Outreach to beneficiaries to confirm receipt of services
    - b. Outreach to providers to require documentation of provided services
- 3. As part of the state's overarching oversight strategy, the state's Program Integrity Division must review and monitor the MCOs' policies, including sample sizes and targeted provider types, and sample visit verification cases. Ensuring action is taken to address identified non-compliance.
- 4. Recoupment of Overpayments. Under the state's Medicaid program integrity requirement, the state must require the MCOs to monitor payments and identify issues of overpayment. MCOs must regularly monitor their payments to providers to identify potential overpayments.
- 5. Suspension, Withhold, Sanctions and Termination Activities due to Findings of Fraud or Abuse. In accordance with the state's Medicaid program integrity requirements:
  - i. The state reserves the right to direct a MCO to impose a payment suspension or withhold on any provider due to a credible allegation of fraud in accordance with 42 CFR 455.23.
  - ii. The state and MCOs will have the right to terminate a provider for reasons related to actions consistent with 42 CFR 455.
  - iii. The state will have the right to impose other sanctions or intermediate sanctions on, or require a corrective action plan from a MCO or pilot provider.
  - iv. The state must require MCOs to submit monthly reports to the state on all pilot provider terminations or non-renewals due to fraudulent behavior.
    - a Auditing compliance. The state must audit MCOs to ensure their compliance with the program requirements and take action to address any identified non-compliance.
    - Pilot Termination. The state may suspend or terminate the entire CIS Program if it is found to be ineffective in meeting the state's goals or beneficiaries needs.
- g. **Community Participation.** The state, either directly or through its MCO contracts, must ensure that participants' engagement and community participation is supported and facilitated to the fullest extent desired by each participant.
- h. **CIS Exclusions.** The following are prohibited under CIS:
  - 1. Payment of ongoing rent or other room and board costs;
  - 2. Capital costs related to the development of housing;
  - 3. Expenses for ongoing regular utilities or other regular occurring bills;
  - 4. Goods or services intended for leisure or recreation;
  - 5. Duplicative services from other state or federal programs

- 6. Services furnished to individuals in a correctional institution or an IMD (other than services that meet an exception to the IMD exclusion).
- i. **Pathway to Value-Based Payments (VBP)**. The state must use its existing managed care contracts to incentivize the delivery of high quality care to CIS beneficiaries through MCOs by progressively linking payments to progress towards improved health and socioeconomic outcomes among beneficiaries during the demonstration period by using a combination of the following strategies:
  - 1. Withhold arrangements, as defined in and consistent with 42 CFR 438.6, may be used to incentivize plans to establish processes and protocols to support a variety of mechanisms required for data exchange, reporting, and beneficiary enrollment, as well as to enhance the quality of service delivery and improve beneficiary outcomes.
  - 2. Incentive arrangements, as defined in and consistent with 42 CFR 438.6, may be used to incentivize plans to enhance the quality of service delivery and improve beneficiary outcomes.
  - 3. The state must also establish VBP strategies directed at a range of providers to incentivize the delivery of high quality care for CIS Program beneficiaries. The state must work with stakeholders to develop a VBP strategy focused on providers that serve CIS Program beneficiaries. These stakeholders may include, but would not be limited to, hospitals, primary care providers, CIS providers, and post-acute providers. These VBP arrangements will be effectuated through managed care, but the state will need to seek directed payments authority under 42 CFR 438.6 to put payment arrangements into place.
  - 4. Year by Year Breakdown for Managed Care Plan Incentives
    - i. Year 1: In the first year of the CIS Program, a withhold measure may be established to provide the MCOs with time to establish a provider network, develop processes and protocols for program operationalization, operationalize enrollment criteria, collaborate to develop shared data collection forms, and standardize the collection of appropriate process measures and outputs from service providers to support the reporting requirements of the state. The withhold will be released contingent upon submission of the full package of instruments, protocols, and processes, along with a demonstration through test data submission of the ability for MCOs to fully comply with all reporting requirements of the program; the withhold may be treated as a process measure, with full release of payment upon satisfactory completion of requirements within the established timelines.
    - ii. Year 2: In the second year of the CIS Program, a withhold arrangement may support evidence of enrollment of beneficiaries in the CIS Program, and the use of various components of the CIS Program. The state must require that MCOs be evaluated on their ability to assess, consent, and enroll beneficiaries into the CIS Program, and sharing information with the state on enrollment phase. The state must require that data submitted by MCOs must demonstrate use of multiple new services offered through the benefit. Reporting must meet data quality standards, and adequately capture data at the desired level of granularity. Output measures such as percent of potentially eligible beneficiaries referred to the CIS Program, percent of qualifying beneficiaries enrolled in the CIS Program may be used to track MCO progress in identifying potential beneficiaries,

- conducting assessments to determine eligibility for the CIS Program, and enrolling consenting beneficiaries.
- iii. Year 3: In the third year of the CIS Program, a combination of withhold and incentive arrangement measures may be implemented to support increased service utilization. A withhold may be used to support the MCOs' implementation of performance incentives for one or more types of providers in the CIS network to support the delivery of high quality care. Withholds and/or incentive arrangements may be used by the state to incentivize MCOs to (a) support continued enrollment and engagement of beneficiaries, and (b) provide services consistent with the benefit. Types of additional metrics required may include percent of CIS enrolled beneficiaries who have completed a functional needs assessment, and percent of CIS Program enrolled beneficiaries who have an individualized service plan.
- iv. Year 4: By the fourth year of the CIS Program, the state must require MCOs to demonstrate short and intermediate outcomes from the program, including appropriate healthcare utilization and use of community-based social supports. Withhold and/or incentive arrangements may be used to incentivize MCO efforts to increase the percentage of CIS beneficiaries who are stably housed, as well as demonstrating re-engagement in the receipt of healthcare services. Indicators selected may include percent of CIS Program beneficiaries with one or more primary care visits since enrollment; enhanced receipt of specialty treatment and behavioral health services among beneficiaries, based on specific needs, may also be tracked.
- v. Year 5: By the fifth year, the state anticipates improvement in health outcomes among beneficiaries enrolled in the program, including decreased ER and inpatient utilization. Withholds may be used to continue enrollment, engagement, and ongoing service utilization; while withholds and withhold and incentive arrangements may be provided for decreases in use of emergency departments and inpatient hospitalizations among beneficiaries enrolled in the program. Other types of quality measures that indicate greater control of conditions may also be included.
- j. **Evaluation of the CIS Program**. The state must incorporate the CIS Program into the demonstration evaluation design. The evaluation design must meet the requirements of section XII of these STCs. In addition to the evaluation design requirements, the state must include the following in the evaluation design:
  - 1. The state must develop a pilot services evaluation strategy that will incorporate rapid cycle assessments (RCAs) into the process to obtain timely information on the effectiveness of pilot services. These evaluations will allow the state to discontinue services determined to have minimal effectiveness and redeploy resources to more valuable strategies, serving as another mechanism for promoting value within the program. RCAs must be conducted by an independent entity identified by the state. The state, in collaboration with stakeholders, must develop process-based and outcome-based metrics, which must be submitted for review and approval by CMS in the evaluation design, and the state must report annually to CMS on these metrics.
  - 2. The state, in consultation with stakeholders, must develop process-based and outcome-based metrics, many of which would be relevant for evaluating

demonstration implementation and demonstration impact, and must be submitted for review and approval by CMS in the evaluation design. Some of these same and a few other process and outcome measures may also be appropriate for routine annual monitoring. The state must finalize any such metrics in discussion with CMS, and report annually to CMS in the monitoring reports or in the RCAs, as appropriate. The state must develop metrics for pre-tenancy supports, housing stability, tenancy sustaining services, and health needs based criteria that are quantifiable, and for which data sources can be identified. Outcome measures of housing stability, health status, utilization, and cost of care should be identified – as applicable – for the short, medium and long-term assessment of the pilot program.

