



SMD# 20-001

RE: Healthy Adult Opportunity

January 30, 2020

Dear State Medicaid Director:

The Centers for Medicare & Medicaid Services (CMS) is pleased to announce a new opportunity for states to potentially achieve new levels of flexibility in the administration and design of their Medicaid programs while providing federal taxpayers with greater budget certainty. The Healthy Adult Opportunity (HAO) initiative will allow states to carry out demonstrations under section 1115(a)(2) of the Social Security Act (the Act) to provide cost-effective coverage using flexible benefit designs under either an aggregate or per-capita cap financing model for certain populations without being required to comply with a list of Medicaid provisions identified by CMS.

CMS recognizes that states, as administrators of the program, are in the best position to assess the needs of their respective Medicaid-eligible populations and to drive reforms that result in better health outcomes. States that agree to implement demonstrations under either of these financing models and to increased transparency and accountability for effective administration of their programs, quality and access to care, which in the judgment of CMS, are likely to assist in promoting the objectives of the Medicaid program, will be granted extensive flexibility to test alternative approaches to implementing their Medicaid programs, including the ability to make many ongoing program adjustments without the need for demonstration or state plan amendments that require prior approval. The list of Medicaid provisions with respect to which we will consider providing flexibility for states participating in demonstrations approved under the HAO initiative is provided in Appendix A. This includes flexibility on provisions such as retroactive coverage, cost-sharing limits, presumptive eligibility, and other requirements that CMS historically has waived under section 1115 of the Act.

Through the HAO initiative, CMS is inviting states to design demonstrations for consideration by CMS that will promote the objectives of the Medicaid program, including the furnishing of medical assistance in a manner that promotes the sustainability of government health care spending through use of an annual budget neutrality limit, calculated in the aggregate or on a per capita basis. While federal funding will be capped, federal financial participation (FFP) will continue to flow to states as it does today; nothing in this letter changes the need for states to submit claims reflecting actual expenditures to obtain federal matching funds for the Medicaid program. Demonstrations approved utilizing this approach will offer states far greater flexibility and discretion than is available under ordinarily-applicable Medicaid rules as well as the freedom to manage their programs within certain parameters and expectations without the need for complex amendments or advance federal approval of certain changes.

In addition to added flexibility, states that agree to an aggregate cap financing model and meet certain performance criteria may be eligible to access shared savings when expenditures for the demonstration population are less than the annual allotment provided under the aggregate cap. The HAO initiative thus will allow CMS and states to test whether greater administrative flexibility will enable states to more efficiently run their Medicaid programs, while increasing state accountability, facilitating enrollment of eligible persons, ensuring timely beneficiary access to effective care, improving quality outcomes, and potentially freeing up resources for additional investment in coverage or benefits not offered under the state plan or other initiatives that advance the objectives of the Medicaid program. While every application by states will be considered on its own merits, this will potentially allow states that practice greater fiscal responsibility to invest in projects designed to benefit Medicaid populations.

This guidance does not impose any requirements on states and does not bind CMS to approve any state's application for demonstration authority under the HAO initiative. Rather, CMS will consider applications on a case-by-case basis and make an independent decision about whether the demonstration satisfies the requirements under section 1115 of the Act for approval.

A. Overview

Under the demonstration authority granted by section 1115(a) of the Act, in the case of a demonstration that CMS determines is likely to assist in promoting the objectives of the Medicaid program, CMS can waive under section 1115(a)(1) of the Act, or not apply under section 1115(a)(2) of the Act, many federal requirements so that states can test new or existing ways to deliver and pay for health care services under the Medicaid program. CMS can provide expenditure authority under section 1115(a)(2) of the Act to allow states to provide coverage to individuals not eligible under the state plan, which can offer significantly more flexibility without the need for individual section 1115 waivers. The HAO initiative will involve the use of section 1115(a)(2) authority to provide coverage to individuals not eligible for benefits under the state plan, while affording states maximum flexibility in the administration of benefits for such individuals.

The HAO initiative encourages states to apply for all flexibilities that have been previously approved in other demonstrations where such flexibilities would be likely to promote the objectives of the Medicaid program, such as:

- The ability to cover adults who qualify for Medicaid on a basis other than disability or need for long-term care services and supports and who are not covered under the state plan, including covering all individuals described in section 1902(a)(10)(A)(i)(VIII) of the Act and 42 CFR 435.119 (“adult group”), using section 1115(a)(2) expenditure authority at the Federal Medical Assistance Percentage (FMAP) that would apply if they were covered under the state plan;
- Providing populations covered under an HAO demonstration with coverage more consistent with insurance benefits provided through the Exchanges, rather than the traditional Medicaid benefit package;
- The ability to pay for services that cannot traditionally be funded by Medicaid, including those designed to address certain health determinants, such as enhanced case management services that link individuals to housing or other supports;

- Design of flexible premium and cost sharing structures that are not required to comply with the terms of section 1916(f) of the Act;
- The ability to impose additional conditions of eligibility, such as community engagement requirements for non-elderly, non-pregnant adult Medicaid beneficiaries who are eligible for Medicaid on a basis other than disability;
- The ability to make certain changes in benefits, premiums, and co-payments during the course of the demonstration without the need for state plan or demonstration amendments and further approval by CMS;
- The ability to change eligibility and enrollment processes, such as eliminating retroactive eligibility.

Additionally, the HAO initiative potentially offers states new opportunities, including:

- The ability to make certain administrative changes during the course of the demonstration, such as certain changes in provider payment rates and application of claims review prior to making payment, without amendments or further approval by CMS;
- The ability to adopt a closed formulary in line with Essential Health Benefit (EHB) requirements (with special protections for individuals with HIV and behavioral health conditions);
- The ability to include coverage of services provided by a federally qualified health center as part of the state's value-based payment reform efforts.
- The opportunity to propose alternative approaches to compliance with statutory managed care provisions that differ from those set forth in regulations;
- The opportunity for states implementing an aggregate cap demonstration to be eligible for shared savings when actual FFP is less than the FFP allotment under the aggregate cap, provided a state meets certain performance criteria.

While the intent of this initiative is to provide states with a menu of maximum up-front flexibilities with which to design their program, states are not automatically entitled to all of the flexibilities described in this guidance; whether a demonstration will be approved is determined on a case-by-case basis and will depend on the details of each application. CMS will need to determine whether the demonstration as a whole with the flexibilities requested supports the goals of the demonstration and is likely to promote the objectives of the Medicaid program. Similarly, any parameters set forth in this guidance reflect the conditions that CMS expects will be necessary to approve an application to implement an HAO demonstration. CMS will make a state-by-state determination of the specific requirements needed for HAO demonstrations designed by each state, which will be reflected in the Special Terms and Conditions (STCs) for each state's demonstration.

The HAO initiative described in this guidance is available to all states as a mechanism to cover populations not covered under their state plan. HAO demonstrations also could be used to extend coverage to populations a state has previously covered in its state plan or under other section 1115 demonstrations, but for whom the state has elected to end coverage. We expect that coverage under an HAO demonstration will focus on adults under age 65 who are not eligible for coverage under the state plan. CMS may consider state requests to include other adult populations who are not eligible for coverage under the state plan.

With the significant flexibility afforded under this demonstration opportunity, states will continue to be held to a high standard of accountability for health outcomes and will be subject to regular and thorough monitoring and evaluation, consistent with CMS's approach to other section 1115 demonstrations. As discussed in greater detail in Section D of this guidance relating to Oversight, we expect that states will also provide baseline data on a set of Adult Core metrics, as well as on a set of quarterly continuous performance indicators, relating to enrollment and retention, access and quality of care, health outcomes, and financial management, and to other effects for testing policies under HAO demonstrations, such as community engagement and federal matching funds for services provided during an Institution for Mental Diseases (IMD) stay consistent with CMS guidance for substance use disorder (SUD) or Serious Mental Illness and Severe Emotional Disturbance (SMI / SED). States will be expected to report on these metrics and indicators throughout the demonstration, and engage in rapid course correction if needed, in accordance with guidance provided by CMS. In addition, states will be expected to conduct interim and summative impact evaluations for each demonstration period of performance, consistent with academic standards and guidance provided by CMS.

CMS is providing an application template for the HAO initiative, which will include lists of the most typical administrative program requirements applicable to section 1115 demonstrations, with which the state would be expected to comply – for example, compliance with federal civil rights laws, program performance and program integrity standards; non-supplanting or duplication of other federal funding; and Transformed Medicaid Statistical Information System (T-MSIS) submissions and maintenance. States will have the opportunity in the application template to propose demonstration-specific processes for complying with these administrative program requirements. These administrative program requirements will be incorporated into the demonstration's STCs. CMS will review the state's proposed flexibilities and other materials submitted as part of the application, and make a determination of whether the demonstration can be approved. After an application is approved, the state will submit an implementation plan for CMS approval, that will contain greater detail on how the state plans to implement the flexibilities authorized under the STCs. As with other section 1115 demonstrations, states may not begin implementation of their approved HAO demonstration until CMS approves the implementation plan. The application process and implementation plan are discussed in section E.

States with existing section 1115 demonstrations that cover populations eligible to be covered in an HAO demonstration may also propose to transition such demonstrations into HAO demonstrations. CMS will work with states interested in such a transition to ensure a seamless conversion of coverage into the HAO demonstration and orderly close-out of the existing section 1115 demonstration in a manner consistent with the STCs for the existing demonstration. More information about this process is provided in Appendix B.

This guidance describes additional programmatic and budgetary parameters for state consideration in the development of demonstrations that will utilize an annual aggregate or per capita cap approach.

B. State Flexibility in Program Design

States will have broad flexibility in the initial design of an HAO demonstration as well as the ability to make certain changes over the course of the demonstration, which generally will be

allowed without need for a demonstration amendment. CMS reserves the right to require an amendment, and to subject the amendment to the requirements in 42 CFR 431.412, if CMS determines that the state is proposing a significant change that is outside the scope of flexibilities approved in the STCs for a state’s HAO demonstration, or that would impact the baseline for determining budget neutrality. The breadth of this flexibility in key program areas is discussed below. Section E of this guidance includes a discussion of the extent of state flexibility and process for making changes to an HAO demonstration once the initial application and implementation plan have been approved.

1. Eligibility and Enrollment

Eligible Populations

The HAO initiative is focused on coverage provided to adults under age 65 who qualify for Medicaid on a basis other than disability or need for long-term care services and supports and who are not covered in the state plan, including individuals described in the new adult group at section 1902(a)(10)(A)(i)(VIII) of the Act and 42 CFR 435.119. The demonstration opportunity is available to all states, including those with existing section 1115 demonstrations, providing flexibility for populations eligible to be covered in an HAO demonstration. To provide coverage under an HAO demonstration, participating states may need to phase out and transition, in whole or in part, an existing demonstration into an HAO demonstration. CMS will work with states to ensure a smooth transition (see Appendix B).

States will have the opportunity to impose conditions of eligibility on coverage under an HAO demonstration that do not generally apply to Medicaid coverage under state plans, such as community engagement requirements, as described in [SMDL #18-002](#), and consistent with other applicable federal laws, including title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (PPACA). CMS, in consultation and coordination with the Department of Health and Human Services (HHS) Office for Civil Rights, is available to assist states in designing projects that comply with the civil rights laws.

States may propose to impose such additional conditions of eligibility on coverage under an HAO demonstration at the beginning of the demonstration, or to adopt subsequent to initial implementation provided that, either during the initial application process or prior to imposing the additional condition, notice and transparency requirements at 42 CFR part 431, subpart G, have been met and CMS has determined that the additional condition on eligibility would promote the objectives of the Medicaid program.

States choosing to participate in the HAO initiative also will have the opportunity to set the income standard for eligibility for coverage under an HAO demonstration, as well as to change the standard over the course of the demonstration, and/or to limit coverage to a defined subset of individuals, such as individuals with severe mental illness, individuals needing treatment for substance use disorder, or individuals with HIV/AIDS. States also may propose to require an asset test for individuals seeking coverage under an HAO demonstration. Under the HAO initiative, and in other demonstration projects covering the adult group under section 1115(a)(2) authority, increased FMAP will be available in

accordance with sections 1905(y) and 1905(z) of the Act, provided that the demonstration includes a standard for eligibility based on a household income standard of at least 133 percent of the federal poverty level (FPL), no asset test for those with income at or below 133 percent FPL, and eligibility for all individuals described in the adult group, even when benefits are not provided in accordance with section 1937 of the Act, as required under sections 1902(a)(10)(A)(i)(VIII) and 1902(k) and 1903(i)(26) of the Act in the case of state plan coverage. To claim increased FMAP for individuals described in the adult group, states participating in this initiative also would need to work with CMS develop a methodology for identifying those for whom increased FMAP is available, in accordance with 42 CFR part 433 subpart E. Increased FMAP is not available for coverage of individuals with household income above 133 percent FPL.

Eligibility and Enrollment Processes

For populations covered under an HAO demonstration, CMS will not require compliance with the effective date of eligibility prescribed under 42 CFR 435.915. Instead, states may propose to not provide retroactive eligibility, as well as to establish a prospective effective date of coverage – for example, to coincide with enrollment in a managed care plan or a Qualified Health Plan (QHP). States also could propose to conduct an individual’s first regularly-scheduled renewal of eligibility prior to the end of the 12-month renewal called for in 42 CFR 435.916(a)(1), in order to align with the open enrollment period for Exchange coverage. In addition, states may propose to not comply with the requirement to operate Hospital Presumptive Eligibility (HPE), described in section 1902(a)(47)(B) of the Act and 42 CFR 435.1110, under an HAO demonstration, although states implementing an HAO demonstration can elect to offer such coverage to individuals covered under an HAO demonstration.¹

States will be expected to implement other processes, in particular those designed to ensure coordination with enrollment in other Medicaid categories, as well as coverage through an Exchange at initial application and as changes in beneficiaries’ circumstances require transition between programs. These include use of income methodologies based on modified adjusted gross income (MAGI); use of a single streamlined application for all insurance affordability programs, which may include revisions to accommodate state-specific criteria included in the state’s HAO demonstration (42 CFR 435.907(a) or (b)); increased availability of, and primary reliance on, electronic verification (42 CFR 435.948 – 435.956); streamlined data-driven renewal processes (42 CFR 435.916(a)); and coordination between enrollment in Medicaid and coverage through the Exchange (42 CFR 435.1200). CMS also expects that states will recognize applicants’ and beneficiaries’ authorized representatives (42 CFR 435.923), make timely determinations of eligibility (42 CFR 435.912), provide adequate notice of a grant, denial or termination of eligibility, or other adverse actions (42 CFR 431.210 – 431.214 and 435.917), and provide electronic notification in accordance with each individual’s election (42 CFR 435.918). As part of this demonstration, states may develop eligibility and enrollment policies that will improve upon the administrative efficiency of these processes, e.g., by periodically checking electronic data sources between regular eligibility renewals; however, we expect that the federal requirements governing these

¹ HPE requires states to provide benefits for individuals determined presumptively eligible by a participating hospital for coverage for a temporary period pending completion of a regular application and determination of eligibility by the state agency.

fundamental components of states' eligibility and enrollment systems will apply to coverage under an HAO demonstration.

2. Benefits

Benefit Package

For populations covered under an HAO demonstration, states generally will be expected to align coverage with the individual health insurance market, such as QHPs offered through the Exchange in the state or in another state. Additionally, CMS may consider other benefit proposals providing comprehensive coverage that meet larger health reform and Medicaid objectives.

