

*F. Executive Order 13175: Coordination With Indian Tribal Governments*

This action does not have tribal implications, as specified in Executive Order 13175, because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

*G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

*H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer and Advancement Act (NTTAA)*

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

*J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population*

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: August 15, 2022.

**Martha Guzman Aceves,**

*Regional Administrator, Region IX.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 433, 437, and 457**

**[CMS–2440–P]**

**RIN 0938–AU52**

**Medicaid Program and CHIP; Mandatory Medicaid and Children’s Health Insurance Program (CHIP) Core Set Reporting**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would establish the requirements for mandatory annual State reporting of the Core Set of Children’s Health Care Quality Measures for Medicaid and Children’s Health Insurance Program (CHIP), the behavioral health measures on the Core Set of Adult Health Care Quality Measures for Medicaid, and the Core Sets of Health Home Quality Measures for Medicaid. This proposed rule would also establish compliance requirements.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 21, 2022.

**ADDRESSES:** In commenting, please refer to file code CMS–2440–P. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2440–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services,

Department of Health and Human Services, Attention: CMS–2440–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:**

Virginia Raney, (410) 786–6117, Children and Adults Health Care Quality Measurement  
Sara Rhoades, (410) 786–4484, Health Home Quality Measurement  
Candace Anderson, (410) 786–1553, Health Care Quality Measurement for Dual Eligible (Medicaid and Medicare) Beneficiaries

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

**I. Background**

*A. Quality Measurement in Medicaid and CHIP*

Medicaid was enacted in 1965 as Title XIX of the Social Security Act (the Act) to provide health coverage for certain groups of people with lower incomes. Over the ensuing years, coverage under Medicaid has been extended to additional low-income populations. In addition, in 1997, upon enactment of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted August 5, 1997), the Children’s Health Insurance Program (CHIP) was enacted as Title XXI of the Act. Today, Medicaid and CHIP provide health coverage to approximately 88 million beneficiaries, approximately half of whom are children (40.4 million).<sup>1</sup> Medicaid and CHIP provide

<sup>1</sup> March 2022 Medicaid and CHIP Enrollment data: <https://www.medicaid.gov/medicaid/national->

health care for some of the most vulnerable Americans, including individuals with very low incomes, pregnant women and children, and people with physical, cognitive, mental, and other disabilities who require long term services and supports (LTSS).

Despite the significant role that Medicaid and CHIP play in America's health care system, this regulation would require—for the first time—States, the District of Columbia (DC) and territories to mandatorily report on measures of the quality of health care provided to Medicaid and CHIP beneficiaries. Until the reauthorization of CHIP in 2009 by the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3, enacted February 4, 2009), there were no Federal requirements regarding quality measurement to assess the care delivered to beneficiaries. Some quality measurement occurred at the State-level, but there was wide variation in the reliability and completeness of the data, as well as the types of measures reported. Different States focused on different health domains, and significant differences existed in the amount of State resources directed toward quality measurement, the data collection systems and capabilities for measuring quality in each State, and each State's priorities for quality improvement.

Since the establishment of CHIP, participating States have been required to report annually on the operation of their CHIP State plan and progress in reducing the number of uninsured children under section 2108 of the Act. Section 2108 of the Act also requires States to report data about enrollee access to networks of care, such as access to primary and specialty services and care coordination, using quality and satisfaction measures included in the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey.

CHIPRA expanded upon these initial requirements. Not only were State reporting requirements for CHIP enhanced, but CHIPRA also required the Federal government to begin monitoring the quality of care and health outcomes for children enrolled in Medicaid and CHIP. Section 401 of CHIPRA added new section 1139A to the Act, which required development of a Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) which could be voluntarily reported by States. Section 1139A of the

[medicaid-chip-program-information/downloads/march-2022-medicaid-chip-enrollment-trend-snapshot.pdf](https://www.medicaid-chip-program-information/downloads/march-2022-medicaid-chip-enrollment-trend-snapshot.pdf).

Act directed the Secretary to publish for general comment an initial recommended core set of child health quality measures set based on existing quality of care measures for children not later than January 1, 2010.

To assist the Federal Government in establishing priorities for the development and advancement of the Child Core Set, section 1139A of the Act also directed the Secretary to consult with a variety of specific interested parties in developing the initial measures and to work with interested parties annually to update the measures. Following several rounds of review by the initial interested parties and comments from the public, CMS released the initial Child Core Set consisting of 24 measures in 2009, with voluntary State-level reporting to begin in FFY 2010.<sup>2</sup>

The importance of quality reporting was emphasized by Congress again in 2010 when section 2701 of the Affordable Care Act<sup>3</sup> established a new section 1139B of the Act, extending the measurement of health care quality to Medicaid eligible adults. Like the Child Core set, the initial Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set) was designed to reflect the health needs of adults enrolled in Medicaid, with measures capturing cancer screenings and management of chronic conditions. While not required by statute, including separate CHIP enrollees in reporting on the Adult Core Set measures is encouraged; therefore, both Medicaid and CHIP populations are referenced in descriptions of the Adult Core Set (see additional discussion in section II.E. of this proposed rule). The initial Adult Core Set also included five behavioral health measures to capture use of preventive and treatment services for mental health and substance use disorders. CMS issued the initial Adult Core Set consisting of 26 quality measures in 2012, and voluntary reporting of these measures began in FFY 2013.<sup>4</sup>

Congress has continued to advance quality reporting in Medicaid and CHIP

<sup>2</sup> Initial Child Core Set: <https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SHO11001.pdf>.

<sup>3</sup> The Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) was enacted on March 23, 2010. The Healthcare and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this rulemaking, the two statutes are referred to collectively as the "Affordable Care Act" or "ACA."

<sup>4</sup> Initial Adult Core Set: <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib-01-04-12.pdf>.

by extending the appropriations for Core Sets reporting on a regular basis. The Protecting Access to Medicare Act of 2014 (PAMA), (Pub. L. 113–93, enacted April 1, 2014), the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), (Pub. L. 114–10, enacted April 16, 2015) and the Helping Ensure Access for Little Ones, Toddlers, and Hopeful Youth by Keeping Insurance Delivery Stable Act of 2017 (HEALTHY KIDS Act) (Pub. L. 115–120, enacted January 22, 2018) all directed funding to the continued development, submission, and reporting of health care quality measures in Medicaid and CHIP for the Child Core Set.<sup>5</sup>

This regulation would implement mandatory annual reporting of the Child Core Set and the behavioral health measures on the Adult Core Set using a standardized format, as required by section 50102 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) and section 5001 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), (Pub. L. 115–271, enacted October 24, 2018).

#### *B. Quality Measurement of the Medicaid Health Home Benefits Under Sections 1945 and 1945A of the Act*

In addition to requiring reporting on the Child Core Set and specified measures on the Adult Core Set, this proposed rule would establish reporting requirements for States that elect to implement one or both of the optional Medicaid health home benefits under sections 1945 or 1945A of the Act. Sections 1945 (added by section 2703 of the ACA and later amended by section 1006(a) of the SUPPORT Act) and 1945A (added by section 3 of the Medicaid Services Investment and Accountability Act of 2019)<sup>6</sup> give States options for implementing two different Medicaid health home State plan benefits. The section 1945 health home benefit is for Medicaid-eligible individuals with two or more chronic conditions, with at least one chronic condition and who are at risk for a second, or with at least one serious and persistent mental health condition. Chronic conditions are defined in section 1945(h)(2) of the Act to include mental health conditions, substance use disorders, asthma, diabetes, heart disease, and being overweight (body

<sup>5</sup> The HEALTHY KIDS Act was enacted as part of H.R. 195, the Fourth Continuing Appropriations for Fiscal Year 2018, **Federal Register** Printing Savings, HEALTHY Kids, Health-Related Taxes, and Budget Effects (Pub. L. 115–120).

<sup>6</sup> Public Law 116–16, enacted April 18, 2019.

mass index over 25).<sup>7</sup> The section 1945A health home benefit is for Medicaid-eligible children with medically complex conditions, as defined in section 1945A(i)(1) of the Act.<sup>8</sup> States were able to begin covering the section 1945 health home benefit on January 1, 2011. States will be able to begin covering the section 1945A health home benefit on October 1, 2022.

Under both of these optional Medicaid benefits, a health home is a designated provider (including a provider that operates in coordination with a team of health care professionals) or a health team that is selected to provide health home services by a person who is eligible for the optional benefit. See sections 1945(h)(3) and section 1945A(i)(3) of the Act. Sections 1945 and 1945A of the Act also define health home services similarly. Section 1945 health home services are defined at section 1945(h)(4) of the Act as comprehensive care management; care coordination and health promotion; comprehensive transitional care, including appropriate follow-up, from inpatient to other settings; patient and family support (including authorized representatives); referral to community and social support services, if relevant; and the use of health information technology to link services, as feasible and appropriate. Section 1945A(i)(4) of the Act defines health home services as comprehensive care management; care coordination, health promotion, and providing access to the full range of pediatric specialty and subspecialty medical services, including services from out-of-State providers, as medically necessary; comprehensive transitional care, including appropriate follow-up, from inpatient to other settings; patient and family support (including authorized representatives); referrals to community and social support services, if relevant; and use of health information technology to link services, as feasible and appropriate.

As a condition for receiving payment for section 1945 health home services, section 1945(g) of the Act requires section 1945 health home providers to report to the State, in accordance with such requirements as the Secretary shall specify, on all applicable measures for

determining the quality of health home services. Additionally, section 1945(c)(4)(B) of the Act requires certain States with an approved substance use disorder (SUD)-focused section 1945 health home State plan amendment (SPA) to report to the Secretary on the following with respect to SUD-eligible individuals provided health home services under the SUD-focused health home SPA: (1) the quality of health care provided to these individuals, with a focus on outcomes relevant to the recovery of each such individual; (2) the access of these individuals to health care; and (3) the total expenditures of these individuals for health care. Section 1945(c)(4)(B) further provides that the Secretary shall specify all applicable quality measures that would be included in the reporting required under that provision. Per section 1945(c)(4)(B) of the Act, States must submit the required report at the end of the period of such [SPA]. CMS has interpreted this language to mean that the report should provide data relating to the enhanced Federal medical assistance percentage (FMAP) period available to the State under section 1945(c)(4) of the Act and that States should submit the report within 6 months after the enhanced FMAP period ends.<sup>9</sup> Apart from the one-time-only required report under section 1945(c)(4)(B) of the Act, section 1945 of the Act does not require States to submit quality measure reporting to CMS or the Secretary related to the section 1945 health home benefit. However, since 2013, CMS has encouraged States (including States subject to the one-time-only report specified at section 1945(c)(4)(B) of the Act) to report

annually on a set of section 1945 health home quality measures (section 1945 Health Home Core Set).<sup>10</sup>

The new optional section 1945A health home benefit also requires providers of that benefit to report to States on quality measures as a condition of payment. As a condition of receiving payment for section 1945A health home services, section 1945A(g)(1)(B) of the Act requires section 1945A health home providers to report information to the State on all applicable measures for determining the quality of health home services provided by the provider, including, to the extent applicable, child health quality measures and measures for centers of excellence for children with complex needs developed under Title XIX, Title XXI, and section 1139A of the Act (which would include the Child Core Set). Additionally, unlike section 1945 of the Act, which requires States to report on quality measures to the Secretary only if the State is subject to section 1945(c)(4)(B) of the Act, section 1945A of the Act requires all States implementing that benefit to submit reports to the Secretary on a range of topics. Under section 1945A(g)(2)(A)(i) of the Act, these reports must include all information reported by providers to the State under section 1945A(g)(1) of the Act, including the quality measure reporting required under section 1945A(g)(1)(B) of the Act. CMS interprets the language in section 1945A(g)(2)(A)(i) of the Act to refer to reporting on core measures developed for purposes of evaluating the quality of section 1945A health home services, because that provision cross-references the language in section 1945A(g)(1)(B) of the Act that mentions quality measures developed under various provisions of the Act, including the Child Core Set.

CMS published an initial core set of section 1945 health home quality measures (section 1945 Health Home Core Set) on January 15, 2013, in SMD letter #13-001, regarding “Health Home Core Quality Measures.” In developing the initial section 1945 Health Home Core Set, we consulted with States considering implementing the section 1945 health home benefit, conducted technical assistance calls, presentations, and webinars, and worked with Federal partners, including the Office of the Assistant Secretary for Planning and Evaluation and the Substance Abuse and Mental Health Services Administration (SAMHSA). SMD letter #13-001 provided a recommended list

<sup>7</sup> On November 16, 2010, we issued State Medicaid Director (SMD) letter #10-024, which provided States with guidance on implementing the section 1945 health home benefit. See <https://www.medicaid.gov/federal-policy-guidance/downloads/SMD10024.pdf>.

<sup>8</sup> On August 1, 2022, we issued State Medicaid Director (SMD) letter #22-004, which provides States with guidance on implementing the section 1945A health home benefit. See <https://www.medicaid.gov/federal-policy-guidance/downloads/smd22004.pdf>.

<sup>9</sup> Under section 1945(c)(1) of the Act, State payments for section 1945 health home services provided during the first 8 fiscal year quarters that a section 1945 SPA is in effect are Federally matched at a 90 percent Federal Medical Assistance Percentage (FMAP). Section 1006(a) of the SUPPORT Act, “Extension of Enhanced FMAP for Certain Health Homes for Individuals with Substance Use Disorders,” amended section 1945(c) of the Act to permit an extension of this period of 90 percent FMAP for certain section 1945 health home SPAs for individuals with substance use disorders (SUD) for two additional quarters (such that there could be a total of 10 quarters for the 90 percent FMAP). CMS provided guidance to States about this amendment to section 1945 in a May 7, 2019, Center for Medicaid and CHIP Services (CMCS) Informational Bulletin (CIB), “Guidance for States on the Availability of an Extension of the Enhanced Federal Medical Assistance Percentage (FMAP) Period for Certain Medicaid Health Homes for Individuals with Substance Use Disorders (SUD).” <https://www.medicaid.gov/federal-policy-guidance/downloads/cib050719.pdf>. We released further guidance on the section 1945(c)(4)(B) reporting requirements in a CIB entitled “New Reporting Measures for Substance Use Disorder (SUD)-Focused Health Homes” on November 27, 2019, <https://www.medicaid.gov/federal-policy-guidance/downloads/cib112719.pdf>.

<sup>10</sup> <https://www.medicaid.gov/federal-policy-guidance/downloads/smd-13-001.pdf>.

of 8 core measures that were chosen because they reflected key priority areas such as behavioral health and prevention measures.<sup>11</sup> CMS also explained in that SMD letter that reporting on the section 1945 Health Home Core Set would be *voluntary* until regulations were promulgated to require it. However, to ease the reporting burden, all but one of the recommended measures was aligned with measures in the Adult Core Set.

Subsequent updates to the section 1945 Health Home Core Set have been made on an annual basis. In developing and updating the section 1945 Health Home Core Set, CMS has generally tried to align it with the Child and Adult Core Sets. In November 2019, CMS released a CIB, which added two additional measures specific to SUD-focused health home programs to the 2020 section 1945 Health Home Core Set on which States could consider reporting as part of the required reporting under section 1945(c)(4)(B) of the Act.<sup>12</sup>

One feature of the section 1945 Health Home Core Set that differs from the Child and Adult Core Sets is that States collect provider-specific data on health home program beneficiaries from providers as a condition of payment (per section 1945(g) of the Act) and then aggregate that data at the health home program (that is, SPA) level for reporting to CMS rather than reporting State-level data as is done for the Child and Adult Core Sets. States with multiple home health programs submit a separate report for each program to CMS. Program level reporting is necessary as a result of flexibilities in section 1945 of the Act, which allows States to provide health home services on a less than statewide basis, allowing coverage of section 1945 health home services to be targeted to specific geographic areas within the State.

This proposed rule would establish the following requirements for States electing to implement the benefit under sections 1945 or 1945A of the Act. CMS proposes to require States that have implemented the section 1945 and/or 1945A health home benefit to report annually on the mandatory measures in the section 1945 Health Home Core Set and/or a proposed section 1945A Health Home Core Set (depending on which of the two benefits the State has opted to cover), and to require their health home providers to report to the State on those measures. CMS proposes that annual CMS reporting guidance will provide

information on specific measures for which reporting is mandatory for the section 1945 and section 1945A Health Home Core Sets (including any specific measures that would be mandatory for States with SUD-focused section 1945 health homes). For States covering the section 1945 health home benefit, this requirement would be based on section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. For measures specific to States with SUD-focused health home SPAs subject to section 1945(c)(4)(B) of the Act, this requirement would also be authorized by the language in section 1945(c)(4)(B) of the Act stating that the Secretary shall specify all applicable measures for determining quality for purposes of section 1945(c)(4)(B) of the Act, but the proposals do not otherwise address the reporting requirements under section 1945(c)(4)(B) of the Act. Requiring States to require their section 1945 health home providers to report to the State on the Health Home Core Set would be further supported by the language in section 1945(g) of the Act providing that section 1945 health home providers shall report to States on all applicable measures for determining the quality of section 1945 health home services, in accordance with such requirements as the Secretary shall specify. For States covering the section 1945A health home benefit, these requirements would be authorized by section 1945A(g)(1) and (2) of the Act (see discussion of those provisions above), as well as by section 1902(a)(6) of the Act. While this proposed rule addresses part of the reporting required under section 1945A(g)(2)(A) of the Act (specifically, the proposed rule would implement section 1945A(g)(2)(A)(i) of the Act), section 1945A(g)(2)(A) of the Act requires States to report to the Secretary on several additional topics that are not addressed in this proposed rule. CMS expects to provide information to States about the rest of the reporting requirements under section 1945A(g)(2)(A) of the Act in the future.

