DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 437, and 457

[CMS–2440–F]

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: Final rule.

SUMMARY: This document establishes requirements for mandatory annual State reporting of the Core Set of Children's Health Care Quality Measures for Medicaid and the 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.

DATES:

Effective Date: These regulations are effective January 1, 2024.

Applicability Date: The initial round (2024) of Core Sets reporting must be submitted and certified by States by December 31, 2024.

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SUPPLEMENTARY INFORMATION:

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. 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. Combined, as of April 2023, the two programs provided health coverage to more than 94 million people, nearly half of whom are children (more than 42 million).[1]

Given the significant role that Medicaid and CHIP play in America's health care system, this rule requires—for the first time—States, the District of Columbia (DC) and certain territories to mandatorily report on measures of the quality of health care provided to Medicaid and CHIP beneficiaries.

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3, enacted February 4, 2009), established Federal requirements regarding voluntary quality measurement to assess the care delivered to beneficiaries in both 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, and directed the Secretary to publish for general comment an initial recommended core set of child health quality measures 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. CMS released the initial Child Core Set, consisting of 24 measures, in 2009, with voluntary State-level reporting beginning in Federal Fiscal Year (FFY) 2010.[2]

Section 2701 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted March 23, 2010) as amended and revised by the Healthcare and Education Reconciliation Act (Pub. L. 111–152, enacted March 30, 2010), referred to collectively as the Affordable Care Act (ACA), added a new section 1139B of the Act, extending the measurement of health care quality to Medicaid-eligible adults. 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 the proposed rule). CMS issued the initial Adult Core Set consisting of 26 quality measures in 2012, and voluntary reporting of these measures began in FFY 2013.[3]

This rule implements 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 behavioral health measures on the Adult Core Set, this rule establishes 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. Section 1945 of the Act (added by section 2703 of the ACA and later amended by section 1006(a) of the SUPPORT Act) and section 1945A of the Act (added by section 3 of the Medicaid Services Investment and Accountability Act of 2019)[4] give States options for implementing two different Medicaid health home State plan benefits. The section 1945 health home benefit is for Medicaid-eligible individuals who have (1) two or more chronic conditions, as defined in section 1945(h)(2) of the Act, (2) at least one chronic condition, as defined in section 1945(h)(2) of the Act, and who are at risk for a second, or (3) at least one serious and persistent mental health condition.[5] 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.[6] States were able to begin covering the section 1945 health home benefit on

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[1] February 2023 Medicaid and CHIP Enrollment data: *https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/april-2023-medicaid-chip-enrollment-trend-snapshot.pdf.*

[2] Initial Child Core Set: *https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SHO11001.pdf.*

[3] Initial Adult Core Set: *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib-01-04-12.pdf.*

[4] Public Law 116–16, enacted April 18, 2019.

[5] 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.*

[6] On August 1, 2022, we issued 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.*

January 1, 2011. States were able to begin covering the section 1945A health home benefit on October 1, 2022.

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. Section 1945(c)(4)(B) of the Act also requires certain States with an approved substance use disorder (SUD)-focused section 1945 health home State plan amendment (SPA) to report information to the Secretary on certain topics, including on the quality of health care provided to SUD-eligible individuals receiving health home services under the SUD-focused health home SPA.[7] Section 1945(c)(4)(B) of the Act 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. We have 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.[8]

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, we have 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).[9] We published an initial core set of section 1945 health home quality measures in 2013, with updates issued annually. We also explained when publishing the initial core set of section 1945 health home quality measures 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.[10] 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, we have generally tried to align it with the Child and Adult Core Sets. In November 2019, we released a Center for Medicaid and CHIP Services (CMCS) Informational Bulletin (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.[11]

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. We interpret 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.

This rule establishes the following requirements for States electing to implement the benefit under sections 1945 or 1945A of the Act. Under the provisions of this rule, States that have implemented the section 1945 and/or 1945A health home benefit must 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 must require their health home providers to report to the State on those measures. 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 a SUD-focused section 1945 health home). For States covering the section 1945 health home benefit, this requirement is 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 is also 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 this rule does 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 is further supported by the language in

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[7] Center for Medicaid and CHIP Services (CMCS) Informational Bulletin, ''New Reporting Measures for Substance Use Disorder (SUD)-focused Health Homes,'' November 27, 2019, at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib112719.pdf.*

[8] 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.*

[9] SUD Health Home reporting CIB at *https://www.medicaid.gov/Federal-policy-guidance/downloads/cib112719.pdf.*

[10] Initial section 1945 Health Home Core Set: *https://www.medicaid.gov/federal-policy-guidance/downloads/smd-13-001.pdf.*

[11] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib112719.pdf.*

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 are 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 rule implements 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 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 and Adult Core Sets, and the sections 1945 and 1945A Health Home Core Sets, represents 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. The ability to assess the quality of and access to care furnished by State Medicaid and CHIP programs is critical given that more than 93 million Americans receive coverage in Medicaid and CHIP, and the annual expenditures for the programs are over $600 billion.[12]

1. Development of Core Sets

To ensure that the measures included in the Child and Adult Core Sets reflect the needs of Medicaid and CHIP beneficiaries and provide the types of information necessary to assess the overall national quality of health care, sections 1139A and 1139B of the Act establish a number of specific parameters for the development of these core sets. For a complete and full description of these requirements see sections 1139A and 1139B of the Act.

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. We have updated the section 1945 Health Home Core Set annually since 2013, and in 2021 we established a Health Home Annual Review Workgroup to align this update process with the CMS process to annually update the Child and Adult Core Sets (as further discussed below).

We formed a joint Child and Adult Core Sets Annual Review Workgroup in 2019, consolidating what had previously been two separate workgroups, to implement the statutory requirements and to ensure that measures in the Core Sets are meaningful for States and interested parties and feasible for State-level reporting.[13] In 2021, the Health Home Annual Review Workgroup was implemented, 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 Sets Annual Review Workgroup and the Health Home Annual Review Workgroup (''Workgroups'') 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 and then submitted to CMS. All meetings are open to the public, and public comment is invited during each meeting.

D. Shifting From Voluntary to Mandatory Reporting

In 2018, Congress passed two laws 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 (Pub. L. 115–123, enacted February 9, 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 FFY 2024. Specifically, section 1139A(a)(4)(B) of the Act provides that beginning with the annual State report on FFY 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, section 5001 of the SUPPORT Act (Pub. L. 115–271, enacted October 24, 2018), added a new subparagraph (B) to section 1139B(b)(3), 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 FFY 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, this final rule also implements certain statutory requirements in sections 1902(a)(6), 1945, and 1945A of the Act to require States that have opted to implement the section 1945 or section 1945A health home benefit to report on the section 1945 or 1945A Core Sets, as applicable, and also to require their health home providers to report on the applicable health home core set.

II. Summary of the Proposed Provisions and Analysis of and Responses to the Public Comments

We received 93 public comments from individuals and organizations, including, but not limited to, State government agencies, non-profit health care organizations, advocacy groups, associations, law firms, managed care organizations, academic groups, tribal organizations, and private citizens. We thank the commenters for their consideration of the proposed requirements for mandatory reporting and appreciate the submission of all of the comments received. In general, commenters supported the proposed rule. In this section, arranged by subject area, we summarize the proposed provisions, the public comments received, and our responses. For a complete and full description of the proposed mandatory reporting requirements, see the 2022 proposed rule, ''Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting'' (87 FR 51303, August 22,

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[12] January 2023 Medicaid and CHIP Enrollment data: *https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/january-2023-medicaid-chip-enrollment-trend-snapshot.pdf;* and *https://www.medicaid.gov/state-overviews/scorecard/annual-medicaid-chip-expenditures/index.html.*

[13] Annual Review and Selection Process: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/annual-core-set-review.pdf.*

2022) hereafter referred to as the ''proposed rule''.

A. Basis, Scope, Purpose and Applicability

As discussed in section II.A. of the proposed rule, we proposed in § 437.1 to specify the basis and scope of the proposed requirements and to establish the purpose of the Child Core Set, Adult Core Set, and the Health Home Core Sets. We also proposed in § 437.10 to implement a process through which we would develop and update the Child Core Set, Adult Core Set, and the Health Home Core Sets (sections 1945 and 1945A) and proposed in § 437.10 the process through which we would establish requirements that State agencies would have to meet when reporting on the measures included in these Core Sets. We also proposed in §§ 437.10 and 437.15 the form, reporting, time, and manner requirements for reporting the Core Sets. We proposed that the requirements for Child and Adult Core Sets reporting would apply to the 50 States, DC, Puerto Rico, the Virgin Islands, and Guam; and throughout the rule the term ''States'' is used to collectively refer to these States and territories when we are 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 Set measures. We also proposed requirements for State reporting of health home quality measures in §§ 437.10 and 437.15 and noted the Secretary has the authority under sections 1945(g) and 1945A(g) of the Act to require States to require their health home providers to report on the Home Health Core Sets measures. 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. We also proposed, in § 437.15(a)(1), to set the deadline to meet these requirements for State reporting on the 2024 Core Sets as no later than December 31, 2024.

In general, commenters who submitted public comments on the proposed general requirements for mandatory reporting supported the proposed scope, purpose, and process. We are finalizing those provisions in §§ 437.1, 437.10 and 437.15 with revisions to § 437.10 to specify timelines for Child and Adult Core Sets updates and timelines for CMS reporting of Child and Adult Core Sets data. We added § 437.15(a)(1)(i) to specify timelines for the first year of mandatory reporting of the Child Core Set and behavioral health measures on the Adult Core Set. The addition of this new provision shifted the numbering of the remainder of the provisions in § 437.15(a)(1), redesignating § 437.15(a)(1)(i) to § 437.15(a)(1)(ii), etc. We also edited § 437.15(a)(1)(iv), originally proposed as § 437.15(a)(1)(iii), to include only the measures on the Adult Core Set that are not included in § 437.15(a)(1)(i) and (ii) as optional for states to report, removing the reference to the Health Home Core Sets to align with changes in other sections. Below is a summary of the public comments we received related to the scope, purpose, and applicability of the requirements as proposed and our responses.

Comment: Several commenters supported the proposed rule in its entirety or specifically indicated their support for reporting of a specific component such as the behavioral health measures on the Adult Core Set. Many of the comments referred to the positive outcomes that CMS expects from finalization of these proposals. The commenters generally expressed support for these proposals and noted that the proposed changes to the requirements for reporting the Core Sets will support the improvement of health outcomes for Medicaid and CHIP beneficiaries overall in addition to addressing health disparities and inequities.

Response: We appreciate the support for our proposal and thank those who took the time to give us feedback.