To promote access to a benefit package that includes coverage of important services not otherwise required in traditional Medicaid, such as mental health and substance use disorder treatment and a minimum set of preventive services, and to ensure comparability of benefits with the individual market, states electing to participate in this demonstration initiative generally will be expected, at a minimum, to provide coverage of items and services in the categories of EHBs, as implemented by CMS in regulations at 45 CFR part 156, subpart B and 45 CFR 155.170. The categories of EHBs are (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care, which generally are not applicable for the populations that would be covered under an HAO demonstration. For example, states may select (a) the EHB-benchmark plan used for plan years beginning in 2017 by another state in its entirety or (b) select their own EHB-benchmark plan used for plan years beginning in 2017 and replace coverage of any of the categories of EHB with coverage from another state's 2017 EHB-benchmark plan or (c) select a set of benefits to become their new EHB-benchmark plan. It is important to note that states also will generally be expected to cover state-mandated benefits that are considered EHB as part their benefit package. Specifically, states should take into account both the EHB-benchmark plan benefits and benefits required by state action taking place on or before December 31, 2011. Additional details on how states can identify which items and services within the ten categories will be considered EHB, consistent with the regulations implementing EHB for the individual health insurance market, are provided in Appendix C.

Under this initiative, state proposals will not be expected to meet additional Alternative Benefit Plan (ABP) wrap-around service requirements such as, for example, coverage of non-emergency medical transportation (NEMT) and early and periodic screening, diagnostic and treatment services (EPSDT) for individuals age 19-20 included in this demonstration. States, however, may choose to cover these benefits in addition to EHB.

Subject to certain limitations, states also will have the opportunity under this demonstration to provide, at their discretion, coverage of other items and services in addition to EHB to improve health outcomes for beneficiaries, enhance coverage and address certain health determinants to promote independence. Coverage of additional items and services could, for

example, be based on benefits found in sections 1905(a), 1915(c), 1915(i), 1915(j), 1915(k) or 1945 of the Act.² In addition, if a state elects to include nursing facility services in the benefit package, the state will generally be expected to offer home and community-based services.

Provider qualifications generally should be defined for benefits not already covered by the state. However, Medicaid funds may not be used for reimbursement of room and board, except for certain facility-based services, and funds in this demonstration cannot be used to supplant or duplicate funds from other federal programs. Expenditure authority to cover services provided to patients in an IMD also is available if the state meets the program requirements under section 1115 of the Act, as outlined in the State Medicaid Director Letters (SMDLs), Strategies to Address the Opioid Epidemic issued on November 1, 2017, available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf> and Opportunities to Design Innovative Service Delivery Systems for Adults with a Serious Mental Illness or Children with a Serious Emotional Disturbance available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18011.pdf>.

Federally Qualified Health Centers

CMS is also providing states with flexibility regarding the coverage of and payment for federally qualified health center (FQHC) services as part of the state's value-based payment (VBP) reform efforts. Under this demonstration initiative, states pursuing the value-based payment option may cover services consistent with section 1905(a)(2)(C) of the Act, or may propose to otherwise determine what services provided by FQHCs will be covered, similar to QHP coverage of services provided by FQHCs. States not exercising this flexibility would still be expected to comply with the requirements applicable to Medicaid state plan coverage and reimbursement rules at section 1905(a)(2)(C) of the Act.

States also may be permitted to select a methodology for FQHC payments. Under a state plan, section 1902(bb) of the Act requires reimbursement for the required services under section 1905(a)(2)(C) of the Act using a Prospective Payment System (PPS) or using an Alternative Payment Methodology (APM) if agreed upon by the health center. As an additional alternative, states could propose a VBP methodology consistent with regulations applicable to QHPs at 45 CFR 156.235(e). When proposing VBP methodologies, states should include reasonable, auditable performance targets and anticipated payment rates based on those targets, in their initial application or request a subsequent demonstration amendment. Additionally, we would expect the state to describe how the state's VBP strategy for FQHCs relates to other VBP arrangements or delivery system reform in the state.

Other Applicable Federal Benefit Standards

Any benefits covered under this demonstration in addition to EHB also would be expected to comply with the certain standards applicable to EHB. Specifically, benefits would be expected to comply with the requirements of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as implemented in 45 CFR 147.160 and 146.136; non-discrimination standards defined in 45 CFR 156.125; and other applicable standards related to coverage of items and services as EHB found at 45 CFR 156,

² Enhanced match for 1915(k) and 1945 is dependent upon the covered population being covered in the state plan and all program rules for the respective authorities being followed.

as will be specified in the applicable STCs. Additional details on the EHB standards can be found in Appendix C.

Prescription Drugs and the Medicaid Drug Rebate Program

With respect to drug coverage under this initiative, it is important to note that states may be provided with flexibility to offer formularies under an HAO demonstration similar to those provided in commercial health insurance markets, consistent with the EHB requirements. This flexibility exists because prescription drug coverage would not be covered under the state plan, but instead would be covered under section 1115(a)(2) expenditure authority for individuals covered by an HAO demonstration. This means that the open formulary requirements in section 1927 that apply to state plan drug coverage do not apply. Under this initiative, we would not make the open formulary requirements in section 1927 of the Act applicable as a term and condition of the demonstration as we have done in other demonstrations when section 1115(a)(2) expenditure authority has been used. While the open formulary requirements in section 1927 thus would not apply, and drugs could be made available under a limited formulary, such as in accordance with EHB rules applicable in the individual market, the obligation under section 1927(b) of the Act for a drug manufacturer with a drug rebate agreement to pay rebates would apply. Section 1115(a)(2) provides that expenditures made under its authority are to be “*regarded as expenditures under the State plan.*” Therefore, the requirement in section 1927(b) of the Act to pay rebates on drugs “*for which payment was made under the State plan*” would apply, even though the drugs would not be covered under the state plan, and the beneficiaries would not be regarded as eligible under the state plan.³ States would also be free to negotiate supplemental rebates with manufacturers in exchange for the inclusion of their drugs on the state’s formulary. States wishing to continue to meet the coverage requirements of section 1927 of the Act would be free to do so.

CMS notes that if states elect the flexibility to establish formularies, CMS will expect states to comply with EHB requirements regarding prescription drug benefits. These requirements will help ensure that states have robust formularies in place. In addition, to ensure that this demonstration supports CMS’s objectives related to the treatment of HIV and opioid use disorders (OUD), CMS expects states to provide coverage of (1) substantially all drugs for mental health (that is, antipsychotics and antidepressants) consistent with Medicare Part D coverage; (2) substantially all antiretroviral drugs (including PrEP) consistent with Medicare Part D coverage, and (3) all forms, formulations, and delivery mechanisms for drugs approved by the Food and Drug Administration (FDA) to treat OUDs for which there are rebate agreements in place with the manufacturers. Additional coverage requirements may be negotiated between the state and CMS. In addition to coverage requirements, CMS will expect states to comply with drug utilization review, state reporting, and program integrity requirements generally consistent with those of section 1927.

³ We note that expenditures under section 1115(a)(2) of the Act are treated as “expenditures under the State plan” for other purposes as well (e.g., in calculating disproportionate state hospital (DSH) payments).

3. Premiums and Cost-Sharing

States may propose under an HAO demonstration may propose to not be required to comply with restrictions on premiums and cost-sharing imposed under sections 1916 and 1916A of the Act and 42 CFR 447.50 – 447.56. Instead, states will have broad flexibility to propose alternative premiums and cost sharing structures. We would expect states to adhere to two overarching limitations:

1. Aggregate out-of-pocket costs incurred by beneficiaries covered under the demonstration would not exceed 5 percent of the beneficiary's household income, measured on a monthly or quarterly basis.
2. Premiums and cost-sharing charges for tribal beneficiaries as well as individuals needing treatment for substance use disorder and individuals living with HIV, as well as cost-sharing charges for prescription drugs needed to treat mental health conditions, would not exceed amounts permitted under the statute and implementing regulations. States similarly would not be permitted to suspend enrollment for such individuals for failure to pay premiums or cost-sharing, even if authorized for other individuals under the demonstration.

CMS does not expect other restrictions on premiums and cost-sharing that are imposed under the statute and regulations to be needed for HAO demonstrations. For example, we expect that, if consistent with promoting the objectives of the Medicaid program, states could charge premiums and cost-sharing above the maximum levels set forth in the regulations, impose higher cost-sharing charges on non-emergency services provided in a hospital emergency department, and suspend individuals who fail to pay a required premium after a grace period as long as the aggregate out-of-pocket costs incurred by beneficiaries does not exceed the 5 percent limit.

States would be expected to calculate the 5 percent limit on a monthly or quarterly basis and would be expected to explain how they would ensure that beneficiaries do not incur cost-sharing that exceeds the 5 percent limit. States would be expected to count toward the 5 percent aggregate cap premiums and cost-sharing incurred by a spouse, children and other members of the beneficiary's household, as defined in 42 CFR 435.603(f), in determining the aggregate of total premiums and cost-sharing for purposes of the 5 percent limit.

States will be expected to provide the beneficiary and public notice of premiums, cost-sharing and similar charges under the demonstration, consistent with the notice requirements described in 42 CFR 447.57, without regard to whether or not the state is required to provide notice to, or obtain CMS approval of, such charges.

4. Delivery Systems, Payment Models and Managed Care

Delivery System Reform and Payment Models

CMS encourages states applying for this demonstration to implement payment and delivery system reforms to improve the effectiveness of coverage, improve health outcomes and reduce the cost of health care. States generally will have broad flexibility in the type of delivery system(s) and payment models adopted for an HAO demonstration. In general, states will be

able to use any combination of fee-for-service and managed care delivery systems and will have flexibility to alter these arrangements over the course of the demonstration, as long as the state's design supports the demonstration hypothesis and is determined to advance the objectives of the Medicaid program. States are encouraged to propose innovative plan designs consistent with the expectations set forth in this guidance and will be able to leverage employer sponsored insurance, the individual health insurance market or align with a coverage program designed under an applicable complementary section 1332 waiver.

States are encouraged to address state laws that inhibit choice and competition in their health care system – such as certificate of need laws and laws limiting providers' scope of practice or imposing unnecessarily restrictive supervisory requirements – which undermine efforts to generate greater efficiencies in the delivery of quality care. The Departments of Health and Human Services, Labor, and the Treasury issued a report, *Reforming America's Healthcare System through Choice and Competition*,⁴ in December 2018 that describes the influence of state and federal laws, regulations, guidance, and policies on choice and competition in health care workforce, provider, and insurance markets and identifies actions that states or the federal government could take to develop a better functioning health care system. As part of their implementation plan, states with demonstrations approved under this guidance will be expected to review the recommendations in this report and assess their current competitive landscape to determine whether anti-competitive barriers in the state have impeded access or increased Medicaid costs, and develop a plan to address the identified barriers. We will prioritize applications that demonstrate that the state has taken or is taking steps to address state barriers to competition. We also will consider proposals that drive greater efficiency and improved outcomes from other providers, such as rural health clinics, which are entitled to higher reimbursement rates under the Act, in order to achieve increased state flexibility and improved outcomes. As part of the demonstration application, states will need to explain the payment or delivery system reforms they will apply to achieve the desired outcome. Delivery system reforms that have significant financial implications will still need to go through the formal amendment process.

In order to promote alignment with Medicare and commercial payers, CMS encourages states to consider implementing models similar to those developed by CMS' Center for Medicare & Medicaid Innovation (CMMI) into their HAO demonstration and to explain in their application the models chosen. States should review payment and delivery system models that have been tested by CMMI and show promising results, and consider how to use those strategies as part of their HAO demonstration to improve quality and control costs. This does not necessarily require that states apply for and be participants in CMMI models (although CMS encourages states to do so), but could take the form of state-developed models that are aligned with CMMI payment and delivery system strategies. To promote further alignment, measures of quality and cost used in the CMMI models should also be integrated into the states' quality strategy. CMS will provide technical assistance to states regarding selection of models and applicability to their HAO demonstration.

⁴ <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>

Managed Care

Under the HAO initiative, states will not need separate state plan or Medicaid waiver authorities to operate the delivery system for populations covered under the demonstration. States utilizing a managed care delivery system to serve populations under an HAO demonstration generally will be expected to meet specified managed care statutory requirements under sections 1903(m) and 1932 of the Act that provide beneficiary protections, facilitate beneficiary decision making, support access to services, monitor program administration, ensure efficient use of funds, and measure the quality of the delivery system. However, states may be given flexibility to propose alternative approaches in the application template to meet the statutory provisions that differ from those set forth in 42 CFR part 438.

For example, while states will be expected to meet the statutory requirements that managed care rates be actuarially sound and the regulatory requirements pertaining to the development of capitation rates, states will have the opportunity under an HAO demonstration to demonstrate actuarial soundness without requiring prospective CMS review ordinarily required under 42 CFR 438.7(a). Alternative approaches to ensuring actuarially sound rates are explained in section D.1 of this guidance on Oversight. Similarly, states will be expected to certify that their managed care plans have the capacity to meet the state's standards for access to care and availability of services. However, states will have the opportunity under this demonstration to adopt alternative approaches to network adequacy, access to care, and availability of services to those required under 42 CFR 438.68. Potential alternatives are explained below in section B.5 of this guidance, relating to Access to Care and Availability of Services. Regardless of the approach elected, all states implementing an HAO demonstration will be required to submit routine data reports as described in the discussion of Monitoring and Evaluation in section D.3 of this guidance.

States seeking to implement other, alternative approaches to meeting the statutory requirements for managed care in addition to the areas of access to care and rate certification that are not consistent with the regulations in 42 CFR part 438 will need to include the alternative approach(es) in their demonstration application, including establishing alternative standards subject to CMS approval and providing reasonable evidence that the alternative approach meets the statutory requirements of 42 CFR 438. Absent inclusion of an alternative approach in the approved STCs, the regulatory provisions in 42 CFR part 438 will be applied to HAO demonstrations.

Managed Care Contract Review

States seeking to implement managed care in a manner that differs from the statutory and regulatory requirements also may propose to exercise additional flexibilities in the administration of their managed care plan contracts, particularly for contract amendments, during the demonstration period for an HAO demonstration. A state would be expected to submit its initial managed care contracts to CMS for review and approval, and to submit subsequent amendments to CMS. However, we do not anticipate requiring approval of contract amendments prior to their execution. Any amendments would be expected to be consistent with the terms of the HAO demonstration, as well as statutory and regulatory requirements that otherwise would apply to Medicaid coverage. CMS will monitor managed care contract amendments to ensure compliance with the terms of the demonstration and legal requirements. If the monitoring finds that a state's managed care contracts are not consistent

with the terms of the demonstration, CMS would work with the state to bring it into compliance before initiating corrective action, which could include deferral or disallowance of costs, or termination of the demonstration. For states that would prefer the certainty that comes with approval, CMS also would allow states to seek formal approval for contract changes.

Consistent with current requirements, states would be expected to incorporate the potential impact of substantive contract amendments into the capitation rates paid to managed care plans. Additional information on state responsibilities related to contract amendments that modify managed care capitation rates are explained in the section D of this guidance.

State Directed Payments

States also will have the opportunity to direct managed care plans' expenditures, consistent with the requirements of 42 CFR 438.6(c). However, unlike the current process, which requires CMS's prior approval, under an HAO demonstration, CMS intends to assess compliance with the regulatory requirements through ongoing monitoring. States will be expected to have clear documentation that any direction of managed care plans' expenditures is based only on delivery and utilization of services to Medicaid beneficiaries covered under the contract or outcomes and quality of the delivered services during the rating period associated with the directed payment. If CMS were to find that states' payments are not compliant with the state direct payment requirements (*i.e.*, 42 CFR 438.6(c)), CMS may take corrective action, which could include deferral or disallowance of costs or termination of the demonstration, consistent with the STCs. If a state intends to make pass-through payments or supplemental payments to providers, rather than using state directed payments, the supplemental payments would need to be explicitly authorized in the state's HAO demonstration and paid to providers outside of the managed care capitation rates.