- **23. Community Transition Services Pilot Program.** The state will be authorized to establish Community Transition Services under the CIS program throughout the state from August 1, 2019 through July 31, 2024. The state must provide services to beneficiaries who meet the eligibility criteria in STC 22 on a voluntary basis.
  - a. Community Transition Services Pilot Program Benefits:

Service Category	Community Transition Services
Transitional Case Management Services	Services that will assist the individual with moving into stable housing, including assisting the individual in arranging the move, assessing the unit's and individual's readiness for move-in, assisting the individual) (excluding financial assistance) in obtaining furniture and commodities. This pilot service is furnished only to the extent it is reasonable and necessary as clearly identified through an enrollee's care plan and the enrollee is unable to meet such expense or when the services cannot be obtained from other sources.
	Funding related to one-time utility set-up and moving costs provided that such funding is not available through any other program.
Housing Quality and Safety Improvement Services	Repairs or remediation for issues such as mold or pest infestation if repair or remediation provides a costeffective method of addressing occupant's health condition, as documented by a health care professional, and remediation is not covered under any other program. This pilot service is furnished only to the extent it is reasonable and necessary as clearly identified through an enrollee's care plan and the enrollee is unable to meet such expense or when the services cannot be obtained from other sources.  Modifications to improve accessibility of housing (e.g., ramps, rails) and safety (e.g., grip bars in bathtubs) when necessary to ensure occupant's health and modification is not covered under any other provision
	such as the Americans with Disabilities Act.
Legal Assistance	Assisting the individual by connecting the enrollee to expert community resources to address legal issues impacting housing and thereby adversely impacting health, such as assistance with breaking a lease due to unhealthy living conditions. This pilot service does not include legal representation or payment for legal representation.

Service Category	Community Transition Services
Securing House Payments	Provide a one-time payment for security deposit and/or first month's rent provided that such funding is not available through any other program. This payment may only be made once for each enrollee during the life of the demonstration, except for state determined extraordinary circumstances such as a natural disaster. This pilot service is furnished only to the extent it is reasonable and necessary as clearly identified through beneficiary's individualized care and the beneficiary is unable to meet such expense or when the services cannot be obtained from other sources.

- **24. HCBS Standards.** The state must assure compliance with CMS standards for HCBS settings as articulated in current section 1915(c) and 1915(i) policy and as modified by subsequent regulatory changes. HCBS requirements include the following:
  - a. **HCBS Electronic Visit Verification System**. The state must demonstrate compliance with the Electronic Visit Verification System (EVV) requirements for personal care services (PCS) by January 1, 2020 and home health services by January 1, 2023 in accordance with section 12006 of the 21<sup>st</sup> Century CURES Act.
  - b. **HCBS Quality Systems and Strategy**. The state must is expected to implement systems that measure and improve its performance to meet the waiver assurances set forth in 42 CFR 441.301 and 441.302. The Quality Review provides a comprehensive assessment of the state's capacity to ensure adequate program oversight, detect and remediate compliance issues and evaluate the effectiveness of implemented quality improvement activities.
  - c. **For 1915(c)-Approvable HCBS**, for services that could have been authorized to individuals served under a 1915(c) waiver, the state must have an approved Quality Improvement Strategy and is required to develop and measure performance indicators for the following waiver assurances:
    - i. **Administrative Authority**: A performance measure should must be developed and tracked identifying any authority that the State Medicaid Agency (SMA) delegates to another agency, unless already captured in another performance measure.
    - ii. **Level of Care**: Performance measures are required for the following two sub-assurances: applicants with reasonable likelihood of needing services receive a level of care determination and the processes for determining level of care are followed as documented. While a performance measure for annual levels of care is not required to be reported, the state is expected to must be sure that annual levels of care are determined.
    - iii. **Qualified Providers**: The state must have performance measures that track that providers meet licensure/certification standards, that non-certified providers are monitored to assure adherence to waiver requirements, and that the state verifies that training is given to providers in accordance with the waiver.

- iv. **Service Plan**: The state must demonstrate it has designed and implemented an effective system for reviewing the adequacy of service plans for HCBS participants. Performance measures are required for choice of waiver services and providers, service plans address all assessed needs and personal goals, and services are delivered in accordance with the service plan including the type, scope, amount, duration, and frequency specified in the service plan.
- v. **Health and Welfare**: The state must demonstrate it has designed and implemented an effective system for assuring HCBS participants health and welfare. The state must have performance measures that track that on an ongoing basis it identifies, addresses and seeks to prevent instances of abuse, neglect, exploitation and unexplained death; that an incident management system is in place that effectively resolves incidents and prevents further singular incidents to the extent possible; that state policies and procedures for the use or prohibition of restrictive interventions are followed; and, that the state establishes overall health care standards and monitors those standards based on the responsibility of the service provider as stated in the approved waiver.
- vi. **Financial Accountability**: The state must demonstrate that it has designed and implemented an adequate system for insuring financial accountability of the HCBS program. The state must have performance measures that track that it provides evidence that claims are coded and paid for in accordance for services rendered, and that it provides evidence that rates remain consistent with the approved rate methodology throughout the five year waiver cycle.
- vii. Medicaid Authorities Transition. During the demonstration period, the state must evaluate which portions of the demonstration could be transitioned to 1915(c) and 1915(i) authorities. There will be a five year transition plan as follows:
  - 1. January 2019 through December 2021 CMS and the state conduct joint transition planning activities in order to identify which portions can be transferred.
  - 2. January 2022 through December 2022 The state must develop and submit 1915(c) and 1915(i) authorities for the portions to be transitioned for CMS review and approval.
  - 3. January 2022 through December 2023 The state and CMS will work to approve any 1915(c) waivers or 1915(i) SPAs no later than December 31, 2023.
- 25. The state must submit a report to CMS following receipt of an Evidence Request letter and report template from the Regional Office no later than 21 months prior to the end of the approved demonstration period which includes evidence on the status of the HCBS quality assurances and measures that adheres to the requirements outlined in the March 12, 2014, CMS Informational Bulletin, Modifications to Quality Measures and Reporting in §1915(c) Home and Community-Based Waivers. (1915(c) and 1915(i) HCBS). The Regional Office will send a DRAFT report to the state which will have 90 days to respond to the DRAFT report. The Regional Office will issue a FINAL report to the state 60 days following receipt of the state's response.

- **26.** The CMS Regional Office will evaluate each evidentiary report to determine whether the assurances have been met and will issue a final report to the state 12 months prior to expiration to the demonstration.
- 27. The state must report annually the deficiencies found during the monitoring and evaluation of the HCBS waiver assurances, an explanation of how these deficiencies have been or are being corrected, as well as the steps that have been taken to ensure that these deficiencies do not reoccur. The state must also report on the number of substantiated instances of abuse, neglect, exploitation and/or death, the actions taken regarding the incidents and how they were resolved. Submission is due no later than 6 months following the end of the demonstration year.
- **28. For 1915(i)-Approvable HCBS**, for services that could have been authorized to individuals served under a 1915(i) waiver, the state must have an approved Quality Improvement Strategy and is required to develop performance measures to address the following requirements:
  - a. Service plans that:
    - i. address assessed needs of 1915(i) participants;
    - ii. are updated annually; and
    - iii. document choice of services and providers.
  - b. Eligibility Requirements: The state will must ensure that:
    - i. an evaluation for 1915(i) State plan HCBS eligibility is provided to all applicants for whom there is reasonable indication that 1915(i) services may be needed in the future;
    - ii. the processes and instruments described in the approved program for determining 1915(i) eligibility are applied appropriately; and
    - iii. the 1915(i) benefit eligibility of enrolled individuals is reevaluated at least annually (end of demonstration year) or if more frequent, as specified in the approved program.
  - c. Providers meet required qualifications.
  - d. Settings meet the home and community-based setting requirements as specified in the benefit and in accordance with 42 CFR 441.710(a)(1) and (2).
  - e. The SMA retains authority and responsibility for program operations and oversight.
  - f. The SMA maintains financial accountability through payment of claims for services that are authorized and furnished to 1915(i) participants by qualified providers.
  - g. The state identifies, addresses, and seeks to prevent incidents of abuse, neglect, and exploitation.
  - h. The state must also describe the process for systems improvement as a result of aggregated discovery and remediation activities.
- **29. Person-centered planning**. The state must assure there is a person-centered service plan for each individual determined to be eligible for HCBS. The person-centered service plan must be developed using a person-centered service planning process in accordance with 42 CFR 441.301(c)(1) (1915(c)) or 42 CFR 441.725(c) (1915(i)), and the written person-centered service plan meets federal requirements at 42 CFR 441.301(c)(2) (1915(c)) or 42 CFR 441.725(b) (1915(i)). The person-centered service plan is reviewed, and revised upon