Comment: Several commenters recommended the following revisions (indicated below in bold typeface) to the proposed § 437.1(c)(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 and promote comparative analysis at multiple levels, including the State, program, plan and provider levels; and eliminate health disparities across populations;** and improve the quality of health care.'' They cite the following statutes:

- Section 1139A(a)(8) of the Act to support the definition of the Child Core Set as a ''group of valid, reliable, and evidence-based quality measures.''
- Section 1139A(b) of the Act established the Pediatric Quality Measures program to advance the development of evidence-based quality measures for children which, per sections 1139A(b)(2)(B) and (C) of the Act, ''shall, at a minimum, be . . . designed to identify and eliminate racial and ethnic disparities in child health and the provision of health care'' and ''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.''
- Section 1139A(a)(3)(D) of the Act to highlight health disparities and comparative analysis in its requirement that the initial Child Core Set ''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.''
- Sections 1139B(a) and (b)(5) of the Act that direct the Secretary to develop the Adult Core Set ''in the same manner'' as the Child Core Set.

Response: We appreciate the suggestion to revise this section of the regulation and agree with the commenters on the importance of aligning quality measurement across multiple levels and measure sets, as feasibility and applicability allow. We consider measuring and reporting health disparities to be a cornerstone of CMS' approach to advancing health equity and improving quality as outlined in the proposed rule. The public comment recommending that the purpose of the Child and Adult Core Sets include ''comparison of quality and data at a State, program, plan, and provider level'' cites the statutory requirement as section 1139A(b)(2)(C) of the Act. That statutory requirement applies to measures developed under the pediatric quality measures program and does not refer to the reporting requirements for the Child Core Set, which are established in section 1139A(c) of the Act and require ''Annual State Reports Regarding State-Specific Quality of Care Measures Applied Under Medicaid or Chip.'' Section 1139A(c) of the Act requires reporting of State-level Child Core Set data, and does not require program-, plan- or provider-level reporting. In addition, it does not necessarily require comparative analysis of such data. There is similar language in section 1139B(d) of the Act, which requires reporting of Adult Core Set data at the State-level. Given these considerations, we are finalizing § 437.1(c)(1) as proposed, with the purpose of the Medicaid and CHIP Child Core Set and the Medicaid Adult Core Set to measure the overall national quality of care for beneficiaries, monitor performance at the State-level, and improve the quality of health care.

Comment: Several commenters recommended that CMS add a provision to the final rule to require CMS to collect, analyze, and make publicly available Child and Adult Core Sets data annually by September 30th. Other commenters recommended that CMS add a provision to the final rule to require CMS to publish recommended changes to the Child and Adult Core Set measures by January 1 of each year.

Response: The statutory authority for the Core Sets at sections 1139A(c)(2) and 1139B(d)(2) of the Act requires the Secretary to collect, analyze, and make publicly available, by September 30th of each year, the information reported in the annual State reports described in sections 1139A(c)(1) and 1139B(d)(1) of the Act. Similarly, sections 1139A(b)(5) and 1139B(b)(5)(B) of the Act require the Secretary to publish recommended changes to the Child and Adult Core Sets by January 1st annually. We have historically followed this timeline for updating Core Sets. To address the recommendations received in public comments regarding the Child and Adult Core Sets to add these provisions to the final rule, we added these requirements at § 437.10(a)(1) and (4). Although the comment is not specific to Health Home Core Sets, we are specifying at § 437.10(a)(5) that the Secretary shall collect, analyze, and make publicly available data from the Health Home Core Sets annually.

Comment: One commenter recommended that because most of the current Health Home Core Sets measures have continuous enrollment periods of ''no gaps in coverage,'' ''no more than 45-day gap in coverage,'' and ''no more than 90-day gap in coverage,'' CMS should alter § 437.15(a)(1)(ii) in the proposed rule from ''the applicable health home program has an effective date and has been implemented more than 6 months prior to the December 31st reporting deadline'' to ''. . . implemented for nine or more months . . .''

Response: In an effort to include as many active health home programs as possible in quality measurement reporting, we believe it is preferable to maintain the minimum requirement as it was proposed, even if this means a health home program may lack sufficient data to report on certain measures, as what a health home program can report will still be useful to help us and the State to understand the quality of care provided in the health home program. Specifically, the requirement states that a health home program must report if it has been implemented for more than 6 months prior to the December 31st reporting deadline. Therefore, we are finalizing the proposed § 437.15(a)(1)(ii) at § 437.15(a)(1)(iii) (to accommodate addition of a new provision at § 437.15(a)(1)(i), as discussed previously in this final rule) without other changes.

Comment: A few commenters expressed support for the proposed changes but provided feedback on areas that were not addressed in the proposed rule. One commenter noted that it is critical that health plans reporting on Core Set quality measures have effective tools to communicate with enrollees in order to ensure that enrollees understand plan benefits and recommended health care screenings and services, and that these plans can also address barriers to higher quality care. This commenter requested that CMS issue guidance to States to help improve communication with beneficiaries due to confusion regarding the Telephone Consumer Protection Act (TCPA) (Pub. L. 102–243, enacted December 20, 1991). Another commenter recommended that CMS work with State Medicaid programs to remove undue pharmacy scope of practice restrictions, and to adopt payment pathways that recognize pharmacists as eligible providers and enable pharmacies to provide and be reimbursed for clinical care interventions that improve the health and wellbeing of beneficiaries. Another commenter suggested CMS consider a pilot to apply the pediatric measures to all payers, starting with States with all-payer claims databases as this would help demonstrate the impact of different interventions on children's health more broadly and may address some of the ''small numbers'' challenges when looking at subgroups of children, such as children with special health care needs. Lastly, one commenter recommended the development of national standards for assessing access to Medicaid and CHIP services to include at minimum: time and distance standards, coverage of reimbursement for a variety of health care services, and consistent standards across fee-for-service (FFS) and managed care.

Response: We thank the commenters for their support of the proposed requirements for mandatory reporting and appreciate the submission of these comments but note that these areas are outside of the scope of this rulemaking.

Comment: One commenter requested confirmation that States with section 1115 demonstrations are included in mandatory reporting.

Response: States are required to report mandatory Core Set measures for all required populations, even if those beneficiaries are enrolled in a section 1115 demonstration. States with section 1115 demonstrations are required under demonstration Special Terms and Conditions (STCs) to monitor their demonstration's performance. Section 1115 demonstration monitoring and reporting requirements are in addition to and not in lieu of requirements for State-level Core Set reporting as outlined in this final rule. As part of the demonstration monitoring process, we may require that States report a select set of Core Set measures that support assessing performance and progress toward specific goals and objectives of the demonstration. This reporting, which may be adapted for demonstration populations, is in addition to mandatory Core Set reporting. Additionally, States may leverage Core Set measures as part of their section 1115 demonstration evaluation.

Comment: Several commenters recommended that CMS streamline the language in § 437.15(a) to remove references to the specific sets of measures (that is, the Child Core Set or behavioral health measures on the Adult Core Set) that will become mandatory under this final rule as redundant, noting that section 1139B of the Act does not preclude CMS from using its authority under section 1902(a)(4) of the Act to require reporting on additional measures if necessary to ensure the proper and efficient administration of the Medicaid program. Other commenters encouraged CMS to consider its independent authority, outside of sections 1139A and 1139B of the Act to require mandatory reporting of additional measures to advance quality in Medicaid through section 1902(a)(6) of the Act.

Response: We believe the Congressional intent is for mandatory reporting to apply to the Child Core Set and the behavioral health measures of the Adult Core Set, and not to apply to the remaining quality measures. For the Child and Adult Core Sets, this rulemaking is not proposing to make mandatory any measures beyond those under sections 1139A and 1139B of the Act. Therefore, we are maintaining the proposed scope of mandatory reporting and are not making any changes to § 437.15(a) in response to this comment.

Comment: One commenter urged CMS to consider ways to help address any burden that new data collection efforts may cause for States by exploring funding opportunities to assist States in conducting the necessary activities to implement these important provisions effectively.

Response: We appreciate the submission of this comment but note that this issue is outside of the scope of this rulemaking. As noted in the proposed rule, in Medicaid, enhanced

Federal Financial Participation (FFP) is available at 90 percent for the design, development, and installation (including of enhancements) 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.[14] Receipt of these enhanced Federal Medicaid matching rates is conditioned upon States meeting a series of standards and conditions.[15] 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. We also note that under section 1903(a)(7) of the Act, Federal Medicaid matching funds may be available at a 50 percent Federal match rate for staffing and contracting related to implementing Core Set reporting requirements, as these activities might, subject to certain conditions, be necessary for the proper and efficient administration of the State plan. To the extent these system expenditures 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 expenditure, States can claim at a State's CHIP enhanced FMAP (eFMAP) available under section 2105(b) of the Act. We note that systems expenditures are administrative expenditures, and CHIP administrative funding is limited to 10 percent of either a State's total computable allotments for a FFY or its total expenditures reported for a FFY, whichever is lower.[16]

B. Definitions

As discussed in section II.B. of the proposed rule, in § 437.5 we proposed the definitions related to quality measurement and reporting. Commenters generally supported the proposed definitions, and we are finalizing these provisions with a revision to the definition of behavioral health in § 437.5 and other minor wording changes to clarify cross-references within the same subpart. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters recommended that CMS revise (with revisions indicated in boldface type below) the definition of ''behavioral health'' proposed at § 437.5: ''Behavioral health means a beneficiary's whole emotional and mental well-being, which includes, but is not limited to, the prevention, treatment **and recovery** from mental disorders **and** substance use disorders.'' The commenters recommended adding ''and recovery'' to the meaning of behavioral health and replace ''including'' with ''and'' regarding the inclusion of substance use disorders in this definition.

Response: We agree with the recommendation to add ''and recovery,'' as recovery is a key part of improving the health outcomes for individuals with behavioral health conditions, and are revising the definition of behavioral health in § 437.5 of this final rule.[17] Regarding the second suggestion, we will retain the language as originally proposed, ''mental disorders including substance use disorders,'' as that aligns with the American Psychiatric Association's position, reflected in the Diagnostic and Statistical Manual of Mental Disorders (DSM–5), that substance use disorders are included in the definition of mental disorders.

Comment: Several commenters supported CMS' proposal to broadly define ''behavioral health'' and ''behavioral health measures.'' Some commenters recommended additional guidance on the potential scope of conditions and quality measures included in the definition to ensure a shared understanding of such definitions and help prepare for reporting.

Response: We appreciate the support for the proposed ''behavioral health'' definition, which aligns with the behavioral health conditions included in the American Psychiatric Association's DSM–5. We plan to use the DSM–5 as a resource in determining which measures on the Adult Core Set should be considered behavioral health measures and thus subject to mandatory reporting requirements and will specify these measures in annual reporting guidance. In November 2022, we issued the annual CIB updating the Core Sets, the 2023–2024 Core Sets measure lists, to include a subset of measures identified as the Behavioral Health Core Set, which includes all the behavioral health measures on the Adult Core Set.[18] [19] As noted, we are finalizing the definition in § 437.5 with one revision, to add ''and recovery.''