5. Access to Care and Availability of Services

States will need to ensure, and will be expected to regularly report, that services covered under an HAO are available and accessible to beneficiaries in a timely manner. States will have several options, depending on whether services are furnished under the demonstration in a fee-for-service, managed care, or alternative delivery system.

1. *Fee-for-Service*. We will primarily consider two approaches to ensuring access to care through fee-for-service in HAO demonstration applications: 1) Comply with section 1902(a)(23) of the Act and implementing regulations at 42 CFR 431.51, which allow a beneficiary to obtain services from any qualified institution, agency, community pharmacy, or person who undertakes to provide such services; or 2) restrict a beneficiary (except in emergency circumstances) to obtaining services from any provider or practitioner who provides services in compliance with the state's written standards for reimbursement, quality, and utilization of covered services, provided that the state's standards are consistent with accessible, high-quality delivery, and efficient and economic provision of covered services.

CMS, in collaboration with the Health Resources and Services Administration (HRSA), will work with states electing option 2 above to identify appropriate metrics for

measuring any impact on FQHCs. Data for these metrics would be included in the quarterly and annual monitoring reports discussed in section D.3 of this guidance. If the data reported indicates a negative impact on the capacity of FQHCs in the state to serve Medicaid beneficiaries and other uninsured or underinsured patients, CMS will engage with the state to determine the cause of the decline and determine whether corrective action, which may include coverage of FQHC services consistent with Medicaid state plan coverage requirements and reimbursement rules, may be necessary. Further, in order to ensure continuity of care for high need populations, including but not limited to individuals with HIV, opioid use disorder and mental health, the state would need to develop a plan to prevent disruptions in treatment for these individuals as a result of any changes in network participation that occurs from implementation of a VBP strategy.

2. *Managed Care.* We will primarily consider two approaches to ensuring access to care through managed care delivery systems in HAO demonstration application: 1) Document compliance with regulatory access requirements in 42 CFR part 438, in which states must establish quantitative standards to ensure that managed care plans' provider networks have adequate capacity to serve beneficiaries; or 2) instead of complying with the provider-specific network adequacy standards in 42 CFR 438.68(b), establish alternative standards subject to CMS approval and provide reasonable evidence of enrollee access to care and satisfaction. For example, 42 CFR 438.206(a) requires that states ensure that managed care plans' provider networks for services covered under the contract meet the standards developed by the state in accordance with 42 CFR 438.68. Likewise, 42 CFR 438.207(a) requires managed care plans to provide supporting documentation that the managed care plans have the capacity to serve the expected enrollment in accordance with the state's standards, including the standards at 42 CFR 438.68. Under an HAO demonstration, we would consider modifications to these standards to require the state and managed care plans to demonstrate, for example, direct measures of access are meeting the state-established standards. Under both options to measure and monitor access, corrective action would be required if satisfactory access is not confirmed.
3. *Alternative Approach.* Through the flexibility offered under this demonstration, states may also propose an alternative approach to their delivery system that leverages the private insurance market or coverage programs designed under an applicable complementary section 1332 waiver. In this instance, states may propose alternative approaches to measuring and ensuring sufficient access to care, including any of the standards described above. States seeking to implement an alternative approach will need to provide advance notice of the approach to the public for comment as well as to CMS, consistent with the transparency requirements described in 42 CFR part 431, subpart G and, where applicable, the state's tribal consultation.

States participating in the HAO initiative will be held accountable for the accessibility of services to beneficiaries served under an HAO demonstration, and states will be expected to timely report on various measures designed to ensure beneficiaries have meaningful access to services, including (1) mandatory reporting on certain of the Adult Quality Core Set measures of access to primary and preventive care; (2) quarterly reporting of continuous performance indicators selected by CMS (including indicators relating to access); and (3) providing

evidence demonstrating beneficiary’s health care experiences, including timely access and barriers to care. These reporting requirements are discussed more fully below.

6. Fair Hearing Rights

As part of an HAO demonstration, states will have the opportunity to not implement fair hearing processes as required under section 1902(a)(3) of the Act and are encouraged to improve upon those processes. Certain of the regulatory requirements governing the Medicaid fair hearing processes, however, which are constitutionally protected, necessarily would apply to any fair hearing process afforded to individuals applying for or receiving coverage in an HAO demonstration. These requirements include, but are not limited to, such basic elements as the right to advance notice of a termination or other adverse action; clearly explaining the reason for the action; a timely fair hearing before an impartial arbiter; the opportunity to be represented by counsel at the hearing and to present evidence, including the right to call witnesses; the right to know opposing evidence and cross examine witnesses; and a requirement that the tribunal hearing the case prepare a record of the evidence presented, make a decision based solely upon the evidence presented at the hearing, and produce written findings of fact and reasons for its decision. Other requirements rooted in laws other than the Medicaid statute, such as accessibility requirements for individuals living with disabilities or individuals with limited English proficiency, also would apply to an HAO demonstration under section 1115(a)(2) authority.

7. Other Flexibilities

CMS has prepackaged into the HAO initiative a suite of flexibilities that we expect generally could be made available through its use of section 1115(a)(2) authority. A list of provisions that we expect states would have the flexibility not to apply under an HAO demonstration is provided in Appendix A. The statutory requirements that we expect will apply to any demonstration under the HAO initiative also are listed in Appendix A. States may request additional flexibilities not addressed in Appendix A in their application, though such requests may delay approval of a state’s application for an HAO demonstration.

Beneficiary protections afforded under other applicable federal statutes also will apply to HAO demonstrations, including those under title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, the Age Discrimination Act of 1975, and section 1557 of the PPACA.

8. Tribal Protections

Under this demonstration initiative, CMS expects that states will provide key protections afforded to tribal and IHS-eligible beneficiaries, IHS providers, and certain other Indian health providers under title XIX of the Act. Protections that CMS expects states will make applicable under an HAO demonstration, as a condition of approval, include the protections related to premiums and cost sharing under sections 1916(j), 1916A(b)(3)(A)(vii), and 1916A(b)(3)(B)(x) of the Act, as implemented at 42 CFR 447.56(a)(1)(x) and 447.56(c)(2); and the protections related to managed care under section 1932(h) of the Act, as implemented

at 42 CFR 438.14. Under an HAO demonstration, CMS will expect states to apply these protections even when other provisions of sections 1916 or 1916A would not otherwise apply to premiums or cost-sharing imposed under the demonstration, or when states implement Medicaid managed care under the HAO demonstration, rather than under section 1932.

The 100 percent FMAP under section 1905(b) of the Act for services “received through” an IHS facility (including an IHS facility operated by an Indian tribe or tribal organization) will be available under an HAO demonstration just as it is available in the absence of an HAO demonstration. CMS will determine whether a service available under an HAO demonstration is “received through” an IHS facility (including those operated by tribes and tribal organizations) for purposes of section 1905(b) in a manner consistent with the CMS interpretation of the statute described in the February 26, 2016 State Health Official Letter (SHO Letter #16-002). Further, as discussed in section C.3 of this guidance, expenditures for services “received through” an IHS facility will be excluded from data used to set the base period cap.

CMS takes seriously concerns expressed by tribal leaders about how implementation of section 1115 demonstrations may affect tribal beneficiaries. Consistent with 42 CFR 431.408(b) and the CMS Tribal Consultation Policy, states developing HAO demonstration applications will be expected to hold meaningful consultation on a government-to-government basis with federally recognized tribes located in their state, in order to develop the details of how an HAO demonstration would be implemented and apply to tribal beneficiaries. In particular, under 42 CFR 431.408(b), states with federally recognized Indian tribes, Indian health programs, and/or urban Indian health organizations must consult with tribes and solicit advice from Indian health programs and urban Indian health organizations in the state, prior to submitting a demonstration application to CMS, if the demonstration would have a direct effect on Indians, tribes, Indian health programs, or urban Indian health organizations.

C. Financing and Shared Savings

1. Budget Neutrality

CMS requires that section 1115 demonstrations be budget neutral, which means that the proposed demonstration cannot cost the federal government more than federal Medicaid costs would be in the state, absent the demonstration.⁵ The HAO initiative described in this guidance is aimed at giving states broad flexibility to design and operate demonstrations that improve access to high quality services, while holding states accountable for managing their programs in a cost-effective manner, and each state demonstration approved under the HAO initiative will operate under a budget neutrality agreement that will limit FFP under section 1115(a)(2) of the Act on an annual basis over the life of the demonstration. These amounts will be determined prior to approval of the demonstration. States with demonstrations approved utilizing an annual aggregate or per capita cap approach will manage their programs under these caps and assume risk for costs exceeding the annual cap. Total computable expenditures in excess of the annual cap will not be eligible for FFP (except in limited

⁵ See August 22, 2018 CMS letter to State Medicaid Director (SMD # 18-009), “RE: Budget Neutrality Policies for Section 1115(a) Medicaid Demonstration Projects,” <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18009.pdf>.

circumstances specified below relating to annual savings offsets). Aggregate cap states that efficiently manage their programs within their annual aggregate cap may be eligible to utilize a portion of available savings for reinvestment in their Medicaid programs, limited to ensure overall federal savings under the demonstration.

2. Setting the Annual Budget Neutrality Cap

Each participating state will elect to operate its demonstration under either an annual aggregate cap or a per capita cap. CMS will calculate the annual aggregate or per capita cap, which will limit the amount of total computable expenditures eligible for FFP under the demonstration. To set the annual aggregate or per capita cap, CMS will use the most recently available eight consecutive quarters of expenditure data to determine a base year amount. CMS will trend the annualized base amount forward to each demonstration year, consistent with the guidelines for trend rates outlined in the Trend Rate Calculation section of this guidance. The CMS Office of the Actuary will participate in the development of the initial baseline and any subsequent adjustments.

Aggregate Cap

For a state electing the aggregate cap option, an annual aggregate cap will be calculated based on the total computable amount of prior year expenditures attributable to populations and services included in the state's demonstration, subject to the expenditure exclusions described below. CMS will trend this amount forward to the demonstration year annually without regard to changes in Medicaid enrollment. Total computable expenditures in excess of the annual cap will not be eligible for FFP (except in limited circumstances specified below relating to annual savings offsets). If a state claims FFP for unallowable excess expenditures, such claims are subject to deferral in accordance with 42 CFR part 430.40 and/or disallowance in accordance with 42 CFR part 430.42. If a state's total computable demonstration expenditures are less than the annual aggregate cap, the state may be eligible to qualify for shared savings reinvestment opportunities described below. As an alternative to shared savings, the amount by which total computable demonstration expenditures are less than the annual aggregate cap for a demonstration year (annual savings) can be used to offset any expenditure amounts that exceed its aggregate cap for the subsequent three demonstration years. Please note that the sum of 1) savings used to generate shared savings reinvestment expenditures and 2) savings used to offset future excess expenditures cannot exceed the total annual savings for a particular demonstration year.

To ensure program investment, adequate provider rates, and an accurate annual cap amount, aggregate cap states must spend (combined federal and state share) a minimum of 80% of their aggregate cap annually or they will have their aggregate cap reduced for subsequent demonstration years. If a state's total computable expenditures for any demonstration year are below this 80% maintenance of effort (MOE), future aggregate cap amounts will be reduced by the dollar amount state expenditures are below the MOE. For example, a state with a total computable aggregate cap of \$50,000,000 for a demonstration year has a \$40,000,000 MOE for that same demonstration year (80% of \$50,000,000). If the state only reports \$35,000,000 total computable expenditures for that demonstration year, the state's aggregate cap will be reduced by \$5,000,000 for future demonstration years.

Aggregate Cap Calculation - Illustrative Example

	Base Year FY 17	FY 18	Demo Year 1 FY 19	Demo Year 2 FY 20
<i>Total Computable Adult Group Expenditures</i>	\$50,000,000	N/A	\$51,500,000	\$55,000,000
<i>Trend Factor</i>	N/A	2.0%	2.0%	2.5%
<i>Aggregate Cap</i>	N/A	\$51,000,000	\$52,020,000	\$53,320,500
<i>Amount (Over)/Under Cap</i>	N/A	N/A	\$520,000 ⁱ	(\$1,670,500) ⁱⁱ

ⁱ State demo expenditures are below annual aggregate cap. FFP is available for all approved demonstration expenditures. Additionally, the state can choose either or a combination of 1) utilizing the annual savings to offset expenditure amounts that exceed the cap over the next three demonstration years, and/or, 2) subject to the state qualifying, utilizing the applicable percentage of the \$520,000 annual savings (which consists of both state funds and FFP) for the Shared Savings Reinvestment opportunity described below.

ⁱⁱ State demo expenditures for Demo Year 2 exceeded the aggregate cap. FFP is not available for \$1,670,500 in state demo expenditures. However, if the state chooses not to use its shared savings reinvestment opportunity in Demo Year 1, it can utilize its \$520,000 annual savings from Demo Year 1 to offset the \$1,670,500 in excess expenditures in Demo Year 2. If the state chooses to do so, FFP will not be available for \$1,150,500 in Demo Year 2 expenditures (\$1,670,500 minus \$520,000).

Reinvestment of Shared Savings (only applicable to aggregate cap demonstrations)

When annual state expenditures remain below the annual aggregate or per capita cap, both the state and federal government achieve savings by spending less on Medicaid expenditures than projected. In addition to this savings, recognizing the added risk states will assume under an aggregate cap model, states that efficiently manage their programs within the annual aggregate cap may also qualify to receive between 25 and 50 percent of the federal savings in the form of FFP for specified Medicaid reinvestment expenditures (discussed further below), as approved by CMS. To qualify for this opportunity, states must spend less than the annual aggregate cap and meet the reporting and quality performance criteria discussed below. Note that states are not eligible for shared savings in the final year of a demonstration. However, if CMS approves a demonstration renewal, shared savings achieved in the last year of the ending demonstration can be carried forward to the first renewed demonstration year.

Qualifying for Shared Savings. To be eligible to receive shared savings, states participating in an HAO demonstration will be expected to establish baseline measurements of access and quality of care performance and fulfill two performance criteria:

1. *Performance maintenance:* Demonstrate that access to and quality of care for the beneficiaries enrolled in the demonstration remains at or above the level established in the base year, based on the reported measures and consumer access survey conducted by the state; and,
2. *Performance improvement:* Achieve certain performance benchmarks on the set of

mandatory quality and access to care measures that represent key domains from the CMS Adult Core Set of quality measures, as described below and in Appendix D.

States that meet the performance maintenance criterion may be eligible for 25 percent of the federal savings. States may be eligible for up to an additional 25 percent of the federal savings depending on the extent to which they meet the performance improvement criterion.

To qualify for the share of savings based on performance improvement, states must meet the performance maintenance criterion and either perform at the 75th percentile or improve by three percent over the state’s prior year performance on a portion of those measures. Performance benchmarks will be set nationally across all states reporting selected Core Set measures.

States that demonstrate performance attainment at the 75th percentile or a three percent improvement on thirteen or more of the required measures will be eligible for an additional 25 percent of shared savings (for a total of 50 percent shared savings). States that are able to demonstrate performance attainment at the 75th percentile or a three percent improvement on seven to twelve of the required measures will be eligible for an additional 12.5 percent of shared savings (for a total of 37.5 percent shared savings). A listing of the annual quality and access reporting requirements is located in Appendix D.