#### *C. Building a System of Reporting To Improve the Quality of Care Delivered*

Implementation of the Child, Adult, and section 1945 Health Home Core Sets represented a major step in the development of a national, evidence-based system for measuring and

improving the quality of care delivered to Medicaid and CHIP beneficiaries. The Core Sets include measures that, taken together, may be used to estimate the overall national quality of health care provided to beneficiaries. For instance, through the Child Core Set, data are collected on the percentage of children who receive preventive dental services and through the Adult and section 1945 Health Home Core Sets, data are collected on the number of adult beneficiaries who have their blood pressure under control. The Core Sets also have the potential to assess changes in the quality of and access to health care provided by State Medicaid and CHIP programs over time, and to make comparisons across States and health home programs. For example, the Core Sets capture data on the numbers of child and adult beneficiaries who have been seen by a provider following a hospitalization for mental illness—follow-up care that is critical to improving health outcomes for individuals suffering from mental illness. The ability to assess the quality of and access to care furnished by State Medicaid and CHIP programs is critical given the large number of vulnerable Americans who receive coverage in Medicaid and CHIP and the significant Federal and State resources needed to fund these programs.

#### 1. Development of Core Sets

To ensure that the measures included in the Core Sets reflect the needs of Medicaid and CHIP beneficiaries and provide the types of information necessary for true quality improvement, sections 1139A and 1139B of the Act establish a number of specific parameters for the development of these core sets. As described in section 1139A(b)(2) of the Act, the measures included in the Child Core Set measures must be, at a minimum: (1) evidence-based and risk-adjusted, (2) designed to identify and eliminate racial and ethnic disparities in child health and the provision of health care; (3) designed to ensure that the data required for such measures is collected and reported in a standard format that permits comparison of quality and data at a State, plan, and provider level; (4) periodically updated; and (5) responsive to the child health needs, services, and domains of health care quality described in sections 1139A(a)(6)(A) (i), (ii), and (iii) of the Act (that is, preventive health services, acute care, chronic health care services, clinical care, health care safety, and family user experience). Section 1139B(a) of the Act requires the Secretary to utilize similar parameters for establishing the Adult Core Set.

<sup>11</sup> <https://www.medicaid.gov/federal-policy-guidance/downloads/SMD-13-001.pdf>.

<sup>12</sup> <https://www.medicaid.gov/federal-policy-guidance/downloads/cib112719.pdf>

To ensure the continued relevance of the Core Sets and allow the measures to grow and change as the health care system changes, sections 1139A and 1139B of the Act require the Secretary to create a Pediatric Quality Measurement Program and a Medicaid Quality Measurement Program and establish an annual, consensus-based process for identifying gaps in existing measures and establishing priorities for the development and advancement of new measures to address these gaps. Section 1139A(b)(3) of the Act requires the Secretary to consult a broad range of interested parties, including States; pediatricians; children's hospitals; other primary and specialized pediatric health care professionals and dental professionals; providers that furnish health care to children and families in urban and rural medically underserved communities or who are members of distinct population sub-groups at heightened risk for poor health outcomes; national organizations representing children, including children with disabilities and children with chronic conditions; national organizations representing consumers and purchasers of children's health care; national organizations and individuals with expertise in pediatric health quality measurement; and voluntary consensus standards setting organizations and other organizations involved in the advancement of evidence-based measures of health care. Section 1139A(b)(5) of the Act directs the Secretary, beginning no later than January 1, 2013, and annually thereafter to publish recommended changes to the core measures described in section 1139A(a) of the Act that shall reflect the testing, validation, and consensus process for the development of pediatric quality measures described in paragraphs (1) through (4) of section 1139A(b) of the Act. Section 1139B(b)(5)(B) of the Act requires that the Secretary engage in a comparable process to annually update the Adult Core Set.

The initial section 1945 Health Home Core Set was established in 2013 as a recommended set of health care quality measures for assessing the section 1945 health home service delivery model. CMS established the initial section 1945 Health Home Core Set quality measures for Medicaid-eligible children and adults following consultation with Federal partners and States considering health homes, technical assistance calls, presentations, and webinars. CMS selected the recommended core set of health home measures because they reflect key priority areas such as

behavioral health and preventive care; and because they aligned with the initial Adult Core Set, the Medicaid Electronic Health Record (EHR) incentive program "Meaningful Use" measures, and with the National Quality Strategy. CMS has updated the section 1945 Health Home Core Set annually since 2013, and in 2021 CMS established a Health Home Annual Review Workgroup to align this update process with how CMS updates the Child and Adult Core Sets (as further discussed below). The updates have generally reflected the same considerations and followed the same process as applied to the development of the initial set.

We have worked diligently with States and other interested parties through the formation of a joint Child and Adult Core Set Annual Review Workgroup to implement the statutory requirements and to ensure that measures in the Core Sets are meaningful for States and interested parties, feasible for State-level reporting, and represent minimal additional burden.<sup>13</sup> In 2021, we established a separate Health Home Annual Review Workgroup following the same structure and guidelines as the workgroup for the Child and Adult Core Sets, to develop and update section 1945 and section 1945A Health Home Core Sets. The joint Child and Adult Core Set Annual Review Workgroup and the Health Home Annual Review Workgroup ("Workgroups") are convened annually to develop recommendations on how to revise, strengthen, and improve the applicable Core Sets measures, and every year the Workgroups' recommended changes are published for public comment. All meetings are open to the public, and public comment is invited during each meeting.

Workgroup members are able to recommend measures for addition or removal from the core sets.<sup>14</sup> <sup>15</sup> The measures that are recommended for addition need to meet criteria that include whether the measure has detailed technical specifications that enable production at the State-level or health home program level (as appropriate), and are available free of charge for State Medicaid and CHIP programs; and whether the measure has been tested or is currently in use by a State Medicaid or CHIP program.

<sup>13</sup> Annual Review and Selection Process: <https://www.medicaid.gov/medicaid/quality-of-care/downloads/annual-core-set-review.pdf>.

<sup>14</sup> Child and Adult Core Sets Annual Report: <https://www.mathematica.org/features/maccoresetreview>.

<sup>15</sup> Health Home Core Set Annual Review: <https://www.mathematica.org/features/hhcoresetreview>.

Measures that meet the criteria are presented for consideration at Workgroup meetings. A recommendation for addition or removal of a measure requires an affirmative vote from at least two-thirds of eligible Workgroup members. When making recommendations, the Workgroups are asked to balance a number of considerations including the technical feasibility of measures, the desirability of measures for Medicaid and CHIP interested parties, and the operational viability for States and to focus on measures that meet all of them. In considering whether a new measure would meet the needs of interested parties and provide meaningful feedback, the Workgroups may consider how a measure would contribute to estimating the overall national quality of health care in Medicaid and CHIP together with other Core Set measures, whether it would provide useful and actionable results to drive improvement in care delivery and health outcomes, and whether it would address a strategic performance measurement priority. Other considerations evaluated by the Workgroups include alignment with measures used by other CMS and HHS programs and whether the prevalence of the condition or outcome being measured will produce meaningful and reliable results across States or health home programs (for example, are there enough beneficiaries with a specific medical diagnosis to allow a State to report on measures related to that diagnosis without jeopardizing the privacy of individual beneficiaries).

Following each Workgroup meeting, a draft report summarizing the Workgroup recommendations is published for public comment. The public comments are then incorporated into the final report for each Workgroup, which is submitted to CMS.<sup>16</sup> CMS then reviews the final report and obtains additional input from other Federal programs and States regarding priority health topics, areas for future measure development, and measure alignment across programs wherever possible, before making a final decision on which recommendations to accept. CMS announces the annual updates through a CIB (a combined CIB for the Child and Adult Core Sets and a separate CIB for the section 1945 Health Home Core Set), which is also available on *Medicaid.gov*.

## 2. Strengthening Voluntary Reporting by States

State reporting on both the Child and Adult Core Sets under sections 1139A

<sup>16</sup> The public comment period for the Annual Workgroup report is 30 days.

and 1139B of the Act, respectively, and on the specific measures in the section 1945 Health Home Core Set, has been voluntary since the inception of these Core Set reporting programs. For almost a decade we have worked closely with every State to improve annual reporting of measures. The number of measures voluntarily reported to CMS has increased every year, with the majority of States now reporting on at least one measure from the Child and Adult Core Sets.

To effectuate meaningful quality improvement both within and across States, it is essential for States not only to report on the Core Sets measures, but to report on them in a clear and consistent manner. Sections 1139A(a)(4) and 1139B(b)(3) of the Act require the Secretary to develop a standardized format and reporting procedures for reporting of the Child and Adult Core Sets. Section 1945(g) of the Act provides that section 1945 health home providers must report quality measures to the State in accordance with such requirements as the Secretary shall specify. Section 1945(c)(4)(B) of the Act provides that the Secretary shall specify all applicable measures for quality reporting required under that provision. Section 1945A(g)(2)(A) of the Act provides that States with an approved section 1945A SPA must report certain information to the Secretary, including quality measures reported to the State under section 1945A(g)(1)(B) of the Act by section 1945A health home providers, in such form and manner determined by the Secretary to be reasonable and minimally burdensome. In addition, section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require.

Each year, we publish updated reporting guidance for the Child, Adult, and section 1945 Health Home Core Sets, which includes a summary of updates, as well as updated reporting tools, technical specifications and resource manual, data quality checklist, and measurement period table. However, considering the voluntary nature of State reporting, we have accepted reporting that does not comply with the reporting guidance, and we note in our annual reporting where States have deviated from measure specifications. After the section 1945A Health Home Core Set is developed, CMS also expects to provide annual updates and other information about this core set through annual reporting guidance.

We publicly report individual measures when 25 or more States report on that Child or Adult Core Sets measure using our published reporting guidance and the data meets standards for data quality. The first year of State reporting was FFY 2010 for the Child Core Set and FFY 2013 for the Adult Core Set. In the first year of Child Core Set reporting (FFY 2010), we publicly reported five measures. In FFY 2014, the first year of public reporting for the Adult Core Set, we reported 10 Adult Core Set measures and 19 Child Core Set measures. In the most recent reporting year (FFY 2020), 21 of the 24 Child Core Set measures and 28 of the 33 Adult Core Set measures met our threshold for public reporting of State-specific results.<sup>17 18</sup>

Despite these improvements, however, not all measures meet the public-reporting threshold of 25 States and, even those that do, remain unreported for many States. The average State is reporting 73 percent of Child Core Set and 67 percent of Adult Core Set measures, the median number of measures reported by States for FFY 2020 is 17.5 for the Child Core Set and 22 for the Adult Core Set. Several important measures remain completely unreported, such as Screening for Depression and Follow-Up Plan (on both the Child and Adult Core Sets). In addition, not all States adhere to the technical specifications for the measures developed by CMS, and most States do not report measures for all their beneficiaries. State variation in reporting has left some populations behind in quality improvement efforts and has made meaningful comparisons across States difficult.

As of June 2022, 19 States and D.C. have 34 different approved health home programs (that is, SPAs) targeting different populations. We publicly report all section 1945 Health Home measures voluntarily submitted by States, if they are reported by at least 15 section 1945 health home programs using our published reporting guidance and the data meets standards for data quality, following data suppression rules when applicable. Of the 37 health home programs on which CMS

encouraged States to report the section 1945 Health Home Core Set measures for FFY 2020 based on program effective date, States voluntarily reported at least one measure for 34 of those programs.<sup>19</sup> For each reporting cycle since FFY 2017, both the number of health home programs that CMS encouraged States to report on and the number of health home programs for which States voluntarily reported at least one section 1945 Health Home Core Set measure have increased. In the most recent reporting data available, FFY 2020, the median number of measures reported by States were 9 (of 12) measures for the section 1945 Health Home Core Set. One example of information ascertained from voluntary Health Home Core Set reporting is that emergency department visits decreased significantly between FFY 2017 and FFY 2020 on the “Ages 18 to 64” rate, the “Age 65 and older” rate, and the total rate among those States that reported these rates all three years, representing better performance because lower rates are better on this measure.

This data collection and reporting process is a critical foundation to driving improvement in the quality of care for Medicaid and CHIP beneficiaries, and we have worked extensively with States to encourage the use of Core Sets measure results to improve the quality of care delivered to their beneficiaries. We provide ongoing technical assistance to States to improve measure reporting, measure performance, quality of care delivered to beneficiaries, and the use of measures to gauge the effectiveness of quality improvement efforts. One-on-one technical assistance is offered directly to States, and CMS regularly hosts webinars and learning collaboratives in specific quality areas, such as oral health care, maternal and infant health, behavioral health, primary care and prevention, and care of chronic conditions. Through learning collaboratives, State Medicaid and CHIP agencies and their State partners have the opportunity to expand their knowledge of evidence-based interventions; improve their ability to conduct quality improvement projects; and engage in State-to-State learning on topics identified by States and other interested parties as most critical to

<sup>17</sup> Child Core Set Reporting: <https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/childrens-health-care-quality-measures/index.html>.

<sup>18</sup> Adult Core Set Reporting: <https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/adult-health-care-quality-measures/index.html>.

<sup>19</sup> Section 1945 health home programs that have been in effect and implemented for a minimum of 6 months are encouraged to report on the 1945 Health Home Core Set annually to CMS.

servicing their beneficiaries, including asthma, oral health, and maternal and infant health.<sup>20 21 22 23</sup> Core Sets reporting is also used to develop CMS's Medicaid and CHIP Scorecard; to measure the quality of care authorized through State section 1115 demonstration projects and Center for Medicare and Medicaid Innovation models focused on Medicaid; and in Medicaid managed care quality work to monitor plans' performance and drive improvement.<sup>24 25</sup>

#### *D. Shifting From Voluntary to Mandatory Reporting*

In 2018, two bills were signed into law that mandate State reporting of the Child Core Set and the behavioral health measures on the Adult Core Set. These laws help address the limitations of voluntary reporting and significantly strengthen the ability of the Core Sets to drive quality improvements for Medicaid and CHIP beneficiaries nationwide.

First, section 50102(b) of the Bipartisan Budget Act of 2018 added a new subparagraph (B) to section 1139A(a)(4) of the Act to mandate annual reporting of the Child Core Set beginning with the annual State report on fiscal year 2024. Specifically, section 1139A(a)(4)(B) of the Act states that beginning with the annual State report on fiscal year 2024, the Secretary shall require States to use the initial core measurement set and any updates or changes to that set to report information regarding the quality of pediatric health care under titles XIX and XXI. Additionally, section 1139A(a)(4)(B) of the Act requires, once mandatory reporting begins, that States submit such information using the standardized format for reporting information and procedures developed by CMS in consultation with States in accordance with section 1139A(a)(4)(A) of the Act.

Second, the SUPPORT Act, added a new subparagraph (B) to section 1139B(b)(3) of the Act, to make mandatory the annual reporting of behavioral health measures in the Adult Core Set. The SUPPORT Act requirement also becomes effective beginning with the annual State report on fiscal year 2024. Per section 1139B(b)(3)(B) of the Act, States are required to report on all behavioral health measures included in the core set of adult health quality measures and any updates or changes to such measures, and as with the Child Core Set, reporting of the behavioral health measures must be submitted using the standardized format for reporting information and procedures developed by CMS in consultation with States.

As discussed previously in this proposed rule, section 1945 of the Act, as initially enacted in 2010, required section 1945 health home providers to report information to States about implementation of the section 1945 health home benefit, but did not require States to submit reports to CMS about implementation of the section 1945 health home benefit. In 2018, the SUPPORT Act made State reporting of certain information about certain SUD-focused section 1945 health homes mandatory. Section 1945A of the Act also requires certain State reporting for that health home benefit. As discussed previously in this proposed rule, we are now proposing to require States that have opted to implement the section 1945 or section 1945A health home benefit to report to the Secretary on any measures identified by the Secretary through guidance as mandatory in either a section 1945 Health Home Core Set or a new section 1945A Health Home Core Set, or both (depending on which health home benefit(s) the State has elected to implement). The section 1945 Health Home Core Set would include measures that are required for State reporting under section 1945(c)(4)(B) of the Act for certain SUD-focused health homes. To enable States to provide these reports to CMS, we are also proposing to require States to require their health home providers to report on these measures to the State. These requirements would be authorized under section 1902(a)(6) of the Act, section 1945(c)(4)(B) and (g) of the Act, and section 1945A(g) of the Act, as discussed previously in this proposed rule. By establishing requirements for reporting on both Health Home Core Sets concurrently with the requirements for reporting on the Child and behavioral health measures in the Adult Core Sets, we can significantly improve alignment between the measures under

all these quality reporting programs and ensure that States do not have to navigate multiple reporting processes and standards for these measures.

## **II. Provisions of the Proposed Rule**

### *A. Basis, Scope, Purpose and Applicability*

This proposed rule would implement sections 1139A and 1139B of the Act, as amended, which set forth requirements for mandatory reporting on a core set of measures which assess the quality of care provided to child beneficiaries in Medicaid and CHIP and the quality of behavioral health care for Medicaid eligible adults. In Medicaid, the Adult and Child Core Set proposals are also authorized under section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require. This proposed rule would help to fulfill the Secretary's obligation to establish and update a Child Core Set and Adult Core Set and to establish a standardized format and reporting procedures for States to use when reporting on these Core Sets and to publicly report this data. The proposals for the Health Home Core sets would implement sections 1902(a)(6), 1945(c)(4)(B), 1945(g), and 1945A(g) of the Act, which require or (in the case of section 1902(a)(6) of the Act) authorize the Secretary to require State reporting of health home quality measures and to set form and manner requirements for that reporting, and which also give the Secretary the authority to require States to require their health home providers to report on the same measures. The proposed rule would establish requirements for section 1945 health home quality measure reporting by providers, consistent with section 1945(g) of the Act, and would establish a process through which the Secretary would establish the form and manner of State reporting to CMS on section 1945A health home quality measures under section 1945A(g)(2)(A)(i) of the Act. Proposed § 437.1(a) and (b) would set forth the basis and scope for these proposed requirements. The proposed rule would also set forth the process through which CMS would develop and update the Child Core Set, Adult Core Set, and the Health Home Core Sets (sections 1945 and 1945A) and the process through which CMS would establish requirements that State agencies would have to meet when reporting on the measures included in these Core Sets.

The Child, Adult, and both Health Home Core Sets have tremendous

<sup>20</sup> Quality Improvement Initiatives: <https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/index.html>.