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

As discussed in section II.C. of the proposed rule, in § 437.10 we proposed to continue the existing annual process of identifying and updating the measures comprising the Child, Adult, and Health Home Core Sets through annual consultation with States and other interested parties to establish priorities for the development and advancement of the Child, Adult, and both Health Home Core Sets. We proposed in § 437.10(a)(2) to identify any gaps in the measures included in each Core Set; to identify measures which should be removed because they no longer strengthened the Core Sets; and to ensure that all measures included in the Core Sets would reflect an evidence-based process (including testing, validation, and consensus among interested parties). The measure(s) selected would be meaningful for States and feasible for State-level and/or health-home program level reporting, as appropriate.

Commenters generally supported the process proposed in § 437.10(a) and (e) by which we would update the Core Sets and publicly report data on such measures. Commenters also asked several questions about specific measures on the Core sets. We will be finalizing these provisions in this final rule with a revision to § 437.10(a)(iv), where we describe measure criteria for the Core Sets, and with revisions to §§ 437.10(b) and 437.15(a), where we have provided additional detail on reporting requirements, and we discuss these changes further in sections II.D.2. and II.D.3. of this final rule. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters provided feedback on areas that were not addressed in the proposed rule such as: proposing specific changes to the Core Sets, proposing measure additions or removals, identifying measure gaps on the Core Sets, adding non-behavioral health measures to the list of Adult Core Set measures required in mandatory reporting, and measure development and testing. Specifically, a few commenters recommended a ''duration of coverage'' measure as called for by existing statute (section 1139A(a)(3)(A) of the Act) to assess the negative impact of churn on the quality of care that children receive and recommended that this measure be added to the Child Core Set no later than mandatory reporting for 2024.

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[14] See section 1903(a)(3)(A)(i) and (B) of the Act, § 433.15(b)(3) and (4), and subpart C of 42 CFR part 433.

[15] 42 CFR 433.112 and 42 CFR 433.116.

[16] See 42 CFR 457.618(e)(1).

[17] CMS Behavioral Health Strategy: *https://www.cms.gov/cms-behavioral-health-strategy.*

[18] 2022 Core Set CIB: *https://www.medicaid.gov/sites/default/files/2022-11/cib111522_0.pdf.*

[19] 2023–2024 Behavioral Health Core Set: *https://www.medicaid.gov/sites/default/files/2022-11/2023-bh-core-set.pdf.*

Response: We appreciate the submission of these comments, and we will consider these comments as part of the measure adoption subregulatory process. We encourage the commenters to attend meetings of the joint Child and Adult Core Sets Annual Review Workgroup and the Health Home Annual Review Workgroup (Workgroups), which are convened annually to develop recommendations on how to revise, strengthen, and improve the applicable Core Sets measures.[20] All meetings are open to the public, public comment is invited during each meeting, and every year the Workgroup recommendations are published for public comment.[21]

We agree with the commenters regarding the importance of understanding the continuity of coverage among Medicaid and CHIP beneficiaries, recognizing that disruptions in coverage can lead to periods of uninsurance, delayed care, and reduced access to preventive care and other essential care for beneficiaries. Beneficiaries moving on and off Medicaid and CHIP coverage (sometimes called ''churning'') can lead to higher administrative costs, less predictable State expenditures, and higher monthly health care costs due to pent-up demand for health care services. To help address this issue, section 5112 of subtitle B of title V of division FF of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328), which was signed into law December 29, 2022, requires all States to provide 12 months of continuous eligibility for most children under the age of 19 in Medicaid and CHIP, effective January 1, 2024. There are no existing standardized quality measures in this area; however, we published a data brief in November 2022 on Medicaid and CHIP Access: Coverage and Behavioral Health Data Spotlight, which provides in depth data on continuity of coverage.[22] We will consider the best venue for continued reporting of these important metrics.

Comment: One commenter encouraged CMS to consider making the National Core Indicators Survey (NCIDD–AD) within the Adult Core Set a voluntary component, because they believe that there would be a low response rate to this survey, which is administered in person.

Response: While we appreciate the submission of this comment, the issue of which specific measures will be voluntary versus mandatory will be considered in the subregulatory measure revision process described previously in this final rule. The NCIDD–AD measure is an experience of care survey that was added to the Adult Core Set to address a gap in measures for long-term services and supports. It has not been identified as a behavioral health measure and will not become mandatory for State reporting in 2024. Measure administration and technical specifications are set by the measure steward, the National Association of State Directors of Developmental Disabilities Services and Human Services Research Institute.

Comment: One commenter encouraged CMS to work with States to ensure that contraceptive care measures are used appropriately in the Child Core Set without reference to an external benchmark that may suggest an appropriate level of contraceptive use, and without provider incentives that could promote forms of coercion.

Response: This comment is outside the scope of rulemaking. However, we appreciate this comment identifying potential issues related to the appropriate use and interpretation of the contraceptive care measure results. Specific to the Contraceptive Care measure, we note that we do not publish a benchmark for this measure, which examines provision of a most or moderately effective method of contraception and provision of a long-acting reversible method of contraception. The lack of benchmark reflects that some individuals will make informed decisions to choose methods in the lower tier of efficacy even when offered the full range of methods.[23] To help ensure that data users understand that the goal is not prescribing contraceptives to 100 percent of women, we include language in public reporting (that is, the Child Core Set Chart Pack)[24] indicating the estimated percentage in need of contraceptive services. Additionally, we cite resources from Office of Population Affairs (OPA) with language about the goal and guidance for how to interpret the measure.[25]

Comment: Several commenters recommended that CMS not use the Core Set data for State comparisons without accounting for State variation, including program and benefit design, geography and resources, and beneficiary characteristics.

Response: We appreciate the submission of these comments and will take this feedback into consideration when developing Core Set reporting guidance and materials for public reporting.

Comment: One commenter requested that the Secretary require managed care organizations (MCOs) to deliver stratified data in a timely manner to Federally Qualified Health Centers (FQHCs), facilities, and providers.

Response: While we appreciate the submission of this comment, this issue is outside the scope of this rulemaking.

Comment: Several commenters provided recommendations on our publication of Core Set data, including that CMS limit phasing-in the publication of State-level data to no more than 3 years; that CMS publish all State-level data even if not enough States have reported for CMS to conduct comparative analysis and to report quartile rankings; that CMS reconsider its policy to limit public reporting of voluntary Core Set measures to measures that are reported by at least 25 States; and that CMS publish standardized core measures data with national benchmarks that would permit comparisons across States and over time.

Response: We will continue to publish Core Set data annually, as required under sections 1139A(c)(2) and 1139B(d)(2) of the Act for the Child Core Set and the Adult Core Set, respectively. We have worked to find a balance in the reporting of State data that meets these statutory reporting requirements while taking into consideration data quality and the ability to conduct comparative analysis. We appreciate the submission of these comments and will take them into consideration as we review State data as well as for future policymaking.

Comment: Several commenters recommended that CMS seek to align the Core Set measures with other national reporting systems such as the Core Quality Measures Collaborative (CQMC) or the Medicaid and CHIP Quality Rating System (MAC QRS) in order to minimize additional reporting burden on providers and to ensure parsimony, alignment, harmonization, and the avoidance of competing quality measures. Other commenters noted that CMS should align with measures appropriate for State health care goals as defined by the National Committee for

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[20] *https://www.medicaid.gov/medicaid/quality-of-care/downloads/annual-core-set-review-11102022.pdf.*

[21] *https://www.mathematica.org/features/maccoresetreview.*

[22] *https://www.medicaid.gov/medicaid/access-care/index.html.*

[23] *https://opa.hhs.gov/research-evaluation/title-x-services-research/contraceptive-care-measures.*

[24] Annual Reporting on the 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#AnnualReporting.*

[25] *https://opa.hhs.gov/sites/default/files/2020-07/interpreting-rates-for-contraceptive-care-measures.pdf.*

Quality Assurance (NCQA), National Quality Forum (NQF), and the Utilization Review Accreditation Commission (URAC).

Response: We agree with the commenters on the importance of parsimony, alignment and harmonization in quality measurement and will consider these comments for subsequent rulemaking. Throughout the annual Core Set review process, we facilitate measure alignment through engagement with a variety of internal and external interested parties, Federal partners, other reporting systems related to Medicaid and CHIP, and Medicare and Marketplace quality programs, as well as through initiatives such as the Universal Foundation, a set of quality measures around which programs at CMS are aligned.[26] In some cases, we may use different measures in order to capture quality at different levels of the health system, such as at the State level. Given that these processes are in place, we are not making changes to § 437.10(a) in response to these comments.

Comment: Several commenters stated that that the proposed language requiring consideration of regulatory burden would hinder CMS' ability to add new measures to the Core Sets and to require States to report measures by specific populations or demographic characteristics. They recommended amending the proposed § 437.10(a)(2)(iv) to delete the reference to burden to the States as follows (edits in bold): ''(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; **and** are feasible for State-level and/or Health Home program level reporting as appropriate.''

Response: We agree with this comment that this language is open to interpretation and therefore accept the suggestion to revise § 437.10(a)(2)(iv) to remove the language ''and represent minimal additional burden to States.'' The remaining language in the provision regarding feasibility will help to ensure that we will not overburden States when adding measures to the Core Sets, and we agree that the additional language about minimal additional burden may hinder our ability to require more complex measures and stratification over time. While section 1945A(g)(2)(A) of the Act, which applies to the section 1945A Health Home Core Set, requires any State reporting under that provision to be ''in such form and manner determined by the Secretary to be reasonable and minimally burdensome,'' this requirement applies to CMS regardless of whether it is repeated in CMS' regulations. We believe that we can and will meet this requirement by taking multiple steps and intend to keep doing so for all Core Sets. For example, as specified in § 437.10(a) and (e) of the proposed rule, States and providers of health home services under sections 1945 and 1945A of the Act are among the interested parties that are consulted in development of the Core Sets, and this process is designed to consider burden of reporting in measure selection. We have already released the list of measures included in the 2024 Child, Adult, and section 1945 Health Home Core Sets.[27] Additionally, we have released the list of measures under consideration for the 2024 section 1945A Health Home Core Set to allow States and health home programs time to prepare.[28] We also aim to align measures across programs as much as possible, and to identify measures for additional reporting that States already have the infrastructure to calculate. For example, the section 1945A Health Home Core Set under consideration currently contains 7 quality measures, all of which can be calculated using administrative claims data only.

Comment: One commenter recommended that CMS harmonize the Core Sets so that reporting is not duplicated across different programs, such that State reporting of the Child Core Set would mean that reporting would not be required again for the subset of children included in the health home. This commenter recommended that, for those children, only the additional health home-specific measures should need to be reported.