Portion of Federal Savings Available to State

Criteria	Federal Savings Potentially Available to State
1. Maintain performance (No decline in access to or quality of care)	25 percent
2. Maintain performance and, with respect to 7-12 of the 25 required measures, demonstrate either <ul style="list-style-type: none"> • 3% improvement; or • Performance at 75th percentile 	37.5 percent
3. Maintain performance and, with respect to 13 or more of the 25 required measures, demonstrate either <ul style="list-style-type: none"> • 3% improvement; or • Performance at 75th percentile 	50 percent

Unless the state has complete baseline information for purposes of performance measurement and performance-based incentive payments for the demonstration population at the time its HAO demonstration is approved, it is important to note that the base year for this purpose could be 1-2 years after implementation of the demonstration. One year would be needed to collect baseline data, and additional time would be required to assess that baseline data against future year data to determine whether the state would qualify for shared savings.

Use of Shared Savings. After CMS determines that a state has qualified for shared savings under the demonstration, we anticipate exercising expenditure authority for reinvestment during the state's next demonstration year in programs which could include matching state expenditures up to a percentage for existing state-funded health programs that have not previously qualified for federal funding (limited to 30% of the total amount eligible for shared savings reinvestment) or for new health-related initiatives targeting the demonstration population or other Medicaid beneficiaries that would not otherwise be eligible for matching funds under the state plan or another demonstration.⁶ Examples of initiatives that could be funded with matching funds through shared savings include providing Medicaid services for populations not currently covered by the state's state plan or another demonstration, such as supported work or service coordination; paying for services not included in the state plan or another demonstration for Medicaid beneficiaries, such as pre-vocational services; initiatives designed to improve the quality of and access to care provided to Medicaid beneficiaries; and allowable benefits and services designed to address certain social determinants of health. For programs or initiatives funded through shared savings to be eligible, CMS will need to determine that they will be likely to promote the objectives of the Medicaid program. For examples of initiatives that may be considered to promote the objectives of the Medicaid program, see <https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html>. Any shared savings for which a state may be eligible based on its performance in a particular demonstration year would be expected to be available to states for the next three years only, including into a new demonstration period if the three-year period extends into a new demonstration period and CMS has approved a demonstration renewal. Shared savings should not be used to supplant or duplicate other federal funding.

In some cases, states may seek to use a portion of the shared savings expenditure authority to invest in existing state-funded programs. For example, the state may be operating state-funded tobacco cessation program that supports many Medicaid beneficiaries. Earning federal share for investing in this program would free existing state resources that states could choose to reinvest in expanded services or benefits for other Medicaid enrollees, including mandatory state plan populations not covered under this demonstration.

Below is an illustrative example of the shared savings reinvestment calculation. The example assumes that the state has elected to operate its HAO demonstration under an aggregate cap, which is calculated at \$60 million for the year; the state's actual total computable expenditures for the year are \$50 million; and the state's regular FMAP is 60 percent. The example also assumes that the state is eligible for the increased 90 percent FMAP for newly-eligible individuals (which begins in calendar year 2020) and that the state's performance (in accordance with the criteria described above) results in 50 percent of the federal share of savings being available to the state for additional expenditures.

⁶ CMS has previously announced that it would no longer accept demonstration proposals that rely on federal matching funds for designated state health programs due to concerns that the policy could result in increased federal expenditures. This policy remains in effect outside of this demonstration opportunity, in which a state has generated both federal and state savings through participation in the HAO initiative.

Shared Savings Reinvestment Calculation – Illustrative Example (60% FMAP State)

	Total Computable Expenditures	State Share	Federal Share
<i>Demonstration Expenditures for Newly Eligible Adults (90% FMAP)</i>	\$50,000,000	\$5,000,000	\$45,000,000
<i>Aggregate Cap</i>	\$60,000,000	N/A	N/A
<i>Savings Achieved Relative to Aggregate Cap</i>	\$10,000,000	\$1,000,000	\$9,000,000
<i>Shared Savings Percentage</i>	N/A	N/A	50%
<i>Additional Amount Eligible for Shared Savings Reinvestment (60% FMAP)ⁱ</i>	\$7,500,000	\$3,000,000 ⁱⁱ	\$4,500,000 ⁱⁱⁱ

ⁱ Shared Savings Reinvestment expenditures are matched at existing matching rates applicable to the specific expenditures. For purposes of this example, CMS assumes the Shared Savings Reinvestment Expenditures are matched with a 60% FMAP.

ⁱⁱ States that are eligible for Shared Savings Reinvestment expenditures remain required to fund the non-federal share of those expenditures. Note: Subject to the 30% limit described above, any amount the state was already spending prior to the demonstration on existing state-funded health programs that are approved as Shared Savings Reinvestment expenditures would represent a continuing state investment of funds, not a new state investment.

ⁱⁱⁱ For a state to access the full \$4,500,000 federal share available for Shared Savings Reinvestment Expenditures, it must expend \$7,500,000 (total computable) on existing state-funded health programs or new health-related initiatives at 60% FMAP, as approved by CMS. The state is still required to fund the non-federal share of the expenditures and states should use existing processes to claim FFP for the expenditures on the Form CMS-64. Any unused shared savings authority available for a particular demonstration year is available to states for the next three years only, including into a new demonstration period if the three-year period extends into a new demonstration period and CMS has approved a renewal.

In this example, the state has generated \$10 million of total savings (\$60 million aggregate cap minus \$50 million in demonstration expenditures), reflecting \$9 million in savings for the federal government and \$1 million for the state. The federal share of the savings achieved (\$9 million) is available to the state in federal matching expenditures for the next three years for reinvestment, as specified above. Fifty percent of \$9 million equals \$4.5 million. Thus, in this example, the state may be eligible for up to an additional \$4.5 million in federal matching funds for a demonstration determined by CMS to be likely to promote the objectives of the Medicaid program. To draw down all of the \$4.5 million available to it at 60% FMAP, the state would need to spend \$3 million in state funds, yielding a total of \$7.5 million total computable funds for the additional services provided by the state through the shared savings component of the demonstration.

Per Capita Cap

Under the per capita option, CMS will determine a per capita base amount for each eligibility group included in the demonstration by dividing the total amount of prior year expenditures for each group by the actual number of enrolled individuals for that group for the period.

CMS will trend each base amount forward to the demonstration year, multiply each trended base amount by the number of respective enrollees for the applicable demonstration year, and then sum these amounts to create an overall per capita cap. Total computable expenditures in excess of the annual overall per capita cap based on actual enrollment will not be eligible for FFP.

Per Capita Cap Calculation – Illustrative Example

	Base Year FY 17	FY 18	Demo Year 1 FY 19	Demo Year 2 FY 20
<i>Total Computable Adult Group Expenditures</i>	\$50,000,000	N/A	\$51,500,000	\$55,000,000
<i>Trend Factor</i>	N/A	2.0%	2.0%	2.5%
<i>Adult Group Enrollment</i>	10,000	N/A	10,200	11,000
<i>Per Capita Amount</i>	\$5,000	\$5,100	\$5,202	\$5,332.05
<i>Per Capita Cap</i>	N/A	N/A	\$53,060,400	\$58,652,550
<i>Amount (Over)/Under Cap</i>	N/A	N/A	\$1,560,400	\$3,652,550

3. Calculating Base Period Amounts and Data Requirements

Overview

Calculating accurate base period expenditure amounts is crucial for ensuring the financial integrity of the initiative for states and CMS. States report Medicaid expenditures to CMS quarterly through the Form CMS-64, which will serve as the basis for calculating base period expenditures for aggregate or per capita caps. To ensure an appropriate cap for the base year of an HAO demonstration, states seeking approval of an HAO demonstration will need to demonstrate that their eligibility, enrollment and claims systems and processes yielded accurate data upon which the base year amount for their funding under either an aggregate or per capita cap model is determined. If a state cannot make such demonstration, CMS will work with the state to identify and correct any deficiencies so that reliable data can be generated. In the event that problems with the integrity of the data used for the base period expenditures are identified after the base amount for a state's aggregate cap or per capita cap is calculated, CMS will work with the state to make appropriate adjustments to the base amount.

Determining Base Period Expenditures

Except for newly covered populations as described in the next section, CMS will calculate an annual base amount by annualizing the most recently available eight consecutive quarters after December 31, 2016, of finalized CMS-64 expenditure data. CMS will review and validate this data to ensure the accuracy of reporting and that such reported expenditures are representative of expenditures attributable to the base period. If necessary, CMS will adjust base period amounts to ensure accuracy and fiscal integrity.

Data Availability

Currently, the Form CMS-64 collects expenditure information by eligibility category only for the adult group. In instances when CMS does not have CMS-64 expenditure data necessary to determine base period expenditures by eligibility group for groups that were previously covered and that will be covered under an HAO demonstration, states must provide at least two years of auditable expenditure data for the relevant population and services that ties directly to expenditures reported on the Form CMS-64. The state must obtain an external independent audit to validate the expenditure data and demonstrate how the data ties directly to the state's expenditures reported on the CMS-64 for the base period.

Newly Covered Populations

For newly covered populations for which there is insufficient historical claims experience, CMS will determine a base amount by estimating annual expenditures relying on 1) the national average of Medicaid expenditures for the population and services, 2) geographic specific factors, and 3) other information necessary to ensure the accuracy of the estimate. CMS will consider commonly-used adjustments for new populations, including pent-up demand, acuity or health status, and adverse selection. CMS may also consider data provided by the state relating to the newly covered population. After two years of state expenditures are available, CMS will re-base the estimate if actual state expenditures are 3 percent or more below or above the initial year cap amount, or if the medical loss ratio is outside required levels for states using managed care for the newly covered population (either too low or too high). If the expenditures exceed the estimate by 3 percent or more, the state must also demonstrate to CMS that the excess expenditures were due to circumstances beyond the state's control.

States that elect the aggregate cap option for a *newly covered* population (one that the state did not provide coverage during some past period) must start their demonstrations with the per capita cap model for at least two years, and then may transition to the aggregate cap model once satisfactory base enrollment data is available to calculate an accurate aggregate cap.

Excluded Expenditures

The following will be excluded from data used to set the base period cap: Medicaid Disproportionate Share Hospital (DSH) payments; state administrative expenditures; expenditures for public health emergencies; expenditures for services "received through" an IHS facility, whether operated by the IHS or by an Indian tribe or tribal organization, that can be federally matched at 100 percent under section 1905(b) of the Social Security Act; and certain supplemental and pool payments (as detailed below).

Supplemental and Pool Payments

As applicable, CMS will include standard fee-for-service supplemental payments and managed care pass-through payments in data used to set the base period cap by allocating these expenditures to the populations included in the demonstration. The allocation will be based on the percentage of base payments, on a service-specific basis, made for these populations during the base period. For example, if a state made \$4 million in inpatient hospital supplemental payments or managed care pass-through payments during the base period for all Medicaid populations and \$100 million in Medicaid inpatient hospital base payments, 50 percent of which was paid for a population to be covered under an HAO demonstration, then \$2 million in inpatient hospital supplemental payments or managed care pass-through payments would be included as base period expenditures.

CMS will exclude certain temporary supplemental payments made under section 1115 authority from base period expenditures including, but not limited to: Designated State Health Program (DSHP) payments, Delivery System Reform Incentive Payments (DSRIP), and Uncompensated Care Cost (UCC) Payments. Additionally, CMS intends to monitor existing and proposed section 1115 payments to ensure compliance with overall budget neutrality and the annual caps under an HAO demonstration.

Applicability of Expenditures to a Base Period and Demonstration Year

For purposes of calculating base period caps and complying with the applicable cap on an annual basis, expenditures will generally be applied to a particular demonstration/base year based on the date the payment is made, consistent with 45 CFR 95.13(b).

Enrollment Changes and Annual Caps

CMS will adjust the base amount or subsequent annual caps to adjust for state flexibilities that could significantly affect enrollment to ensure that states do not achieve savings from disenrolling individuals.

Compliance with Annual Caps

Total computable demonstration expenditures eligible for FFP will be limited to the aggregate or per capita cap on an annual basis (except in limited circumstances specified in the “Aggregate Cap” section above relating to annual savings offsets). If a state claims FFP for unallowable excess expenditures, such claims are subject to deferral in accordance with 42 CFR part 430.40 and/or disallowance in accordance with 42 CFR part 430.42.

Improving the Accuracy and Fiscal Integrity of Annual Aggregate or Per Capita Caps

To ensure accuracy of annual caps, ensure overall fiscal integrity, and preserve state flexibility, CMS may modify the financing requirements in section C of this guidance through future guidance as necessary.

Special Circumstances Adjustment

Recognizing the dynamic health care landscape in which state Medicaid programs are operating, CMS will provide states with the opportunity to propose updates to an approved HAO demonstration to account for any changes to projected expenditures or enrollment in the current demonstration year due to unforeseen circumstances out of the state’s control, such as a public health crisis or major economic event. Under such circumstances, states will have the

opportunity to submit new information and relevant data, describe the circumstances and proposed amendment, and renegotiate relevant STCs. The data provided by the state will be validated by the CMS Office of the Actuary in consultation with other appropriate federal entities.

Calculating Base Period Amounts for Demonstration Extensions

If a state seeks to extend an approved HAO demonstration, providing a new demonstration period, CMS would follow the process explained above to re-calculate the base period expenditures needed to establish a new aggregate or per capita cap associated with the new demonstration period. This would be consistent with the policy established for budget neutrality calculations for demonstration extensions set forth in the August 22, 2018, CMS letter to State Medicaid Director (SMD # 18-009), “Re: Budget Neutrality Policies for Section 1115(a) Medicaid Demonstration Projects,” <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18009.pdf>.

4. Trend Rate Calculation

For states implementing a per capita cap model, the per capita caps determined for the base year will be increased by a growth factor based on the lesser of the growth rate in the state over the prior five years and by the medical care component of the consumer price index for all urban consumers (CPI-M). Because states opting to implement an aggregate cap model assume greater risk due to the uncertainty in enrollment, the annual aggregate cap determined for the base year will be increased by the lower of growth rate in the state over the prior five years and CPI-M plus one-half of a percentage point (CPI-M + .5%).

5. Implications of Reaching or Exceeding the Annual Budget Neutrality Cap

Regardless of the type of annual budget neutrality cap being utilized under an HAO demonstration, states will be expected to remain apprised of demonstration expenditures in relation to the cap on federal spending. States will be expected to notify CMS as soon as possible if demonstration expenditures are expected to exceed the annual cap, so corrective actions can be initiated. CMS would offer technical assistance in these circumstances.

D. Oversight

The HAO initiative is intended to provide significant flexibility for states in designing and implementing demonstrations under an aggregate or per capita cap, and participating states’ projects will be subject to robust oversight. States will be expected to demonstrate that their eligibility, enrollment and claims systems and processes yielded accurate data upon which the base year amount for their funding under either an aggregate or per capita cap model is determined, and states will be expected to participate in program integrity efforts that include a strong focus on assuring appropriate use of expenditures qualifying for an increased FMAP. States also would be expected to develop and provide a quality strategy program and report annually in accordance with CMS guidance. (See Appendix E for details on the key elements of a quality strategy and performance assessment.) In addition, states would be expected to report quarterly on metrics that comprise the continuous performance indicators, as well as quarterly and annually on other quality and performance metrics and qualitative information that align

with the state’s implementation and monitoring plans to be approved by CMS after the demonstration is approved. These oversight activities would be complementary and not duplicative. Participating states will also be expected to design and conduct an interim and summative evaluation in accordance with guidance that CMS will provide. States could be subject to a deferral of funding, as described in the STCs, if the state did not submit timely and complete deliverables, such as monitoring data and evaluation reports, or failed to make adequate progress on information technology (IT) systems and data development and submission important to the state’s demonstration implementation and CMS oversight.