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

- **30. Conflict of Interest**: The state agrees that the entity that authorizes the services is external to the agency or agencies that provide the HCB services. The state also agrees that appropriate separation of assessment, treatment planning and service provision functions are incorporated into the state's conflict of interest policies.
- **31.** Each beneficiary eligible for long term services and supports must have informed choice on their option to self-direct LTSS, have a designated representative direct LTSS on their behalf, or select traditional agency-based service delivery. Both level of care and personcentered service planning personnel will receive training on these options. (MLTSS with self-direction)
- **32.** The state, either directly or through its MCO contracts must ensure that participants' engagement and community participation is supported to the fullest extent desired by each participant. (MLTSS)
- **33.** The state must assure compliance with the characteristics of HCBS settings as described in 1915(c) and 1915(i) regulations in accordance with implementation/effective dates as published in the Federal Register.
- **34.** Beneficiaries may change managed care plans if their residential or employment support provider is no longer available through their current plan. (MLTSS).
  - a. Any revisions to the QUEST Integration delivery system for Behavioral Health Services as defined in this STC requires a revision to Attachment E.
  - b. **Cost of Room and Board Excluded from Capitation Rate Calculations**. For purposes of determining capitation rates, the cost of room and board is not included in noninstitutional care costs.

#### VIII. DELIVERY SYSTEM

- **35. Forms of Managed Care.** The state is authorized to contract with Managed Care Organizations (MCOs) and Prepaid inpatient health plans (PIHPs) all of which are defined under 42 CFR 438.2. The state must comply with 42 CFR 438 in connection with managed care offered under this demonstration unless specified otherwise herein.
- **36. QUEST Integration Plans**. QUEST Integration (QI) plans are MCOs as defined under 42 CFR 438.2. Eligible individuals will be enrolled in a QI plan upon initial eligibility consistent with 42 CFR 438.54 and as outlined here. Eligible individuals will choose among participating QI plans offered to provide the full range of primary, acute, home and community based services and standard behavioral health benefits (including substance abuse treatment). Eligible individuals must be provided with information on the available health plans by the state. The state must ask each applicant to select a health plan upon determination of eligibility. If an eligible individual does not make a selection at the time of the approval of eligibility, the individual is automatically assigned to a plan that operates on

the island of residence, consistent with 42 CFR 438.54, and will have 15 days from the date of auto assignment to select a different health plan from the list provided. The state must send a notice of enrollment upon auto assigning the individual. The state may place an enrollment limit on health plans in order to assure adequate capacity and sufficient enrollment in all participating health plans, as long as at least two QI health plans operating on an island do not have an enrollment limit.

- **37. Specialized Behavioral Health plan**. Acting as a PIHP as defined under 42 CFR 438.2, the Community Care Services (CCS) provides standard behavioral health services to all beneficiaries, and specialized behavioral health services to beneficiaries 18 and older with serious mental illness (SMI), serious and persistent mental illness (SPMI), or requiring support for emotional and behavioral disorder (SEBD).
- 38. Physical and Behavior Health Integration. If the state chooses to integrate the specialized behavioral health services provided to any beneficiaries or subset of beneficiaries with SMI, SPMI, or SEBD into the QI Plans, the state must assess readiness pursuant to § 438.66(d). Assignment of any beneficiaries or subset of beneficiaries with SMI, SPMI, or requiring SEBD into the QI Plans must comply with § 438.54 and may only begin when each QI Plan has been determined by the state and CMS to meet certain readiness and network requirements. The state must notify CMS of the intended integration at least 9 months prior to the assignment of beneficiaries. Any beneficiaries or subset of beneficiaries with SMI, SPMI, or SEBD, may be mandatorily enrolled into a QI Plan providing fully integrated services pursuant to the state's expenditure and waiver authorities that provide for plan choice.

### 39. Enrollment and Disenrollment Processes.

- a. **Enrollment process.** The state must maintain a managed care enrollment and disenrollment process that complies with 42 CFR Part 438, except that disenrollment without cause from a MCO will be more limited in cases where the enrollee was not passively enrolled to the MCO. If the enrollee was not passively enrolled to the MCO, the state must maintain a process by which the enrollee may change MCOs (consistent with STC 36) only if both MCOs agree to the change. The state must track and report to CMS these requests on an annual basis;
- b. **Disenrollment With and Without Cause**. The provisions of 42 CFR section 438.56(c), relating to disenrollment with and without cause, must apply to individuals enrolled in QUEST Integration health plans, except that the without cause change period after enrollment in a plan will be 60 days, rather than 90 days. The state must accommodate and grant all reasonable plan change requests from aged, blind and disabled beneficiaries that occur days 61-90. The state must track the number of plan change requests from aged, blind and disabled beneficiaries that occur during that timeframe and include this data in quarterly reports described in STC 51.
  - i. Individuals who have been enrolled in a plan within the last 6 months will be reassigned to the prior plan unless the beneficiary exercises his/her option to disenroll for cause.

- **40. Member Services**. Following the selection of a health plan, the plan will call the individual or send the individual a survey to identify special health needs (such as the need for long-term services and supports). If the individual is sent a survey and does not respond, the health plan shall be required to call the individual.
- **41. Service Coordination Model.** After a beneficiary selects a health plan and completes the function described in STC 36, the health plan will assign a licensed or qualified professional as the beneficiaries' service coordinator. The following are required to ensure QUEST Integration program integrity.
  - a. Service Coordinator Responsibilities.
    - i. Assuring that the health plan promptly conducts a face-to-face health and functionality assessment (HFA) for each individual who is identified as having special health needs as described in STC 40. Members who are identified as having special health needs will receive a face-to-face HFA within 15 days of the documentation of special health needs through STC 40;
    - ii. Referring any member appearing to meet a nursing facility level of care to the state's Contractor for a functional eligibility review;
    - iii. Providing options counseling regarding institutional placement and HCBS alternatives;
    - iv. Coordinating services with other providers such as physician specialists, Medicare fee-for-service and/or Medicare Advantage health plans and their providers, mental health providers and DD/ID case managers;
    - v. Facilitating and arranging access to services;
    - vi. Seeking to resolve any concerns about care delivery or providers;
    - vii. Leading a team of decision-makers to develop a care plan for those members meeting functional eligibility. The care planning team may include the primary care provider (who may be a specialist); the beneficiary, family members, and significant others (when appropriate); legal guardians, an Ombudsman if so requested by the beneficiary; and other medical care providers relevant to the beneficiary needs; and
  - viii. For those members meeting functional eligibility, leading the care planning team in the development of a case-specific, person-centered, cost-effective plan of care in the community, using industry best practices and guidelines established in STC 41(b) below.
  - b. Written Comprehensive Care Plans. For each enrollee who meets the functional Level of Care (LOC) or "At Risk" assessment for long-term care, the state must require that the MCOs develop and implement a person-centered written care plan that analyzes and describes the medical, social, HCBS, and/or long-term care institutional services that the member will receive. In developing the care plan, the state must that require the MCOs consider appropriate options for the beneficiary related to his/her medical, behavioral health, psychosocial, case-specific needs at a specific point in time, as well as for longer term strategic planning and must emphasize services that are provided in members' homes and communities in order to prevent or delay institutionalization whenever possible. Service plans must be updated annually or more frequently in conjunction with the health and functional assessment.
  - c. **Ombudsman Program.** The state must require that the Ombudsman Program must be available to all beneficiaries under the demonstration. The purpose of the program is to

ensure access to care, to promote quality of care, and to strive to achieve recipient satisfaction with QUEST Integration. The Department of Human Services (DHS) must seek a qualified independent organization to assist and represent members in the resolution of problems and conflicts between the health plan and its members regarding QUEST Integration services to act as the Ombudsman prior to the initial date for delivery of services.