Response: While we aim to align measures across programs as much as possible, the Child, Adult, and Health Home Core Sets data are reported at different levels. Specifically, the Child and Adult Core Sets data is reported to us at the State level, and Health Home Core Sets data is reported to us at the program level. For this reason, the same calculation cannot be used in both the Child Core Set or Adult Core Set and either of the Health Home Core Sets, as States have not submitted the data in their Child and Adult Core Sets reporting that would be necessary for us to derive health home program rates from State-level reporting. Regarding duplication of reporting, section 1945A(g)(1)(B) of the Act requires section 1945A health home providers to report to the State information on all applicable measures for determining the quality of health home services provided by that health home provider, including to the extent applicable, child health quality measures and measures for centers of excellence for children with complex needs developed under section 1139A of the Act. Per section 1945A(g)(2)(A)(i) of the Act, the State then reports this information to us.

Comment: One commenter recommended that CMS remove measures which do not have National Quality Forum (NQF) endorsement from the Core Sets.

Response: We appreciate the submission of this comment, and it will be considered in the subregulatory measure identification process. However, we note that statute (sections 1139A and 1139B of the Act) does not limit the Child and Adult Core Sets to measures with NQF endorsement and, as required under the statute (sections 1139A and 1139B of the Act) for Child and Adult Core Sets, measures are selected through the Annual Core Set Workgroup process established by CMS. Health Home Core Sets are also selected through the Annual Core Set Workgroup process established by CMS, even though this process is not statutorily required for these core sets.

Comment: Several commenters recommended that CMS review the list of individuals who participate in the Annual Core Set Workgroup to ensure meaningful representation from beneficiaries of all ages and their advocates, including people with disabilities and behavioral health disorders (including substance use disorders). Several commenters requested that the Workgroup have representation of specific types of organizations and individuals, including but not limited to: beneficiaries, MCOs, purchasers of health care, providers and consumers and/or national organizations that represent adults, FQHCs, pharmacies and pharmacists, providers and health care professionals, and beneficiaries served through a Health Home (this would apply only to the Health Home Core Sets).

Response: We appreciate the submission of these comments and will take them into consideration as we organize future Workgroups. All

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[26] *https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf.*

[27] CMS released both the 2023 and 2024 Child and Adult Core Sets in November 2022 (*https://www.medicaid.gov/federal-policy-guidance/downloads/cib111522.pdf*) and the 2023 and 2024 Health Home Core Sets in December 2022 (*https://www.medicaid.gov/medicaid/quality-of-care/downloads/2023-health-home-core-set.pdf*).

[28] Proposed 1945A Health Home Core Set *https://www.medicaid.gov/medicaid/quality-of-care/downloads/2024-1945a-health-home-core-set.pdf.*

Workgroup meetings are open to the public, and public comment is invited during each meeting.

Comment: One commenter recommended that CMS monitor the Workgroup process to determine if interested parties' feedback is being adequately addressed or if a formal rulemaking process is necessary.

Response: We appreciate the submission of this comment and will take it into consideration as we organize future Workgroups and monitor the public comment process.

Comment: One commenter recommended that CMS offer States and health care organizations financial assistance to develop and deploy health equity efforts, including funding support in addressing the capture of self-reported data. Another commenter recommended that CMS require States to submit plans for mitigating persistent disparities and regularly report on their progress to close access and quality gaps.

Response: While we appreciate these comments, they are outside the scope of this rulemaking, which addresses only Core Sets data and measurement. However, we note that Medicaid and CHIP Federal matching funds are available for State expenditures on the design, development, and installation (including of enhancements), and for operation, of mechanized claims processing and information retrieval systems. This could include State expenditures related to operating such systems for Core Sets reporting. We also note that under section 1903(a)(7) of the Act, Federal matching funds are available for activities necessary for the proper and efficient administration of the Medicaid State plan. This may include improving data reporting, which could promote greater health equity.

Comment: One commenter recommended that CMS examine and prioritize the selection of Child Core Set measures that can provide actionable data at the level of providers to continue to improve pediatric outcomes and focus on health disparities and measures that can provide the most value in terms of informing the quality of pediatric care.

Response: While we appreciate this comment, provider-level data is outside the scope of the rulemaking, which addresses reporting at the State and health home program level. We note also that the statutory mission of the Child Core Set, as stated in section 1139A(3)(D) of the Act, specifies "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."

Comment: One commenter recommended that CMS improve the measure sets' relevance to children with special health care needs and children with medically complex conditions included in sections 1945 and 1945A health home programs.

Response: We agree with the importance of reflecting all populations that are served in both section 1945 and 1945A health home programs in the Health Home Core Sets. The specific measures to be included in the Health Home Core Sets, which are determined through the workgroup process finalized in § 437.10(a), will be released through annual subregulatory guidance.

1. Annual Reporting Guidance

As discussed in section II.C.1. of the proposed rule, we proposed in §§ 437.10 and 437.15 to require that States use standardized formats and procedures established by the Secretary when reporting on the Child, Adult, and Health Home Core Sets. We also proposed in § 437.10(a)(3) and (b) that we would develop and annually update the reporting guidance needed by States to report on all applicable Core Sets and described the components of the annual reporting guidance. For a complete discussion of the components of the annual reporting guidance, please refer to the proposed rule section II.C.1.

In general, commenters supported the proposed annual reporting process, but requested clarification on what would be included in the reporting guidance. We are finalizing these provisions with revisions to §§ 437.10(b) and 437.15(a), where we have provided additional detail on reporting requirements. We discuss these revisions in sections II.D.2. and II.D.3. of this final rule. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Commenters noted that there are many details related to the contents of reporting guidance that were not addressed by the regulatory text. In particular, they asked for additional guidance as to: (1) whether CMS would continue to arrange licensing agreements with measure stewards related to the use and reporting of Core Set measures; (2) how CMS would identify the mandatory measures, populations to be included in mandatory reporting, and the process for reporting; (3) the timeline for reporting new measures; and (4) attribution rules for beneficiaries enrolled in different coverage during the reporting period and how to operationalize them.

Response: To address concerns raised by these commenters, through revisions to §§ 437.10 and 437.15, we have provided additional detail on reporting requirements and populations to be included in mandatory reporting, and we discuss these revisions in sections II.D.2. and II.D.3. of this final rule. We currently provide annual reporting guidance to States to support voluntary reporting, and as explained in this rule, this guidance will, in the future, include the requirements associated with mandatory reporting and will continue to be updated annually.[29] As specified in § 437.10(b), we will continue to provide detailed reporting guidance annually to States, which will include all of the information and technical specifications required for reporting of each of the Core Set measures, including the mandatory measures, populations to be included in mandatory reporting, the process for reporting, the timeline for requiring reporting new measures, and attribution rules and how to operationalize them. We will continue to execute licensure agreements with measure stewards as needed for States to report Core Set measures to CMS.

Comment: Multiple commenters recommended that, as future modifications or additions are made to the Core Set, CMS issue reporting guidance as soon as possible to give States, MCOs, and health care providers time to prepare for reporting. Some commenters recommended that CMS release reporting guidance in alignment with the NCQA reporting guidance release, while others recommended that CMS set a deadline for publishing reporting guidance by January 1st annually.

Response: We will take this feedback into consideration when developing Core Set reporting guidance and materials for public reporting. Measure stewards release updated guidance throughout the calendar year. Due to the need to adapt the reporting guidance developed by individual measure stewards, such as NCQA, for State-level reporting, simultaneous release of these materials with the measure steward is not feasible. We recognize the time and effort it takes States to prepare for Core Set reporting and expect to make every effort to publish reporting guidance as

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[29] Reporting guidance will be posted here: *https://www.medicaid.gov/medicaid/quality-of-care/quality-of-care-performance-measurement/index.html.*

soon as possible following the release of the updated Core Sets.

Comment: Multiple commenters recommended that CMS consult MCOs and/or behavioral health organizations (BHOs) as CMS develops annual reporting guidance for States in order to promote awareness of these resources, as many States rely on MCOs to provide data for reporting on the Core Sets and will need to update their reporting systems to implement standardized reporting. Another commenter recommended that CMS clarify the role of MCOs in supporting providers and State agencies in their efforts to improve Medicaid and CHIP quality measurement.

Response: As part of our annual process to update reporting guidance, we review all of the technical assistance requests received related to specific measures, which often include questions submitted by MCOs/BHOs that are working on behalf of States to calculate Core Sets measures. The publication of reporting guidance and any updates regarding the Core Sets, including the publication of Core Set data products, is disseminated through a public listserv.[30] We defer to each individual State's Medicaid and CHIP agencies to determine the role MCOs and BHOs will have in in their State's Core Sets reporting and efforts to improve quality measurement within their State.

Comment: One commenter agreed with reporting data for partial-year enrollees at the State level, but recommended against attributing these data to specific MCOs if CMS stratifies reporting by health plan, noting that MCOs would have limited opportunity to work with members to accomplish necessary screenings and visits.

Response: Decisions regarding the continuous enrollment period and allowable gaps are established by the measure stewards for each measure. Core Set reporting applies to all beneficiaries who meet enrollment criteria in State Medicaid and/or CHIP programs. We will take this comment regarding health plan attribution into consideration as we develop reporting guidance regarding attribution and stratification categories.

2. Advancing Health Equity Through Data Stratification

Measuring and reporting on health disparities is a cornerstone of CMS' approach to advancing health equity. As discussed in section II.C.2. of the proposed rule, we proposed in § 437.10(d) requirements for stratification of Child, Adult, and Health Home Core Set data to enable us to monitor health outcomes for disparities between groups of individuals who may have different determinants of health. This approach to data reporting and stratification is aligned with Executive Order 13985, which calls for advancing equity for underserved populations.[31] We proposed that the annual reporting guidance identify the specific measures in the Child Core Set, the behavioral health measures on the Adult Core Set, and 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. We note that in collecting and reporting data in accordance with the requirements of this rule, States and providers would be expected to comply with all applicable Federal non-discrimination laws. We also note that data stratification is intended to promote health equity for all patients and is not intended to promote discrimination or to create a conflict between a CMS requirement and a State's civil rights laws. Please refer to the proposed rule, section II.C.2., for specific discussions of the method for identifying measures for stratification, stratification factors, data suppression policies, and proposed timeline for phased-in stratification.