1. Program Integrity

CMS has an important responsibility to ensure that states continue to make accurate Medicaid eligibility determinations and that states receive appropriate federal funds for Medicaid expenditures, including for populations covered under HAO demonstrations. CMS places a particular emphasis on this responsibility for populations whose expenditures qualify for an increased FMAP. The Government Accountability Office (GAO) and the HHS Office of Inspector General (OIG) have conducted several studies or audits of expenditures for individuals enrolled in the adult group.⁷ CMS has examined these and other audit findings and recommendations and issued guidance explaining the measures states need to take in order to ensure the integrity of state eligibility, enrollment and claims processes. Consistent with the CMCS Informational Bulletin, *Oversight of State Medicaid Claiming and Program Integrity Expectations*, published on June 20, 2019,⁸ we will expect states seeking approval of an HAO demonstration to provide documentation demonstrating compliance with program integrity provisions in 42 CFR part 455 and systems capacity to make accurate and timely determinations of eligibility and renewals, and to accurately categorize individuals as newly eligible or not newly eligible so that claims for FFP are paid at the statutorily authorized matching rate. We expect that the documentation provided will reflect the state’s comprehensive test plans, including an end-to-end-testing strategy, demonstrating such operational capacity and up-to-date training materials, policies and procedures for the agency workforce.

Eligibility Reviews

CMS has multiple tools to oversee the accuracy of Medicaid and CHIP eligibility determinations, including through the Payment Error Rate Measurement (PERM) and the Medicaid Eligibility Quality Control (MEQC) programs, which play a critical role in ensuring the accuracy of eligibility determinations and payment. The [July 2017 rule](#) established a new harmonized Medicaid eligibility oversight process that meets the requirements of section 1903(u) of the Act through a combination of the PERM program and a revised MEQC program, where there will be PERM reviews and state conducted MEQC pilots as part of a 3-year cycle. The PERM reviews will focus on measuring erroneous payments due to ineligibility and will calculate an eligibility improper payment rate. While the MEQC pilots

⁷ *CMS Needs to Better Target Risks to Improve Oversight of Expenditures*, GAO-18-564 (Aug 2018); *Additional Efforts Needed to Ensure that State Spending is Appropriately Matched with Federal Funds*, GAO-16-53 (Oct 2015); *California Made Medicaid Payments on Behalf of Newly Eligible Beneficiaries who did not meet Federal and State Requirements*, OIG A-09-16-02023 (February 2018); *New York Did Not Correctly Determine Medicaid Eligibility for Some Newly Enrolled Beneficiaries*, OIG A-02-15-01015 (January 2018).

⁸ Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/cib062019.pdf>.

will focus on areas not addressed through PERM reviews, such as negative cases and understated/overstated liability, as well as permit states to conduct focused reviews of areas identified as error-prone through the PERM program. This creates a complementary approach to ensuring accuracy of the eligibility determination process.

Populations covered under this demonstration initiative will be included in the reviews conducted under PERM and MEQC. As determined necessary, states participating in this demonstration may also be subject to the enhanced monitoring of Medicaid eligibility determinations outlined in the [2018 CMS Medicaid Program Integrity Strategy](#) and other relevant regulatory or sub-regulatory guidance.

Fiscal Integrity, Operations, and Oversight

Certain fiscal integrity provisions of section 1903 of the Act, such as rules regarding FFP rates, eligibility errors, and the requirement for states to fund the non-federal share of expenditures, will apply to HAO demonstrations, and states should use existing processes to claim FFP for demonstration expenditures. In addition to monitoring and evaluation activities described later in this guidance, CMS also intends to continue its standard financial oversight activities for demonstration expenditures, including, but not limited to, establishing with the state budget neutrality parameters, and tracking actual expenditures, consistent with the State Medicaid Director's Letter #18-009, entitled, "*Budget Neutrality Policies for Section 1115(a) Medicaid Demonstration Projects*;" quarterly CMS-64 expenditure reviews; focused financial management reviews; and deferrals and disallowances of claims for FFP. Please note that any services claimed at increased FMAP or other matching rates are subject to additional scrutiny.

Federal Review of Managed Care Capitation Rates

As stated previously in Section B of this guidance, states generally will be expected to meet both statutory and regulatory requirements that managed care capitation rates be actuarially sound in order to ensure that beneficiaries receive covered services without overspending state and federal tax dollars. However, states will be given additional flexibility in how the capitation rates are ultimately approved by CMS. CMS expects that states would use one of two options available to states to demonstrate and document that capitation rates are actuarially sound:

Option 1: Federal Actuarial Review

CMS to complete an actuarial review, consistent with existing procedures:

1. States develop capitation rates consistent with the requirements of 42 CFR part 438 and CMS' Managed Care Capitation Rate Development Guide; and
2. CMS conducts an actuarial review of the actuary's rate certification in order to issue an actuarial opinion about the actuarial soundness of the capitation rates.

Additionally, states submit to CMS a final set of managed care capitation rates supported by a rate certification at least 30 days prior to the start of a rating period and make all modifications to managed care capitation rates on a prospective basis.

Option 2: Fiscal Integrity through Transparency, Medical Loss Ratios, and Audits

The requirements of 42 CFR 438.7(a),⁹ would not apply and CMS would eliminate the prospective federal review, and rely on more transparency, use of medical loss ratios (MLRs) with remittance, and additional independent financial audits to assure that the managed care capitation rates are actuarially sound. Under this option, CMS would expect states to submit an actuary's certification that the managed care capitation rates are actuarially sound, and likely would accept such a certification if the following conditions are met:

1. Capitation Rate Transparency
 - a. States develop capitation rates annually consistent with the requirements of 42 CFR 438 and an enhanced CMS Managed Care Capitation Rate Development Guide, which establishes a specific outline for the rate certification and required tables to document assumptions and data used for the capitation rate development.
 - b. The rate certification is publicly displayed on the state Medicaid agency's website at least 60 days prior to the start of the annual rating period and notify CMS of the display location. Any changes to these capitation rates (e.g., contract amendments) would be clearly identified in a rate amendment certification, which would be provided to CMS and posted on the state Medicaid agency's website at least 30 days prior to making the change in rates.
2. Components of the Rate Development
 - a. The state's managed care capitation rates are based only upon approved Medicaid services covered under:
 - 1) The Medicaid state plan;
 - 2) A section 1115 demonstration;
 - 3) A section 1915 waiver; and
 - 4) Additional services deemed by the state to be necessary to comply with the requirements of MHPAEA, as implemented in 42 CFR part 438, subpart K, 42 CFR 440.395, and 45 CFR 147.160 and 146.136, as applicable.
 - b. The state's managed care capitation rates are based only upon the expected utilization and delivery of services for the time period and the population covered under the terms of the state's contract with the managed care plans.
 - c. The state's managed care capitation rates may not include any pass-through

⁹ This provision of the regulations requires states to submit to CMS for review and approval, all risk-based managed care plan rate certifications concurrent with the review and approval process for managed care plan contracts.

payments or supplemental provider payments. To the extent that the state intends to make pass-through payments or supplemental payments to providers, CMS would expect that the payments would be explicitly authorized in the state's section 1115 demonstration and paid to providers outside of the managed care capitation rates.

3. Use of an MLR with Remittance

- a. The state's contract with each managed care plan requires remittance based on a corridor around the MLR defined in 42 CFR 438.8.
- b. States will have flexibility in establishing the exact requirements of the remittance associated with each managed care plan's MLR; consistent with guidelines developed by CMS. Remittances will be required by plans if the MLR falls below the 85 percent level, with the federal share of such remittances to be returned by the state to CMS; states will be required to pay remittances to plans if MLR is above 95 percent (see Appendix F). However, remittances required to be paid by the state in excess of the annual cap will not be eligible for FFP. States and managed care plans will need to calculate and reconcile remittances more quickly than otherwise required in 42 CFR 438.8. Specifically, states will need to calculate and reconcile each managed care plan's MLR and report calculations to CMS within 12 months of the rating period.

4. Use of Audits

The state will be expected to meet enhanced requirements for receiving and reviewing audited financial reports for managed care plans. Regulations at 42 CFR 438.3(m) require states to contractually require managed care plans to submit to the state audited financial reports specific to the Medicaid contract on an annual basis. In addition, states and managed care plans will need to ensure that:

- a. The financial audit is conducted by an independent entity in accordance with generally accepted accounting principles and auditing standards and be of sufficient detail that the state and managed care plan can reconcile the data used for the MLR calculations to the information reported in the independent financial audit; and
- b. The audited financial reports, as well as documentation reconciling the data used for the MLR, are submitted to CMS within 12 months of the end of the rating period.

2. Quality Strategy and Performance Assessment

Under an HAO demonstration, CMS may grant states significant programmatic and administrative flexibility to more efficiently operate their programs within the approved

demonstration expenditure cap. This greater flexibility would enable states to redesign their Medicaid programs to ensure beneficiaries receive appropriate services in the most cost-effective manner that promotes the objectives of the Medicaid program. In turn, states will be expected to ensure accountability for the health and well-being of the Medicaid beneficiaries enrolled in this demonstration. To demonstrate accountability, states will be expected to develop and maintain a written quality strategy for assessing access to care, quality of care, and the health outcomes of beneficiaries covered under this demonstration.

Discussed more fully in Appendix E, the quality strategy will be expected to contain specific objectives, defined as measurable performance targets, for different segments of the demonstration population. Because measurement is critical for quantifying performance, we would expect that central to the quality strategy will be mandatory reporting of 25 quality and access measures drawn from the CMS Adult Core Set that are either included in the CMS Medicaid and CHIP Scorecard¹⁰ or are feasible for states to report, either because they are derived from administrative data sources like claims and encounter data or are currently reported by at least 25 states. These measures will be adjusted for the population covered under an HAO demonstration and are described in Appendix D.

The Adult Core Set currently includes 33 measures targeting specific clinical domains of high priority for the adult Medicaid population: (1) Primary Care Access and Preventive Care, (2) Maternal and Perinatal Health, (3) Care of Acute and Chronic Conditions, (4) Behavioral Health Care, and (5) Long Term Services and Supports (see Appendix D for the list of 2020 Adult Core Set measures). It also includes the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Plan survey. Vetted and updated annually through robust stakeholder engagement with states, health plans, providers, consumer advocates, and measurement experts, the Adult Core Set will provide a snapshot of health care quality within the demonstration based on key indicators of health care access and quality for the beneficiaries served in the demonstration. CMS may identify additional measures that we would expect would be added to the required Core Set reporting as well as additional measure domains, such as specialty care. Recognizing that states already have established quality measurement and improvement initiatives underway, states may also include any other quality measures used to monitor access and quality of care for beneficiaries in the demonstration.

States with managed care or alternative private market delivery systems can leverage existing quality strategies, quality assessment and performance improvement (QAPI) requirements, and external quality review to fulfill these requirements. However, states would be expected to integrate all beneficiaries covered by this demonstration model – even if they receive their care through fee-for-service – into these quality strategies. Although the reporting under the quality strategy would be distinct from the other monitoring and evaluation activities required generally for all demonstrations, the quality strategy would need to be closely coordinated with these other monitoring and evaluation activities.

¹⁰ Information on the Medicaid and CHIP Scorecard is available at <https://www.medicaid.gov/state-overviews/scorecard/index.html>.

3. Monitoring and Evaluation

General Monitoring Requirements

CMS remains committed to monitoring and evaluation in order to understand the outcomes and the impacts of the state innovations being demonstrated. CMS is undertaking efforts to help states monitor the elements of their programs, while giving them the flexibility to adapt to changing conditions in their states. In addition to the quality strategy and measurement described above, we would expect states to provide timely and accurate T-MSIS data in order to be able to participate in the HAO initiative. CMS may also consider annual site visits as an additional monitoring strategy. As with all demonstrations authorized under section 1115 of the Act, states will be required to develop monitoring plans and submit performance metrics for quarterly and annual monitoring reports. Quarterly and annual monitoring reports will consist of both narrative updates and qualitative and quantitative data on pre-determined metrics. CMS is developing metrics and other parameters specifically for the HAO initiative and will work with each state implementing an HAO demonstration to ensure that the metrics and other parameters to be used are appropriate to the state's demonstration and that the state understands the expectations and is prepared to report in accordance with CMS' guidance. CMS will also leverage metric sets and monitoring strategies already being implemented for 1115 demonstration types that a state may opt to include under an HAO demonstration, including, for example, community engagement, SUD and SMI / SED demonstrations.

The metrics selected would need to reflect the major elements of the demonstration, and uniformity in the metrics and the availability of national specifications will be considered to support cross state monitoring and evaluation. States would be expected to independently verify their metric data. CMS will combine these programmatic metrics with general metrics aimed at monitoring beneficiary enrollment, the overall functioning of the demonstration and the reporting under the Quality Strategy and Performance Assessment.

We expect that states will comply with other monitoring and reporting requirements, consistent with regulations in 42 CFR 431.420 and 431.428. State monitoring reports will be required to provide sufficient information to document key challenges, underlying causes of those challenges, and strategies for addressing those challenges, as well as key achievements and the conditions and efforts that lead to those successes. States will be expected to engage an independent assessor to conduct a mid-point assessment of the demonstration, and to provide recommendations for mid-course corrections for the state's consideration. This information, along with the state's plan for responding to the recommendations will be provided to CMS.

Continuous Performance Indicators

It will be critical for both states and CMS to know as soon as possible if beneficiary access to care is being adversely affected by one or more elements of the demonstration. Toward that end, CMS has designed a set of continuous performance indicators composed of 13 metrics which participating states will be expected to report to CMS and post on the state's website on a quarterly basis. The metrics selected are not intended to provide a comprehensive understanding of the demonstration or monitor the state's progress in meeting the demonstration's goals and objectives. Rather, the continuous performance indicators are intended to provide CMS and the state with a timely indicator of potential issues impacting

beneficiary access to coverage or care, so that needed adjustments can be made. These indicators fall into one of four categories: enrollment, retention, access to care, and financial management. A list of the specific metrics and specifications for this continuous performance indicator system is found in Appendix H.

A change in a given metric, in and of itself, may not provide definitive evidence that there is a serious problem with the demonstration requiring adjustment. Instead, a decline, or in some cases an uptick, in one or more metrics signals the need for CMS to engage with the state to determine the cause(s) of the change and whether corrective action is needed. If the state, with technical assistance from CMS, is not able to identify and correct the problem, CMS may direct the state to engage an independent assessor to conduct a rapid cycle evaluation of one or more elements of the demonstration within 60 days of such CMS direction. The purpose of a rapid cycle evaluation is to identify recommendations for policy and/or operations to reverse the change in the continuous performance indicators and other monitoring and evaluation findings. If the problem is not remedied, CMS may initiate corrective action, which could include deferral or disallowance of costs, or termination of the demonstration consistent with the STCs.

Specific details related to monitoring and reporting for each state's demonstration will be discussed with states and described in the demonstration STCs.

Budget Neutrality Monitoring

The characteristics of the budget neutrality test for each section 1115 Medicaid state demonstration are determined as part of CMS and state negotiations that culminate in the demonstration's STCs. STCs for HAO demonstrations will include a section describing the monitoring of budget neutrality, general financial requirements and corrective actions in the event that actual spending exceeds the specified caps. The STCs will describe the process by which the state should perform the respective calculations, as well as how to report the expenditures to CMS, and reconciliation processes.

Per each demonstration's STCs, states will be required to submit to CMS quarterly monitoring reports within 60 days of the end of each quarter, as well as an annual report within 90 days of a demonstration year's completion. These reports are required to include fiscal reporting to assist in the determination of whether or not the demonstration is tracking as budget neutral. In the event that a state is found to have exceeded its annual budget neutrality expenditure limit(s), states will be required to return excess funds to CMS. States will be required to return funds by entering a negative adjustment to expenditures claimed on their CMS-64 reports (OMB 0938-1265). Please note that all participating states are subject to overall budget neutrality as well as annual budget neutrality caps, as described above in section C, Financing and Shared Savings.