- i. **Delivery of Ombudsman Services.** The Ombudsman must assist in the resolution of issues/concerns about access to, quality of, or limitations to, services. The contracting organization must not be affiliated with any of the QUEST Integration health plans contracted by DHS and operate independently of the Med-QUEST Division.
- ii. **Services Offered by Ombudsman Program.** Ombudsman services must be available to QUEST Integration members to navigate and access covered health care services and supports to include choice counseling, general program-related information, access point for complaints, concerns related to health plan enrollment, and access to services.
- iii. Scope of the Ombudsman Program. The Ombudsman Program must not replace the grievance and appeals process that all health plans that contract with the state must have in place, nor replace the right of a recipient to an administrative hearing. The Ombudsman may assist and represent members up to the point of an Administrative Hearing under state law. They may also assist a member during the hearing process but must not represent the member in an Administrative Hearing. The QUEST Integration member shall file a grievance or appeal with the contracted health plan. An Administrative Hearing may be filed once the health plan's appeal process has been exhausted.
- **42. Contracts.** All contracts and contract modifications of existing contracts between the state and Managed care entities must be prior approved by CMS in accordance with 42 C.F.R. 438.3. The state must provide CMS with a minimum of 90 days to review changes for consideration of approval.
- **43. Statewideness.** For rural and non-rural Islands on which only one health plan is available, the state must require the health plan assure that members have a choice of primary care providers (PCPs).
- **44. Dual-eligible Beneficiaries.** Dual eligible beneficiaries may select a PCP and will be assigned a service coordinator to assure coordination of Medicare and Medicaid services.
- **45. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)**. The MCOs must fulfill the state's responsibilities for coverage, outreach, and assistance with respect to EPSDT services that are described in the requirements of sections 1905(a)(4)(b) (services), 1902(a)(43) (administrative requirements), and 1905(r) (definitions).
- **46. Monitoring Activities by State and/or External Quality Review Organization (EQRO).** The state's EQRO process must meet all the requirements of 42 CFR §438 Subpart E. In addition, the state, or its EQRO having sufficient experience and expertise and oversight by

the State Medicaid Agency (SMA), must monitor and annually evaluate the MCOs' and/or contracting providers performance on the HCBS requirements under QUEST Integration. These include but are not limited to the following:

- a. Level of care determinations to ensure that approved instruments are being used and applied appropriately and as necessary, and to ensure that individuals being served with the Community Benefit have been assessed to meet the required level of care for those services.
- b. Service plans to ensure that MCOs are appropriately creating and implementing service plans based on enrollee's identified needs.
- c. MCO credentialing and/or verification policies to ensure that HCBS services are provided by qualified providers.
- d. Health and welfare of enrollees to ensure that the MCO, on an ongoing basis, identifies, addresses, and seeks to prevent instances of abuse, neglect and exploitation.

### IX. COST SHARING

- **47. Cost sharing.** Cost sharing must be in compliance with Medicaid requirements that are set forth in statute, regulation and policies. Standard Medicaid exemptions from cost-sharing set forth in 42 CFR §447(b) applies to the demonstration.
- **48. Enrollment fee.** Notwithstanding subparagraph (a), the following enrollment fee is permitted under QUEST Integration:

Population	Amount
Medically Needy with Spend-down	An enrollment fee equal to the spend-down obligation or, where applicable, the amount of patient income applied to the cost of long-term care.

# X. GENERAL REPORTING REQUIREMENTS

- **49. Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.
  - a. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of \$5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state 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.
    - 1. The follow process will be used: 1) Thirty (30) 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 state in writing that the deliverable was not accepted for being inconsistent with the

requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

- i. 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).
- ii. For each deliverable, the state 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 state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.
- iii. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets 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 state.
- iv. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.
- b. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state'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.
- **50.** Compliance with Federal Systems Updates. As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state must work with CMS to:
  - a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
  - b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
  - c. Submit deliverables to the appropriate system as directed by CMS.

# XI. MONITORING

51. Monitoring Reports. The state must submit three (3) Quarterly Reports and one (1) compiled Annual Report each DY. The fourth quarter information that would ordinarily be provided in a separate report must be reported as distinct information within the Annual Report. The Quarterly Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The compiled Annual Report is due no later than ninety (90) calendar days following the end of the DY. The reports must include all required elements as per 42 CFR 431.428, and must not direct readers to links outside the report.

Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

- a. Operational Updates Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports must 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 must 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 must also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
- b. <u>Performance Metrics</u> 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 must also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and must follow the framework provided by CMS to support federal tracking and analysis.
- c. <u>Budget Neutrality and Financial Reporting Requirements</u>- Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements (Section XIII) of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration must 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 state must include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed. The discussion must also include interim findings, when available; status of contracts with independent evaluator(s), if applicable; status of Institutional Review Board approval, if applicable; and status of study participant recruitment, if applicable.
- **52. Corrective Action.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 11.
- **53.** Close-Out Report. Within 120 calendar days after to the expiration of the demonstration, the state 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 must 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 c-out report may subject the state to penalties described in STC 49.
- **54. Monitoring Calls**. CMS will convene periodic conference calls with the state.
  - a. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, enrollment and access, budget neutrality, and progress on evaluation activities.
  - b. CMS will provide updates on any amendments or concept papers under review, as well as federal policies and issues that may affect any aspect of the demonstration.
  - c. The state and CMS will jointly develop the agenda for the calls.
- **55. Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 calendar 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 state must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

# XII. EVALUATION OF THE DEMONSTRATION

- **56. Independent Evaluator.** Upon approval of the demonstration, the state must begin arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party must conduct the demonstration evaluation in an independent manner in accord with the CMS-approved draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.
- **57. 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 evaluation 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 design is not sufficiently developed, or if the estimates appear to be excessive.

- **58. Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) calendar days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design must not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state must use an independent evaluator to develop the draft Evaluation Design.
- **59.** Evaluation Design Approval and Updates. The state must submit a revised draft Evaluation Design within sixty (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 state must publish the approved Evaluation Design to the state's website within thirty (30) calendar days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Monitoring Reports. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.
- 60. 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 must have at least one hypothesis and pertinent research question(s) to test each hypothesis. In addition, the state must include a hypothesis and evaluation questions focusing specifically on CIS programs. The state must also include additional hypotheses and evaluation questions that measure progress in any areas identified as needing improvement during the previous demonstration period. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
- **61. Interim Evaluation Report.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Report must be posted to the state's website with the application for public comment.
  - a. The interim evaluation report must discuss evaluation progress and present findings to date as per the approved evaluation design.
  - b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
  - c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and

- hypotheses, and how the design was adapted must be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
- d. The state 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 state's website.
- e. The Interim Evaluation Report must comply with Attachment B of these STCs.
- **62. Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period August 1, 2019 June 30, 2024, 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 state must 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 state's Medicaid website within 30 calendar days of approval by CMS.
- **63. State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the interim evaluation, and/or the summative evaluation.
- **64. Public Access**. The state must post the final documents (e.g., Monitoring Reports, Close-Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 calendar days of approval by CMS.
- **65. Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS must be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS must be provided a copy including any associated press materials. CMS must be given ten (10) 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.
- **66.** Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state 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 state 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 state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 50.