We believe that this stratification of data in the Child Core Set, Adult Core Set, and Health Home Core Sets measures is 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 us. 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. 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 received public comments on the proposed approach to stratification of Core Set data, and in general, commenters supported the proposed process. We are finalizing these provisions generally as proposed in § 437.10(b)(7) and (d), with minor wording changes. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters supported the proposed requirement to phase in stratified reporting over a period of 5 years and recommended that the Secretary specify which measures must be stratified in order to promote consistency and comparability across States rather than allowing States to decide the measures and factors for which they will submit stratified data each year. A few commenters recommended instead that States be able to choose based on data availability or State health care priorities. Multiple commenters also supported the proposed requirements that States stratify certain measures by demographics, health care delivery systems, and other characteristics to enable better care comparisons and identification of health disparities. Some commenters recommended that CMS ensure that stratified data be reported for both managed care and FFS delivery systems. Several commenters supported the improved and expanded

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[30] To join the Core Set listserv email: *MACQualityTA@cms.hhs.gov.*

[31] 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/.*

collection of data, and analysis of quality measures by population (such as dually eligible individuals), stratification categories (such as race and ethnicity or disability status), and delivery systems and provider types. They noted that these activities would allow for the deployment of strategies that better account for the needs of beneficiaries and further understanding of barriers to care and health disparities. One commenter also recommended that CMS make available reporting guidance, information on potential or expected data sources, and share examples of State data collection, organization, and lessons learned.

Response: We worked to find a balance in the reporting of State data that meets the statutory reporting requirements under sections 1139A(c)(2) and 1139B(d)(2) of the Act while taking into consideration data quality and the ability to conduct comparative analysis, and we determined that allowing States to choose which measures to stratify based on data availability or State health care priorities would limit our ability to publish standardized core measure data that could be compared across States and over time. Therefore, in the methodology we are finalizing in § 437.10(b)(7) and (d), stratified reporting will be phased in over a period of 5 years, and the Secretary will specify which measures should be stratified and by which factors data will be stratified. We will provide technical assistance to support mandatory reporting of stratified data and will ensure that States have access to reporting guidance and other tools in order to assist with annual reporting.[32]

Comment: One commenter stated that the Core Sets were initially developed as a within-State quality improvement tool. Because State Medicaid programs vary greatly in eligibility and offerings, it is important that proposed stratifications do not lead to State-to-State comparison without consideration for the populations served. The commenter also stated that stratifications would add to State reporting burden while not adding additional value or information for improvement, and recommended stratification be piloted first to determine if it is needed.

Response: The Child Core Set was intended not only to provide States with a tool to drive improvement for their enrollees but also to provide an estimate of the overall national quality of health care for children (section 1139A(a)(5) of the Act). As discussed previously in this final rule, we believe that stratification of data in the Child Core Set, Adult Core Set, and Health Home Core Sets measures is consistent with our statutory authorities. Stratified Core Set quality measure data will enable CMS and States to identify the health outcomes of underserved populations as well as potential differences in health outcomes between populations. Stratified data can also inform adoption of broadly applicable quality improvement initiatives that address the drivers of health disparities experienced by underserved populations. Due to the variability across States in the populations served by Medicaid and CHIP, and the different populations and health care services included in each core measure, a pilot project using a subset of States and/or measures would not provide sufficient data or results that could be generalized to provide an understanding of differences in health outcomes overall.

Comment: Several commenters submitted recommendations and requests related to the details of stratified reporting, such as definitions of specific categories, data suppression policies and how to handle missing data, and different measures of delivery systems.

Response: We will take these comments into consideration when developing annual reporting guidance. We are finalizing the list of stratification factors in § 437.10(b)(7) with minor edits, to include race, ethnicity, sex, age, rural/urban status, disability, and language, as well as additional factors as may be specified by the Secretary and informed by annual consultation with States and interested parties.

Comment: Several commenters recommended that consistent data standards for stratification of race, ethnicity, and language, across programs and agencies would clarify and facilitate data collection. However, one commenter noted that new standards should not inhibit the ability of States to tailor their data fields to reflect their populations as long as they are able to be aggregated to Federal categories and that any guidance provided by CMS in this area should also recognize the experiences of people with multiple racial and/or ethnic identities. Additionally, several commenters suggested that CMS include a ''Middle Eastern or North African'' response among the race and ethnicity measures, allowing for stratified health outcomes for a population that experiences disparities.

Response: The specific response categories included in stratified reporting will be addressed as part of the reporting guidance process that is discussed in the rule. We will take these recommendations into consideration when developing annual reporting guidance, considering data availability, data quality, and burden to States. We expect to align with Department of Health and Human Services (HHS) data standards for stratification, based on the disaggregation of the 1997 Office of Management and Budget (OMB) Statistical Policy Directive No 15.[33] We expect to update Core Set reporting stratification categories if there are any changes to OMB or HHS Data Standards.

Comment: One commenter recommended that unknown, missing, or nonresponses on demographic variables be its own stratification category with its own associated measure rate. Another commenter recommended that CMS provide technical assistance to States on how to collect and report race and ethnicity information, including how States should handle large percentages of data records with ''unknown'' race and ethnicity. Several commenters recommended that an optional category for ''declined to answer'' or similar category be included in State reporting. A few commenters recommended a methodology for identifying beneficiaries with a disability based on disability questions from the American Community Survey. Another commenter noted that there is not a Federal standard defining ''disability'' and requested that CMS establish one for consistency in reporting in this and other programs.

Response: We will take this feedback into consideration when developing Core Set reporting guidance on stratification requirements. This area of data collection and reporting is evolving rapidly, and we expect to provide additional technical assistance and support in this space in the future.

Comment: Several commenters supported all the proposed requirements for stratification but recommended either faster or slower implementation. Some commenters suggested that States be required to report stratified data by the 2024 reporting period rather than phase in this requirement. Another commenter noted that a shorter phase-in period would not be overly burdensome to States given the enhanced Federal

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[32] Technical Assistance Fact Sheet: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

[33] The categories for HHS data standards for race and ethnicity are based on the disaggregation of the OMB standard: *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=53.*

Medicaid match for upgrading computer systems for this kind of reporting. Multiple commenters provided alternate phase-in schedules for stratification of Core Set measures.

Response: We agree on the importance of reporting stratified data to help identify and eliminate health disparities across populations. Reporting of stratified data is a cornerstone of our approach to advancing health equity, as outlined in the proposed rule. We determined that a shorter phase-in period, such as between 1 and 4 years, would not likely be operationally feasible because of the potential systems and contracting changes (to existing contracts or the establishment of new contracts) that States may be required to make in order to collect these data. For example, additional reporting requirements may need to be added to State contracts, changes may be needed to data sharing agreements with MCOs, and modifications of databases or systems might be required to record new variables. Based on discussions with States regarding the feasibility of reporting stratified data, and the comments received supporting the proposed timeframe, we have addressed the comments recommending a longer duration of phase-in by revising § 437.10(b)(5) to include flexibility in the reporting of some populations in the initial years of reporting the Child and Adult Core Sets. Of note, the section 1945A health home benefit requires providers of that benefit to report to States on quality measures as a condition of payment. The populations which will be optional for States to include in reporting of the Child and Adult Core Sets will be specified in annual subregulatory guidance. In addition, we anticipate 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 plan to work collaboratively with States to provide the technical assistance and reporting guidance necessary to support reporting of stratified data.[34] While States may be eligible for an increased Federal match for systems changes, States still bear a share of the cost, and making the needed systems changes is time-intensive, likely requiring several years or more to implement. We have therefore determined that the proposed 5-year phased-in approach to data stratification is reasonable and would also be consistent with section 1945A(g)(2)(A) of the Act for 1945A health home programs. With this approach, we are balancing our strong interest in identifying differences in health outcomes between populations (as supported by our statutory authorities, as discussed previously in this final rule) with the operational challenges that States may face in implementing these requirements. We are finalizing the proposed phase-in time frames under § 437.10(b)(7) and (d) as proposed. States will thus 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 Home 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 such 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 § 437.10(b)(7), such as race and ethnicity, sex, age, rural/urban, disability and language.

Comment: One commenter recommended that CMS modify the stratification schedule to consider a phased-in approach based on the stratification factor, for example, race, instead of the number of measures.

Response: We appreciate this feedback and will consider it when developing annual reporting guidance. Specific factors by which data will by stratified will be delineated in annual reporting guidance, and we will select these factors based on relevance and feasibility with the plan to add over time as the quality and completeness of data improve. We are finalizing § 437.10(d) generally as proposed.

Comment: Multiple commenters recommended strategies for determining which measures should be stratified first and by which stratification factor(s) (that is, separate factors or multiple factors simultaneously). These strategies included working collaboratively with States and State-contracted entities, aligning with the measures and timeline for stratification as determined by NCQA Healthcare Effectiveness Data and Information Set (HEDIS) for their measures, beginning the phase-in with measures that are currently stratified for NCQA HEDIS reporting, and giving States the flexibility to decide the measures and factors for which they will submit stratified data each year. Several commenters recommended that CMS prioritize how measure stratification is phased in based on the topics of most urgent need, such as maternal and behavioral health, or measures addressing disease prevention. Some commenters encouraged stratification of the Core Set measures based on data obtained from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey, while others encouraged CMS not to require stratified CAHPS data. Some commenters encouraged CMS to ensure buy-in from interested parties such as States, beneficiary groups, and providers on measures selected for stratification so that States have adequate time to ensure that they are reporting high quality data.

Response: We will take these ideas into consideration when developing annual reporting guidance, and plan to work collaboratively with States to provide the technical assistance and reporting guidance necessary to support reporting of stratified data.[35] We are finalizing as proposed the phase-in process for reporting stratified Core Set measures in § 437.10(b)(7) and (d) of this final rule.

Comment: We received many comments making recommendations on stratification factors for State reporting of Core Sets in § 437.10(b)(7) and (d) such as:

- Addition of sexual orientation and gender identity; socio-demographic data; pregnancy status; and socioeconomic status;
- Addition of the State's Medicaid expansion status with respect to coverage of adults under age 65 who are described in 42 CFR 435.119, as well as extended coverage during the 12-month postpartum period under section 1902(e)(16) and 2107(e)(1)(J) of the Act; and
- Recommendations both for and against addition of health care delivery system as a stratification factor. Many commenters noted that stratification by health plan could identify trends in quality, advance State alternative payment methodologies, and support oversight. One commenter noted that stratification by health plan would be especially helpful in comparing plans that are engaged in quality improvement projects to those that are not. Other commenters suggested that it may be helpful for certain measures to be stratified on a multi-level basis, for example, health plan data disaggregated by race, ethnicity, and other factors. Another commenter suggested that stratification by delivery system be used

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[34] Technical Assistance Fact Sheet: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

[35] Technical Assistance Fact Sheet: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

for quality improvement efforts only, and public reporting occur at the State level. A few commenters recommended that CMS not require stratification by health plan given the regional and population differences served by Medicaid managed care in States unless CMS can account for variation in geography, population, and benefits.