To support more efficient, timely and accurate review of states' budget neutrality submissions, CMS has developed a standardized budget neutrality reporting form, known as the Budget Neutrality Workbook ("BN Workbook"). Specifically, this BN Workbook consolidates into a unified report a standard set of financial data. The standardization of the reporting methodology, together with automation of the reporting submission supports:

- Consistency of evaluation;
- Streamlined communication methodology between states and CMS;
- Increases in reporting accuracy; and
- Reduced timeframes required for monitoring and evaluation.

The new Budget Neutrality Workbook automates the entire submission process. By incorporating the BN Workbook into the Medicaid section 1115(a) Performance Metrics Database & Analytics (PMDA) workflow, submissions are parsed and validated—notifying the state of any upfront potential problems with their submissions, reducing downstream communication, and subsequent needs for clarification or modifications to the BN Workbook. The BN Workbook has been formulated for use for the entire life span of demonstrations. This allows reuse of the same document, with updates for the quarterly period being reported, and discards the need to produce different documents for each quarterly or annual submission.

The PMDA application, which is used for BN Workbook submission, will historically retain all financial data and related documents, reducing the number of duplicate records required and the need for respondents to retain records.

Evaluation

Per 42 CFR 431.424, and the demonstration STCs, states will be required to submit for CMS review and approval an evaluation design. The evaluation design is expected to be robust and rigorous and consider the use of comparison groups and advanced statistical analyses (including impact analyses). A rigorous cost analysis will be required as a component of the evaluation design. The evaluation design must include an assessment of health outcomes, in addition to the quality metrics described above, of individuals that have been enrolled in and subject to the provisions of the demonstration, and will be required to conduct robust, independent program evaluations. Evaluations must be designed to determine whether the demonstration is meeting its objectives, as well as the impact of the demonstration on Medicaid beneficiaries. States will be required to submit for CMS approval a draft evaluation design no more than 180 days after demonstration approval. CMS will provide technical assistance and will encourage states to leverage existing CMS guidance related to evaluation of section 1115 demonstrations, including specific hypotheses, outcomes, data sources, and comparison groups for alternatives to Medicaid policies that might be tested under an HAO demonstration. As the state modifies its program, the state will be required to re-submit to CMS an evaluation design which adequately represents the programmatic elements modified.

State evaluation designs will be expected to include a discussion of the evaluation questions and hypotheses that the state intends to test, including whether and how the additional flexibilities provided through an HAO demonstration enable states to more efficiently administer their Medicaid programs. The hypothesis testing should include, where possible, assessment of both process and outcome measures, and proposed measures should be selected from nationally-recognized sources and national measures sets, as well as state-defined measures of program efficiency. The evaluation design should use both quantitative and qualitative methods, and will need to identify comparison groups and appropriate statistical analyses to evaluate the impact of the demonstration. Evaluation designs should also include

descriptions of multiple data sources to be used, including but not limited to multiple stakeholder perspectives, surveys of beneficiaries, claims data, and survey data. States participating in this demonstration opportunity must agree to cooperate with, and provide any data or other information requested by CMS for purposes of evaluating the demonstration.

Consistent with other section 1115 demonstrations, states participating in the HAO initiative also will be required to submit an interim evaluation report and a summative evaluation report. The interim report should identify any programmatic changes and recommendations based on the evaluation. A new evaluation design which reflects changes made based on the interim report findings should be submitted to CMS for the purposes of the summative evaluation report.

Changes made in the implementation plan, or through an amendment or renewal, likely will require a corresponding update to the monitoring plan and/or evaluation design. CMS would work with the state to make needed updates, which would be subject to CMS approval.

If CMS undertakes a federal evaluation to further understand the effectiveness and impacts of the HAO demonstration, the state is expected to comply with all requirements, consistent with 42 CFR 431.424(f).

E. Demonstration Application and Amendments

Application

Demonstrations under the HAO initiative will generally be approved for an initial five-year period from the date of implementation. CMS will provide an application template to support states in providing a complete application. The template will help to guide states in describing how each state's demonstration project will support the objectives of the Medicaid program using the approach outlined in this guidance. The template also will facilitate provision of accurate data needed to develop a demonstration budget agreement.

More specifically, the application template will enable states to provide the following information in a streamlined manner:

- Check-off list of flexibilities with regard to applicability of Medicaid provisions that the state intends to implement;
- Administrative program requirements lists of compliance standards typical to section 1115 demonstrations, for example, with federal civil rights laws, non-supplanting other federal programs and non-duplicating funding, and program performance standards;
- A description of the populations covered, income standard and other conditions of, or limitations on, eligibility required for coverage under the demonstration;
- A description of the proposed health care delivery system, eligibility requirements; eligibility and enrollment process (if different from the process for other MAGI populations) benefit coverage, and cost-sharing (premiums, copayments, and deductibles) required of individuals who will be covered under the demonstration;

- Demonstration that the state has, or has a plan for developing, the IT systems capability needed to support the demonstration and meet the reporting requirements;
- Data described in section C. Financing and Shared Savings (including enrollment data for each category of beneficiary who received health care coverage under the Medicaid program prior to the implementation of the demonstration);
- Baseline performance data on the mandatory subset of the Medicaid Adult Core Set quality measures described in Appendix D. If the population under this demonstration is newly eligible, the state should include a plan and timeline for how it will collect the required quality and access data that will establish the baseline for the demonstration;
- Baseline data on the continuous performance indicators in Appendix H;
- Written documentation of the state’s compliance with the public notice requirements at 42 CFR part 431, subpart G, with a report of the issues raised by the public during the comment period and how the state considered those comments when developing the final demonstration application submitted to CMS;
- The research hypotheses that are related to the demonstration’s proposed changes, goals, and objectives, and a general plan for testing the hypotheses, including, if feasible the identification of appropriate evaluation indicators; and
- A transition plan for if the demonstration is terminated or not renewed.

Transparency

CMS supports state public input processes that provide a meaningful opportunity for consideration of the views of Medicaid beneficiaries, applicants, and other stakeholders and allows states to gather input that may support continuous improvement of the program. Applications for an HAO demonstration are subject to all relevant public notice and transparency requirements, including those described in 42 CFR part 431, subpart G. Where applicable, states will also be required to comply with the state’s tribal consultation process and describe how the state is responding to comments received through the tribal consultation process.

Implementation Plan

Within 90 days after application approval, each state will submit for CMS approval an implementation plan that will provide detailed information on the state’s approach to implementing its approved demonstration, including key milestones of what the state will achieve, by when and how, as well as a program integrity plan. CMS will provide a template for the state’s implementation plan.

Transition of Existing Demonstrations to an HAO Demonstration

States with existing section 1115 demonstrations that cover populations eligible to be covered in an HAO demonstration may also propose to transition coverage and other features of those existing demonstrations into the HAO demonstration. The application template provided by CMS will accommodate such proposed transitions. CMS will work with states interested in such a transition to ensure a seamless conversion of coverage into an HAO demonstration and orderly close-out of the existing section 1115 demonstration in a manner consistent with the STCs for the existing demonstration. As needed, CMS will help states develop a framework and key milestones for conversion, including implementation of the phase-out process of the existing

demonstration, determining the appropriate public notification process for the planned conversion, and guidance on the development of the HAO demonstration application to effectuate the conversion of coverage. In advance of formal submission, CMS can work with states to identify potential program changes necessary for the state to accomplish its goals and objectives for the transition of coverage into an HAO demonstration.

State Flexibility During the Demonstration Period

States with an approved demonstration may make administrative and programmatic changes to their program without prior approval from CMS, provided that the planned change is consistent with the authorities approved in the STCs for the demonstration, unless the change has the potential to substantially impact enrollment. If the change has the potential to substantially impact enrollment, CMS will work with the state to determine whether an adjustment in the aggregate or per capita cap initially approved may be required. If new authority is needed, or the state seeks to make a change to its HAO demonstration that is not consistent with the approved STCs, the state would need to submit a formal demonstration amendment, and comply with the transparency requirements in 42 CFR part 431, subpart G.

The HAO initiative seeks to provide states with broad flexibility to operate a demonstration project to maximize health outcomes for Medicaid beneficiaries in a cost-effective, administratively efficient manner for the state, thereby generating savings for other initiatives benefiting the state's Medicaid program. In order to maximize their ability to make such administrative and programmatic changes after an HAO demonstration is approved, without need for additional CMS approval, states can include a range of policy options they may implement over the course of the demonstration in their initial application. This will ensure that the transparency requirements in the regulations have been met, and that CMS has approved the range of policy options as having a valid demonstration purpose and promoting the objectives of the Medicaid program. For example, a state may want to include minimum and maximum premium and other cost-sharing charges that may be imposed under the demonstration, as well as the initial premiums and cost-sharing to be imposed, or propose several EHB-benchmark plans it may adopt at a later date, or optional benefits it may eliminate. This would enable the state to titrate the amount or premiums or cost-sharing charged, or benefits covered, over the course of the demonstration period more easily.

States seeking to make a change to the policy, design, or operation of a demonstration that is authorized under the approved STCs will need to reflect the change in the state's implementation plan. Although prior CMS approval will not be needed for changes authorized under the STCs, states would be expected to provide CMS with at least 60 days advance notice of a planned change. Further, for any such changes which may impact beneficiaries, plans, providers or other stakeholders, states will be expected to provide at least 60 days advance public notice and a meaningful opportunity to comment, as well as follow the state's tribal consultation process, prior to revising the state's implementation plan or implementing the change.

The notice provided to the public would include a clear description of the planned change as well as the anticipated impact on beneficiaries, plans, providers and other stakeholders. We would expect that the public notice process generally described in 42 CFR part 431, subpart G would be followed, including posting in a conspicuous location on the state's website; publication in the newspapers of widest circulation; distribution through other mechanisms, such as an electronic

mailing list of interested parties; consultation with the Medical Care Advisory Committee established by the state in accordance with 42 CFR 431.12; and sufficient time to enable the state to make changes in response to comments received. If the state revises a planned change in response to public comments, the state would be expected to provide CMS with written notification of the revisions at least 30 days prior to implementation.

Advance notice of an adverse action to individual beneficiaries affected by a change in demonstration policy, such as a state reducing or eliminating a benefit, also would be required in accordance with 42 CFR part 431, subpart E, and any applicable STCs.

Advance public notice or tribal consultation would not be expected for administrative changes only minimally impacting stakeholders. CMS will work with each state to define in the STCs when an administrative change would be considered to have a minimal versus meaningful impact on stakeholders and when advance notice and tribal consultation would be required.

Any changes to a state's program after initial implementation of the demonstration must be reflected in the implementation plan. States will be expected to post on their website, and provide to CMS, an updated implementation plan on a quarterly basis, along with the quarterly monitoring report discussed in section D.3, above. If no changes are made in a given quarter, the state would certify that it had made no changes. Some changes may require a corresponding update to the monitoring plan and/or evaluation design, discussed in section D.3, above. CMS would work with the state to make needed updates, which would be subject to CMS approval.

As noted, changes to an implementation plan consistent with the approved STCs for the demonstration will not require CMS approval. However, if CMS believes that a particular change is not authorized under the approved STCs or other applicable federal laws, CMS may notify the state that it may not implement the change as planned, but must submit an amendment and obtain CMS approval of the amendment, in accordance with its STCs. Similarly, if CMS believes that a particular change may substantially impact enrollment such that an adjustment to the aggregate or per capita cap may be needed, CMS may notify the state that it may not implement the change as planned, but must delay implementation until CMS and the state have agreed upon an appropriate adjustment.

Conclusion

While nothing in this letter represents final approval of any program or is binding on any state or any Medicaid recipient, CMS hopes this information is helpful and looks forward to continuing to work with states to consider and implement innovative solutions to improve their Medicaid programs. CMS is available to provide technical assistance to states, as well as to preview states' draft section 1115 proposals to help ensure states have the best chance possible of meeting federal requirements. Questions and comments regarding the HAO initiative may be directed to Judith Cash, Director, State Demonstrations Group, at 410-786-9686.

Sincerely,

Calder Lynch
Director

Cc:

National Association of Medicaid Directors
National Academy for State Health Policy
National Governors Association
American Public Human Services Association
Association of State and Territorial Health Officials
Council of State Governments
National Conference of State Legislatures
Academy Health
National Association of State Alcohol and Drug Abuse Directors

Appendix A: Flexibilities Table**Flexibilities Available Under the HAO Initiative**

Flexibility	Associated Statutory and Regulatory Provisions (states can request that these provisions not apply to an HAO demonstration)
ELIGIBILITY	
Flexibility to elect income standard best suited to state at, above or below 133 percent FPL. (Income standard of at least 133 percent FPL is required for increased FMAP for adults with income at or below 133 percent FPL in accordance with sections 1905(y) and 1905(z) of the Act.)	Section 1902(a)(10)(A)(i)(VIII); 42 CFR 435.119
Ability to limit eligibility to defined subset of individuals described in adult group, based on geographic or other criteria. (Eligibility for all individuals described in the adult group is required for increased FMAP in accordance with sections 1905(y) and 1905(z) of the Act.)	Section 1902(a)(1); 42 CFR 431.50 Section 1902(a)(10)(A)(i)(VIII); 42 CFR 435.119
Flexibility to receive FMAP for services rendered to the adult group without having to provide such coverage through benchmark or benchmark-equivalent coverage	Section 1903(i)(26)
Ability to impose additional eligibility requirements to further objectives of Medicaid program	Section 1902(a)(8); 42 CFR 435.911(c)(1) Section 1902(a)(10); 42 CFR 435.119
Flexibility to establish prospective enrollment for eligible applicants	Section 1902(a)(8); 42 CFR 435.911(c)(1)
Flexibility to eliminate retroactive eligibility	Section 1902(a)(34); 42 CFR 435.915
Flexibility to eliminate hospital presumptive eligibility	Section 1902(a)(47)(B); 42 CFR 435.1110
Flexibility to provide continuous eligibility up to 12 months	Section 1902(e)(14)(C); 42 CFR 435.603(g) 42 CFR 435.916(d)

Flexibility	Associated Statutory and Regulatory Provisions (states can request that these provisions not apply to an HAO demonstration)
Ability to renew eligibility of new beneficiaries prior to regular 12-month renewal in order to align Medicaid renewal cycle with Marketplace	Section 1943 42 CFR 435.916(a)(1)
BENEFITS	
Broad flexibility in benefit package design, including but not limited to flexibility to offer drug formularies similar to those provided in the health insurance markets, consistent with the EHB requirements	Section 1902(a)(10)(B); 42 CFR 440.230, 440.240
No requirement to provide mandatory state plan services or required Alternative Benefit Plan services – including NEMT, EPSDT, and nursing facility services – not included in Essential Health Benefits	42 CFR 431.53 (authorized by section 1902(a)(4)) Section 1902(a)(10)(A); 42 CFR 440.210, 440.220 Section 1902(a)(10)(B); 42 CFR 440.230, 440.240 Section 1902(k), 1937; 42 CFR 440.300
Flexibility to determine appropriate amount, duration and scope of covered benefits	Section 1902(a)(10)(B); 42 CFR 440.230, 440.240
Flexibility relating to FQHC covered services	1905(a)(2)(C)
COST-SHARING AND PREMIUMS	
Ability to charge premiums at all income levels	Sections 1902(a)(14), 1916 and 1916A; 42 CFR 447.55, 447.56
Broad flexibility to impose cost-sharing, including non-emergency use of the emergency room, up to aggregate limit equal to 5 percent of beneficiaries' income and subject to protections for populations specified in the guidance	Sections 1902(a)(14), 1916 and 1916A (other than section 1916A(b)(1)(B)(ii) and (b)(2)(A)); 42 CFR 447.52, 447.53, 447.56(a) - (e) Section 1916(f)
Broad flexibility to target premium and cost-sharing charges, except with respect to the aggregate limit on premiums and cost-sharing charges equal to 5 percent of beneficiaries' income	Sections 1902(a)(14), 1916 and 1916A; 42 CFR 447.56(b) Section 1916(f)