<sup>21</sup> Asthma Learning Collaborative: <https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/improving-asthma-control-learning-collaborative/index.html>.

<sup>22</sup> Oral Health Learning Collaborative: <https://www.medicaid.gov/medicaid/quality-of-care/improvement-initiatives/advancing-prevention-and-reducing-childhood-carries-medicaid-and-chip-learning-collaborative/index.html>.

<sup>23</sup> Maternal and Infant Health Quality Initiative: <https://www.medicaid.gov/medicaid/quality-of-care/improvement-initiatives/maternal-infant-health-care-quality/index.html>.

<sup>24</sup> Scorecard: <https://www.medicaid.gov/state-views/scorecard/state-health-system-performance/index.html>.

<sup>25</sup> Medicaid Managed Care Quality: <https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care-quality/index.html>.

potential to assist States in monitoring and improving the quality of care provided to Medicaid and CHIP beneficiaries. As States see the actual impacts of the care provided to their beneficiaries and to compare the health outcomes of their beneficiaries to the outcomes achieved in other States, and for other Health Homes programs, their successes and the areas in which they need to improve will become clearer. As certain Medicaid and CHIP programs begin to stand out as models of care in specific areas, other States will be able to learn from them and adopt new models that are likely to improve the quality of care provided to their beneficiaries as well. With this in mind, we propose at § 437.1(c)(1) to establish the purpose of the Child and Adult Core Sets. The purpose of the Medicaid and CHIP Child Core Set and the Medicaid Adult Core Set is to measure the overall national quality of care for beneficiaries, monitor performance at the State-level, and improve the quality of health care. At § 437.1(c)(2), we propose to establish the purpose of the section 1945 and section 1945A Health Home Core Sets. The purpose of these Core Sets is to measure the overall program quality of health home services for Medicaid beneficiaries enrolled in a health home program under section 1945 or 1945A of the Act, monitor the impact of these optional State plan benefits, monitor performance of these benefits at the program level, and improve the quality of health care. We believe these stated purposes would set a high bar for effective measurement of the quality of health care provided to millions of Americans every year and that resulting improvements in the health and well-being of Medicaid and CHIP beneficiaries would lead to better health for the entire nation.

Applicability of the provisions in subpart A of part 437 differs based on the statutory basis for the Core Set reporting. The requirements for the Child and Adult Core Sets are described in Title XI of the Act, while the requirements for the Health Home Core Sets are described in Title XIX of the Act, and for purposes of section 1945A of the Act should include, to the extent applicable, child health quality measures and measures for centers of excellence for children with complex needs developed under Titles XIX and XXI and section 1139A of the Act. Section 1101(a)(1) of the Act defines a State, for purposes of Title XI, to include D.C., the Commonwealth of Puerto Rico, the Virgin Islands, and Guam. For purposes of Title XIX, American Samoa and the Mariana

Islands are also included in the definition of State under section 1101(a) of the Act. Therefore, we propose at § 437.1(d)(1) that the requirements for Child and Adult Core Sets reporting would apply to the 50 States, D.C., Puerto Rico, the Virgin Islands, and Guam; and throughout the proposed rule the term “States” is used to reflect these entities when CMS is referring to the Child and Adult Core Sets. American Samoa and the Mariana Islands could, but would not be required to, report Child and Adult Core Sets measures. We propose at § 437.1(d)(2) that the requirement for reporting on one or both of the Health Home Core Sets would apply to any State (as defined under section 1101 of the Act for purposes of Title XIX) with an approved Medicaid Health Home SPA under section 1945 or 1945A of the Act. When CMS refers to a “State” when discussing the Health Home Core Sets in this proposed rule, this is the definition that CMS means. States that implement the section 1945 health home benefit would report on the section 1945 Health Home Core Set, States that implement the section 1945A health home benefit would report on the section 1945A Health Home Core Set, and States that implement both benefits would report on both Health Home Core Sets. For all Child, Adult, and Health Home Core Sets measures, proposed § 437.1(e) would provide that the requirements in subpart A apply no later than State reporting on the 2024 Core Sets by December 31, 2024.

### B. Definitions

Proposed § 437.5 would establish definitions related to quality measurement and reporting. We propose to define the terms “Child Core Set,” “Adult Core Set,” “Core Sets,” “Health Home Core Sets,” “1945 Health Home Core Set,” and “1945A Health Home Core Set,” to include the health care quality measures established and updated annually by the Secretary through subregulatory guidance, as described in proposed § 437.10(a) and discussed in section I.C.1. of this proposed rule.

We also propose to define “behavioral health,” and “behavioral health measure” at § 437.5. Section 1139B(b)(5)(C) of the Act requires States to report on all behavioral health measures included in the core set of adult health quality measures and any updates or changes to such measures.<sup>26</sup>

<sup>26</sup> Section 1139B of the Act: [https://www.ssa.gov/OP\\_Home/ssact/title11/1139B.htm](https://www.ssa.gov/OP_Home/ssact/title11/1139B.htm), Public Law 115–271, section 5001, amended paragraph (3) to include subparagraph (B). Effective October 24, 2018.

However, the statute does not define “behavioral health” or “behavioral health measures.” We currently do not have a definition of behavioral health for use in the Adult Core Set for voluntary reporting and not all measures that are relevant to behavioral health are included in the behavioral health domain of the Adult Core Set, because such measures span multiple domains. For example, the “Screening for Depression and Follow-up Plan” measure is in the “Primary Care Access and Preventative Care” domain on the Adult Core Set because it is provided in the primary care setting. However, we believe this is clearly a behavioral health measure as well.

While the definitions differ slightly, other Department of Health & Human Services (HHS) agencies generally define behavioral health as including mental health and the identification of and treatment for SUD. In its criteria for certification of Certified Community Behavioral Health Clinics, SAMHSA defines behavioral health as “the promotion of mental health, resilience and wellbeing; the treatment of mental and substance use disorders; and the support of those who experience and/or are in recovery from these conditions, along with their families and communities.”<sup>27</sup> The Public Health Service Act (Pub. L. 78–410) requires health centers under the Health Resources & Services Administration’s (HRSA) Bureau of Primary Health Care to provide additional health services . . . including (A) behavioral and mental health and substance use disorder services.<sup>28</sup> The Indian Health Care Improvement Act, the underlying authority for the Indian Health Service (IHS) provides, “(A) In general the term “behavioral health” means the blending of substance (alcohol, drugs, inhalants, and tobacco) abuse and mental health disorders prevention and treatment for the purpose of providing comprehensive services.”<sup>29</sup>

The only CMS regulation that currently defines “behavioral health” can be found in the requirements for long term care facilities at § 483.40, relating to the conditions of participation for skilled nursing facilities participating in Medicare and nursing facilities participating in

<sup>27</sup> Definition of behavioral health for Certified Community Behavioral Health Clinics: [https://www.samhsa.gov/sites/default/files/programs\\_campaigns/ccbhc-criteria.pdf](https://www.samhsa.gov/sites/default/files/programs_campaigns/ccbhc-criteria.pdf).

<sup>28</sup> Health Center Program Statute: Section 330 of the Public Health Service Act (42 U.S.C. 254b).

<sup>29</sup> Indian Health Services statute: 25 U.S.C. 1603 (2): [https://www.law.cornell.edu/uscode/text/25/1603#2\\_A](https://www.law.cornell.edu/uscode/text/25/1603#2_A), <https://www.govinfo.gov/content/pkg/USCODE-2011-title25/pdf/USCODE-2011-title25-chap18.pdf>.

Medicaid. This regulation defines “behavioral health” as encompassing a resident’s whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders. CMS resources for behavioral health of American Indians and Alaska Natives similarly explain that, “Behavioral health includes the emotions and behaviors that affect your overall well-being. Behavioral health is sometimes called mental health and often includes substance use.”<sup>30</sup>

While few programs appear to have formal definitions codified in statute, regulations or otherwise, there appears to be a general consensus that behavioral health services include services to address mental health conditions as well as SUDs. Some extend further to embrace psychological or emotional well-being. As such, at § 437.5, we propose definitions of “behavioral health” and “behavioral health measure” for purposes of quality reporting by Medicaid and CHIP agencies that are derived from the definition at § 483.40. We propose to define “behavioral health” as a beneficiary’s whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental disorders and substance use disorders. A “behavioral health measure” would be defined as a quality measure that could be used to evaluate the quality of and improve the health care provided to beneficiaries with, or at-risk for a behavioral health disorder(s).

### C. The Child, Adult, and Health Home Core Sets

As discussed in section I.A. of this proposed rule, the Secretary published the initial Child and Adult Core Sets in 2009 and 2012 respectively. These initial core sets were developed with input from States and interested parties and comments from the public. The first updates to the Core Sets were published in 2013 (Child Core Set) and 2014 (Adult Core Set). After receiving input from States and other interested parties, CMS has updated the Core Sets annually through a CIB.

The section 1945 Health Home Core Set was initially introduced in 2013, in SMD letter #13–001. Prior to the 2021 implementation of the Health Home Annual Review Workgroup process, CMS updated the 1945 Health Home Core Set annually through a web posting, based on agency wide efforts to

align quality measures across CMS programs.<sup>31</sup> Currently, updates to the 1945 Health Home Core Set are conducted through an Annual Review Workgroup process that aligns with how similar workgroups are used to develop updates to the Child and Adult Core Set. Annual updates to the 1945 Health Home Core Set are currently developed through the Health Home Annual Review Workgroup review process and CMS releases the updates through a CIB. CMS anticipates developing and updating the section 1945A Health Home Core Set through this same workgroup process.

In revising sections 1139A and 1139B of the Act to require State reporting on the Child Core Set and behavioral health measures on the Adult Core Set, neither CHIPRA nor the SUPPORT Act altered the statutory requirements regarding the annual updates to the Core Sets described in section I.C. of this proposed rule. As such, we propose at § 437.10(a)(1) that we continue the existing annual process of identifying and updating the child health quality measures and adult health quality measures to be included in the Child and Adult Core Sets. We also propose to apply this annual process when identifying and updating the health home quality measures to be included in both Health Home Core Sets.

At § 437.10(a)(2), we propose that the Secretary consult annually with States and other interested parties identified in paragraph § 437.10(e) to establish priorities for the development and advancement of the Child, Adult, and both Health Home Core Sets; to identify any gaps in the measures included in each Core Set; to identify measures which should be removed because they no longer strengthen the Core Sets; and to ensure that all measures included in the Core Sets reflect an evidence-based process (including testing, validation, and consensus among interested parties), are meaningful for States, are feasible for State-level and/or health-home program level reporting as appropriate, and represent minimal additional burden to States.

#### 1. Annual Reporting Guidance

As discussed in section I.C.2. of this proposed rule, sections 1139A(a)(4) and 1139B(b)(3) of the Act require States to use the standardized format and procedures established by the Secretary

when reporting on the Child and Adult Core Sets. In addition, section 1945(g) of the Act provides that reporting by section 1945 health home providers to the State on quality measures must be in accordance with such requirements as the Secretary shall specify. Section 1945(c)(4)(B) of the Act provides that the Secretary shall specify all applicable quality measures that certain States with SUD-focused section 1945 health homes must report under that provision. Section 1945A(g)(2)(A) of the Act provides that States with an approved section 1945A SPA must report certain information to the Secretary, including quality measures reported to the State by section 1945A health home providers, in such form and manner determined by the Secretary to be reasonable and minimally burdensome. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. At proposed § 437.10(a)(3), we propose that the Secretary would develop and annually update reporting guidance needed by States to report on all Core Sets on which States would be required to report under this proposed rule.

Providing States with clear and detailed guidance for reporting on measures in the Core Sets is essential to facilitating consistent reporting across States. Only with consistent, accurate reporting from States can we conduct meaningful analysis of quality measures, make comparisons across States, and support more effective quality improvement. Proposed § 437.10(b) describes the components of the annual reporting guidance to be issued by CMS.

As described at § 437.10(b)(1), the first part of the reporting guidance would be the identification of quality measures in the Child Core Set, Adult Core Set, and the two Health Home Core Sets.<sup>32</sup> As described in proposed § 437.10(b)(1)(i) through (v), this would include: measures newly added to the Core Sets and measures removed from the prior year’s Core Sets; measures included in the Adult Core Set that are identified as behavioral health measures; the specific Core Sets measures for which reporting is mandatory for the Child, Adult, and both Health Home Core Sets; the measures for which the Secretary would

<sup>30</sup> <https://www.cms.gov/outreach-education/american-indianalaska-native/aian-behavioral-health>.

<sup>31</sup> See, for example, Meaningful Measures: <https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization>. <https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization>.

<sup>32</sup> Core Set Measure lists are available at <https://www.medicare.gov/medicaid/quality-of-care/index.html>.

complete reporting on behalf of States; and the measures for which States may elect to have the Secretary report on their behalf (see additional discussion in section II.D. of this proposed rule); as well as the measures (if any) for which the Secretary would provide States with additional time to report, along with the amount of additional time that would be provided.

The second part of the reporting guidance, described at proposed § 437.10(b)(2) through (b)(7), would specify the form and manner requirements for reporting. This includes information on how to collect and calculate the data on the Core Sets (§ 437.10(b)(2)) and the standardized format and procedures for reporting Core Sets measure data (§ 437.10(b)(3) and (4)).

As described at proposed § 437.10(b)(5) and (6), the reporting guidance would also identify the populations for which States must report on each measure and the attribution rules for reporting on beneficiaries who are included in more than one population during the reporting period. Proposed § 437.10(b)(5) specifically notes three types of populations about which the Secretary would provide guidance: (1) beneficiaries receiving services through specified delivery systems (such as managed care or fee-for-service (FFS)), (2) beneficiaries receiving care through specified health care settings and/or provider types, and (3) beneficiaries who are dually eligible for Medicare and Medicaid. See additional discussion of this proposal in section II.D.3. of this proposed rule. We anticipate that, for State reporting on the Adult and Child Core Sets, the guidance on attribution rules described at proposed § 437.10(b)(6), would call for inclusion in quality reporting based on a beneficiary's continuous enrollment in Medicaid and CHIP. This would ensure that the State has enough time to render services during the measurement period and would be based on a beneficiary's enrollment date in Medicaid and CHIP (not inclusive of retroactive eligibility). In the guidance, we anticipate that we would set attribution rules to address transitions between Medicaid and CHIP or between different Medicaid eligibility groups, delivery systems, managed care plan assignment, etc. within a reporting year, for example, based on the length of time the child or adult was enrolled in each. For State reporting on the section 1945 and section 1945A Health Home Core Sets, we anticipate that the guidance on attribution rules described

at proposed § 437.10(b)(6) would call for inclusion in quality reporting based both on a beneficiary's continuous enrollment in Medicaid and their enrollment in an approved health home program. States would be expected to report on the applicable Health Home Core Set(s) when the applicable approved health home program has been in effect and implemented for 6 or more months of the measurement period (see discussion of proposed § 437.15 below). If a State has recently changed or expanded an existing health home program through a SPA, we anticipate that it would be expected to include data related to the changed or expanded program with data from the original (that is, unchanged or unexpanded) health home program when the SPA has been in effect and implemented for 6 or more months of the measurement period.

As described at proposed § 437.10(b)(7), the reporting guidance would also provide information on the stratification of certain measures by factors such as race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary. Core Sets data stratification would be consistent with the statutory requirements outlined in section 1139A(b)(2) of the Act and the goals of the Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.<sup>33</sup> At proposed § 437.10(d), we propose that in specifying the measures for which data must be stratified and the factors by which such data must be stratified, the Secretary shall take into account whether stratification can be accomplished based on valid statistical methods and without risking a violation of beneficiary privacy and, for measures obtained from surveys, whether the original survey instrument collects the variables necessary to stratify in the measures, and such other factors as the Secretary determines appropriate.

Proposed § 437.10(c) would provide the Secretary with discretion to provide a phase-in period for mandatory reporting of certain measures and certain populations for all the Core Sets. This phase-in is discussed in more detail in sections II.D.2. and II.D.3. of this proposed rule.

## 2. Advancing Health Equity Through Data Stratification

Measuring and reporting health disparities is a cornerstone of CMS's approach to advancing health equity. Stratification of Child and Adult Core

Sets data (sections 1139A and 1139B of the Act) and of data from the two Health Home Core Sets (sections 1945 and 1945A of the Act) is key to identifying health disparities among Medicaid and CHIP beneficiaries regarding those measures. Stratified data would allow us to monitor health outcomes for disparities between groups of patients who may have different determinants of health.<sup>34 35 36 37</sup> These determinants of health include access to timely, high quality health care in addition to other social determinants of health such as a home environment that promotes health, and access to transportation and nutritious foods.<sup>38 39 40</sup> Without this stratified data, disparities in health outcomes may be hidden, limiting opportunities for interventions to improve health outcomes and reduce health inequity.<sup>41 42 43</sup>

<sup>34</sup> Racism and Health. Centers for Disease Control. <https://www.cdc.gov/healthequity/racism-disparities/index.html>.

<sup>35</sup> Improving Data Collection across the Health Care System. Content last reviewed May 2018. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/research/findings/final-reports/iomracereport/reldata5.html>.

<sup>36</sup> Berg S. Improve health equity by collecting patient demographic data. American Medical Association. 2018. <https://www.ama-assn.org/delivering-care/population-care/improve-health-equity-collecting-patient-demographic-data>.

<sup>37</sup> Dorsey R., Graham G., Glied S., Meyers D., Clancy C., Koh H. Implementing Health Reform: Improved Data Collection and the Monitoring of Health Disparities. *Annual Review of Public Health* 2014 35:1, 123–138. <https://www.annualreviews.org/doi/full/10.1146/annurevpublhealth-032013-182423>.

<sup>38</sup> Social Determinants of Health. *Healthy People 2030*. <https://health.gov/healthypeople/objectives-and-data/social-determinants-health>.

<sup>39</sup> CMS, State Health Official Letter #21–001, Opportunities in Medicaid and CHIP to Address Social Determinants of Health, Jan 7 2021. <https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf>.