Response: We will take these comments into consideration when developing annual reporting guidance, which will include stratification factors. We are finalizing § 437.10(b)(7) and (d) generally as proposed to allow for the additional stratification by other factors as may be specified by the Secretary and informed by annual consultation with States and interested parties per § 437.10(a)(3), which could include stratification by health plan or other factors described previously in this final rule. This approach provides us with flexibility to adjust stratification requirements by factors that are both feasible and relevant in a rapidly evolving field.

Comment: Many commenters discussed both the positives and negatives of CMS potentially using geolocation or other types of data to impute identification of race and ethnicity. Several commenters recommended that CMS not use imputed data to calculate race and ethnicity data, and instead focus efforts on improving the collection and completeness of self-reported race and ethnicity data, and minimizing the burden of data collection and reporting, particularly on consumers. Multiple commenters recommended that CMS use imputed data sparingly, with some suggesting that CMS share any imputed data with States for review prior to publication, or not publicly report the results of stratification based on imputed data given the lack of validity of such data. Commenters noted it is critical that CMS provide details on what specific imputation methods would be used to stratify the Medicaid data, as many methods have been developed based on Medicare data and may not yield as accurate results in the Medicaid population. Additionally, one commenter recommended use of standardized imputation methods across the industry.

Response: We agree that self-reported beneficiary data should be used whenever possible, and that it is important to undertake efforts to improve data quality. To that end, in our efforts to improve the quality of race and ethnicity data, we have: issued guidance on reporting race and ethnicity in Transformed Medicaid Statistical Information System (T–MSIS);[36] provided State technical assistance on identifying and investigating data quality issues based on unspecified, unknown, missing or invalid race and ethnicity data and worked with States to improve data quality and completeness; and published data quality assessments in the Medicaid Data Quality (DQ) Atlas. Complete demographic information from beneficiaries is the optimal source of data for stratification, and our development of imputation models is intended to complement this source with a reliable method to identify disparities in the face of missing or inaccurate data.[37] We will release detailed documentation about the methodology used to develop imputations prior to the release of these data. We will take these suggestions into consideration and will consult with States on the use of imputed race and ethnicity when developing annual reporting guidance, technical assistance, and other resources for States.

Comment: We received several comments about other sources of demographic data. Several commenters recommended that CMS use demographic data collected on the Medicaid and CHIP eligibility application and provide guidance that covers the entire process of data collection, reporting, and sharing. In reference to self-reported data, one commenter suggested CMS ensure that consumers are aware of the reasons why the data are being collected, that the process is voluntary, that no adverse action will result for failing to provide the data (that is, no loss of health benefits or access to services), and of how the data may be used, shared, and disclosed. Multiple commenters recommended that the CMS Single, Streamlined Online Application be revised to allow beneficiaries to select a ‘‘decline to answer’’ option in response to demographic questions. Other commenters suggested using State administrative data to supplement missing demographic information, and the use of electronic data in general, and recommended that CMS provide technical assistance on how to report measures for individuals with ‘‘unknown’’ race/ethnicity. One commenter suggested providing detailed measure information, such as indicating the data source or imputation methodology for demographic and performance data.

Response: Modifications to the Single Streamlined Application and State eligibility forms are outside the scope of this rulemaking; however, we will take the suggestions into consideration when making updates to the Single Streamlined Application. The Single Streamlined Application follows the OMB data standards for collection of race and ethnicity data, and use of this application is optional for States.[38] When developing their own applications, States are encouraged to use the same standards and must ensure that questions asking about race and ethnicity are optional. The Single Streamlined Application eligibility application available through HealthCare.gov includes the following language alongside questions about race and ethnicity: ‘‘Selecting this person’s race and ethnicity helps the U.S. Department of Health and Human Services improve service to all people using the Marketplace. We use this information to make sure everyone gets fair access to coverage. Providing this information won’t impact eligibility, plan options, or costs.’’[39] State Medicaid and CHIP agencies have the flexibility to choose to include similar language in their eligibility applications and are better positioned than CMS to collect this data directly.[40]

Comment: Several commenters recommended that CMS acknowledge that States with smaller and/or more homogeneous populations may not be able to report data for a sufficient number of individuals for some stratification categories, such that CMS will need to suppress data to ensure privacy protections.

Response: We agree with the need to protect beneficiary privacy. We noted in the proposed rule that we will follow data suppression policies for measure stewards in addition to the CMS Cell Size Suppression Policy such that if sample sizes are too small, data will not be publicly reported to avoid a potential violation of privacy. We are finalizing § 437.10(d) generally as proposed.[41] We plan to provide technical assistance to

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[36] *https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/tmsis-blog/109701.*

[37] Elliott, Marc N., et al. ‘‘Using the Census Bureau’s surname list to improve estimates of race/ethnicity and associated disparities.’’ Health Services and Outcomes Research Methodology 9.2 (2009): 69–83.

[38] The categories for HHS data standards for race and ethnicity are based on the disaggregation of the OMB standard: *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=53.*

[39] Health Insurance Marketplace Application Instructions: *https://www.healthcare.gov/downloads/marketplace-application-for-family-instructions.pdf.*

[40] States could adopt this or similar language in their application, regardless of the modality (paper, online, phone).

[41] CMS Cell Suppression Policy: *https://www.hhs.gov/guidance/document/cms-cell-suppression-policy.*

States as needed and will publish data suppression guidance in annual reporting guidance.

Comment: One commenter recommended establishing minimum denominators to identify statistically significant changes in disparities.

Response: We will take this comment into consideration for future guidance regarding health disparity analysis.

Comment: Some commenters suggested methods for CMS to align with other measure sets and organizations. Several commenters requested that CMS align with NCQA HEDIS as much as possible, including stratification categories and age ranges, and that other stratification factors be phased in after race and ethnicity. One commenter recommended that CMS explore using data submitted to NCQA for accreditation to ease burden on providers, plans, and States. Another commenter recommended that CMS encourage States to use the NCQA Electronic Clinical Data System (ECDS) reporting method for applicable measures. One commenter suggested the Federal government streamline efforts and standardize measures sets across all payers, and that CMS, Health Resources and Services Administration (HRSA), and HHS provide available data when possible to reduce burden to States and providers. Another commenter suggested CMS explore opportunities to get a broader view of child health by connecting different Federal databases, including those that collect data for Title V, public health, child welfare and children's mental health programs, and encourage these same connections at the State level.

Response: We will take these ideas into consideration when developing annual reporting guidance. We agree with the commenters on the importance of parsimony, alignment, and harmonization in quality measurement to the extent possible. Throughout the annual Core Set review process, we actively engage with a variety of internal and external interested parties, Federal partners, other reporting agencies related to Medicaid and CHIP, and Medicare and Marketplace. This process facilitates measure alignment as appropriate, noting areas of needed divergence due to differences in reporting levels.

Comment: Several commenters recommended that CMS work with other Federal agencies on Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (API) standards, stating that aligning with FHIR standards would resolve many of the challenges in accessing both administrative and clinical data required to report Core Set measures, including demographic data required for stratification. These commenters encouraged CMS to explore ways to leverage the current interoperability and information sharing regulations to promote data sharing across systems and minimize the reporting burden on consumers. One commenter recommended that CMS undertake an assessment of the barriers and opportunities to enable data exchange and information systems interoperability in order to help report outcomes-based measures. Another commenter noted that simply relying on Electronic Health Record (EHR) vendors to implement FHIR and United States Core Data for Interoperability (USCDI) standards will not be enough to ensure complete and accurate data. One commenter noted challenges with sharing data across systems with different EHRs. Several commenters expressed concern about data entry errors creating an increased State burden and recommended that CMS consider technical interventions such as open-source tools or use of structured electronic data files, standardized spreadsheets, API or other upload options to reduce burden and errors created through manual data entry.

Response: We will take these comments into consideration when developing annual reporting guidance, technical assistance, and other resources for States.

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

As discussed in section II.D. of the proposed rule, we proposed in §§ 437.10 and 437.15 the key requirements and procedures for States in reporting both mandatory and voluntary measures, including the procedures to identify measures that States would report, measures that we would report on behalf of States, and measures for which States may elect to have us report on their behalf. We also solicited comments on what technical assistance we should provide to support these activities.

We received public comments on the process proposed in §§ 437.10 and 437.15, and in general, commenters supported the proposed process. We are finalizing these provisions with revisions to §§ 437.10 and 437.15. We describe in section II.D.2. of this final rule our revisions to §§ 437.10 and 437.15 regarding reporting of mandatory measures, in addition to a revision regarding survey-based measures in § 437.10(b)(1)(v). We describe in section II.D.3. of this final rule our revisions to §§ 437.10 and 437.15 regarding populations required for mandatory reporting. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters recommended that CMS allow States the option to self-report; or allow other alternate data sources such as Transformed Medicaid Statistical Information System (T–MSIS) Analytic Files (TAF) to be used to calculate measures on States' behalf. However, these and other commenters requested additional information on the use of T–MSIS/TAF and noted that alternate data sources should be used only under certain conditions, namely: that States are allowed to opt-out; that States are provided the opportunity to review and confirm results; and that the calculation methodology adheres to the measure specifications including use of denied claims, among other stipulations. One commenter also requested that CMS provide States with assistance in investigating data discrepancies or measurements that seem to be in error.

Response: We will continue to assess whether T–MSIS/TAF or other alternate data sources can be used to calculate Core Set measures on behalf of States. As stated in § 437.10(b)(1)(iv), we will continue to calculate selected measures on States' behalf using alternative data sources and, in these cases, we anticipate providing States with an opportunity to preview data. For other selected measures, as stated in § 437.10(b)(1)(iv), we will allow States the option to either self-report (if they adhere to CMS-issued reporting guidance as per § 437.15(a)(3)), or allow the measures to be calculated on States' behalf using alternate data sources. We currently provide States an opportunity to preview data for any measure calculated utilizing alternate data sources such as ''Live Births Weighing Less Than 2,500 Grams'' on the Child Core Set and ''National Core Indicators Survey'' on the Adult Core Set and intend to continue doing so. We are finalizing §§ 437.10(b)(1)(iv) as proposed and § 437.15(a)(3) with a minor wording change.

Comment: Several commenters raised concerns with the use of T–MSIS/TAF data to calculate Core Set data or for stratification, as there may be issues with the data validity for many States, and recommended that CMS not use T–MSIS for reporting on behalf of States. For example, some measures may require more years of data than are available through T–MSIS, or data reported through T–MSIS may be incomplete.

Response: We assess each Core Set measure individually to determine if it is able to be calculated using T–MSIS/

TAF data, based on the technical specifications, considering the years of data available in T–MSIS and also the types of data required to accurately calculate that measure. As stated previously in this final rule preamble, we also intend to allow States to preview all Core Set data generated by T–MSIS.

Comment: One commenter recommended that CMS develop a third-party validation process that certifies State measure logic and audits Information Technology (IT)/measurement systems in a standardized way. This commenter also suggested validating supplemental data from the source, providing the example of NCQA's Data Aggregatory Validation program. Another commenter recommended that CMS test and validate stratified results to ensure they are accurate.