Flexibility	Associated Statutory and Regulatory Provisions (states can request that these provisions not apply to an HAO demonstration)
PROVIDER PAYMENTS AND ACCESS TO CARE	
Greater flexibility in rate-setting and payment methodologies	Section 1902(a)(30)
Flexibility in amount of DSH payments made to hospitals	Sections 1902(a)(13) and 1923
Flexibility in application of claims review prior to payment of providers	Section 1902(a)(37)
Flexibility to use alternative access standards in fee-for-service and managed care environments	Section 1902(a)(23) and (30) 42 CFR 438.68
Flexibility to reimburse FQHCs with a VBP	Section 1902(a)(10)(A); 42 CFR 440.230, 440.240; Section 1902(bb)
MANAGED CARE DELIVERY SYSTEM	
Flexibility in delivery system requirements	Section 1902(a)(1), (a)(10)(B), (a)(23), (a)(30)(A)
Elimination of prior CMS approval for rate certification, contract amendments, retroactive rate adjustments, and directed payments	42 CFR 438.3(a), 438.6(c)(2)(i), 438.7(a), 438.7(c)(2), 438.806(b)
Flexibility in allowing alternative approaches to achieve statutory requirements for managed care delivery systems	42 CFR part 438
FAIR HEARINGS	
Flexibility to streamline fair hearing processes within constitutional due process protections	Section 1902(a)(3); 42 CFR part 431 subpart E
ADMINISTRATIVE FLEXIBILITY	
Ability to make many program changes without prior CMS approval, consistent with the terms of this guidance	Section 1902; 42 CFR part 430 subpart B

Key Statutory and Regulatory Requirements Expected to be Applicable Under the HAO Initiative

Description of Statutory and Regulatory Requirements	Statutory and Regulatory Provision(s) Expected to be Applicable under the HAO Initiative
FINANCING	
FMAP and other FFP matching rates	Sections 1905(b), (y), (z), (aa), (cc); 42 CFR parts 432 and 433
Limitation on non-state federal share financing and availability and extent of FFP; compliance with expenditure reporting and budgetary requests	Section 1903; 42 CFR parts 430 and 433, except as specified above
PROGRAM INTEGRITY	
Medicaid Eligibility Quality Control (MEQC)	Section 1903(u); 42 CFR part 431 subpart P
Payment Error Rate Measurement program (PERM)	Improper Payments Information Act of 2002 (P.L. 107-300); 42 CFR part 431 subpart Q
Exclusion of providers Establishment and operation of Medicaid fraud control unit independent of the single state agency Mechanism for beneficiaries to report fraud and abuse	Sections 1902(a)(39), and (61), 1903(q); 42 CFR part 455 subpart A Section 1902(a)(64)
All other applicable program integrity regulations unless explicitly provided otherwise in the special terms and conditions of the state’s demonstration.	42 CFR part 455 and other provisions
ELIGIBILITY AND ENROLLMENT PROCESSES	
Use of single streamlined application, verification and renewal processes	Section 1943; 42 CFR 435.907, 435.910, 435.912, 435.916, 435.923, 435.945-960
BENEFICIARY PROTECTIONS	

Description of Statutory and Regulatory Requirements	Statutory and Regulatory Provision(s) Expected to be Applicable under the HAO Initiative
Protection of beneficiary information and confidentiality	Section 1902(a)(7) and 42 CFR part 431 subpart F
Assistance with application and renewal, including for individuals who are limited English proficient.	42 CFR 435.908
Five percent limit on aggregate premiums and cost-sharing	Section 1916A(b)(1)(B)(ii) and (b)(2)(A); 42 CFR 447.56(f)
No premiums or cost sharing charges for tribal beneficiaries	Sections 1916(j), 1916A(b)(3)(A)(vii), and 1916A(b)(3)(B)(x); 42 CFR 447.56(a)(1)(x) and 447.56(c)(2)
Prohibition on discrimination on the basis of race, color, national origin, sex, religion, national origin, disability, and age.	Protections afforded under other federal statutes and implementing regulations, including Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, the Age Discrimination Act of 1975, Section 1557 of the Affordable Care Act; 42 CFR 435.901 (regarding eligibility determinations and the provision of information; and as to state laws prohibiting religious discrimination).
BENEFITS	
Limitation on payments with respect to care or services for any individual who is an inmate of a public institution	Section 1905(a)(29)(A), 42 CFR 435.1010
Limitations on payments with respect to coverage of services for individuals residing in IMDs except for statutory and regulatory exceptions to the exclusion and expenditure authority to cover services provided to individuals residing in an IMD if the state meets the section 1115 program requirements as outlined in the State Medicaid Director Letters, Strategies to Address the Opioid Epidemic , issued on November 1, 2017, and Opportunities to Design Innovative Service Delivery Systems for Adults with Serious	Section 1905(a)(29)(B), 42 CFR 435.1010

Description of Statutory and Regulatory Requirements	Statutory and Regulatory Provision(s) Expected to be Applicable under the HAO Initiative
Mental Illness or Children with a Serious Emotional Disturbance, issued on November 13, 2018.	
MANAGED CARE DELIVERY SYSTEMS AND CERTIFICATION STANDARDS	
Statutory requirements must be met as well as regulatory requirements pertaining to the development of capitation rates. However, states may have flexibility to achieve goals of statute through approaches alternative to those prescribed in Medicaid regulations at 42 CFR part 438	Sections 1903(m) and 1932 of the Act
Standards for provider screening and enrollment	Sections 1902 (a)(77), (a)(78), and (kk); 42 CFR part 455 subpart E
Tribal protections related to managed care under section 1932(h) of the Act	section 1932(h) of the Act; 42 CFR 438.14
OTHER	
All statutory and regulatory requirements applicable to state plan coverage that are not identified in either table in this Appendix will be expected to apply unless the state requests in its demonstration application that such a requirement not apply and CMS approves the request in the special terms and conditions	

Appendix B: Process for Transitioning Existing Section 1115 Demonstrations into a State's HAO demonstration

States with existing section 1115 demonstrations that cover populations eligible to be covered in an HAO demonstration may also propose to transition coverage and other features of that existing demonstration into an HAO demonstration. The application template provided by CMS will accommodate such proposed transitions. CMS will work with states interested in such a transition to ensure a seamless conversion of coverage into an HAO demonstration and orderly close-out of the existing section 1115 demonstration in a manner consistent with the STCs for the existing demonstration.

As needed, CMS will help states develop a framework and key milestones for conversion, including implementation of the phase-out process of the existing demonstration, determining the appropriate public notification process for the planned conversion, and guidance on the development of the state's HAO demonstration application to effectuate the conversion of coverage. In advance of formal submission, CMS can work with states to identify potential program changes necessary for the state to accomplish its goals and objectives for the transition of coverage into an HAO demonstration in some of the following ways:

- Analysis of the state's goals, objectives and program features implemented in the existing demonstration to discern the extent to which HAO demonstration coverage may vary in its impact on beneficiary eligibility for services and benefits, healthcare delivery, and/or cost-sharing requirements;
- Analysis of the existing demonstration waiver and expenditure authorities to ensure that the state both retains, and is appropriately leveraging, the flexibilities available under an HAO demonstration to continue to meet the state's intended goals for the population; and,
- Analysis of the existing demonstration evaluation design to determine whether evaluation parameters may require revision to ensure the appropriate evaluation indicators are identified to understand the outcomes and the impacts of the state's intended goals for transitioning coverage of the population into an HAO demonstration.

Appendix C: Summary of Implementation of the EHB Requirements in the Individual Health Insurance Market

This appendix summarizes the standards for providing EHB, as implemented in 45 CFR 156.100 through 156.125. This is not intended to supersede any laws or regulations, and any conflict between this summary and the applicable legal authority should be resolved in favor of the legal authority. For a complete description of the regulatory standards, please consult the cited regulations.

EHB-Benchmark Plans in the Individual and Small Group Market

To implement section 1302(b) of the PPACA for the individual and small group markets, HHS defines EHB based on a benchmark plan approach. States selected from one of 10 base-benchmark plans, identified at 45 CFR 156.100. States were required at 45 CFR 156.110 to supplement their base-benchmark plan, if necessary, to ensure the ten EHB categories were being covered, and to ensure an appropriate balance among the EHB categories to ensure that benefits are not unduly weighted toward any category. The supplemented base-benchmark plan established the state's EHB-benchmark plan. States most recently completed this process to establish EHB-benchmark plans for the 2017 plan year. The 2017 EHB-benchmark plans continue to apply until the state makes a new selection under new benchmark plan selection options available for the 2020 plan year. If a state does not make a new selection applicable in 2020, the 2017 EHB-benchmark plan will continue to apply.

Under the new options to be available for the 2020 plan year, states may select as their EHB-benchmark plan the 2017 EHB-benchmark plan used by another state. They also may replace the coverage in any of the 10 categories of EHB from their 2017 EHB-benchmark plan with the coverage of the same category from another state's 2017 EHB-benchmark plan. Finally, states may select a set of benefits to become their new EHB-benchmark plan. Under any of these options, the state must ensure that the covered benefits are equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category, the scope of benefits provided under a typical employer plan, defined at 45 CFR 156.111(b)(2)(i). The scope of benefits also must not exceed the generosity of a set of comparison plans, identified at 45 CFR 156.111(b)(2)(ii). Finally, the EHB-benchmark plan must not have benefits unduly weighted towards any of the ten categories of EHB; must provide benefits for diverse segments of the population, including women, children, persons with disabilities, and other groups; and must not include discriminatory benefit designs that contravene the non-discrimination standards defined in 45 CFR 156.125.

Individual and Small Group Market Insurance Coverage of EHB based on the EHB-Benchmark Plans

To provide EHB, individual market health insurance coverage must provide benefits that are substantially equal to the EHB-benchmark plan, including covered benefits and limitations on coverage such as amount, duration, and scope. Annual or lifetime dollar limits in the EHB-benchmark plan may be converted to treatment limitations, consistent with 45 CFR 147.126. Additionally, the coverage may substitute actuarially equivalent benefits for those provided in

the EHB-benchmark plan, other than the prescription drug benefit, consistent with 45 CFR 156.115(b).

In addition to the benefits covered by the applicable EHB-benchmark plan, pursuant to 45 CFR 155.170(a)(2), any benefit required to be covered by state action taking place on or before December 31, 2011 must be covered and is considered an EHB.

To provide EHB, coverage also must: provide coverage of the greater of one drug or the same number of prescription drugs covered by the EHB-benchmark plan in every United States Pharmacopeia (USP) category and class, subject to the prescription drug benefit requirements in 45 CFR 156.122; comply with the MHPAEA requirements, as implemented in 45 CFR 146.136 and 147.160; include preventive health services described in 45 CFR 147.130; cover habilitative services and devices as specified in 45 CFR 156.115(a)(5); and for benefits under the pediatric services category of EHB, provide coverage for enrollees until at least the end of the month in which the enrollee turns 19 years of age.

EHBs may not include the following services: routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia.

EHB-Benchmark Plans in HAO Demonstration Coverage

States currently are not required to select the same EHB-benchmark plan for ABP as they do for their individual and small group markets. Similarly, CMS does not expect that states cover EHB under an HAO demonstration using the same EHB-benchmark used for other purposes. Rather, states may select, for purposes of covering EHB under an HAO demonstration, any EHB-benchmark plan that otherwise could have been selected for the state's individual and small group insurance markets for plan year 2017, or that could be selected for such markets for plan years beginning in 2020 under current regulations.

This includes the option to select from among the ten base-benchmark plans among which states selected for plan year 2017, supplemented as necessary, in accordance with 45 CFR 156.100 and 110, and the option to select from among the options in 45 CFR 156.111. Moreover, under any of the benchmark plan options (though it generally would not be applicable under the option at 45 CFR 156.111(a)(3)), states may change which benefits are considered EHB under the benchmark plan they select by substituting benefits for those provided in the EHB-benchmark plan in a manner consistent with 45 CFR 156.115(b).

Regardless of which option the state implements to select an EHB-benchmark plan for purposes of the HAO initiative, we expect the coverage a state provides under this demonstration initiative would be substantially equal to the EHB-benchmark, and would comply with the standards at 45 CFR 156.100 through 156.125.

Additionally, any benefits that must be covered by individual market health insurance in accordance with state action taking place on or before December 31, 2011 would be expected to be covered as EHB by Medicaid under an HAO demonstration.

Appendix D: Annual Quality and Access Reporting Requirements for Aggregate and Per Capita Cap Demonstration Models

Annual Quality and Access Measures

Measure Name	NQF #	Measure Steward	Mandatory Measure*
Primary Care Access and Preventive Care			
Cervical Cancer Screening (CCS-AD)	0032	NCQA	Yes
Chlamydia Screening in Women Ages 21–24 (CHL-AD)	0033	NCQA	Yes
Flu Vaccinations for Adults Ages 18 to 64 (FVA-AD)	0039	NCQA	No
Breast Cancer Screening (BCS-AD)	2372	NCQA	Yes
Screening for Depression and Follow-Up Plan: Age 18 and Older (CDF-AD)	3148	CMS	No
Adult Body Mass Index Assessment (ABA-AD)	NA	NCQA	Yes
Maternal and Perinatal Health			
PC-01: Elective Delivery (PC01-AD)	0469/2829	TJC	No
Prenatal and Postpartum Care: Postpartum Care (PPC-AD)	1517****	NCQA	Yes
Contraceptive Care – Postpartum: Ages 21–44 (CCP-AD)	2902	OPA	Yes
Contraceptive Care – Most and Moderately Effective Methods: Ages 21–44 (CCW-AD)	2903	OPA	Yes
Care of Acute and Chronic Conditions			
Controlling High Blood Pressure (CBP-AD)	0018	NCQA	Yes
Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Poor Control (>9.0%) (HPC-AD)	0059	NCQA	Yes
PQI 01: Diabetes Short-Term Complications Admission Rate (PQI01-AD)	0272	AHRQ	Yes
PQI 05: Chronic Obstructive Pulmonary Disease (COPD) or Asthma in Older Adults Admission Rate (PQI05-AD)	0275	AHRQ	Yes
PQI 08: Heart Failure Admission Rate (PQI08-AD)	0277	AHRQ	Yes
PQI 15: Asthma in Younger Adults Admission Rate (PQI15-AD)	0283	AHRQ	Yes
Plan All-Cause Readmissions (PCR-AD)	1768	NCQA	Yes
Asthma Medication Ratio: Ages 19–64 (AMR-AD)	1800	NCQA	Yes
HIV Viral Load Suppression (HVL-AD)	2082	HRSA	No
Behavioral Health Care			
Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (IET-AD)	0004	NCQA	Yes
Medical Assistance with Smoking and Tobacco Use Cessation (MSC-AD)	0027	NCQA	No
Antidepressant Medication Management (AMM-AD)	0105	NCQA	Yes
Follow-Up After Hospitalization for Mental Illness: Age 21 and Older (FUH-AD)	0576	NCQA	Yes
Diabetes Screening for People With Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications (SSD-AD)	1932	NCQA	Yes
Follow-Up After Emergency Department Visit for Alcohol and Other Drug Abuse or Dependence (FUA-AD)	3488*****	NCQA	Yes
Follow-Up After Emergency Department Visit for Mental Illness (FUM-AD)	3489*****	NCQA	Yes

Diabetes Care for People with Serious Mental Illness: Hemoglobin A1c (HbA1c) Poor Control (>9.0%) (HPCMI-AD)	2607	NCQA	No
Use of Opioids at High Dosage in Persons Without Cancer (OHD-AD)	2940	PQA	Yes
Adherence to Antipsychotic Medications for Individuals with Schizophrenia (SAA-AD)	NA***	NCQA	Yes
Concurrent Use of Opioids and Benzodiazepines (COB-AD)	NA	PQA	Yes
Use of Pharmacotherapy for Opioid Use Disorder (OUD-AD)**	3400	CMS	Yes
Long Term Services and Supports			
National Core Indicators Survey (NCIDDS-AD)**	NA	NASDDDS/ HSRI	No

* Measures in the Adult Core Set are considered mandatory for this demonstration model if they meet the following criteria: 1) Measure is included in the Medicaid Scorecard or 2) are feasible for states to report either because they can reliably be reported using administrative data sources alone (like claims and encounter data) or as evidenced by the fact that at least 25 states reported the measure in the 2019 Core Set reporting cycle of the 2018 Adult Core Set.