# XIII. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

- **67. Allowable Expenditures.** This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs. <sup>1</sup>
- **68. Unallowable Expenditures.** In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:
  - a. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.
  - b. Costs for services provided in a nursing facility as defined in section 1919 of the Act that qualifies as an IMD.
  - c. Costs for services provided to individuals who are involuntarily residing in a psychiatric hospital or residential treatment facility by operation of criminal law.
  - d. Costs for services provided to beneficiaries under age 21 residing in an IMD unless the IMD meets the requirements for the "inpatient psychiatric services for individuals under age 21" benefit under 42 CFR 440.160, 441 Subpart D, and 483 Subpart G.
- **69. Standard Medicaid Funding Process.** The standard Medicaid funding process must be used for this demonstration. The state must provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state must estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within thirty (30) days after the end of each quarter, the state must submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

Hawaii's QUEST Integration Medicaid Section 1115 Demonstration Approval Demonstration Period: August 1, 2019 through July 31, 2024

<sup>&</sup>lt;sup>1</sup> For a description of CMS's current policies related to budget neutrality for Medicaid demonstration projects authorized under section 1115(a) of the Act, see State Medicaid Director Letter #18-009.

- **70.** Extent of Federal Financial Participation for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the budget neutrality expenditure limits described in Section XIV:
  - a. Administrative costs, including those associated with the administration of the demonstration;
  - b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
  - c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.
- **71. Sources of Non-Federal Share.** The state certifies that its match for the non-federal share of funds for this demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.
  - a. The state acknowledges that CMS has authority to 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 must be addressed within the time frames set by CMS.
  - b. The state acknowledges that any amendments that impact the financial status of the demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.
- **72. State Certification of Funding Conditions.** The state must certify that the following conditions for non-federal share of demonstration expenditures are met:
  - a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.
  - b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
  - c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.

- d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
- e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.
- **73. Program Integrity.** The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.
- **74. Medicaid Expenditure Groups (MEG).** MEGs are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The Master MEG Chart table provides a master list of MEGs defined for this demonstration.

# **Master MEG Chart**

EG subject to BN	Hypothetical (Yes/No)
EG 1 – Children	No
EG 2 – Adults	No
EG 3 – Aged	No
EG 4 – Blind/Disabled	No
EG 5 – Group VIII	Yes
EG 6 - CIS	Yes
EG 7 – CIS Community	Yes
Transition Pilot	

**75. Reporting Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00001/9). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year

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

- a. <u>Cost Settlements.</u> The state must report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments must be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.
- b. Premiums and Cost Sharing Collected by the State. The state must report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) must also be reported separately by DY on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year must be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.
- c. Pharmacy Rebates. Because pharmacy rebates are included in the base expenditures used to determine the budget neutrality expenditure limit, the state must report the portion of pharmacy rebates applicable to the demonstration on the appropriate forms CMS-64.9 WAIVER and 64.9P waiver for the demonstration, and not on any other CMS-64.9 form (to avoid double counting). The state must have a methodology for assigning a portion of pharmacy rebates to the demonstration in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of the demonstration population, and which identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must also be approved in advance by the Regional Office. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.
- d. <u>Administrative Costs.</u> The state must separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the Master MEG Chart table, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.
- e. Member Months. As part of the Quarterly and Annual Monitoring Reports described in section XI, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive

- services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.
- f. <u>Budget Neutrality Specifications Manual.</u> The state must create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.
- **76. Demonstration Years.** Demonstration Years (DY) for this demonstration are defined in the Demonstration Years table below.

De	emonstration Years
Demonstration Year 26	August 1, 2019- July 31, 2020
Demonstration Year 27	August 1, 2020- July 31, 2021
Demonstration Year 28	August 1, 2021- July 31, 2022
Demonstration Year 29	August 1, 2022- July 31, 2023
Demonstration Year 30	August 1, 2023- July 31, 2024

77. Budget Neutrality Monitoring Tool. The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing demonstration's actual expenditures to the budget neutrality expenditure limits described in Section XIV. CMS will provide technical assistance, upon request.<sup>2</sup>

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

- **78. Claiming Period.** The state must report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state must continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.
- **79. Future Adjustments to Budget Neutrality.** CMS reserves the right to adjust the budget neutrality expenditure limit:
  - a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments, CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets must reflect the phase out of impermissible provider payments by law or regulation, where applicable.
  - b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement must be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.
  - c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, must result in a modified budget neutrality expenditure limit.

# XIV. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

**80. Limit on Title XIX Funding.** The state must be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

- **81. Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions; however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.
- 82. Calculation of Budget Neutrality Limit and How it is Applied. To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.
- 83. Main Budget Neutrality Test. The Main Budget Neutrality Test allows the state to show that demonstration waivers granted have not resulted in increased costs to Medicaid, and that federal Medicaid "savings" have been achieved sufficient to offset the additional projected federal costs resulting from expenditure authority. The table below identifies the MEGs that are used for the Main Budget Neutrality Test. MEGs designated as "WOW Only" or "Both" are components used to calculate the budget neutrality expenditure limit. MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against the budget neutrality expenditure limit. In addition, any expenditures in excess of limit from Hypothetical Budget Neutrality Tests count as expenditures under the Main Budget Neutrality Test. The Composite Federal Share for this test is calculated based on all MEGs indicated as "Both."

# **Main Budget Neutrality Test Table**

MEG	TREND	DY 26 PMPM	DY 27 PMPM	DY 28 PMPM	DY 29 PMPM	DY 30 PMPM
Children	1.0%	\$448.48	\$452.96	\$457.49	\$462.07	\$466.69
Adults	3.7%	\$925.47	\$959.72	\$995.23	\$1,032.05	\$1,070.24
Aged	3.4%	\$1,939.17	\$2,005.11	\$2,073.28	\$2,143.77	\$2,216.66
Blind/Disabled	4.4%	\$2,646.76	\$2,763.22	\$2,884.80	\$3,011.73	\$3,144.25

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

# 85. Hypothetical Budget Neutrality Tests

- a. **Hypothetical Budget Neutrality Test 1: Group VIII.** Low income adults with FPL up to 133%.
- b. **Hypothetical Budget Neutrality Test 2: CIS.** Expenditures related to the CIS benefits of pre-tenancy supports and tenancy supports; excludes expenditures related to the Community Transition Services Pilot Program.
- c. **Hypothetical Budget Neutrality Test 3: CIS Community Transition Pilot.** Expenditures related to the Community Transition Services Pilot Program.