Response: We agree with the commenter on the importance of data quality in Core Set reporting. We have built a pre-publication quality assurance process into the review of all Core Sets data. Through this process, we work with States to resolve data quality issues and confirm any deviations from the reporting guidance. Sections 1139A and 1139B of the Act require the Secretary to collect, analyze, and make publicly available the information reported by States; however, these sections do not require the levels of data validation recommended by these commenters. While sections 1945(g) and 1945A(g) of the Act give the Secretary the authority to establish requirements related to the form and manner of health home quality reporting, they do not specify that the Secretary must require data validation of submissions. We will continue to evaluate data validation needs in developing resources for Core Set reporting.

Comment: One commenter recommended that CMS maximize the use of performance data that can be collected and transmitted electronically, and to minimize manual data collection. We understand the commenter to be recommending that the measures on the Core Sets primarily be those that can be calculated using only administrative or EHR data versus those that require manual chart reviews or in-person surveys.

Response: We appreciate the submission of these comments and will take this feedback into consideration in the subregulatory measure review process.

Comment: One commenter noted that if Health Homes are required to report to the State, each Health Home will require extensive technical assistance, funding for technical assistance and result validation, expertise in quality measure specifications, and staff. Some commenters noted that Health Home programs and their providers of Care Management do not have reliable, current, and consistent access to claims, encounter, and clinical data to effectively report on these measures. They further stated that Health Home care management is not itself a clinical protocol model of care management, but rather a set of care management practices that facilitate clinical care, address social care needs, provide education, increase member health literacy, and address health equity and disparities to improve health outcomes, all of which makes it challenging to report on the Health Home Core Sets.

Response: This final rule implements statutory reporting requirements for providers of section 1945 and section 1945A health home services at sections 1945(g) and 1945A(g)(1)(B) of the Act. Providers of section 1945 health home services are required to meet the reporting requirements specified at section 1945(g) of the Act, and providers of section 1945A health home services are required to meet reporting requirements specified at section 1945A(g)(1)(B) of the Act. If a Health Home provider is submitting data into a State-based system that the State is then using to calculate and report the Health Home Core Sets measures to us, those data submissions from the provider to the State would satisfy the statutory requirements under sections 1945(g) and 1945A(g)(1)(B) of the Act. Comprehensive care management services are not a set protocol but rather one of the six services included in both the section 1945 and section 1945A Health Home benefits, as specified at sections 1945(h)(4)(B)(i) and 1945A(i)(4)(B)(i) of the Act. We have provided additional information about how we interpret this component of the section 1945 benefit in frequently asked questions (FAQs).[42] Health Home quality measure reporting has always been mandatory for participating providers under both sections 1945 and 1945A of the Act (even if using CMS' recommended measures has not been mandatory), and health home providers will need to coordinate with the State Medicaid Agency to seek assistance with Core Set reporting. We understood the comment to express the belief that the Health Home Core Set measures will be challenging to report, because the health home model does not provide direct, clinical care services to patients. This health home benefit is designed to be a care coordination model, and we recognize that implementing a service model that is separate from the provision of direct, clinical care services to patients may be a shift for some providers and States from models that provide direct, clinical care services, and that data sources may be different between the two types of models. We are available to provide technical assistance to States to navigate any challenges they may have when reporting Health Home Core Sets, and as such, we do not believe the reporting burden on States and providers is unreasonable.[43]

Comment: One commenter recommended allowing a minimum of 18 months to develop, test, and deploy new reporting requirements from a health IT standpoint once a State provides technical specifications to developers. Another commenter proposed that CMS consider that whenever multiple mandatory hybrid and survey measures are introduced in 1 year, staffing constraints, contractual agreements, procurement cycles, and similar issues may have an impact on States' abilities to gather data and calculate rates.

Response: We will take these comments into consideration when determining additions to the Core Sets for mandatory reporting.

Comment: One commenter requested that we explain whether the reporting requirements would increase the reporting burden on States and would *not* increase the burden on Indian Health Service (IHS) or Tribal facilities. They further recommended that if there was a reporting burden on IHS or Tribes and Tribal Organizations that CMS provide the same technical assistance to Tribes as it provides to States.

Response: We will provide States with technical assistance[44] related to Core Set reporting and will encourage States to work with Tribes and Tribal Organizations to improve data sharing. We recognize that States and Tribes establish individual contractual agreements that might affect the availability of Tribal data for Core Sets reporting. Given the different responsibilities for reporting that States and health care providers (such as those operated by IHS, Tribes, and Tribal Organizations) will have and the

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[42] Health Home FAQs (January 21, 2016), *https://www.medicaid.gov/sites/default/files/2020-02/health-homes-section-2703-faq.pdf.*

[43] Technical Assistance Fact Sheet: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

[44] About the Medicaid and CHIP Core Set Technical Assistance and Analytic Support Program: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

differences in resources available to them, it is hard to gauge for whom the burden of reporting will be greater or lesser. States should undertake Tribal Consultation related to reporting of Core Set measures, and are encouraged to coordinate with IHS, Tribes, and Tribal Organizations, to support data sharing.

Comment: One commenter noted a need for technical assistance incorporating States' Immunization Registry into their data warehouse, with tasks such as mapping individuals from the registry against Medicaid members and identifying the percent match rate. This commenter also stated that their State may need assistance with including CHIP enrollees' birth and mortality records from the State's Vital Statistics Office into their Medicaid and CHIP data warehouse.

Response: We will take this feedback into consideration when developing technical assistance resources and reporting guidance for Core Set reporting.

Comment: Multiple commenters recommended that CMS continue to offer technical assistance using a variety of formats including written guidance, standard templates, FAQs, measure specification and coding assistance, sharing of best practices, one-on-one State-specific technical assistance, learning collaboratives, direct communication with the technical assistance contractor, and instructional webinars that allow for questions. Commenters noted these have been effective mechanisms and will be needed in the future to meet mandatory reporting requirements. One commenter recommended templates and examples as part of technical assistance, while another recommended further clarification, structuring, and additional details in the reporting guidance to help streamline reporting and reduce error, but also to help States conduct quality assurance for their results. Additionally, several commenters requested technical assistance on data sharing with Federal and commercial partners, data stratification requirements, and how to address data limitations such as small sample sizes.

Response: We thank the commenters for their feedback on technical assistance methods and needs. We will provide technical assistance and will consider the suggestions when developing future technical assistance resources.

1. Adherence to Reporting Guidance

As discussed in section II.D.1. of the proposed rule, we proposed in § 437.15(a)(3) to require States to report on the Core Sets in a manner that adheres to CMS-issued reporting guidance described in § 437.10(b), which we proposed would include procedures and standardized formats for reporting measure data.

In general, commenters supported these proposals, and we are not making any changes to them in response to these comments. Below is a summary of the public comments we received regarding specific components of these proposals and our responses.

Comment: Multiple commenters concurred with CMS requiring States to adhere to the annual reporting guidelines to enable comparisons across States on quality performance and to calculate national performance rates for quality of care. Other commenters noted that standardized reporting should be the minimum requirement, and expectations for reporting should increase over time.

Response: We agree that requiring States to adhere to the reporting guidance, which we are finalizing in § 437.15(a)(3), is essential to provide effective comparisons across States on quality measure performance and to derive national performance rates for the care provided to Medicaid and CHIP beneficiaries. We also recognize that adherence to CMS-issued reporting guidance as described would be a substantial change from current reporting for some States. Recognizing the challenges that States may face in reporting stratified measure data and data for certain populations, we are finalizing in this rulemaking a phase-in approach for both the required stratification in § 437.10(d) and the reporting for certain populations in § 437.10(c), with stratified reporting of all mandatory measures required in the fifth year of annual reporting after the effective date of part 437 of this final rule.

Comment: Multiple commenters expressed concerns regarding strict adherence to reporting guidance as some deviations are the result of underlying differences in how State Medicaid programs or their data systems are structured. For example, some States limit the number of diagnosis codes that MCOs can submit, which may result in an eligible beneficiary being excluded from, for example, a diabetes measure if diabetes was not one of the highest diagnosis codes submitted for a visit in which multiple conditions were addressed. Another commenter requested that allowances be made for States to use the most reliable data source available, stating for example, the use of birth/vital records data vs. claims data for pregnancy/birth-related measures provides more specific information than can be found in claims data alone. One commenter proposed that if adherence is required, States should be permitted to explain any underlying systems differences that result in un-representative rates, and CMS should include this information with public reporting.

Response: Adherence to the reporting guidance is essential to provide effective comparisons across States on standardized quality measure performance and to derive national performance rates for the care provided to Medicaid and CHIP beneficiaries. As such, we are finalizing § 437.15(a)(3) to require that States adhere to reporting guidance issued by CMS. We will provide technical assistance to States to support their ability to do so.

Comment: Several commenters requested that reporting guidance address the level of data completeness required to ensure that the stratified rate would be considered valid. Another commenter recommended that technical assistance be focused first on improving data quality.

Response: We will take these ideas into consideration when developing technical assistance resources and reporting guidance for Core Set reporting.

Comment: Several commenters requested that CMS reporting guidance for the Core Sets be identical to the measure developers' specifications to allow organizations to report measures used in multiple programs consistently. Several commenters made this recommendation specifically due to the burden associated with reporting measures that deviate from NCQA HEDIS specifications, while others also recommended this approach specifically if deviation from CMS guidance is no longer permitted. One commenter also recommended that CMS continue allowing States to report using audited MCO NCQA HEDIS rates.

Response: We will consider these comments when developing reporting guidance. Core Set reporting is State-level or health home program-level reporting, while NCQA HEDIS is plan-level reporting, and therefore, measure adaptations are necessary for us to provide guidance to States for State- or Health Home program-level reporting. In making measure adaptations, we work closely with measure stewards, including NCQA, to develop reporting guidance and to make as few adaptations to the technical specifications as possible. Such adjustments generally are limited to adjusting the age ranges of a measure to align with either the Child or Adult Core Sets.

Comment: One commenter encouraged CMS to be mindful of implementation timelines, which may overlap with States' work related to the restoration of eligibility and enrollment operations, including terminations of enrollment, following the end of the continuous enrollment condition under section 6008(b)(3) of the Families First Coronavirus Response Act, as amended by the CAA, 2023, a process referred to as ''unwinding.''

Response: The timeline for mandatory reporting was statutorily established in 2018 to implement mandatory annual reporting of the Child Core Set and the behavioral health measures on the Adult Core Set, and these statutes do not include any provisions allowing us to modify the implementation timeline. We interpret the language in the Bipartisan Budget Act of 2018 and the SUPPORT Act to mandate annual reporting of these Core Sets beginning with the annual State report on FFY 2024 and align with State reporting of the 2024 Core Sets, currently projected to occur in Fall 2024. However, consistent with § 437.10(c) and (d), to minimize State burden, we plan to phase in requirements for measure stratification and Child and Adult Core Sets reporting for populations for which States do not have data access.