** This measure was added to the 2020 Adult Core Set. More information on 2020 Updates to the Child and Adult Core Health Care Quality Measurement Sets is available at <https://www.medicaid.gov/federal-policy-guidance/downloads/cib111919.pdf>.

*** The Adult Core Set includes the NCQA version of the measure, which is adapted from the CMS measure (NQF #1879).

**** This measure is no longer endorsed by NQF but retained in the Adult Core Set following consultation with states, who reported that the measure concept remains important for the Medicaid adult population and no better measure currently exists.

***** The NQF number for the FUA-AD and FUM-AD measures was previously listed as 2605. These measures now have separate NQF numbers but are the same measures included in the FFY 2019 Adult Core Set

AHRQ = Agency for Healthcare Research & Quality; CMS = Centers for Medicare & Medicaid Services; HRSA = Health Resources and Services Administration; NA = Measure is not NQF endorsed; NCQA = National Committee for Quality Assurance; NQF = National Quality Forum; OPA = U.S. Office of Population Affairs; PQA = Pharmacy Quality Alliance; TJC = The Joint Commission.

Appendix E: Key Elements of the Quality Strategy and Performance Assessment

States that choose to pursue an HAO demonstration should develop a state Quality Strategy and Performance Assessment that is comprised of five key components laid out as a cohesive plan: (1) measurable goals, (2) interventions, (3) performance measures, (4) baselines and targets, and (5) rapid-cycle assessment and continuous quality improvement. The Quality Strategy and Performance Assessment should address all populations covered under an HAO demonstration, even if they receive their care through a fee-for-service delivery system.

1. ***Identify objectives and articulate them as measurable goals.*** The foundation of an effective Quality Strategy and Performance Assessment is a set of clearly defined objectives that are articulated as measurable goals that are meaningful for the population(s) covered in the demonstration. In order to identify these goals, states should start with a data-based baseline analysis (e.g., cost, utilization patterns, health needs of target populations, quality of life issues facing beneficiaries, barriers to care, past performance) of the beneficiaries in this demonstration. This analysis should help states identify opportunities for improvement by looking at the root causes of the issues and targeting quality improvement resources accordingly. At a minimum, this baseline analysis should include the mandatory subset of the Medicaid Adult Core Set quality measures identified in Appendix D. These are the measures that are in Scorecard and are feasible for states to report, either because they derived from administrative data sources or as evidenced by the fact that at least 25 states reported them to CMS as of the 2019 Core Set reporting cycle, which reflects state reporting of the 2018 Adult Core Set.

These specific measurable health care quality goals should drive the entire Quality Strategy and Performance Assessment: the interventions, payment model, and metrics should all be rooted in the specific goals identified. States should consider how the interventions will help achieve these goals as well as how the performance measures will enable states to assess progress toward these goals. Tools such as driver diagrams and run charts can help visualize some of these components together as pathways.

2. ***Identify the interventions that will help the state achieve these goals.*** Under the HAO initiative, states will have broad flexibility in selecting the types of interventions that would advance their quality improvement goals. However, the interventions selected should have a strong evidence base for driving progress towards the identified goals.

States may wish to consult the Agency for Healthcare Research and Quality's [Health Care Innovations Exchange](#), an interactive database of innovative care models with demonstrated impact that is searchable by state, health care condition, patient population, and health care setting. States may also wish to consult the Centers for Disease Control and Prevention's [6|18 Initiative](#), a multi-state and multi-payer partnership targeting **six** common and costly health conditions – tobacco use, high blood pressure, health care-associated infections, asthma, unintended pregnancies, and diabetes – and, initially, **18** specific interventions that have been proven to be effective in improving health outcomes for individuals with these conditions.

States may consider conducting several small tests of change and Plan-Do-Study-Act

(PDSA) cycles to quickly identify which interventions have the greatest potential to impact change and drive progress towards the goals and aims of the state's quality strategy.¹¹ States can receive coaching and technical assistance in these types of quality improvement techniques by emailing MACQualityTA@cms.hhs.gov.

3. ***Measure and monitor progress toward these goals.*** Once the objectives, goals, and interventions have been selected, the appropriate performance measures that can be directly tied to these goals and interventions should be selected. At a minimum, these measures should enable the state to assess the impact of this demonstration on access to care and the quality and appropriateness of the care furnished to beneficiaries, including both underutilization and overutilization. States should also annually survey these beneficiaries to understand their experience of care, including access and perceived barriers.

These measures will allow a state to understand when an intervention has resulted in improvement as well as indicate if there is any slippage where quality improvement resources are not presently focused. States should consider a blend of process and outcome-focused measures along with measures that can help to reflect unintended consequences of change, including to other parts of the system or other systems.

States will be expected to collect and report the mandatory subset of the Medicaid Adult Core Set quality measures as noted in Appendix D. These measures, along with the beneficiary's experience of care survey, will serve as the baseline for the demonstration and to measure impact of the demonstration on beneficiary's ongoing access to and quality of care. In addition, these measures will be used to reward states on a pay-for-performance basis. The state may also use measures already in use by the state, if different from the Core Sets. CMS will develop a set of tools that will aid states in selecting appropriate, standardized measures for specific settings of care that are also aligned with the Core Set.

When selecting which measures to use, it is important to consider the rationale for selecting each measure and determine how each measure ties to the improvement goal or intervention. This assessment will help the state identify which programmatic goals are and are not reflected with the available measures. In addition, clarifying the connection from goal to measurement is useful in meaningfully conveying to internal/external stakeholders and to CMS what the state intends to achieve and how it will know that progress is occurring.

In order to support alignment with federal programs, improve consistency and comparability in measurement, and minimize reporting burden, states are encouraged to consult the [CMS measures inventory](#) which includes the majority of the measures used in CMS's public reporting programs.

¹¹ See <https://www.medicaid.gov/medicaid/quality-of-care/downloads/qi-201-designing-interventions.pdf>; <https://www.medicaid.gov/medicaid/quality-of-care/downloads/qi-201-planning-and-doing.pdf>;

4. ***Defining the starting point and targets for performance.*** Using the data-based analysis, [previous state performance on the Adult Core Set measures](#), and national benchmarking data, the state should identify baselines for each of the measures it intends to collect. If states undertaking new initiatives or populations do not have baseline data for their measures, they should create a timeline for identifying and setting baselines.

For the mandatory subset of the Medicaid Adult Core Set measures, CMS will set benchmarks nationally across all states reporting the given Core Set measures and organize them into quartiles. To qualify for the performance-based portion of the shared savings, states will need to either achieve performance at the 75th percentile or demonstrate a 3 percent improvement over the prior year on a portion of those measures in order to qualify for the performance-based share of savings. The reporting and quality performance requirements for shared savings is further described in the Financing and Shared Savings section of this guidance.

States may choose to provide financial incentives to providers for absolute achievement, targeted improvement on metrics, or both. There are multiple ways this can be accomplished. The nature of the split between absolute achievement and targeted improvement will depend on the characteristics of the metric and the basic goals of the effort.¹² States may also find CMS's [guidance on shared savings](#) to be useful to clarify state responsibilities on these financial incentives.¹³

5. ***Measure submission and use for rapid-cycle assessment and continuous quality improvement.*** Quality improvement and measurement is best approached in cycles designed to continuously drive improvement in access to care, quality of care, and health outcomes. Regularly monitoring performance assessment data and feeding it back to the health care providers and health plans participating in this demonstration is necessary in order to understand what measures of quality are improving (or not), and create the opportunity for developing and diffusing best practices, avoiding a repeat of problems and driving quality improvement more broadly.

A critical element of transparency and feedback is the availability of appropriately structured, reliable and timely data that can support rapid cycle assessment to support mid-course corrections in interventions and to accelerate local learning and improvement. States must collect and submit this performance measurement data to CMS and publish them on their website at least annually, with quarterly submission of data for performance measures derived from administrative data sources like claims.

¹² For instance, a state may choose to align with CMS's Hospital Value-Based Purchasing incentive structure, which awards points for both achievement relative to a national benchmark and improvement based on a hospital's past performance, at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Hospital-Value-Based-Purchasing->. Another approach would be to set a target of 90th percentile of national performance for its measures. In brief, providers earn the reward in one of two ways—either the provider meets this performance target, or the provider closes the gap between current performance (baseline) and this 90th percentile target by a pre-specified amount.

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

Where the focus of the demonstration is less than statewide, the state must report these measures at the state and the demonstration levels: the difference between how a state is performing at the demonstration-level and at the state-level on a given measure is important information and provides context for understanding the demonstration-level performance.

Relationship of Managed Care Requirements and Quality & Application to Fee-For-Service

Managed care has existing quality requirements at 42 CFR part 438 subpart E. When developing this overall quality strategy, states should think broadly across all delivery systems, including but not limited to managed care. States with managed care delivery systems can leverage existing quality strategies, QAPI requirements, and external quality review to fulfill these requirements. However, all beneficiaries covered by an HAO demonstration – even if they receive their care through fee-for-service arrangements in an otherwise managed care delivery system – will need to be integrated into these quality strategies, QAPI plans, and external quality review activities.

Stakeholder Engagement and Transparency

Stakeholder engagement in designing and implementing each of these components is critical. From consumers, to providers, to patients, multi-stakeholder approaches to quality are not only necessary for viability but have historically been a key to the success of quality improvement initiatives. Stakeholder perspectives and values should be incorporated into this process from the initial conception of a quality improvement model, and should be reflected in the programmatic goals and measurement approaches.

Technical Assistance

Technical assistance on any aspect of these quality provisions, including the development of driver diagrams, measure selection, data collection and submission, and quality improvement approaches and techniques is available to states at no cost by emailing MACQualityTA@cms.hhs.gov.

Appendix F: Guidelines for MLR Remittances

Managed Care Plan MLR	Minimal Remittance Required
Less than 75%	<p>The managed care plan must remit to the state 100% of:</p> <p>a. (.75 minus (the actual MLR)) multiplied by (total revenue)</p> <p>Additionally for being below 80%, the managed care plan must remit to the state no less than 80% of:</p> <p>b. .05 multiplied by (total revenue)</p> <p>Additionally for being below 85%, the managed care plan must remit to the state no less than 50% of:</p> <p>c. .05 multiplied by (total revenue)</p>
75% - 80%	<p>The managed care plan must remit to the state no less than 80% of:</p> <p>a. (.80 minus (the actual MLR)) multiplied by (total revenue)</p> <p>Additionally for being below 85%, the managed care plan must remit to the state no less than 50% of:</p> <p>b. .05 multiplied by (total revenue)</p>
80% - 85%	<p>The managed care plan must remit to the state no less than 50% of:</p> <p>a. (.80 minus (the actual MLR)) multiplied by (total revenue)</p>
85% - 95%	<p>The state and managed care plans do not need to make a remittance</p>
95% - 100%	<p>The state must remit to the managed care plan no less than 50% of:</p> <p>a. ((the actual MLR) minus .95) multiplied by (total revenue)</p>
100% - 105%	<p>The state must remit to the managed care plan no less than 80% of:</p> <p>a. ((the actual MLR) minus 1.00) multiplied by (total revenue)</p> <p>Additionally for being above 95%, the state must remit to the managed care plan no less than 50% of:</p> <p>b. .05 multiplied by (total revenue)</p>
Greater than 105%	<p>The state must remit to the managed care plan 100% of:</p> <p>a. ((the actual MLR) minus 1.05) multiplied by (total revenue)</p> <p>Additionally for being above 100%, the state must remit to the managed care plan no less than 80% of:</p> <p>b. .05 multiplied by (total revenue)</p> <p>Additionally for being above 95%, the state must remit to the managed care plan no less than 50% of:</p> <p>c. .05 multiplied by (total revenue)</p>

Appendix G: Schedule of Deliverables for the Demonstration

Date	Deliverable
30 days after “approval date” by CMS	State acceptance of demonstration STCs, and Expenditure Authorities
90 days after approval date	Implementation Plan
90 days after approval date	Quality Strategy
90 days after approval date	Baseline Quality & Access Measure Reporting and Beneficiary Access to Care, Barriers to Care and Experience of Care Survey results
120 days after approval date	Monitoring Protocol
180 days after approval date	Evaluation Design
Quarterly Deliverables Due 60 days after end of each quarter, except 4 th quarter	Quarterly Monitoring Reports
	Quarterly Implementation Plan Update Quarterly Expenditure Reports
Annual Deliverables - Due 90 days after end of each 4 th quarter	Annual Monitoring Reports Annual Quality and Access Measure Report Annual Survey of Beneficiary Access to Care, Barriers of Care and Experience of Care
3 years after approval date	Mid-point Assessment
1 year prior to the expiration of the demonstration, or with the demonstration extension application	Draft Interim Evaluation Report
60 days after receipt of CMS comments	Final Interim Evaluation Report
18 months following the end of the demonstration approval period	Draft Summative Evaluation Report
60 days after receipt of CMS comments	Final Summative Evaluation Report
Monthly Deliverables	Monitoring Call

Appendix H: METRICS FOR CONTINUOUS PERFORMANCE INDICATOR SYSTEM

Access to care and availability of services	
1	Provider active participation: # providers enrolled with service claims for 3 or more beneficiaries a) Primary provider b) Specialist provider
2	Managed care states: Provider availability by plan a) Number of calls to state or plan's call center indicating difficulty in finding provider or timely access to primary care services b) Number of calls to state or plan's call center indicating difficulty in finding provider or timely access to specialty care services
3	Emergency department (ED) utilization a) Total ED visits/number of member months in quarter b) Total nonemergency ED visits
4	Inpatient admissions/member months in quarter a) Total b) Avoidable
5	Diabetes Short-Term Complications Admission Rate / Adult Core Set (PQI01-AD) (NQF 0272)
Enrollment	
6	Total demonstration enrollment
7	Retention at renewal a) Total due for renewal b) Percent successfully renewed c) Percent terminated at renewal d) Pending disposition
8	Suspensions and lockouts (if applicable)
9	Total pending applications
Appeals and grievances	
10	Number of appeals requested/demonstration enrollment a) Medicaid eligibility b) Denial of benefits
11	Number of grievances, by plan (managed care)/ demonstration enrollment
Financing	
12	Claims processing (by plan if managed care) a) The percentage total claims that were clean as submitted b) Percentage of clean provider claims paid within (i) 14 days; (ii) over 45 days
13	Medical loss ratio (MLR) (managed care) a) Estimated for the quarter b) Estimated year-to-date (YTD)