# **Hypothetical Budget Neutrality Test Table**

MEG	TREND	DY 26 PMPM	DY 27 PMPM	DY 28 PMPM	DY 29 PMPM	DY 30 PMPM
<b>Group VIII</b>	4.8%	\$899.37	\$942.54	\$987.78	\$1,035.20	\$1,084.89
CIS	4.8%%	\$1,184.76	\$1,241.63	\$1,301.23	\$1,363.69	\$1,429.15
CIS	4.8%					
Community						
Transition						
Pilot		\$3,231.17	\$3,386.27	\$3,548.81	\$3,719.15	\$3,897.67

d. The Hypothetical Group VIII and CIS expenditures caps consist of the total computable dollar limits presented in the above table, summed across all DYs. The federal share of

- the caps is obtained by multiplying the total computable by the federal share rate for that DY.
- e. If total FFP for a hypothetical group should exceed the federal share of cap, the difference must be reported as a cost against the budget neutrality limit described in STC 88.
- 86. Composite Federal Share. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Main or Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.
- 87. Transitional Phase-Down of Newly Accrued Savings. Beginning with DY 26, the net variance between the without-waiver cost and actual with-waiver cost will be reduced for selected Medical population based MEGs. The reduced variance, calculated as an applicable percentage times the total variance, will be used in place of the total variance to determine overall budget neutrality for the demonstration. (Equivalently, the difference between the total variance and reduced variance could be subtracted from the without-waiver cost estimate.) The applicable percentages have been determined in accordance with the policy for Transitional Phase-Down of Newly Accrued Savings described in State Medicaid Director Letter # 18-009. This provision only applies to the Main Budget Neutrality Test, and to the MEGs that are designated "Both" without-waiver and with-waiver. The MEGs affected by this provision and the applicable percentages are shown in the table below. If the total variance for an MEG in a DY is negative, the applicable percentage is 100 percent.

# **Savings Phase Down Table**

MEG					
Children	25%	25%	25%	25%	25%
Adults	25%	25%	25%	25%	25%
Aged	25%	25%	25%	25%	25%
Blind/Disabled	25%	25%	25%	25%	25%

**88. Exceeding Budget Neutrality**. CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from August 1, 2019 to July 31, 2023. The Main Budget Neutrality Test may incorporate net savings from the immediately prior demonstration period of January 1, 2013 through December 31, 2018 (but not from any earlier approval period). If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds must be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget

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

<b>Demonstration Year</b>	<b>Cumulative Target Definition</b>	Percentage
DY 1 through DY 26	Cumulative budget neutrality limit	2.0 percent
DY 1 through DY 27	Cumulative budget neutrality limit	1.5 percent
DY 1 through DY 28	Cumulative budget neutrality limit	1.0 percent
DY 1 through DY 29	Cumulative budget neutrality limit	0.5 percent
DY 1 through DY 30	Cumulative budget neutrality limit	0 percent

# XV. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION EXTENSION PERIOD

Due Date	Deliverable
30 calendar days from approval letter date	State Acceptance of Demonstration Extension, STCs, Waivers, and Expenditure Authorities.
120 calendar days from approval letter date	Ensure that all prior MSIS reports are timely and accurate (STC 50)
180 calendar days from approval letter date	Submit Draft Evaluation Design (STC 58)
60 calendar days after receipt of CMS comments	Submit Final Evaluation Design (STC 59)
30 calendar days after CMS Approval	Approved Evaluation Design published to state's website (STC 59)
Quarterly Deliverables Due 60 calendar days after end of each	Quarterly Progress Reports (STC 51)
quarter, except 4 <sup>th</sup> quarter	Quarterly Expenditure Reports (STC 69)
Annual Deliverables – Due 90 calendar days after end of each 4 <sup>th</sup> quarter	Annual Report (STC 51)
150 calendar days after the approval of the demonstration extension	Submit Behavioral Health Services Protocol (STC 21)

### ATTACHMENT A

# **Developing the Evaluation Design**

# Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform both Congress and CMS about Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration must 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 could benefit from improved quantitative and qualitative evidence to inform policy decisions.

# **Expectations for Evaluation Designs**

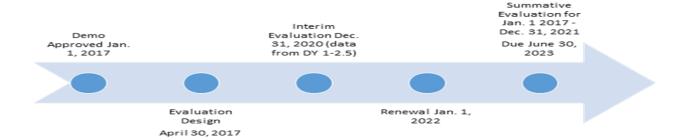
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses,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

# The format for the Evaluation Design is as follows:

General Background Information; Evaluation Questions and Hypotheses; Methodology; Methodological Limitations; 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 thirty (30) days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



# **Required Core Components of All Evaluation Designs**

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

- **A. General Background Information** In this section, the state must 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 must:
  - 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:
- 4) Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
- 5) Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.
- **C. Methodology** In this section, the 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 must 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 must:
  - 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 Hypothesis 1	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
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 must also identify any efforts to minimize the limitations. Additionally, this section must 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. For example:
  - 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.

# E. Attachments

- 1) **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design must include "No Conflict of Interest" signed by the independent evaluator.
- 2) **Evaluation Budget.** A budget for implementing 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 evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.
- 3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design must incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline must also include the date by which the Final Summative Evaluation report is due.

# ATTACHMENT B Preparing the Interim and Summative Evaluation Reports

# Introduction

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

# **Expectations for Evaluation Reports**

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

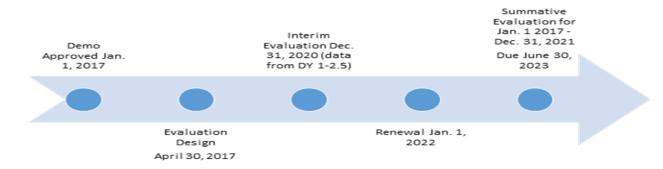
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved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

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

- A. Executive Summary;
- B. General Background Information;
- C. Evaluation Questions and Hypotheses;
- D. Methodology;
- E. Methodological Limitations;
- F. Results:
- G. Conclusions:
- H. Interpretations, and Policy Implications and Interactions with Other 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 to the state's website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS, pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



# **Required Core Components of Interim and Summative Evaluation Reports**

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state's Driver Diagram (described in the Evaluation Design guidance) must be included with an explanation of the depicted information. The Evaluation Report must 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 must include basic information about the demonstration, such as:
  - 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.
  - 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
  - 3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration:
  - 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the 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.
  - 5) Describe the population groups impacted by the demonstration.

# **C. Evaluation Questions and Hypotheses** – In this section, the state must:

- 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 must 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 must provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design must 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 must 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.
  - **A. Methodological Limitations** This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.
  - **B. 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

must visually depict the demonstration results (tables, charts, graphs). This section must include information on the statistical tests conducted.

- **C. 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?
    - **D.** 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 must 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 must also include a discussion of the implications of the findings at both the state and national levels.
    - **E. 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?

### E. Attachment

Evaluation Design: Provide the CMS-approved Evaluation Design

# **ATTACHMENT C: Reserved for Evaluation Design**

The following are the provider guidelines and service definitions for HCBS provided by section 1915(c) waivers, as well as the QUEST integration program.

Service/Provider	Service Definition
Adult Day Care	Adult day care is defined as regular supportive care provided to four (4) or more disabled adult
Center	participants in accordance with HAR§17-1417. Services include observation and supervision by center staff, coordination of behavioral, medical and social plans, and implementation of the instructions as listed in the participant's care plan. Therapeutic, social, educational, recreational, and other activities are also provided as regular adult day care convices.
	and other activities are also provided as regular adult day care services.
	Adult day care staff members may not perform healthcare related services such as medication administration, tube feedings, and other activities which require healthcare related training. All healthcare related activities must be performed by qualified and/or trained individuals only, including family members and professionals, such as an RN or LPN, from an authorized agency.
	Adult Day Care Centers are licensed by the Department of Human Services and maintained and operated by an individual, organization, or agency.
	Included in the sub-set of services for the "At Risk" population.
Adult Day Health Center	Adult Day Health refers to an organized day program of therapeutic, social, and health services provided to adults with physical, or mental impairments, or both which require nursing oversight or care in accordance with HAR §11-96 and HAR §11-94-5. The purpose is to restore or maintain, to the fullest extent possible, an individual's capacity for remaining in the community.
	Each program must have nursing staff sufficient in number and qualifications to meet the needs of participants. Nursing services must be provided under the supervision of a registered nurse. If there are members admitted who require skilled nursing services, the services will be provided by a registered nurse or under the direct supervision of a registered nurse.
	In addition to nursing services, other components of adult day health may include: emergency care, dietetic services, meals which do not constitute a full nutritional program, occupational therapy, physical therapy, physician services, pharmaceutical services, psychiatric or psychological services, recreational and social activities, social services, speech-language pathology, and transportation services.
	Adult Day Health Centers are licensed by the Department of Health.
	Included in the sub-set of services for the "At Risk" population.
Assisted Living Facility	Assisted living services include personal care and supportive care services (homemaker, chore, attendant services, and meal preparation) that are furnished to members who reside in an assisted living facility. Assisted living facilities are home-like, non-institutional settings. Payment for room and board is prohibited.
	Section 30.200 describes Assisted Living Facilities as a facility, as defined in HRS 321-15.1, that
	is licensed by the Department of Health. This facility must consist of a building complex offering
	dwelling units to individuals and services to allow residents to maintain an independent assisted living lifestyle. The facility must be designed to maximize the independence and self-esteem of
	limited-mobility persons who feel that they are no longer able to live on their own.
Community Care	CCMA services are provided to members living in Community Care Foster Family Homes and
Management	other community settings, as required. A health plan may, at its option, demonstrate the ability to
Agency (CCMA)	provide CCMA services by contracting with an entity licensed under HAR subchapters 1 and 2. The following activities are provided by a CCMA: continuous and ongoing nurse delegation to the caregiver in accordance with HAR Chapter 16-89 Subchapter 15; initial and ongoing
	assessments to make recommendations to health plans for, at a minimum, indicated services,