<sup>40</sup> Hood, C., Gennuso K., Swain G., Catlin B. (2016). County Health Rankings: Relationships Between Determinant Factors and Health Outcomes. *Am J Prev Med*. 50(2):129–135. doi:10.1016/j.amepre.2015.08.02.

<sup>41</sup> Bhalla R., Yongue B.G., Currie B.P. Standardizing Race, Ethnicity, and Preferred Language Data Collection in Hospital Information Systems: Results and Implications for Healthcare Delivery and Policy. *Journal for Healthcare Quality*. 2012;34(2):44–52. doi: <https://doi.org/10.1111/j.1945-1474.2011.00180.x>.

<sup>42</sup> Office of the Assistant Secretary for Planning and Evaluation, Building the Evidence Base for Social Determinants of Health Interventions, Sep 23 2021. <https://aspe.hhs.gov/reports/building-evidence-base-social-determinants-health-interventions>.

<sup>43</sup> CMS Office of Minority Health. (Updated August 2018). Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. [https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH\\_Readmissions\\_Guide.pdf](https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf).

This approach to data reporting and stratification is aligned with Executive Order 13985, which calls for advancing equity for underserved populations.<sup>44</sup> Stratified data would enable CMS and States to identify the health outcomes of those underserved populations and potential differences in health outcomes between such populations in these measures. By providing data pertaining to health outcomes for specific underserved populations, this proposal also aligns with the CMS Strategic Priorities.<sup>45 46</sup>

Therefore, we propose at § 437.10(b)(7) that the annual reporting guidance would identify the measures in the Child Core Set, the measures among the behavioral health measures of Adult Core Set, and the measures in the Health Homes Core Sets that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary, and that this set of measures would be informed by annual consultation with States and other interested parties in accordance with proposed § 437.10(a)(2) and (d). We considered giving States the flexibility to choose which measures they would stratify and by what factors; however, more consistent measurement of differences in health outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation those interventions.<sup>47</sup> This consistency could not be achieved if each State made its own decisions about which data it would stratify and by what factors.<sup>48 49</sup>

We believe that this proposed stratification of data in the Child Core Set, Adult Core Set, and Health Homes Core Sets measures would be consistent with our statutory authorities. Regarding

the Child Core Set, section 1139A(b)(2)(B) of the Act specifies that measures under the pediatric quality measures program shall be designed to identify and eliminate racial and ethnic disparities in child health and the provision of health care. In addition, section 1139A(a)(3)(D) of the Act required that the initial Child Core Set contain the types of measures that, taken together, can be used to estimate the overall national quality of health care for children, including children with special needs, and to perform comparative analyses of pediatric health care quality and racial, ethnic, and socioeconomic disparities in child health and health care for children. Regarding the Adult Core Set, section 1139B(a) of the Act requires the Secretary to utilize similar parameters for establishing the Adult Core Set. Additionally, section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, authorizes us to require stratification of the data that States report to CMS. Regarding the Health Home Core Sets, in addition to the authority provided by section 1902(a)(6) of the Act, section 1945(g) of the Act requires section 1945 health home services providers to report to the State, in accordance with such requirements as the Secretary shall specify, on all applicable measures for determining the quality of such services. Section 1945A(g)(2)(A)(i) of the Act requires States implementing the section 1945A health home benefit to submit to the Secretary, in such form and manner determined by the Secretary to be reasonable and minimally burdensome, all section 1945A quality reporting data that was submitted to them under section 1945A(g)(1) of the Act, and the information providers report to the State under section 1945A(g)(1)(B) of the Act includes, to the extent applicable, child health quality measures developed under section 1139A of the Act.

We recognize that States may be constrained in their ability to stratify Core Sets measures and that data stratification would require additional State resources. There are several challenges to stratification of measure reporting. First, the validity of stratification is threatened when the demographic data are incomplete. Complete demographic information is often unavailable to CMS and States due to several factors, including the fact that Medicaid and CHIP applicants and beneficiaries are not required to provide race and ethnicity data. Second, when

States with smaller populations and/or that are more homogeneous stratify data, it may be possible to identify individual data because there are fewer individuals in each demographic category, raising privacy concerns. Therefore, if the sample sizes are too small, the data would be suppressed, in accordance with the CMS Cell Size Suppression Policy and the data suppression policies for associated measure stewards, and therefore, not publicly reported to avoid a potential violation of privacy.<sup>50</sup>

CMS's ability to stratify measures for which it is able to report on behalf of States will be dependent on whether the original dataset or survey instrument (1) collects the demographic information or other variables needed and (2) has a large enough sample size. There may be opportunities to supplement missing information to allow additional stratification, for example, using techniques such as "geocoding" that can be used to impute values for the stratification variables to the reported data. The Transformed Medicaid Statistical Information System (T-MSIS), for example, currently has the capability to stratify some Core Sets measures by sex and urban/rural status, but not by race, ethnicity, or disability status. This is because applicants provide information on sex and urban/rural address, which is reported to T-MSIS by States, whereas applicants are not required to provide information on their race and ethnicity or disability status, and often do not do so. However, CMS is developing the capacity to impute race and ethnicity from claims based on the name and home address of the beneficiary, and anticipates being able to stratify by race and ethnicity, urban/rural status, and sex by the end of 2022. While complete demographic information for beneficiaries would always be preferable to using imputed model values, reliable techniques to impute values is a substitute to enable identification and analysis of health disparities.

With these challenges in mind, we propose at § 437.10(d) that stratification of State reporting of Core Set data would be implemented through a phased-in approach in which the Secretary would specify, through the annual reporting guidance, which measures and by which factors States must stratify reported measures consistent with § 437.10(b)(7). The Secretary would take into account whether stratification can be accomplished based on valid statistical methods and without risking

<sup>44</sup> Executive Order 13985: <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

<sup>45</sup> CMS Framework for Health Equity 2022–2032: <https://www.cms.gov/files/document/cms-framework-health-equity.pdf>.

<sup>46</sup> CMS Strategic Plan 2022: <https://www.cms.gov/cms-strategic-plan>.

<sup>47</sup> Schlotthauer A.E., Badler A., Cook S.C., Perez D.J., Chin M.H. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. *Health Aff (Millwood)*. 2008;27(2):568–573.

<sup>48</sup> Centers for Medicare & Medicaid Services (CMS) Office of Minority Health (OMH). *Stratified Reporting, 2022*; <https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting>.

<sup>49</sup> National Quality Forum. *A Roadmap for Promoting Health Equity and Eliminating Disparities*. Sep 2017. [https://www.qualityforum.org/Publications/2017/09/A\\_Roadmap\\_for\\_Promoting\\_Health\\_Equity\\_and\\_Eliminating\\_Disparities\\_The\\_Four\\_I\\_s\\_for\\_Health\\_Equity.aspx](https://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities_The_Four_I_s_for_Health_Equity.aspx).

<sup>50</sup> CMS Cell Size Suppression Policy, Issued 2020: <https://www.hhs.gov/guidance/document/cms-cell-suppression-policy>.

a violation of beneficiary privacy and, for measures obtained from surveys, whether the original survey instrument collects the variables necessary to stratify the measures, and such other factors as the Secretary determines appropriate. States would be required to submit stratified data for 25 percent of the measures on each of the Core Sets (the Child Core Set, behavioral health measures within the Adult Core Set, and Health Homes Core Sets) for which the Secretary has specified that reporting should be stratified by the second year of annual reporting after the effective date of the final rule; 50 percent of measures for the third and fourth years of annual reporting after the effective date of the final rule; and 100 percent of measures beginning in the fifth year of annual reporting after the effective date of the final rule, on all factors, as specified by the Secretary pursuant to proposed § 437.10(b)(7) such as race and ethnicity, sex, age, rural/urban, disability and language.

We have determined that this proposed phased-in approach to data stratification would be reasonable and minimally burdensome, and thus consistent with section 1945A(g)(2)(A) of the Act, because we are balancing the importance of being able to identify differences in health outcomes between populations under these measures with the potential operational challenges that States may face in implementing these proposed requirements.

We considered other timelines for phasing in mandatory stratification of the Child Core Set, behavioral health measures on the Adult Core Set, and Health Homes Core Sets from as short as 1 year to 7 years, or up to 10 years. We are seeking to balance the changes needed to implement this new requirement with the urgent need to collect stratified data related to health care disparities. We determined that a shorter phase-in period for stratified reporting of the measures identified by the Secretary within the Child Core Set, behavioral health measures on the Adult Core Set, and Health Homes Core Sets, such as between 1 and 4 years, would not likely be operationally feasible and practicable because of the potential systems and contracting changes that States may be required to make in order to collect this data, but allowing implementation to extend beyond 5 years would delay the reporting of stratified data for Core Set measures much longer than would be necessary and would delay the time in which information about health disparities across these measures would be available for analysis. In addition, CMS anticipates that States will not need

more than 5 years to implement systems and contracting changes, or any additional support needed to report stratified data. We seek comment on whether 5 years is sufficient for phasing in required stratification of the Child Core Set, behavioral health measures of Adult Core Set, and Health Homes Core Sets, and whether States, providers, and other interested parties would need more, or less, time.

We would provide technical assistance to assist States in improving their ability to collect the information required to allow for valid stratification. In Medicaid, enhanced Federal Financial Participation (FFP) is available at 90 percent for the design, development, installation, or enhancement of mechanized claims processing and information retrieval systems, and 75 percent enhanced FFP is available for operations of such systems, in accordance with applicable Federal requirements.<sup>51</sup> Receipt of these enhanced Federal Medicaid matching funds is conditioned upon States meeting a series of standards and conditions.<sup>52</sup> Additionally, under section 1903(a)(3)(A)(iii) of the Act, the FFP for State expenditures on systems development or modifications necessary for efficient collection and reporting on the Child Core Set is at the State's FMAP under section 1905(b) of the Act. To the extent these system costs are attributable to a State's CHIP (Medicaid Expansion CHIP (MCHIP), or separate CHIP), cost-allocation methodologies set forth in 45 CFR part 75 apply. For the CHIP-funded portion of the cost, States can claim at a State's CHIP enhanced FMAP (EMAP) available under section 2105(b) of the Act. CHIP administrative funding is limited to 10 percent of either a State's total computable allotments for a fiscal year or its total expenditures reported for a fiscal year, whichever is lower.<sup>53</sup>

In addition to the factors discussed above, we are considering whether the annual reporting guidance would require States to also stratify data based on delivery system for the Child Core Set and behavioral health measures on the Adult Core Set. If we did require this, States would be required to identify whether a beneficiary received services on a FFS basis versus or through a managed care organization, including stratifying by health plan. This reporting would allow States to compare the differences in care

provided to beneficiaries through different delivery mechanisms, and identify more focused interventions and policies to improve care. Given this benefit, CMS would like to include delivery system among stratification factors if feasible. However, due to the smaller sample size that generally would be reported for section 1945 and section 1945A health home programs, we are not considering requiring stratification of data based on delivery system for the Health Home Core Sets, as doing so would likely result in data suppression.

We seek comment on the feasibility and the potential burden of requiring stratification through the guidance that would be issued under proposed § 437.10(b)(7) based on delivery system, health plan, and population subgroup for the Child and Adult Core Sets and by population subgroup for both the section 1945 and section 1945A Health Home Core Sets. In addition, we seek comment on the potential burden of stratified measure reporting by race, ethnicity, and other demographic factors, as well as on the technical assistance that would be needed to support stratified State reporting.

#### *D. Annual Reporting on the Child, Adult, and Health Home Core Sets*

At proposed § 437.15, we propose the key requirements and procedures for States in the reporting of both mandatory and voluntary measures. At § 437.15(a)(1)(i), we propose to require States to report annually, by December 31st, on the measures in the Child Core Set and the behavioral health measures in the Adult Core Set that are identified by the Secretary pursuant to proposed § 437.10(b)(1)(iii). Proposed § 437.15(a)(1)(ii) would require States to report annually, by December 31st, on all measures in the 1945 or 1945A Health Home Core Sets (as applicable) that are identified by the Secretary pursuant to § 437.10(b)(1)(iii), if the State has elected to offer health home services under the State plan under section 1945 or section 1945A of the Act, and if the applicable health home program has an effective date and has been implemented more than 6 months prior to the December 31st reporting deadline. Proposed § 437.15(a)(1)(iii) provides that reporting of all Adult and Health Home Core Sets measures not identified as mandatory by the Secretary pursuant to § 437.10(b)(1)(iii) would be optional (but CMS anticipates that it would strongly encourage States to report on these measures). Other exceptions to these mandatory reporting requirements are proposed at

<sup>51</sup> See Section 1903(a)(3)(A)(i) and (B) of the Act, § 433.15(b)(3) and (4), and subpart C of part 433.

<sup>52</sup> 42 CFR 433.112(b)(1) through (22) and 42 CFR 433.116.

<sup>53</sup> See 42 CFR 457.618(e)(1).

§ 437.15(a)(4) and discussed in sections II.D.2. and II.D.3. of this proposed rule.

As described at proposed

§ 437.15(a)(2), certain measures would be reported by CMS on behalf of States. We currently report measures such as Live Births Weighing Less Than 2,500 Grams and Low-Risk Cesarean Delivery on behalf of States. As noted above, and as specified at proposed

§ 437.10(b)(1)(iv), our annual reporting guidance would identify the measures for which we would complete annual reporting on behalf of States and the measures for which States may elect to have CMS report on their behalf. While the measures which we report on States' behalf are subject to change, any such measures would not be subject to the general reporting requirement at § 437.15(a)(1)(i) and (ii).

In an effort to streamline measure reporting and assist States in reporting overall, we have been assessing whether there are alternate data sources that can be used to calculate specific measures. For example, CMS is currently using pilot testing to determine the applicability of generating measure specific reporting from State data reported to CMS T-MSIS. However, even if CMS determines that T-MSIS Analytic Files (TAF) could be used to generate measure specific reporting, there may be issues which could prevent the use of T-MSIS TAF or reasons why States may prefer to continue to report the measures. For example, measures with a long lookback period may require more years of TAF data than are available. In addition, CMS may be required to enter into licensing agreements with measure stewards for specific measures. We have also been working with Federal partners to assess whether other Federal data sources could be used to report measures for States, including CDC's Wide-ranging Online Data for Epidemiologic Research (WONDER) databases and CAHPS survey measures from Agency for Healthcare Research and Quality. We seek comment on the use of T-MSIS TAF or other alternate data sources for Core Sets reporting and on CMS reporting on States' behalf.

#### 1. Adherence to Reporting Guidance

As discussed in section II.C.1. of this proposed rule, the Secretary, in consultation with States, updates reporting guidance for all measures annually.<sup>54</sup> This reporting guidance

<sup>54</sup> Child and Adult Core Set reporting guidance: <https://www.medicare.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/index.html>.

Health Home Core Set reporting guidance: <https://www.medicare.gov/resources-for-states/>

includes a standardized format and procedures for State reporting of Core Sets measures. Not all States consistently adhere to the specifications and reporting formats prescribed by the Secretary. Each year, we spend several months working with States to resolve data quality issues and confirm any deviations from the reporting guidance. If all States adhere to the CMS reporting guidance, data quality would improve, data analysis would be streamlined and more meaningful, and annual data products would be available for use more quickly. Therefore, we propose at § 437.15(a)(3) that, except as described in § 437.15(a)(4), all State Core Set measure reporting would need to be in accordance with the guidance developed by the Secretary pursuant to proposed § 437.10(b), including the guidance developed by the Secretary under § 437.10(b)(3) and (4) about a standardized format for reporting measure data and procedures State agencies must follow in reporting measure data.

We recognize that adherence to CMS-issued reporting guidance as described in proposed § 437.15(a)(3) would be a substantial change from the way some States currently report measures, which is based on either their own programming specifications or that of their contractors. Therefore, States may need to reprogram their reporting systems to adhere to the reporting guidance. As such, we considered not requiring use of the reporting guidance at all. However, we believe that adherence to the reporting guidance is the best way to provide true comparisons across States on quality measure performance and to derive national performance rates of the care provided to Medicaid and CHIP beneficiaries. In addition, we are actively working to reduce State burden by streamlining reporting and developing alternate methods of reporting measures, including methods described above, by which CMS will obtain data and complete reporting on behalf of States. We seek comments on this approach, as well as strategies that CMS may implement to provide the best technical assistance to States as they transition to standardized reporting and what States have found helpful in the past, such as one-on-one sessions, written guidance, measure specification and coding assistance, site visits, webinars, learning collaboratives, and other opportunities to hear best

[medicaid-state-technical-assistance/health-home-information-resource-center/health-home-quality-reporting/index.html](https://www.medicare.gov/medicaid-state-technical-assistance/health-home-information-resource-center/health-home-quality-reporting/index.html).

practices and from other States, or any other ideas not listed here.

#### 2. Phased-in Reporting for Certain Mandatory Measures

As noted above, proposed § 437.10(c) would allow the Secretary to establish a phase-in period for reporting of certain measures, depending on their complexity, and proposed § 437.15(a)(4) provides exceptions to the mandatory reporting requirements at § 437.15(a)(1) for measures to be phased-in. The Core Sets include more than one type of quality measure, with differing data collection processes and requirements. We recognize that some types of data collection are more administratively burdensome than others.

Some measures, often referred to as "administrative measures," are typically calculated from information included in claims. These measures, which typically are the easiest for States to report, generally focus on health care utilization and cost. Measures which focus on health outcomes for beneficiaries, often referred to as "outcomes measures" or "hybrid measures," typically require clinical information from medical records as well as administrative data from claims. Clinical information may be obtained from chart reviews or information stored in electronic health records (EHRs). Other measures on the Core Sets are calculated from surveys such as CAHPS.