Service/Provider	Service Definition
Term	Service Bernindon
	supplies, and equipment needs of members; ongoing face-to-face monitoring and implementation of the member's care plan; and interaction with the caregiver on adverse effects and/or changes in condition of members. CCMAs shall (1) communicate with a member's physician(s) regarding the member's needs including changes in medication and treatment orders, (2) work with families regarding service needs of member and serve as an advocate for their members, and (3) be accessible to the member's caregiver twenty-four (24) hours a day, seven (7) days a week.  CCMA's are agencies licensed by the DHS or its designee under HAR chapter 17-1454,
	subchapters 1 and 2, to engage in locating, coordinating and monitoring comprehensive services to residents in community care foster family homes or members in E-ARCHS and assisted living facilities. A health plan may be a community care management agency.
Community Care Foster Family Home (CCFFH)	CCFFH services is personal care and supportive services, homemaker, chore, attendant care and companion services and medication oversight (to the extent permitted under state law) provided in a certified private home by a principal care provider who lives in the home. The number of adults receiving services in CCFFH is determined by HAR, Title 17, Department of Human Services, SubTitle 9, Chapter 1454-43. CCFFH services are currently furnished to up to three (3) adults who receive these services in conjunction with residing in the home. All providers must provide individuals with their own bedroom. Each individual bedroom shall be limited to two (2) residents. Both occupants must consent to the arrangement. The total number of individuals living in the home, who are unrelated to the principal care provider, cannot exceed four (4).
	In accordance with HAR, Title 17, Department of Human Services, SubTitle 9, Chapter 1454-42, members receiving CCFFH services must be receiving ongoing CCMA services.  A CCFFH is a home issued a certificate of approval by the DHS to provide, for a fee, twenty-four
	(24) hour living accommodations, including personal care and homemaker services. The home must meet all applicable requirements of HAR §17-1454-37 through HAR §17-1454-56.
Counseling and Training	Counseling and training activities include the following: member care training for members, family and caregivers regarding the nature of the disease and the disease process; methods of transmission and infection control measures; biological, psychological care and special treatment needs/regimens; employer training for consumer directed services; instruction about the treatment regimens; use of equipment specified in the service plan; employer skills updates as necessary to safely maintain the individual at home; crisis intervention; supportive counseling; family therapy; suicide risk assessments and intervention; death and dying counseling; anticipatory grief counseling; substance abuse counseling; and/or nutritional assessment and counseling.
	Counseling and training is a service provided to members, families/caregivers, and professional and paraprofessional caregivers on behalf of the member.
Environmental Accessibility Adaptations	Environmental accessibility adaptations are those physical adaptations to the home, required by the individual's care plan, which are necessary to ensure the health, welfare and safety of the individual, or which enable the individual to function with greater independence in the home, and without which the individual would require institutionalization. Such adaptations may include the installation of ramps and grab-bars, widening of doorways, modification of bathroom facilities, or installation of specialized electric and plumbing systems which are necessary to accommodate the medical equipment and supplies that are necessary for the welfare of the individual. Window air conditioners may be installed when it is necessary for the health and safety of the member.
	Excluded are those adaptations or improvements to the home that are of general utility, and are not of direct medical or remedial benefit to the individual, such as carpeting, roof repair, central air conditioning, etc. Adaptations which add to the total square footage of the home are excluded from this benefit. All services must be provided in accordance with applicable state or local building codes.
Expanded Adult	Residential care services are personal care services, homemaker, chore, attendant care and

Service/Provider	Service Definition
Term	
Residential Care	companion services and medication oversight (to the extent permitted by law) provided in a
Home (E-ARCH) or Residential	licensed private home by a principal care provider who lives in the home.
Care Services	Residential care is furnished: 1) in a Type I Expanded Adult Residential Care Home (E-ARCH), allowing five (5) or fewer residents provided that up to six (6) residents may be allowed at the discretion of the DHS to live in a Type I home with no more than two (2) of whom may be NF LOC; or 2) in a Type II EARCH, allowing six (6) or more residents, no more than twenty percent (20%) of the home's licensed capacity may be individuals meeting a NF LOC who receive these services in conjunction with residing in the home.
	An E-ARCH's is a facility, as defined in HAR §11-100.1.2 and licensed by the Department of Health, that provides twenty-four (24) hour living accommodations, for a fee, to adults unrelated to the family, who require at least minimal assistance in the activities of daily living, personal care services, protection, and healthcare services, and who may need the professional health services provided in an intermediate care facility or skilled nursing facility. There are two types of expanded care ARCHs in accordance with HRS § 321-1562 as described above.
Home Delivered	Home delivered meals are nutritionally sound meals delivered to a location where an individual
Meals	resides (excluding residential or institutional settings). The meals will not replace or substitute for a full day's nutritional regimen (i.e., no more than 2 meals per day). Home delivered meals are provided to individuals who cannot prepare nutritionally sound meals without assistance and are determined, through an assessment, to require the service in order to remain independent in the community and to prevent institutionalization.
	Included in the sub-set of services for the "At Risk" population
Home Maintenance	Home maintenance is a service necessary to maintain a safe, clean and sanitary environment. Home maintenance services are those services not included as a part of personal assistance and include: heavy duty cleaning, which is utilized only to bring a home up to acceptable standards of cleanliness at the inception of service to a member; minor repairs to essential appliances limited to stoves, refrigerators, and water heaters; and fumigation or extermination services. Home maintenance is provided to individuals who cannot perform cleaning and minor repairs without assistance and are determined, through an assessment, to require the service in order to prevent institutionalization.
Moving Assistance	Moving assistance is provided in rare instances when it is determined through an assessment by the care coordinator that an individual needs to relocate to a new home. The following are the circumstances under which moving assistance can be provided to a member: unsafe home due to deterioration; the individual is wheel-chair bound living in a building with no elevator; multi-story building with no elevator, where the client lives above the first floor; member is evicted from their current living environment; or the member is no longer able to afford the home due to a rent increase. Moving expenses include packing and moving of belongings. Whenever possible, family, landlord, community and third party resources who can provide this service without charge will be utilized.
Non-Medical Transportation	Non-medical transportation is a service offered in order to enable individuals to gain access to community services, activities, and resources, specified by the care plan. This service is offered in addition to medical transportation required under 42 CFR 431.53 and transportation services under the Medicaid State Plan, defined at 42 CFR 440.170(a) (if applicable), and must not replace them. Whenever possible, family, neighbors, friends, or community agencies which can provide this service without charge will be utilized. Members living in a residential care setting or a CCFFH are not eligible for this service.
Personal	Personal assistance services Level I are provided to individuals requiring assistance with
Assistance	instrumental activities of daily living (IADLs) in order to prevent a decline in the health status
Services	and maintain individuals safely in their home and communities. Personal assistance services
(Level I)	Level I may be self-directed and consist of companion services and homemaker services.  Homemaker services include:

Service/Provider	Service Definition
Personal	<ul> <li>Routine housecleaning such as sweeping, mopping, dusting, making beds, cleaning the toilet and shower or bathtub, taking out rubbish;</li> <li>Care of clothing and linen by washing, drying, ironing, mending;</li> <li>Marketing and shopping for household supplies and personal essentials (not including cost of supplies);</li> <li>Light yard work, such as mowing the lawn;</li> <li>Simple home repairs, such as replacing light bulbs;</li> <li>Preparing meals;</li> <li>Running errands, such as paying bills, picking up medication;</li> <li>Escort to clinics, physician office visits or other trips for the purpose of obtaining treatment or meeting needs established in the service plan, when no other resource is available;</li> <li>Standby/minimal assistance or supervision of activities of daily living such as bathing, dressing, grooming, eating, ambulation/mobility and transfer;</li> <li>Reporting and/or documenting observations and services provided, including observation of member self-administered medications and treatments, as appropriate; and</li> <li>Reporting to the assigned provider, supervisor or designee, observations about changes in the member's behavior, functioning, condition, or self-care/home management abilities that necessitate more or less service.</li> <li>Included in the sub-set of services for the "At Risk" population</li> <li>Personal assistance services Level II are provided to individuals requiring assistance with</li> </ul>
Assistance Services (Level II)	moderate/substantial to total assistance to perform activities of daily living (ADLs) and health maintenance activities. Personal assistance services Level II must be provided by a Home Health Aide (HHA), Personal Care Aide (PCA), Certified Nurse Aide (CNA) or Nurse Aide (NA) with applicable skills competency. The following activities may be included as a part of personal assistance services Level II:  • Personal hygiene and grooming, including bathing, skin care, oral hygiene, hair care, and dressing; • Assistance with bowel and bladder care; • Assistance with medications and mobility; • Assistance with transfers; • Assistance with medications, which are ordinarily self-administered when ordered by member's physician; • Assistance with routine or maintenance healthcare services by a personal care provider with specific training, satisfactorily documented performance, care coordinator consent and when ordered by member's physician; • Assistance with feeding, nutrition, meal preparation and other dietary activities; • Assistance with exercise, positioning, and range of motion; • Taking and recording vital signs, including blood pressure; • Measuring and recording intake and output, when ordered; • Collecting and testing specimens as directed; • Special tasks of nursing care when delegated by a registered nurse, for members who have a medically stable condition and who require indirect nursing supervision as defined in Chapter 16-89, Hawaii Administrative Rules; • Proper utilization and maintenance of member's medical and adaptive equipment and supplies. Checking and reporting any equipment or supplies that need to be repaired or replenished; • Reporting changes in the member's behavior, functioning, condition, or self-care abilities which necessitate more or less service; and

Service/Provider	Service Definition
Term	
	When personal assistance services Level II activities are the primary services, personal assistance services Level I activities identified on the care plan, which are incidental to the care furnished or that are essential to the health and welfare of the member, rather than the member's family, may also be provided.
	Personal assistance services Level II may be self-directed.
	Personal Assistance is care provided when a member, member's parent, guardian, family member or legal representative employs and supervises a personal assistant who is certified by the health plan as able to provide the designated services whose decision is based on direct observation of the member and the personal assistant during the actual provision of care. Documentation of this certification will be maintained in the member's individual plan of care.
	Included in the sub-set of services for the "At Risk" population
Personal Emergency Response Systems	PERS is a twenty-four (24) hour emergency assistance service which enables the member to secure immediate assistance in the event of an emotional, physical, or environmental emergency. PERS are individually designed to meet the needs and capabilities of the member and includes training, installation, repair, maintenance, and response needs. PERS is an electronic device which enables certain individuals at high risk of institutionalization to secure help in an emergency. The individual may also wear a portable "help" button to allow for mobility. The system is connected to the person's phone and programmed to signal a response center once a "help" button is activated. The response center is staffed by trained professionals. The following are allowable types of PERS items:
	• 24-hour answering/paging;
	Beepers;
	Med-alert bracelets;
	• Intercoms;
	• Life-lines;
	<ul> <li>Fire/safety devices, such as fire extinguishers and rope ladders;</li> <li>Monitoring services;</li> </ul>
	<ul> <li>Light fixture adaptations (blinking lights, etc.);</li> </ul>
	<ul> <li>Telephone adaptive devices not available from the telephone company; and</li> </ul>
	Other electronic devices/services designed for emergency assistance.
	All types of PERS, described above, must meet applicable standards of manufacture, design, and installation. Repairs to and maintenance of such equipment shall be performed by the manufacturer's authorized dealers whenever possible.
	PERS services are limited to those individuals who live alone, or who are alone for significant parts of the day, have no regular caregiver for extended periods of time, and who would otherwise require extensive routine supervision. PERS services will only be provided to a member residing in a non-licensed setting.
	Included in the sub-set of services for the "At Risk" population
Private Duty Nursing	Private duty nursing is a service provided to individuals requiring ongoing nursing care (in contrast to part time, intermittent skilled nursing services under the Medicaid State Plan) listed in the care plan. The service is provided by licensed nurses (as defined in HAR § 16-89) within the scope of state law.
	Included in the sub-set of services for the "At Risk" population
Respite Care	Respite care services are provided to individuals unable to care for themselves and are furnished on a short-term basis because of the absence of or need for relief for those persons normally

Service/Provider Term	Service Definition
	providing the care. Respite may be provided at three (3) different levels: hourly, daily, and overnight. Respite care may be provided in the following locations: individual's home or place of residence; foster home/expanded-care adult residential care home; Medicaid certified NF; licensed respite day care facility; or other community care residential facility approved by the state. Respite care services are authorized by the member's PCP as part of the member's care plan. Respite services may be self-directed.
Specialized Medical Equipment and Supplies	Specialized medical equipment and supplies entails the purchase, rental, lease, warranty costs, assessment costs, installation, repairs and removal of devices, controls, or appliances, specified in the care plan, that enable individuals to increase and/or maintain their abilities to perform activities of daily living, or to perceive, control, participate in, or communicate with the environment in which they live.
	This service also includes items necessary for life support, ancillary supplies and equipment necessary to the proper functioning of such items, and durable and non-durable medical equipment not available under the Medicaid State Plan. All items must meet applicable standards of manufacture, design and installation and may include:
	<ul> <li>Specialized infant car seats;</li> <li>Modification of parent-owned motor vehicle to accommodate the child (i.e., wheelchair lifts);</li> <li>Intercoms for monitoring the child's room;</li> <li>Shower seat;</li> <li>Portable humidifiers;</li> </ul>
	<ul> <li>Electric bills specific to electrical life support devices (ventilator, oxygen concentrator);</li> <li>Medical supplies;</li> <li>Heavy duty items including, but not limited to, patient lifts or beds that exceed \$1,000 per</li> </ul>
	month;  Rental of equipment that exceeds \$1,000 per month such as ventilators; and  Miscellaneous equipment such as customized wheelchairs, specialty orthotics, and bath equipment that exceeds \$1,000 per month.
	Items reimbursed shall be in addition to any medical equipment and supplies furnished under the Medicaid State Plan and shall exclude those items which are not of direct medical or remedial benefit to the individual.
	Specialized medical equipment and supplies shall be recommended by the member's PCP.