While measures of health outcomes are often the most meaningful types of measures, they can also be the most challenging to report. States often struggle with collecting data for measures that depend on either non-claims sources, hybrid specifications, or EHRs. Chart reviews have been a common method of obtaining the clinical information needed for hybrid measures that is not available from claims, such as referral to treatment or blood pressure rates. However, chart reviews are expensive, and require a trained reviewer to manually review and obtain needed information on a set number of charts. Other methods of data collection, such as obtaining clinical information from EHRs, may require complex computerized patient matching processes that take time and resources to develop, as well as negotiation of appropriate data use agreements between State Medicaid and CHIP agencies and other State agencies or private entities (for instance, EHR vendors). We seek comments on how best to phase-in reporting of health outcome and survey measures for Medicaid and CHIP and the frequency of reporting these measures. In addition, to support States in meeting the

proposed mandatory reporting requirements, we seek comment on the technical assistance States might need from CMS to be able to report on health outcomes and survey measures. We also seek comments on promising practices and approaches for accurate electronic data capture of race and ethnicity and other demographics; programmatic requirements; and best practices and lessons learned from linking records from disparate data sources for measure calculation and reporting.

New and modified measures pose additional challenges. When a new measure is added to the Core Sets, or the measure specification changes, States must adjust their collection processes, which may require corresponding contractual updates. As such, it may not always be possible for States to report measures to CMS in the first year after they are added to the Core Sets, even when they rely on claims data alone but especially when they require other types of data.

Thus, while mandatory reporting would be required, as described at proposed § 437.10(b)(1)(iii) and § 437.15(a)(1), beginning with FFY 2024 reporting, we propose at § 437.15(a)(4)(i) that reporting of measures identified by the Secretary for phase-in under § 437.10(c) would be optional for FFY 2024 and subsequent years as identified in the reporting guidance, but not required. Similarly, when a new measure is added to the Child Core Set, a new behavioral health measure is added to the Adult Core Set, or a new measure is added to either of the Health Home Core Sets, reporting of the new measure may not be required immediately. Per proposed § 437.10(c), in determining which measures would be subject to a phase-in period and how long such phase-in period would be, the Secretary would take into account the level of complexity required for States to report the measure. As also proposed in § 437.10(b)(1)(v) and (c), the Secretary would specify any such phase-in periods in the annual reporting guidance described in proposed § 437.10(b). We believe that giving States more time to refine their data collection and reporting systems for “difficult to report” measures, would improve the accuracy of State reporting. Recognizing that the hard-to-report outcomes measures are often the most meaningful measures, we plan to provide intensive technical assistance to assist States in successfully reporting on such measures.

### 3. Phased-in Reporting for Certain Populations

We propose at § 437.10(b)(5) that the Secretary would identify, through annual reporting guidance, those populations for which States would be required to report measure data for a given year. Recognizing the challenges that States face in reporting measure data for certain populations, proposed § 437.10(c) provides that the Secretary would also be authorized to provide, in the annual reporting guidance, that mandatory State reporting for certain populations could be phased in over a specified period of time, and that the Secretary’s identification of such populations would take into account the level of complexity required for States to report the measure for different populations. Historically, due to the voluntary nature of reporting on measures in the Core Sets, States have not included all the populations identified in the measure specifications when reporting Core Sets measures to CMS. For example, some States currently report Medicaid beneficiaries but not CHIP beneficiaries. Other States include only beneficiaries enrolled in managed care but not FFS beneficiaries or omit reporting for beneficiaries enrolled in both Medicaid and Medicare.

Under this proposal, the Secretary would specify each year, in the reporting guidance issued under § 437.10(b), the populations on which States would be required to report the Core Set measures, and whether mandatory reporting for certain populations could be phased in over time. CMS anticipates that this annual guidance would take the following statutory language into consideration. The statutory language in section 1139A(a)(4)(B) of the Act requires mandatory reporting of measures on the Child Core Set for pediatric health care under Titles XIX and XXI of the Act. Section 1139B(b)(3)(B) of the Act provides for development of a core set of adult health quality measures for Medicaid eligible adults and requires that States report on all behavioral health measures included in the Adult Core Set starting in 2024. To improve the quality of care delivered to all Medicaid and CHIP beneficiaries, we interpret this language as requiring that reporting for the Child Core Set include *all* beneficiaries covered by Medicaid and CHIP and reporting for the behavioral health measures in the Adult Core Sets include *all* beneficiaries covered by Medicaid. This includes beneficiaries enrolled in all Medicaid and CHIP delivery systems as well as

services received in all applicable health care settings, such as hospitals, outpatient settings, Federally Qualified Health Centers (FQHCs), rural health clinics (RHCs), and facilities operated by IHS, by Tribes and Tribal Organizations under the Indian Self-Determination and Education Assistance Act, and by Urban Indian Organizations under Title V of the Indian Health Care Improvement Act.

With respect to health home measure reporting, section 1945(g) of the Act provides that section 1945 health home providers must report to the State, in accordance with such requirements as the Secretary shall specify, on all applicable measures for determining the quality of section 1945 health home services. Section 1945(c)(4)(B) of the Act specifies that the reporting required under that provision should be with respect to SUD-eligible individuals provided health home services under the applicable SPA. Section 1945A(g)(1)(B) of the Act requires health home providers to report to the State information on all applicable measures for determining the quality of section 1945A health home services delivered by the provider. Section 1945A(g)(2)(A)(i) of the Act requires a State implementing the section 1945A health home benefit to report to the Secretary all quality information that the State received from its health home providers under section 1945A(g)(1)(B) of the Act. In addition, section 1902(a)(6) of the Act, on which CMS also relies for these proposals, provides that State Medicaid agencies must make such reports, in such form and containing such information, as the Secretary may from time to time require. Taken together, these provisions would support guidance under § 437.10(b) that requires State reporting for the Health Home Core Sets to include *all* beneficiaries enrolled in the applicable health home program. This would include health home program beneficiaries receiving services through all Medicaid delivery systems, as well as health home program beneficiaries who received Medicaid-covered services in all applicable health care settings, such as hospitals, outpatient settings, FQHCs, RHCs, and facilities operated by IHS, Tribes and Tribal Organizations, and Urban Indian Organizations, during the measurement period. We would anticipate that health home programs would have to report on beneficiaries who have received Medicaid-covered services in FQHCs, RHCs, and facilities operated by IHS, Tribes and Tribal Organizations, and Urban Indian Organizations only if a beneficiary who

is enrolled in the applicable health home program received Medicaid-covered services in one of these settings during the measurement period.

Currently, most States do not include all their Medicaid and CHIP population in their Core Set reporting; most States report only on a subset of their entire Medicaid and CHIP population when reporting on the Child and Adult Core Sets, and do not report on the entire population of health home program beneficiaries when reporting on the section 1945 Health Home Core Set. Populations for which many States do not currently report Core Sets measure data include: (1) beneficiaries who are dually-eligible for Medicare and Medicaid; (2) beneficiaries served by IHS, Tribes and Tribal Organizations, or Urban Indian Organizations; (3) beneficiaries served by FQHCs, and (4) beneficiaries receiving services on a FFS basis in a State where most beneficiaries are enrolled in a managed care plan.

Some States do not include in their reporting FFS dually eligible beneficiaries because such reporting often requires additional work to obtain and analyze Medicare utilization data. In 2019, there were 12.3 million individuals simultaneously enrolled in Medicare and Medicaid, also known as dually eligible beneficiaries.<sup>55</sup> This includes beneficiaries who receive full Medicaid benefits and beneficiaries whose Medicaid coverage is limited to payment of Medicare premiums and/or cost sharing. Forty-one percent of dually eligible beneficiaries have at least one mental health diagnosis, and 60 percent have multiple chronic physical and/or mental health conditions.<sup>56, 57</sup> Since Medicare is the primary payer for dually eligible beneficiaries for services covered by both Medicare and Medicaid, we believe State Medicaid data may be insufficient to perform analysis on certain Core Set measures

for dually eligible beneficiaries. For example, Medicare utilization data, along with State Medicaid data, is necessary to report on 12 of the 13 behavioral health measures on the Adult Core Set for dually eligible beneficiaries. Therefore, based on the current measure specifications, we believe States need Medicare utilization data combined with State Medicaid data to fulfill reporting completely and accurately on Core Sets measures for dually eligible beneficiaries. Via the Medicare-Medicaid Data Sharing Program, CMS makes available certain Medicare data to States free of charge, which States can use to help fulfill reporting on Core Sets measures for this population.<sup>58</sup> While we currently provide technical assistance, and will continue to do so, including written instruction, to assist States in requesting and analyzing Medicare data, we solicit comment on additional considerations and technical assistance that would help States more easily obtain and use the Medicare data to calculate the Core Sets measures for dually eligible beneficiaries.

Similarly, States might not include in their reporting measure data for beneficiaries receiving health care services at FQHCs, RHCs, or from IHS, Tribes and Tribal Organizations, or Urban Indian Organizations, because State Medicaid agencies may not receive claims data needed for measure reporting from those facilities. In 2018, more than 1.8 million American Indians and Alaska Natives were enrolled in coverage through Medicaid and CHIP.<sup>59</sup> Currently, there is no national database for health care services provided at Tribal facilities. Each Tribal entity is responsible for reporting its own claims and the level of detail provided, such as type of clinical service provided or diagnosis, varies by facility and by State; each State establishes its own guidance for health care facilities operated by IHS, Tribes and Tribal Organizations, and Urban Indian Organizations. While we are currently working with IHS to determine best practices, we solicit comment on additional considerations and technical assistance support that would help States more easily obtain and use the health care facility data from IHS, Tribes and Tribal Organizations, and Urban

Indian Organizations that would be needed to calculate the Core Sets measures.

FQHCs, defined for Medicaid purposes at section 1905(l)(2)(B) of the Act, are (1) community-based health care providers that either receive grant awards from the HRSA Health Center Program under section 330 of the Public Health Service Act to provide primary care services in underserved areas or are designated by HRSA as Health Center Program look-alikes; or (2) outpatient health programs or facilities operated by a tribe or tribal organization under the Indian Self-Determination Act (Pub. L. 93-638, enacted January 4, 1975) or by an Urban Indian Organization receiving funds under Title V of the Indian Health Care Improvement Act for the provision of primary health services. FQHC clients may include but are not limited to Medicaid and CHIP beneficiaries. HRSA's Health Center Program includes approximately 1,400 health centers with more than 10,000 delivery sites in the U.S., DC, Puerto Rico, the Virgin Islands, American Samoa, Guam, the Federated States of Micronesia, Marshall Islands, and the Northern Mariana Islands.<sup>60</sup> While Health Center Program awardees and look-a-likes report to a Uniform Data System (UDS), which contains clinical quality measures that align with CMS's electronic-specified Clinical Quality Measures (e-CQMs), not all Core Set measures are currently able to be calculated using data from the UDS. Additionally, States vary in their access to these data and therefore inclusion in Core Sets reporting. We are working with HRSA to determine best practices and will then provide technical assistance to States and territories on how to include these data in Core Set reporting. We solicit comment on additional considerations and technical assistance support that would help States and territories more easily obtain and use the FQHC and RHC data needed to calculate the Core Sets measures.

FFS Medicaid beneficiaries in managed care States often are not included in Core Sets reporting because States rely on data collected by their managed care organizations and States have not invested in the infrastructure needed to report data from their smaller FFS populations. Omission of these populations from measure reporting limits the ability to evaluate the quality of care provided to the entirety of a State's Medicaid and CHIP population (or health home program), to determine

<sup>55</sup> <https://www.cms.gov/files/document/medicare-medicaid-dual-enrollment-trends-data-brief.pdf>.

<sup>56</sup> Physical and Mental Health Condition Prevalence and Comorbidity among Fee-For-Service Medicare-Medicaid Enrollees. Centers for Medicare & Medicaid Services, September 2014. Available at [https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Dual\\_Condition\\_Prevalence\\_Comboridity\\_2014.pdf](https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Dual_Condition_Prevalence_Comboridity_2014.pdf).

<sup>57</sup> Medicare-Medicaid Enrollee Information, National 2012. Available at [https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/NationalProfile\\_2012.pdf#:~:text=Nationally%2C%20in%202012%2C%20among%20Medicare%20Medicaid%20FFS%20enrollees%3A,%26%20Medicaid%20Services%20%7C%20Medicare-Medicaid%20Coordination%20O%EF%AC%83ce%204.](https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/NationalProfile_2012.pdf#:~:text=Nationally%2C%20in%202012%2C%20among%20Medicare%20Medicaid%20FFS%20enrollees%3A,%26%20Medicaid%20Services%20%7C%20Medicare-Medicaid%20Coordination%20O%EF%AC%83ce%204.)

<sup>58</sup> For more information on the Medicare-Medicaid Data Sharing Program please see here <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/StateAccessToMedicareData> or contact the State Data Resource Center at <https://www.state-dataresourcecenter.com/home/contact-us>.

<sup>59</sup> <https://www.medicaid.gov/medicaid/indian-health-medicaid/index.html>.

<sup>60</sup> HRSA UDS <https://bphc.hrsa.gov/sites/default/files/bphc/datareporting/reporting/2019-uds-manual.pdf>.

potential health care disparities across delivery systems and subpopulations, and to compare the quality of care across States.

As discussed, reporting guidance published by the Secretary under proposed § 437.10(b) would, per § 437.10(b)(5), identify the populations for which States must report quality measures, and under proposed § 437.10(c) may provide that mandatory State reporting for certain measures and reporting for certain populations of beneficiaries will be phased in over a specified period of time. Per proposed § 437.15(a)(3), which would require States to adhere to the reporting guidance issued by the Secretary under § 437.10(b) when reporting on Core Sets Measures (except as described in § 437.15(a)(4)), reporting on the Child Core Set and the behavioral health measures in the Adult Core Set, as required at proposed § 437.15(a)(1)(i), would have to include all beneficiary populations identified by the Secretary under proposed § 437.10(b)(5). Reporting on both Health Home Core Sets, as required at proposed § 437.15(a)(1)(ii), would have to include all beneficiary populations identified by the Secretary under proposed § 437.10(b)(5). Proposed § 437.15(a)(4)(ii) would exempt States from having to report on populations for whom reporting is not yet phased in. States would initially be encouraged, but not required, to report on populations for whom mandatory reporting is not yet phased in.

We are developing strategies to improve State access to Medicaid data in order to improve reporting capabilities. For example, we are developing strategies to improve reporting for beneficiaries served by IHS, Tribes and Tribal Organizations and Urban Indian Organizations. Some States have been able to leverage their Health Information Exchanges to accomplish more complete reporting of entire Medicaid and CHIP populations, and we are planning to work with those States to identify and share best practices with other States and facilitate peer-to-peer learning. Finally, we are currently piloting technical assistance work with States with the idea of providing written resources and guidance.

Ultimately, as we continue to provide technical assistance and States continue to build capacity, we expect to require States to report on the populations discussed above for each Core Set through the annual reporting guidance. This will help achieve data consistency across States and provide useful and actionable quality measurement data to

identify disparities and support efforts to improve the quality of healthcare provided by State Medicaid and CHIP agencies for all beneficiaries.

In developing these proposals, we considered proposing to require States to report the measures on the Child Core Set for all populations served by Medicaid and CHIP, and the behavioral health measures on the Adult Core Set for all Medicaid adult populations beginning in FFY 2024, with no provision for the Secretary to allow a phased-in approach. We also considered proposing to require States to report the measures for both Health Home Core Sets for all beneficiaries enrolled in approved health home programs beginning in FFY 2024, with no phased-in approach. However, we are concerned that it may not be feasible for States to begin reporting on all populations by the FFY 2024 reporting year. A flexible approach to identifying mandatory populations in annual guidance that permits phasing in mandatory reporting for certain populations, as proposed in § 437.10(b)(5) and (c) and § 437.15(a), would give States time to develop the infrastructure and resources to allow them to report on all Medicaid, CHIP, and health home program beneficiary populations. We seek comments on how best to provide technical assistance to assist States so they can report on all populations specified by the Secretary each year for the Medicaid, CHIP, and Health Home Core Sets, and ultimately, so that they can report on all Medicaid, CHIP, and health home program beneficiary populations, as well as on how long States might need to be able to report on all Medicaid, CHIP, and health home program beneficiary populations.

#### 4. Separate Reporting of the Child Core Set for Medicaid and CHIP Beneficiaries

Currently, some States report the Child Core Set for their Medicaid population, but not for their CHIP population, while other States report these populations together. As discussed previously, it is important that Child Core Set measures are reported for all populations covered in both Medicaid and CHIP. We believe it is also important to monitor and analyze quality performance in separate CHIPs independently from Medicaid programs to allow for comparison of performance between the programs. Therefore, we propose at § 437.15(b) that States with a separate CHIP report on Child Core Set measures in three categories: Medicaid and CHIP combined; Medicaid inclusive of CHIP-funded Medicaid expansion

(Titles XIX and XXI); and separate CHIP (Title XXI).

Most States currently report measures separately for the two programs, yet their methods of collecting and reporting the measures may differ. Under this proposed rule, State Medicaid programs and CHIPs would be required to use the same reporting guidance, as described at proposed § 437.15(a)(3) and proposed § 457.770 respectively, including technical specifications (that is, hybrid, administrative, etc.), for reporting quality measures for both Medicaid beneficiaries and separate CHIP beneficiaries. The use of consistent methodologies would allow the Medicaid and CHIP rates to be validly combined by CMS for an overall State rate.

We recognize that it is not uncommon for children to move between Medicaid and CHIP as their family income fluctuates. Because many measure specifications require 12 months of continuous eligibility to be included in the data reported, there is potential for children who move between the programs during a 12-month period to not be captured when the programs report separately. Under this proposed rule, States would capture children who transfer between the two programs through common reporting guidance. The reporting guidance would include attribution rules, as described at proposed § 437.10(b)(6), for example, based on the length of time the child was enrolled in each program, the attribution rules would clarify in which program (Medicaid or CHIP) a State would count a child who transitioned between programs within a reporting year.

Reporting in this manner would (1) maximize the number of children captured in the data; (2) support production of a median overall combined State performance rate to compare the quality of care across States; (3) enable comparisons of performance between Medicaid and CHIP programs; and (4) identify health disparities in Medicaid and CHIP populations both within a State and nationally.

We considered requiring States with separate CHIPs to report on the Child Core Set measures for all Medicaid and separate CHIP-covered children together to ensure that children who transition between programs would not be lost and, if so, the attribution rules to determine in which program a child who transitioned between Medicaid and CHIP during the reporting period should be included. We seek comment on how best to provide technical assistance to

assist States in resolving data issues when a State with separate CHIP collects Child Core Set measures using different reporting guidance or data sources from those used for the collection of Child Core Set measures in their Medicaid population. We also seek comment on whether States with separate CHIPs should combine Medicaid and separate CHIP Child Core Set reporting in order to ensure that children who transition between programs are not lost and, if so, the attribution rules to determine in which program a child who transitioned between Medicaid and CHIP during the reporting period should be included.

#### *E. Application to CHIP for the Child and Adult Core Sets*

Section 1139A(a)(1) of the Act requires the Secretary to develop a core set of measures for reporting on the quality of health care provided to children by State programs administered under titles XIX and XXI. Beginning with the FFY 2024 annual report, section 1139A(a)(4)(B) of the Act requires State reporting on the quality of pediatric health care provided under both title XIX and title XXI utilizing the standardized format and procedures established by the Secretary. Section 1139B(a) of the Act requires the Secretary to develop a core set of measures for reporting on the quality of health care provided to adults under title XIX in the same manner as that used to develop the Child Core Set. However, section 1139B(b)(3)(B) of the Act makes reporting by States on the Adult Core Set measures mandatory only with respect to the quality of behavioral health care provided to Medicaid-eligible adults. As such, a separate CHIP is encouraged, but not required, to report on the measures in the Adult Core Set.

At § 457.700, we propose to add sections 1139A and 1139B of the Act as additional bases for quality reporting in CHIP. Under these statutory provisions, we propose at § 457.770(a) to require that separate CHIPs report on all measures in the Child Core Set in accordance with the requirements in part 437. Because each measure in the Child Core Set (as well as the Adult Core Set) has its own age requirements, which are established by the measure steward, the State would be required to report on the quality of care provided to all CHIP beneficiaries who fall within the age range for each measure in the Child Core Set, not just those beneficiaries covered as a targeted low-income child. For example, the 2022 Child Core Set includes a measure on asthma medication, which is applicable

to individuals between the ages of 5 and 18. In a State that covers both targeted low-income children and targeted low-income pregnant individuals, the State would be required to report on the asthma medication measure for all beneficiaries aged 5 through 18 who are eligible as either a targeted low-income child or a targeted low-income pregnant individual.

At proposed § 457.770(b), we strongly encourage States to also follow the requirements of part 437 for any voluntary reporting on the measures in the Adult Core Set. As such, if a State elected to report, for example, on the 2022 Adult Core Set Measure of flu vaccinations for individuals ages 18 to 64, the State would report on this measure with respect to targeted low-income children who are age 18 and targeted low-income pregnant individuals, if covered by the State, who are within the age range for this measure.

States also have the option to extend special CHIP child health assistance for the duration of pregnancy (also referred to as the “unborn option”) in compliance with applicable eligibility criteria for coverage under the CHIP State plan, thereby providing coverage to pregnant individuals who themselves are not eligible for Medicaid or CHIP. States that provide coverage for the duration of pregnancy would be required, in accordance with § 457.770(a), to include this population of CHIP beneficiaries when reporting on quality measures in the Child Core Set. If such State reports on the behavioral health measures in the Adult Core Set, or any other Adult Core Set measures for their CHIP population, pregnant individuals receiving coverage for the duration of pregnancy would be included in such reporting if they meet the age parameters for the measure. We believe that reporting on the quality of health care provided to the pregnant individual for the duration of their pregnancy, based on the age of that individual, would provide a more accurate picture of the specific needs of this population and the quality of critical health care services received by pregnant individuals in CHIP. We seek comment on including pregnant individuals receiving coverage under the special CHIP child assistance in the requirements for mandatory reporting of measures in the Child Core Set as described previously in this proposed rule, based on the age of the pregnant individual.

To ensure that States and CMS can measure and improve the quality of care provided to all CHIP beneficiaries, in States that have extended CHIP coverage

to targeted low-income pregnant women, we encourage reporting on not only the behavioral health measures, but all measures in the Adult Core Set. In light of the increasing rates of maternal morbidity and mortality in the United States, highlighted, but not limited to, non-Hispanic black women whose rate of maternal mortality was 55.3 deaths per 100,000 live births, 2.9 times the rate for non-Hispanic white women in 2020, it is more important than ever to collect information on the health of pregnant and postpartum women in CHIP and the care provided to them.<sup>61</sup>

#### *F. Ensuring Compliance With the Mandatory Reporting Requirements*

Section 1904 of the Act and implementing regulations at § 430.35 allow CMS to withhold Federal Medicaid payments, in whole or in part, from a State that is non-compliant with Federal requirements under section 1902 of the Act. The mandate to begin reporting Child and Adult Core Sets measures is set forth in sections 1139A and 1139B of the Act, and it is not cross-referenced in section 1902 of the Act. Similarly, sections 1945 and 1945A of the Act, which authorize the two Medicaid health home benefits to which this proposed rule would apply, are not cross-referenced in section 1902 of the Act. However, section 1902(a)(6) of the Act requires the Medicaid State plan to provide that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time require, and comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. And, as discussed previously in this proposed rule, section 1902(a)(6) of the Act also forms part of the authority for our proposed State reporting requirements related to the Child, Adult, and Health Home Core Sets. Based on our authority at section 1902(a)(6) of the Act, we propose at § 437.20(a) to require the Medicaid State plan to include language attesting that the agency would report on the Child, Adult, and Health Home Core Sets in accordance with the requirements in § 437.15. Health Home SPAs, under proposed § 437.20(a)(3), would also be required to include an attestation that the State would require its providers of health home services to report to the State on the measures that the State has to report. With these attestations in the State plan, we would have authority under section 1904 of the

<sup>61</sup> <https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm>.

Act to withhold Federal Medicaid payments if an agency fails to comply with the Medicaid reporting requirements.

Current § 457.204 provides for financial withholding in the event of noncompliance with CHIP regulations at part 457. Thus, once the mandatory quality Child Core Set reporting requirement is codified at § 457.770, CMS would be able to withhold Federal funds under Title XXI for noncompliance with the reporting requirement in CHIP.

To meet the quality measures reporting requirements proposed in this rule at § 437.10 through § 437.20, States may need to make changes to one or more State systems. As such, we also propose to revise the requirements set out at § 433.112 that States must meet in order to receive enhanced Federal Medicaid match for systems development (at a 90 percent matching rate) and operations (at a 75 percent matching rate). We propose to add to the requirements at § 433.112 that States must comply with the standards and protocols for reporting on the Child, Adult, and Health Home Core Sets as adopted by the Secretary under sections 1139A, 1139B, 1902(a)(6), 1945(c)(4)(B) and (g), and 1945A(g) of the Act and 42 CFR part 437 subpart A. As noted above, State expenditures on systems development or modifications necessary for efficient collection and reporting on the Child Core Set are matched at the State's FMAP under section 1905(b) of the Act.

We believe this proposed requirement would not only incentivize adequate systems development to achieve compliance with the proposed quality reporting requirements, but would also improve States' ability to comply with the proposed reporting requirements. Availability of financial penalties would provide us with leverage to enforce quality measure reporting, which is foundational to improving the quality and health outcomes for Medicaid and CHIP beneficiaries. While enhanced match for systems development and maintenance is not available for CHIP, it is likely that compliance in CHIP and Medicaid would occur in tandem, as States generally use the same system for reporting measures for both programs. In the event this does not happen in a given State, withholding Federal funds under the CHIP regulations would remain an option for CMS to pursue.

We also propose other changes to § 433.112. These proposed changes would apply existing Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, Breach Notification, and Enforcement Rules

under 45 CFR parts 160 and 164, the HIPAA electronic transactions standards under 45 CFR part 162, and the health information technology standards under 45 CFR part 170 subpart B to the Core Sets. In 1996, Congress enacted HIPAA,<sup>62</sup> which included Administrative Simplification provisions requiring the establishment of national standards<sup>63</sup> to protect the privacy and security of individuals' health information, establishing civil money and criminal penalties for violations of the requirements, and electronic transactions standards, among other provisions.<sup>64</sup> The Administrative Simplification provisions and implementing regulations apply to covered entities, which are health care providers who conduct covered health care transactions electronically, health plans, and health care clearinghouses.<sup>65</sup> The Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act)<sup>66</sup> added breach notification requirements and created penalty tiers for HIPAA violations and also authorized the health information technology standards promulgated at 45 CFR part 170 subpart B.

Additionally, we propose to refer to "standards and implementation specifications for health information technology" rather the existing term, "industry standards." The present text refers to "industry standards" that have been adopted in accordance with 45 CFR part 170, subpart B. Subpart B of part 170 is titled "Standards and Implementation Specifications for Health Information Technology," so we propose this change to § 433.112 to conform to that title.

### III. Solicitation of Public Comment

Throughout sections I. and II. of this proposed rule, we have identified a number of technical implementation considerations and requested comment on the appropriateness of the processes

<sup>62</sup> See Public Law 104–191, 110 Stat. 1936 (August 21, 1996).

<sup>63</sup> See also sec. 264 of HIPAA (codified at 42 U.S.C. 1320d–2 note).

<sup>64</sup> See 42 U.S.C. 1320d–1–1320d–9. With respect to privacy standards, Congress directed the Department to address at least the following: (1) The rights that an individual who is a subject of individually identifiable health information should have. (2) The procedures that should be established for the exercise of such rights. (3) The uses and disclosures of such information that should be authorized or required. 42 U.S.C. 1320d–2 note.

<sup>65</sup> See 42 U.S.C. 1320d–1 (applying Administrative Simplification provisions to covered entities); 45 CFR 160.103 (definition of "Covered entity").

<sup>66</sup> Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5).

described to fulfill the proposed requirements for mandatory reporting. Additionally, we have requested input on the types of technical assistance and support which would be most useful for States in meeting the proposed requirements for mandatory reporting. We are seeking both general comments on the proposed rule as well as comments on specific topic areas identified in sections I. and II. of this proposed rule.

Specifically, we are requesting comments on:

1. The proposed phased-in approach to stratifying measures, and whether 5 years is the right amount of time to phase-in stratification. Also, whether the Secretary should establish which measures would have to be stratified each year and by what factors or if States should decide what measures and factors for which they would submit stratified data. (Section II.C.2. of this proposed rule.)

2. The burden of requiring stratification based on delivery system, health plan, and population subgroup for the Child and Adult Core Sets and by population subgroup for both the section 1945 and section 1945A Health Home Core Sets, and the burden of stratified reporting by race, ethnicity, and other demographic factors for all Core Sets. In addition, we seek comments on the technical assistance that would be needed to support stratified State reporting. (Section II.C.2. of this proposed rule.)

3. The use of T–MSIS TAF or other alternate data sources for Core Sets reporting and on CMS reporting on States' behalf. (Section II.D. of this proposed rule.)

4. Requiring adherence to reporting guidance outlined in section II.D.1. of this proposed rule.

5. The most effective technical assistance CMS could provide to States to support their transition to standardized mandatory reporting, including:

a. What technical assistance States have found helpful in the past, such as one-on-one sessions, written guidance, measure specification and coding assistance, site visits, webinars, learning collaboratives, opportunities to hear best practices and from other States, or any other ideas. (Section II.D.1. of this proposed rule.)

b. The type of technical assistance needed in order for States to report both health outcomes and survey measures. (Section II.D.2. of this proposed rule.)

c. Whether the identification of promising practices and lessons learned would assist States in accurately reporting race, ethnicity, and other

demographic data; data linkages; and programmatic requirements. (Section II.D.2. of this proposed rule.)

d. What technical assistance would most assist States so they can report on all populations specified by the Secretary each year for the Medicaid, CHIP, and Health Home Core Sets, and ultimately, so that they can report on all Medicaid, CHIP, and health home program beneficiary populations, as well as on how long States might need to be able to report on all Medicaid, CHIP, and health home program beneficiary populations. (Section II.D.3. of this proposed rule.)

e. How best to provide technical assistance to States to address data issues related to different reporting guidance or data sources between separate CHIP and Medicaid. (Section II.D.4. of this proposed rule.)

6. How best to phase-in reporting of health outcomes and survey measures for Medicaid and CHIP and the frequency of reporting these measures (that is, annually or biennially). (Section II.D.2. of this proposed rule.)

7. Whether States with separate CHIPs should combine Medicaid and separate

CHIP Child Core Set reporting in order to ensure that children who transition between programs are not lost and, if so, the attribution rules to determine in which program a child who transitioned between Medicaid and CHIP during the reporting period should be included. (Section II.D.4. of this proposed rule.)

8. Include in the requirements for mandatory reporting of measures in the Child Core Set pregnant individuals receiving coverage under the special CHIP child assistance. (Section II.E. of this proposed rule.)

**IV. Collection of Information Requirements**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a “collection of information” requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations.

To fairly evaluate whether an information collection must be

approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this rule that contain information collection requirements.

*A. Wage Estimates*

To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ May 2020 National Occupational Employment and Wage Estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)). Table 1 presents BLS’ mean hourly wage along with our estimated cost of fringe benefits and overhead (calculated at 100 percent of salary) and our adjusted hourly wage.

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefits and overhead (\$/hr)	Adjusted hourly wage (\$/hr)
Business Operations Specialists .....	13–1000	37.66	37.66	75.32
Chief Executives .....	11–1011	95.12	95.12	190.24
Computer Programmers .....	15–1251	45.98	45.98	91.96
Data Entry/Information Processing Workers .....	43–9020	17.96	17.96	35.92
General Operations Manager .....	11–1021	60.45	60.45	120.90
Statistician .....	15–2041	46.72	46.72	93.44

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

To estimate the burden on States, it was important to take into account the Federal government’s contribution to the cost of administering the Medicaid and CHIP programs. The Federal government provides funding based on a FMAP that is established for each State, based on the per capita income in the State as compared to the national average. FMAPs range from a minimum of 50 percent in States with higher per capita incomes to a maximum of 83

percent in States with lower per capita incomes. States receive an “enhanced” FMAP for administering their CHIP programs, ranging from 65 to 85 percent. Medicaid funding for U.S. territories works a bit differently than funding for the 50 States and District of Columbia, in that the FMAP for each territory under Medicaid is statutorily set at 55 percent, though the rate has been increased temporarily in recent years, and annual funding is capped.<sup>67</sup> For Medicaid, all States (including the territories) receive a 50 percent Federal Financial Participation (FFP) for administration. As noted previously, States also receive higher Federal matching rates for certain services and for certain systems improvements, redesign, or operations. As such, in taking into account the Federal

contribution to the costs of administering the Medicaid and CHIP programs for purposes of estimating State burden with respect to collection of information, we elected to use the higher end estimate that the States would contribute 50 percent of the costs, even though the burden would likely be much smaller.

To derive average costs for individuals, we used U.S. census data to assume an average household income of \$41,664, or 200 percent of the poverty threshold of \$20,832 for a family of three. Assuming 2,088 work hours per year, this translates to an hourly rate of \$19.95/hr. Unlike our private sector adjustment to the respondent hourly wage, we are not adjusting this figure for fringe benefits and overhead since the individuals’ activities would occur outside the scope of their employment.

<sup>67</sup> Section 1905(b) of the Act: [https://www.ssa.gov/OP\\_Home/ssact/title19/1905.htm](https://www.ssa.gov/OP_Home/ssact/title19/1905.htm).

### B. Proposed Information Collection Requirements (ICRs)

The following proposed collection of information requirements and burden will be submitted to OMB for review under control number 0938–1188 (CMS–10434 #26 for the Child Core Set and the Adult Core Set and #47 for the Health Home Core Sets) and applies to the burden associated with mandatory reporting. The burden for reporting Adult Core Set measures (outside of behavioral health measures) which remain voluntary for States to report is not included in the ICRs. Subject to renewal, the control number is currently set to expire on July 31, 2023. The burden to health home providers for reporting Health Home Core Sets data to States is not included in the ICRs but is included in control number 0938–1188 (CMS–10434 #22) which is in the process of being updated to cover additional benefits and requirements that have been added under section 1945A of the Act.

Under sections 1139A, 1139B, and 1902(a)(6) of the Act, we are granted the authority to collect quality metrics on State-specific Medicaid and CHIP programs with the purpose of measuring the overall national quality of care for Medicaid and CHIP beneficiaries, monitoring performance at the State-level, and improving the quality of health care. Under sections 1902(a)(6), 1945(c)(4)(B), 1945(g), and 1945A(g) of the Act, we are also proposing to require States implementing the section 1945 and/or section 1945A health home benefits to report on certain quality measures to the Secretary and to require their health home providers to report on these same measures to the State. The reported data would provide a comprehensive landscape of the quality of care provided by Medicaid and CHIP because the measures focus on a range of topics including access to primary and preventive care, maternal and perinatal health care, care of acute and chronic conditions, behavioral health care, dental and oral health care, long term services and supports, and overall experience of care.

At the current time, Child, Adult, and section 1945 Health Home Core Sets reporting is voluntary but highly encouraged. Under this proposed rule, our voluntary annual reporting requirements would become mandatory for the Child Core Set (CMS–10434 #26), behavioral health measures in the Adult Core Set (also CMS–10434 #26), and the section 1945 and forthcoming section 1945A Health Home Core Sets (CMS–

10434 #47).<sup>68</sup> This proposed rule does not add, remove, or revise any of the existing measures in the current Core Sets. Annual updates to the Core Sets would continue to be made as required by sections 1139A and 1139B of the Act for the Child and Adult Core Sets and as proposed to be applied to both Health Home Core Sets as described in section I.C. of this proposed rule. Mandatory reporting of the Child Core Set and behavioral health measures on the Adult Core Set would impact all 50 States, DC, Puerto Rico, Guam, and the Virgin Islands as described in section II.A. of this proposed rule. The Health Home Core Sets requirements would apply if a State (as defined under section 1101 of the Act for purposes of Title XIX) has an approved Health Home SPA under section 1945 or 1945A of the Act, and the burden associated with the mandatory reporting requirement is not expected to influence the number of health home SPAs. Currently, 19 States and DC have a total of 34 Health Home SPAs.

Under this proposed rule, we anticipate that the mandatory reporting burden for States would increase in comparison to the current voluntary Core Set reporting burden including anticipated burden to States for system changes as a result of this proposed rule. This is due to the mandatory nature of the proposed data collection which may: increase the number of measures reported by States, adherence to the reporting guidance provided by CMS, and stratification of data by delivery system and demographic characteristics. However, many of the mandatory measures can be calculated from alternate data sources. For example, CMS has been working to use T–MSIS (CMS–R–284, OMB 0938–0345) reporting to generate measure reporting on behalf of States. Among the three Core Sets, approximately 50 measures would become mandatory, two of which CMS currently reports for States and Puerto Rico using alternate data sources, and the remainder would remain voluntary for States to report. CMS is currently assessing whether T–MSIS could be used to report any of the remaining measures. If so, this would reduce the number of measures that States would be required to calculate.

The data fields included in Core Set reporting templates are determined by the measure stewards who own the measures. CMS is not the measure steward for most measures, and therefore does not control the actual

data fields for most of the measures on the Core Sets. As a result, the templates used for Core Sets reporting will not be published for public comment. Measure stewards implement a separate process for public comment during measure development and measurement updates. CMS also has recommendations in the CMS Measures Management System Blueprint for a similar process for public comment during measure development.<sup>69</sup>

#### 1. ICRs Regarding Attestation of Mandatory Reporting (§ 437.20(a))

The following proposed changes will be submitted to OMB for their review under control number 0938–1188 (CMS–10434 #26 and CMS–10434 #47).

With the changes outlined in this proposed rule, each of the 54 States and territories that would be subject to the proposed Child and Adult Core Set reporting requirements would need to submit a single SPA attesting: that the agency would report on the Child and Adult Core Sets in accordance with the requirements in § 437.20(a). The approximately 20 States (with approximately 40 health home programs) with section 1945 Health Home SPAs and the approximately 10 States estimated to apply for section 1945A Health Home SPAs would need to submit a SPA attesting that the agency would report on the Health Home Core Sets in accordance with the requirements in § 437.20(a). Health Home SPAs would also include an attestation that the State will require its providers of health home services to report to the State on the measures that the State has to report in accordance with the requirements in § 437.20(a).

We estimate it would take a business operations specialist 2 hours at \$75.32/hr and a general operations manager 1 hour at \$120.90/hr to update and submit the State or territory SPA to CMS for review. We estimate a one-time burden of 162 hours (54 States and territories × 3 hr/response) at a cost of \$14,688 (54 States and territories × [(2 hr/response × \$75.32/hr) + [1 hr/response × \$120.90/hr]]). Taking into account the Federal contribution to Medicaid and CHIP program administration, the estimated State share of this cost would be \$7,332 (\$14,663 × 0.50).

#### 2. ICRs Regarding Core Set of Children’s Health Care Quality Measures for Medicaid and CHIP (Child Core Set) (Part 437, Subpart A)

The following proposed changes will be submitted to OMB for their review

<sup>68</sup> Core Set Measure lists: <https://www.medicaid.gov/medicaid/quality-of-care/index.html>.

<sup>69</sup> <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint>.

under control number 0938–1188 (CMS–10434 #26).

As required by section 50102(b) of the Bipartisan Budget Act of 2018, a new subparagraph (B) was added to section 1139A(a)(4) of the Act to mandate annual reporting of the Child Core Set beginning with the annual State report on fiscal year 2024. As referenced in in section II.A. of this proposed rule, mandatory reporting of the Child Core Set would be required for all 50 States, DC, Puerto Rico, Guam, and the Virgin Islands. The data collection, as explained in section II.C.1 of this proposed rule, would be required to include: reporting on all mandatory measures following the reporting guidance provided by CMS; populations, identified by CMS, for which States must report on each measure such as specified delivery systems, health care settings, and beneficiaries dually eligible for Medicare and Medicaid; and the stratification of certain measures by factors such as race, ethnicity, sex, age, rural/urban status, disability and language.

The burden for each respondent is dependent on the State reporting structure and the status of the State's Medicaid and CHIP programs. Currently, there are 14 States and territories with Medicaid expansion CHIP only, 2 States with separate CHIPs, and 38 States with both Medicaid Expansion and separate CHIPs.<sup>70</sup> We expect the burden for States with separate CHIPs or both types of CHIPs to be higher than for States with Medicaid expansion CHIP only. This is because States with separate CHIPs or both types of CHIPs would have to report data for children enrolled across both Medicaid and CHIP. This would result in more complex data sets and would require the State to conduct the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey twice, once for Medicaid and once for CHIP.<sup>71</sup> To account for the added reporting and survey effort for States with separate CHIP or with both Medicaid expansion and separate CHIPs, we have applied a multiplier of 1.5 to the burden hours for Child Core Set measure reporting and a multiplier of 2 to the burden estimate for conducting and reporting CAHPS survey data.

For the 14 States with Medicaid expansion CHIP only, we expect that the

reporting of approximately 25 Child Core Set measures would take: 118 hours at \$91.96/hr for a computer programmer to re-program and synthesize the data; 20 hours at \$93.44/hr for a statistician to conduct data sampling; 79 hours at \$120.90/hr for a general operations manager to analyze the data; 210.5 hours at \$35.92/hr for a data entry worker to input the data; and 8.75 hours at \$190.24/hr for a chief executive to verify, certify, and approve a State data submission to CMS.<sup>72</sup> We estimate an annual burden of 6,108 hours (436.25 hr × 14 responses) at a cost of \$440,957 (14 responses × [(118 hr × \$91.96/hr) + [20 hr × \$93.44/hr] + [79 hr × \$120.90/hr] + [210.5 hr × \$35.92/hr] + [8.75 hr × \$190.24/hr]]).

Additionally, we expect the new reporting mandate to require vendor contract modifications in all 14 States. We expect the contract modifications would take 6 hours at \$120.90/hr for a general operations manager to draft a vendor contract and 2 hours at \$190.24/hr for a chief executive to review and approve a modified vendor contract. We estimate an annual burden of 112 hours (8 hr/response × 14 responses) at a cost of \$15,482 (14 responses × [(6 hr × \$120.90/hr) + [2 hr × \$190.24/hr]]).

In aggregate, for States with Medicaid expansion CHIP only, we estimate an annual State burden of 6,220 hours (6,108 hr + 112 hr) at a cost of \$456,439 (\$440,957 + \$15,482).

For the 40 States (with separate CHIPs (2) and States with both Medicaid Expansion and separate CHIPs (38)) we expect a higher burden because States with separate CHIP programs or combination CHIP programs would have to report data for children enrolled across both Medicaid and CHIP programs. We expect the Child Core Set of approximately 25 measures would take: 211 hours at \$91.96/hr for a computer programmer to collect and synthesize the data; 40 hours at \$93.44/hr for a statistician to conduct data sampling; 133 hours at \$120.90/hr for a general operations manager to analyze the data; 419 hours at \$35.92/hr for a data entry worker to input the data; and 13 hours at \$190.24/hr for a chief executive to verify, certify, and approve a State data submission to CMS. We estimate an annual burden of 32,640 hours (816 hr × 40 responses) at a cost of \$2,269,778 (40 responses × [(211 hr × \$91.96/hr) + [40 hr × \$93.44/hr] + [133 hr × \$120.90/hr] + [419 hr × \$35.92/hr] + [13 × \$190.24/hr]]).

Additionally, we expect the new reporting mandate would require vendor contract modifications. We expect the contract modifications to take 6 hours at \$120.90/hr for a general operations manager to draft a vendor contract and 2 hours at \$190.24/hr for a chief executive to review and approve a modified vendor contract. We estimate an annual burden of 320 hours (8 hr × 40 responses) at a cost of \$44,235 (40 responses × [(6 hr × \$120.90/hr) + [2 hr × \$190.24/hr]]).

In aggregate, for States with separate CHIPs and States with both Medicaid Expansion and separate CHIPs, we estimate an annual State burden of 32,960 hours (32,640 hr + 320 hr) at a cost of \$2,314,013 (\$2,269,778 + \$44,235).

The CAHPS measure is the only mandatory measure on the Child Core Set which would include a burden on beneficiaries. We estimate it would take 20 minutes (0.33 hr) at \$19.95/hr for a Medicaid or CHIP beneficiary to complete the CAHPS Health Plan Survey (Child Core Set includes: Child version including Medicaid and Children with Chronic Conditions Supplemental Items). The collected survey data are incorporated into a Child Core Set measure.

For the 14 States with Medicaid expansion CHIP programs only, the survey would be conducted once each year. We estimate an annual per State beneficiary burden of 136 hours (0.33 hr per response × 411 beneficiary responses/State) at a cost of \$2,713 (136 hr × \$19.95/hr).

States with combination CHIP programs or separate CHIP program only would conduct the survey twice each year to account for the separate Medicaid and CHIP populations. There are 40 States and territories with this program structure. We estimate an annual per State beneficiary burden of 271 hours (0.33 hr per response × 822 beneficiary responses/State) at a cost of \$5,406 (271 hr × \$19.95/hr).

For States to administer the survey, we estimate an ongoing aggregate beneficiary burden of 12,749 hours [(136 hours × 14 responses) + (271 hours × 40 responses)] at a cost of \$254,243 [((\$2,713 × 14 responses) + (\$5,406 × 40 responses)].

3. ICRs Regarding Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set) (Part 437, Subpart A)

The following proposed changes will be submitted to OMB for their review under control number 0938–1188 (CMS–10434 #26).

<sup>70</sup> <https://www.medicaid.gov/chip/downloads/chip-map.pdf>.

<sup>71</sup> The Agency for Healthcare Research and Quality is the measure steward for the CAHPS survey (CAHPS health plan database OMB Control No.: 0935–0165).

<sup>72</sup> Child Core Set: <https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/childrens-health-care-quality-measures/index.html>.

As required by the SUPPORT Act, a new subparagraph (b)(3)(B) was added to section 1139B of the Act, to make mandatory the annual reporting of behavioral health measures in the Adult Core Set beginning with the annual State report on fiscal year 2024. As referenced in section II.A. of this proposed rule, mandatory reporting of the Adult Core Set would be required for all 50 States, DC, Puerto Rico, Guam, and the Virgin Islands. The data collection, as explained in section II.C.1 of this proposed rule, would be required to include: reporting on all mandatory measures following the reporting guidance provided by CMS; populations, identified by CMS, for which States must report on each measure such as specified delivery systems, health care settings, and beneficiaries dually eligible for Medicare and Medicaid; and the stratification of certain measures by factors such as race, ethnicity, sex, age, rural/urban status, disability and language.

For the behavioral health measures on the Adult Core Set, consisting of approximately 13 measures, we estimate it would take: 85 hours at \$91.96/hr to program and synthesize the data; 20 hours at \$93.44/hr for a statistician to conduct data sampling; 46 hours at \$120.90/hr for a general operations manager to analyze the data; 207 hours at \$35.92/hr for a data entry worker to input the data; and 4 hours at \$190.24/hr for a chief executive to verify, certify, and approve a State data submission to CMS.<sup>73</sup> We estimate an annual burden of 19,548 hours (362 hr/response × 54 responses) at a cost of \$1,265,933 (54 responses × [(85 hr × \$91.96/hr) + [20 hr × \$93.44/hr] + [46 hr × \$120.90/hr] + [207 hr × \$35.92/hr] + [4 × \$190.24/hr]]).

Additionally, we expect the new reporting mandate would require vendor contract modifications. We expect the contract modifications to take 6 hours at \$120.90/hr for a general operations manager to draft a vendor contract and 2 hours at \$190.24/hr for a chief executive to review and approve a modified vendor contract. We estimate a one-time burden of 432 hours (8 hr × 54 responses) at a cost of \$59,718 (54 responses × [(6 hr × \$120.90/hr) + [2 hr × \$190.24/hr]]).

In aggregate, we estimate an annual State burden of 19,980 hours (19,548 hr + 432 hr) at a cost of \$1,325,650 (\$1,265,933 + \$59,718).

The CAHPS measure is the only mandatory measure on the Adult Core Set which would include a burden on beneficiaries.<sup>74</sup> We estimate it would take 20 minutes (0.33 hr) at \$19.95/hr for a Medicaid beneficiary to complete a CAHPS Health Plan survey. The collected survey data is incorporated into one of the behavioral health measures on the Adult Core Set. For each State Medicaid program, we estimate an annual per State beneficiary burden of 136 hours (0.33 hr/response × 411 beneficiary responses/State) at a cost of \$2,713 (136 hr × \$19.95/hr). For States to administer the survey, in aggregate, we estimate an annual beneficiary burden of 7,324 hours (136 hr/State × 54 States) at a cost of \$146,513 (\$2,713 per State × 54 States).

#### 4. ICRs Regarding Core Sets of Health Home Quality Measures for Medicaid (Health Home Core Sets) (Part 437, Subpart A)

The following proposed changes will be submitted to OMB for their review under control number 0938–1188 (CMS–10434 #47). The burden associated with health home providers submitting data to the States is not included in this ICR and is covered under control number 0938–1188 (CMS–10434 #22); however, we will be submitting a revision to that burden estimate to cover additional benefits and requirements that have been added under section 1945A of the Act.

Sections 1945(g) and 1945A(g)(1)(B) of the Act require health home providers to report to States on measures for determining the quality of health home services provided, as a condition for payment of such services. Sections 1945(c)(4)(B) and 1945A(g)(2) of the Act require States to report on certain health home information to the Secretary, and CMS relies on these authorities, as well as on section 1902(a)(6) of the Act, in proposing to require all States implementing the section 1945 or section 1945A health home benefits to report on mandatory measures in the Health Home Core Sets. Additionally, to enable this State reporting, States would be required to require their health home providers to report on these measures, too, consistent with sections 1945(g) and 1945A(g)(1)(B) of the Act. As discussed in section II.A. of this proposed rule, State reporting of the Health Home Core Sets would be required only if the State (as defined in section 1101 for purposes

of Title XIX) has an approved health home SPA under sections 1945 or 1945A of the Act. The data collection, as explained in section II.C.1 of this proposed rule, would be required to include: reporting on all mandatory measures following the reporting guidance provided by CMS; populations on which States must report for each measure; and the stratification of data under certain measures by factors such as race, ethnicity, sex, age, rural/urban status, disability and language.

The burden for each respondent is dependent on the State's adoption of Health Home programs. We expect approximately 20 States to operate approximately 40 Health Home programs under section 1945 authority and approximately 10 States to operate Health Home programs under section 1945A authority.

*Section 1945 Authority:* The section 1945 Health Home Core Set for section 1945 programs consists of approximately 13 measures. For each respondent with this program, we estimate it would take: 52 hours at \$91.96/hr for a computer programmer to collect and synthesize the data; 52 hours at \$120.90/hr for a general operations manager to analyze the data; 6.5 hours at \$35.92/hr for a data entry worker to input the data; and 6.5 hours at \$190.24/hr for a chief executive to verify, certify, and approve a State data submission to CMS. We estimate an annual burden of 4,680 hours (117 hr × 40 responses) at a cost of \$501,560 (40 responses × [(52 hr × \$91.96/hr) + [52 hr × \$120.90/hr] + [6.5 hr × \$35.92/hr] + [6.5 × \$190.24/hr]]).

Additionally, we expect the new reporting mandate would require vendor contract modifications. We expect the contract modifications to take 6 hours at \$120.90/hr for a general operations manager to draft a vendor contract and 2 hours at \$190.24/hr for a chief executive to review and approve a modified vendor contract. We estimate a one-time burden of 320 hours (8 hr × 40 responses) at a cost of \$44,235 (40 responses × [(6 hr × \$120.90/hr) + [2 hr × \$190.24/hr]]).

In aggregate, we estimate an annual burden of 5,000 hours (5,680 hr + 320 hr) at a cost of \$545,795 (\$501,560 + \$44,235).

Note that the section 1945 Health Home Core Set does not include a survey-based measure; thus, there are no burden and cost estimates associated with a survey, such as the costs of a statistician to conduct sampling and weighting for the survey.

*Section 1945A Authority:* CMS anticipates that the section 1945A Health Home Core Set for section 1945A

<sup>73</sup> <https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/adult-health-care-quality-measures/index.html>.

<sup>74</sup> The Agency for Healthcare Research and Quality is the measure steward for the CAHPS survey (CAHPS health plan database OMB Control No.: 0935–0165).

programs would consist of approximately 7 measures. For each respondent with this program, we estimate it would take: 28 hours at \$91.96/hr for a computer programmer to collect and synthesize the data; 28 hours at \$120.90/hr for a general operations manager to analyze the data; 3 hours at \$35.92/hr for a data entry worker to input the data; and 3 hours at \$190.24/hr for a chief executive to verify, certify, and approve a State data submission to CMS. We estimate an annual State burden of 620 hours (62 hr/response × 10 responses) at a cost of \$66,386 (10 responses × [(28 hr × \$91.96/hr) + 28 hr

× \$120.90/hr] + [3 hr × \$35.92/hr] + [3 × \$190.24/hr])). Additionally, we expect the new reporting mandate would require vendor contract modifications. We expect the contract modifications to take 6 hours at \$120.90/hr for a general operations manager to draft a vendor contract and 2 hours at \$190.24/hr for a chief executive to review and approve a modified vendor contract. We estimate a one-time burden of 80 hours (8 hr × 10 responses) at a cost of \$11,059 (10 responses × [(6 hr × \$120.90/hr) + [2 hr × \$190.24/hr)]). In aggregate, we estimate an annual State burden of 700 hours (620 hr + 80

hr) at a cost of \$77,444 (\$66,386 + \$11,059). Note that CMS anticipates that the section 1945A Health Home Core Set would not include a survey-based measure; thus, there are no burden and cost estimates associated with a survey, such as the costs of a statistician to conduct sampling and weighting for the survey.

*C. Summary of Proposed Requirements and Annual Burden Estimates*

Table 2 sets out our proposed annual burden estimates.

TABLE 2—SUMMARY OF ANNUAL REQUIREMENTS AND BURDEN  
[(OMB Control Number: 0938–1188)]

Section 437 under Title 42 of the CFR	Number of respondents	Total responses	Time per response (hours)	Total time (hours)	Labor cost (\$/hr)	Total cost (\$)	Adjusted cost (\$) (50% FMAP or FFP)
CMS–10434 #26							
§ 437.20 One-time SPA Submission * .....	54	54	2	108	181	9,774	4,887
§ 437.15 (Child Core Set) .....	54	54	Varies	39,180	Varies	2,770,452	1,385,226
§ 437.15 (Adult Core Set) .....	54	54	370	19,980	24,549	1,325,650	662,825
Subtotal (#26) .....	54	54	Varies	59,268	Varies	4,105,876	2,052,938
CMS–10434 #47							
§ 437.20 One-time SPA Submission * .....	54	54	1	54	91	4,914	2,457
§ 437.15 (1945 Health Home Core Set) .....	40	40	125	5,000	13,645	545,795	272,898
§ 437.15 (1945A Health Home Core Set) .....	10	10	70	700	7,744	77,440	38,720
Subtotal (#47) .....	50	50	Varies	5,754	Varies	628,149	314,075
Total .....	Varies	54	Varies	65,022	Varies	4,734,025	2,367,013

\* States will be required to submit a single SPA that attests that the State will be in compliance with Child, Adult, and Health Home Core Sets reporting. Every State would complete the SPA and States with a Health Home would only have to identify as applicable.

*D. Submission of PRA-Related Comments*

We have submitted a copy of this proposed rule to OMB for its review of the rule’s information collection requirements and burden. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit the CMS website at [www.cms.hhs.gov/PaperworkReductionActof1995](http://www.cms.hhs.gov/PaperworkReductionActof1995), or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** section of this proposed rule and identify the rule (CMS–2440–P) the ICR’s CFR citation, and OMB control number.

**V. Response to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

**VI. Regulatory Impact Statement**

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and Executive Orders 12866 and 13563

direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$8.0 million to \$41.5 million in any 1 year. Individuals and

States are not included in the definition of a small entity. This proposed rule applies to new mandatory reporting requirements for information collection from State Medicaid and CHIP agencies who do not meet the definition of a small business. Therefore, we are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on any small entities. In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. This proposed rule applies to State Medicaid and CHIP agencies and would not add requirements to rural hospitals or other small providers. Therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule with comment period would not have a significant impact on the operations of small rural hospitals. Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately \$165 million. This rule would have no consequential effect on State, local, or tribal governments or on the private sector. Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any substantial direct compliance costs on State or local governments, preempt State law, or otherwise have Federalism implications, the requirements of Executive Order 13132 are not applicable. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

**Chiquita Brooks-LaSure,**

*Administrator of the Centers for Medicare & Medicaid Services,*

Approved this document on July 5, 2022.

**List of Subjects**

*42 CFR Part 437*

Administrative practice and procedure, Child support, Claims, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

*42 CFR Part 437*

Administrative practice and procedure, Claims, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

*42 CFR Part 457*

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

**PART 433—STATE FISCAL ADMINISTRATION**

■ 1. The authority citation for part 433 continues to read as follows:

**Authority:** 42 U.S.C. 1302.

■ 2. Amend § 433.112 by revising paragraph (b)(12) to read as follows:

**§ 433.112 FFP for design, development, installation or enhancement of mechanized processing and information retrieval systems.**

\* \* \* \* \*

(b) \* \* \*

(12) The agency ensures alignment with, and incorporation of, standards and implementation specifications for health information technology adopted by the Office of the National Coordinator for Health IT in 45 CFR part 170, subpart B. The agency also ensures alignment with: the HIPAA privacy, security, breach notification and enforcement regulations in 45 CFR parts 160 and 164; and the transaction standards and operating rules adopted by the Secretary under HIPAA and/or section 1104 of the Affordable Care Act. The agency meets accessibility standards established under section 508 of the Rehabilitation Act, or standards that provide greater accessibility for individuals with disabilities, and compliance with Federal civil rights laws; standards and protocols adopted by the Secretary under section 1561 of the Affordable Care Act; standards and protocols for reporting on the Child and Adult Core Sets as adopted by the Secretary under sections 1139A, 1139B, and 1902(a)(6) of the Act, and 42 CFR part 437 subpart A; and standards and protocols for reporting on the Health Home Core Sets as adopted by the

Secretary under sections 1902(a)(6), 1945(c)(4)(B) and (g), and 1945A(g) of the Act and 42 CFR part 437 subpart A.

\* \* \* \* \*

■ 3. Part 437 is added to read as follows:

**PART 437—MEDICAID QUALITY**

**Subpart A—Child, Adult, and Health Home Health Care Quality Measures**

Sec.

437.1 Basis, scope, purpose, and applicability.

437.5 Definitions.

437.10 Child, Adult, and Health Home Core Sets.

437.15 Annual reporting on the Child, Adult, and Health Home Core Sets.

437.20 State plan requirements.

**Subpart B [Reserved]**

**Authority:** 42 U.S.C. 1320b–9a, 42 U.S.C. 1320b–9b, 42 U.S.C. 1396a(a)(6), 42 U.S.C. 1396w–4, and 42 U.S.C. 1396w–4a.

**Subpart A—Child, Adult, and Health Home Health Care Quality Measures**

**§ 437.1 Basis, scope, purpose and applicability.**

(a) *Statutory basis.* This subpart is based on sections 1139A, 1139B, 1902(a)(6), 1945(c)(4)(B), 1945(g), and 1945A(g) of the Act.

(b) *Scope.* This subpart sets forth specifications for issuance and updates to the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set), the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set), and the 1945 and 1945A Core Sets of Health Home Quality Measures for Medicaid (Health Home Core Sets) by the Secretary. It also sets forth requirements related to annual reporting by States of measures in all of the Core Sets, and requirements related to provider reporting to States on the Health Home Core Sets.

(c) *Purpose.* (1) The purpose of the Medicaid and CHIP Child Core Set and the Medicaid Adult Core Set is to measure the overall national quality of care for beneficiaries, monitor performance at the State-level, and improve the quality of health care.

(2) The purpose of the Health Home Core Sets is to measure the overall program quality of health home services for Medicaid beneficiaries enrolled in a health home program under section 1945 or 1945A of the Act, monitor the impact of these two optional State plan benefits, monitor performance of these two benefits at the program level, and improve the quality of health care.

(d) *Applicability.* The provisions of this subpart apply as follows: (1) For the Child and Adult Core Sets, State includes the 50 States, the District of

Columbia, Puerto Rico, the Virgin Islands, and Guam.

(2) For the Health Home Core Sets, State includes any State (as defined under section 1101 of the Act for purposes of Title XIX of the Act) with an approved Medicaid Health Home State Plan Amendment under section 1945 or 1945A of the Act.

(e) *Applicability dates.* States must comply with the requirements of this subpart by no later than State reporting on the 2024 Core Sets, which must be submitted and certified by December 31, 2024.

#### § 437.5 Definitions.

As used in this subpart—

*Adult Core Set* means the Core Set of Adult Health Care Quality Measures for Medicaid established and updated annually as described in § 437.10(a).

*Attribution rules* means the process Medicaid and CHIP and other payers use to assign beneficiaries to a specific health care program or delivery system for the purpose of calculating the measures on the Core Sets.

*Behavioral health* means a beneficiary's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental disorders including substance use disorders.

*Behavioral health measure* means a quality measure that could be used to evaluate the quality of and improve the health care provided to beneficiaries with, or at-risk for a behavioral health disorder(s).

*Child Core Set* means the Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, established and updated annually as described in § 437.10(a).

*Core Sets* means the Child Core Set, the Adult Core Set, the section 1945 Health Home Core Set, and the section 1945A Health Home Core Set, collectively.

*Health Home Core Sets* means, collectively, the two Core Sets of Health Home Quality Measures related to the two Medicaid health home benefits under sections 1945 and 1945A of the Act, established and updated annually as described in § 437.10(a).

*Standardized format* means the format provided by the reporting system that States are required to utilize to submit Core Sets data to CMS.

*1945 Health Home Core Set* means the Core Set of Health Home Quality Measures related to the Medicaid health home benefit under section 1945 of the Act, established and updated annually as described in § 437.10(a).

*1945A Health Home Core Set* means the Core Set of Health Home Quality

Measures related to the Medicaid health home benefit under section 1945A of the Act, established and updated annually as described in § 437.10(a).

#### § 437.10 Child, Adult, and Health Home Core Sets.

(a) The Secretary shall—

(1) Identify, and annually update, the quality measures to be included in the Core Sets;

(2) Consult annually with States and other interested parties identified in paragraph (e) of this section to—

(i) Establish priorities for the development and advancement of the Core Sets;

(ii) Identify any gaps in the measures included in the Core Sets;

(iii) Identify measures which should be removed as they no longer strengthen the Core Sets; and

(iv) Ensure that all measures included in the Core Sets reflect an evidence-based process including testing, validation, and consensus among interested parties; are meaningful for States; are feasible for State-level and/or Health Home program level reporting as appropriate; and represent minimal additional burden to States.

(3) In consultation with States, develop and update annually the reporting guidance described in paragraph (b) of this section.

(b) Annual reporting guidance will include all of the following:

(1) Identification of all measures in all the Core Sets, including:

(i) Measures newly added and measures removed from the prior year's Core Sets;

(ii) Measures included in the Adult Core Set that are identified as behavioral health measures;

(iii) The specific measures for which reporting is mandatory for the Child, Adult, and 1945 and 1945A Health Home Core Sets;

(iv) The measures for which the Secretary will complete reporting on behalf of States and the measures for which States may elect to have the Secretary report on their behalf; and

(v) The measures, if any, for which the Secretary will provide States with additional time to report, as well as how much additional time the Secretary will provide, in accordance with paragraph (c) of this section.

(2) Guidance to States on how to collect and calculate the data on the Core Sets.

(3) Standardized format for reporting measure data required under this subpart.

(4) Procedures that State agencies must follow in reporting measure data required under this subpart.

(5) Identification of the populations for which States must report the measures identified by the Secretary under paragraph (b)(1) of this section, including, but not limited to beneficiaries—

(i) Receiving services through specified delivery systems, such as those enrolled in a managed care plan or receiving services on a fee-for-service basis;

(ii) Receiving services through specified health care settings and/or provider types, such as hospitals, outpatient facilities, Federally Qualified Health Centers and other safety-net providers, rural health clinics, Indian Health Service, Tribes and Tribal Organizations, or Urban Indian Organizations; and

(iii) Who are dually eligible for Medicare and Medicaid, including beneficiaries whose medical assistance is limited to payment of Medicare premiums and/or cost sharing.

(6) Attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population, as described in paragraph (b)(5) of this section, during the reporting period.

(7) The subset of measures among the measures in the Child Core Set, among the behavioral health measures in the Adult Core Set, and among the measures in the Health Home Core Sets that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary and informed by annual consultation with States and interested parties in accordance with paragraphs (a)(2) and (d) of this section.

(c) In issuing the guidance described in paragraph (b) of this section, the Secretary may provide that mandatory State reporting for certain measures and reporting for certain populations of beneficiaries will be phased in over a specified period of time, taking into account the level of complexity required for such State reporting; and

(d) In specifying which measures, and by which factors, States must report stratified measures consistent with paragraph (b)(7) of this section, the Secretary will take into account whether stratification can be accomplished based on valid statistical methods and without risking a violation of beneficiary privacy and, for measures obtained from surveys, whether the original survey instrument collects the variables necessary to stratify the measures, and such other factors as the Secretary determines appropriate; the Secretary will require stratification of 25 percent of the measures on each of the Core Sets (the Child Core Set, behavioral health

measures within the Adult Core Set, and Health Homes Core Sets) for which the Secretary has specified that reporting should be stratified by the second year of annual reporting after the effective date of these regulations, 50 percent of such measures for the third and fourth years of annual reporting after the effective date of these regulations, and 100 percent of measures beginning in the fifth year of annual reporting after the effective date of these regulations; and

(e) For purposes of paragraph (a)(2) of this section, the Secretary must consult with interested parties as described in this paragraph to include the following:

(1) States.

(2) Pediatricians, children's hospitals, and other primary and specialized pediatric health care professionals (including members of the allied health professions) who specialize in the care and treatment of children and adolescents, particularly children with special physical, mental, and developmental health care needs.

(3) Dental professionals, including pediatric dental professionals.

(4) Health care providers that furnish primary health care to children and families who live in urban and rural medically underserved communities or who are members of distinct population sub-groups at heightened risk for poor health outcomes.

(5) National organizations representing children and/or adolescents, including children with disabilities and children with chronic conditions.

(6) National organizations representing consumers and purchasers of children's health care;

(7) National organizations and individuals with expertise in pediatric health quality measurement.

(8) Voluntary consensus standards setting organizations and other organizations involved in the advancement of evidence-based measures of health care.

(9) With respect only to guidance on the Health Home Core Sets, providers of health home services under sections 1945 and 1945A of the Act.

(10) Such other interested parties as the Secretary may determine appropriate.

**§ 437.15 Annual reporting on the Child, Adult, and Health Home Core Sets.**

(a) *General rules.* (1) Except as provided in paragraph (a)(2) and (4) of this section, the agency—

(i) Must report annually, by December 31st, on all measures on the Child Core Set and the behavioral health measures in the Adult Core Set that are identified

by the Secretary pursuant to § 437.10(b)(1)(iii) of this subpart;

(ii) Must report annually, by December 31st, on all measures in the 1945 or 1945A Health Home Core Sets (as applicable) that are identified by the Secretary pursuant to § 437.10(b)(1)(iii) of this subpart, if the agency has elected to offer health home services under the State plan under section 1945 or section 1945A of the Act, and if the applicable health home program has an effective date and has been implemented more than 6 months prior to the December 31st reporting deadline; and

(iii) May report on all other measures in the Adult Core Set and Health Home Core Sets that are not described in paragraphs (a)(1)(i) and (ii) of this section.

(2) Measures identified per § 437.10(b)(1)(iv) will be reported by the Secretary on behalf of the agency.

(3) The agency must adhere to the reporting guidance described in § 437.10(b), except as described in paragraph (a)(4) of this section, when reporting on measures in the Core Sets.

(4) In reporting on all Core Sets measures, the agency may, but is not required to:

(i) Report on the measures identified by the Secretary pursuant to § 437.10(c) for which reporting will be, but is not yet required (that is, reporting has not yet been phased-in).

(ii) Report on the populations identified by the Secretary pursuant to § 437.10(c) for whom reporting will be, but is not yet required.

(b) *Reporting of Medicaid and CHIP beneficiaries.* In States that have implemented a separate child health program ("separate CHIP") under part 457 of this chapter:

(1) The agency must report, in accordance with attribution rules established by the Secretary pursuant to § 437.10(b)(6), on measures included in the Child Core Set for—

(i) Individuals enrolled in Medicaid who are within the measure specified age range for each measure (inclusive of individuals for whom the State claims the enhanced Federal Medicaid Assistance Percentage under § 433.11(a) of part 433 of this subchapter) as per reporting guidance described in paragraph § 437.10(b)(2); and

(ii) Individuals who are in the measure specified age range for each measure who are enrolled in Medicaid or the State's separate CHIP beneficiaries as per reporting guidance described in paragraph § 437.10(b)(2).

(2) If the separate CHIP elects to report on Adult Core Set measures for individuals enrolled in their separate CHIP, the agency must report on

individuals described in paragraphs (b)(1)(i) and (ii) of this section.

**§ 437.20 State plan requirements.**

(a) The State plan must specify that:

(1) The agency will report on the Child and Adult Core Sets in accordance with § 437.15;

(2) If health home services are covered under the State plan pursuant to section 1945 or 1945A of the Act, the agency will report on the applicable Health Home Core Set or Sets in accordance with § 437.15; and;

(3) If health home services are covered under the State plan pursuant to section 1945 or 1945A of the Act, the agency requires health home services providers to report to the agency on the measures in the applicable Health Home Core Set or Sets that are identified by the Secretary pursuant to § 437.10(b)(1)(iii), as a condition for receiving payment for health home services.

(b) [Reserved]

**PART 457—ALLOTMENTS AND GRANTS TO STATES**

■ 4. The authority citation for part 457 continues to read as follows:

**Authority:** 42 U.S.C. 1302.

■ 5. Amend § 457.700 by:

■ a. In paragraph (a)(2) removing the word "and" at the end of the paragraph;

■ b. In paragraph (a)(3) removing the period at the end of the paragraph and adding in its place "; and"; and

■ c. Adding new paragraph (a)(4).

The addition reads as follows:

**§ 457.700 Basis, scope, and applicability.**

\* \* \* \* \*

(a) \* \* \*

(4) Section 1139A and 1139B of the Act, which set forth the requirements for child and adult health quality measures and reporting.

\* \* \* \* \*

■ 6. Add § 457.770 to subpart G to read as follows:

**§ 457.770 Reporting on Health Care Quality Measures.**

(a) *Reporting the Child Core Set.* The State must report on the Core Set of Health Care Quality Measures for Children in Medicaid and CHIP (Child Core Set) for a separate child health program in accordance with part 437 of this chapter.

(b) *Reporting the Adult Core Set.* The State may elect to report on the Core Set of Adult Health Care Quality Measures in Medicaid (Adult Core Set) established by the Secretary in accordance with part 437 of this chapter. If the State reports measures on the Adult Core Set, such reporting must

be in accordance with part 437 of this chapter, except that reporting on behavioral health measures on the Adult Core Set is not mandatory.

(c) *Reporting of Medicaid and CHIP beneficiaries.* The State must report measures included in the Child Core Set

and, if applicable, Adult Core Set both separately from and combined with Medicaid beneficiaries (including title XXI funded Medicaid beneficiaries) in accordance with § 437.15(b) of this chapter.

Dated: August 15, 2022.

**Xavier Becerra,**

*Secretary, Department of Health and Human Services.*

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