2. Reporting of Mandatory Measures

As discussed in section II.D.2. of the proposed rule, we proposed a methodology to phase in reporting of certain measures, including those that may be complex or difficult to report, those that are newly added to the Core Sets, or those that had significant updates to technical specifications from the prior year. We also asked for comment on how best to phase in reporting, the optimal frequency for reporting of outcome and survey-based measures, technical assistance States may need, and promising practices and approaches for data collection and data linkages.

We received comments stating that the Secretary does not have the statutory authority to delay the reporting of selected measures for any of the Core Sets, in addition to many comments supporting the proposed phased-in reporting process for mandatory measures. Upon additional review, we have determined that all of the measures currently on the Child Core Set and all of the behavioral health measures on the Adult Core Set should be subject to mandatory reporting in 2024. The majority of the measures proposed for the initial mandatory measure set for these Core Sets can be calculated using administrative data and have been on these Core Sets for many years, specifically, a median of 7 years for the Child Core Set and 10 years for the behavioral health measures on the Adult Core Set. Based on this analysis, and the fact that we have already released the list of measures included in the 2024 Child and Adult Core Sets,[45] allowing States significant time to prepare to report on these measures, we believe that all measures on the 2024 Child Core Set and all behavioral health measures on the 2024 Adult Core Set can be reported by States and, in this final rulemaking, are requiring that States report on all of them.

We have similarly determined that States and health home providers must report on all measures in the section 1945 and/or 1945A Health Home Core Sets, to better inform CMS evaluations of these health home programs and help us to analyze health home measures. Section 1945(g) of the Act specifies that, as a condition for receiving payment for section 1945 health home services, a health home provider shall 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)(1)(B) of the Act states that to receive payments for section 1945A health home services from the State a health home provider shall report to the State information on all applicable measures for determining the quality of health home services provided by such 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. Additionally, section 1945A(g)(1)(C) of the Act requires section 1945A health home providers to report to the State such other information as the Secretary shall specify in guidance. In sum, both health home program statutes require health home providers to report to States on all applicable health home quality measures and give the Secretary discretion to identify the measures required for reporting each year. Since the inception of the section 1945 health home benefit, we have strongly encouraged States implementing that benefit to report on all applicable Health Home Core Set measures specified by the Secretary, and most have done so. Although prior to this rule, Health Home Core Set reporting has not been mandatory, we have no indication that States currently reporting the section 1945 Health Home Core Set measures have faced major burdens in doing so, and 100 percent of the current section 1945 Health Home Core Set measures can be reported using administrative claims only. When selecting measures to add to the Health Home Core Sets, we have been careful to ensure States and providers are able to report on all selected measures, and to ensure that the data provided when reporting on the measure would be useful for monitoring program performance and the quality of services provided to beneficiaries enrolled in the health home program. Based on the high rate of voluntary health home measure submission thus far, and the careful consideration we have given to measure selection, it is reasonable for CMS to expect States to comply with mandatory reporting for all measures on both of the Health Home Core Sets in the future. Additionally, since both sections 1945 and 1945A state that health home providers are statutorily required to report to the State as a condition of payment, States should have these data readily available for reporting to us. Finally, reporting of all measures on the Health Home Core Sets would inform CMS evaluation of both health home programs, assist us to identify racial, socioeconomic and geographical disparities in health outcomes, and inform future quality-related decisions about national policy for Medicaid health home programs by providing more uniform national data. Therefore, via this rule, we are mandating that both States and health home providers report on all Health Home Core sets measures, consistent with the Secretary's authority under sections 1945, 1945A, and 1902(a)(6) of the Act.

We therefore are revising the final rule as it pertains to the Child, Adult, and Health Home Core Sets as follows. We are removing proposed § 437.10(b)(1)(v), which provided States with additional time to report selected measures. We are replacing that proposed paragraph, in response to public comment, with language specifying that the frequency of reporting survey-based measures will be no more than annual. Additionally, we are revising § 437.10(c) to remove reference to phasing in measures and adding § 437.15(a)(1)(i) to require reporting on all measures in the 2024 Child Core Set and the behavioral health measures in the Adult Core Set. Mandatory reporting of the Health Home Core Sets is required only for an approved health home SPA that has an

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[45] CMS released both the 2023 and 2024 Child and Adult Core Sets in November 2022 and the 2023 and 2024 section 1945 Health Home Core Set in December 2022.

effective date and has been implemented more than 6 months prior to the December 31st reporting deadline. This means that, for the States with approved health home program 1945 SPAs that were effective and implemented prior to June 30, 2023, the section 1945 Health Home Core Set would become mandatory in 2024. For both 1945 and 1945A SPAs that were effective and implemented starting July 1, 2023 through June 30, 2024, reporting the section 1945 and 1945A Core Set(s) would become mandatory in 2025.

Future new mandatory measures will be added to the Core Sets through the subregulatory process described in this rule. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters recommended that all States be required to report all Child and Adult Core Sets quality measures, as specified in statute at sections 1139A(a)(4)(B) and 1139B(b)(3)(B) of the Act, in the 2024 reporting year. Many commenters stated that they did not agree that the Secretary has the statutory authority to delay the reporting of selected measures for any of the Core Sets. One commenter recommended that mandatory State reporting should be required for all Child and Adult Core Sets required in statute, but that CMS could create an exceptions process for States that demonstrated that the requirement would generate unreliable data. This commenter requested that CMS ensure that States operating under such an exception report at least a standardized minimum set of measures to ensure valid comparisons across all States.

Response: Upon additional review, we agree that all of the measures on the Child Core Set and the behavioral health measures on the Adult Core Set should be subject to mandatory reporting in 2024, consistent with sections 1139A(a)(4)(B) and 1139B(b)(3)(B) of the Act.

Comment: Some commenters supported a phased-in approach to the inclusion of measures in mandatory reporting. One commenter recommended that CMS collect feedback from impacted interested parties on the most feasible reporting timeframe for specific measures while another recommended that States be allowed at least 2 years to begin reporting on new measures. One commenter recommended that the ''Screening for Depression and Follow-up Plan'' measure that is on both the Child and Adult Core Sets be required no earlier than the 2026 Core Sets. Another commenter recommended that CMS begin mandatory reporting of outcome measures using measures that only require administrative data and do not require supplementary data from other sources. Other commenters suggested several years of optional reporting for outcome and survey measures, and for measures that require EHR data.

Response: Upon additional review, we have determined that the statute requires that all of the measures on the Child Core Set and the behavioral health measures on the Adult Core Set should be subject to mandatory reporting in 2024. We recognize that some types of data collection are more burdensome than others, and States often struggle with collecting data for measures that depend on non-claims sources, hybrid specifications, or EHRs. We will provide technical assistance including one-on-one support to assist States with mandatory measures.[46] The outcomes of this process would be published in annual subregulatory guidance, as finalized in § 437.10(b) and (c) of this final rule.

Comment: One commenter recommended allowing States flexibility to determine the approach for hybrid- and survey-based measures based on their delivery system and not limiting reporting to one survey type, noting that a survey from an MCO that only serves beneficiaries with serious mental illness would not be comparable to other survey populations.

Response: We appreciate that there is considerable variability between States in how populations are served within their delivery systems and programs and how these populations are represented in State-level and health home program-level reporting. Despite these differences we believe the use of standardized quality measures, reporting guidance, and reporting is needed to accurately assess and compare data across populations and time and to allow for identification of more specific quality improvement opportunities. Use of alternative measures or survey types would undermine this goal. Therefore, we are not making any changes to § 437.10(b) in response to this comment.

Comment: Several commenters made recommendations regarding the survey-based measures in the Child and Adult Core Sets, such as those based on the CAHPS survey. A few commenters recommended that CMS require States to report data biennially (that is, once every 2 years) for all health outcome and survey-based measures. However, one commenter stated that they preferred annual reporting due to the loss of measure consistency, need to monitor quality improvement projects, and staffing and training issues. One commenter recommended that CMS consider the impact of declining response rates to surveys on Core Set reporting, and avoid duplicating efforts, noting that MCOs are also required to conduct CAHPS surveys. Some commenters encouraged CMS to explore alternative patient experience measures before phasing-in mandatory reporting of CAHPS-based measures.

Response: We intend to require annual reporting of health outcome and survey-based measures, which aligns with CHIP reporting requirements in section 2108(e) of the Act, as implemented through section 402 of CHIPRA. Specifically, Title XXI programs are required to annually submit to CMS data regarding access to primary and specialty services, access to networks of care, and care coordination provided under the State child health plan, using quality of care and consumer satisfaction measures included in the CAHPS survey. However, we appreciate the concerns raised regarding barriers to annual reporting of these measures and believe it is important for us to have the flexibility to reconsider frequency as needed based on State feedback. Therefore, we have revised § 437.10 to replace paragraph (b)(1)(v), which now specifies that survey-based measures will be required no more frequently than annually, allowing flexibility to respond to State needs in the future.

3. Populations Required for Mandatory Reporting

In section II.D.3. of the proposed rule, we explained that we interpret sections 1139A and 1139B of the Act to require that reporting for the Child Core Set include *all* beneficiaries covered by Medicaid and CHIP and to require that reporting for the behavioral health measures in the Adult Core Sets include *all* beneficiaries covered by Medicaid. We further explained that this would include 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.

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[46] Technical Assistance Fact Sheet: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

We also explained in section II.D.3. of the proposed rule that sections 1945(g), 1945(c)(4)(B), 1945A(g)(1)(B), and 1945(g)(2)(A)(i) of the Act, together with section 1902(a)(6) of the Act, support CMS guidance requiring State reporting on the Health Home Core Sets to include *all* beneficiaries enrolled in the applicable health home program. We further explained that 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. Further, we explained that we anticipated that health home programs would have to report on beneficiaries who have received Medicaid-covered health home 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 health home services in one of these settings during the measurement period.

As explained in the proposed rule, we ultimately expected to require States to report on the populations discussed previously in this final rule for each Core Set through the annual reporting guidance; however, we did not propose to require this to begin with 2024 Core Set reporting in light of concerns about whether it would be feasible for States to begin reporting on all populations as soon as the rule would apply. Therefore, we proposed that the Secretary could, through the annual reporting guidance, phase in reporting on certain populations. Specifically, we proposed at § 437.10(b)(5) that annual reporting guidance would identify those populations for which States would be required to report measure data for a given year, and also proposed at § 437.10(c) that this annual guidance might provide that mandatory State reporting for certain populations of beneficiaries would be phased in over a specified period of time. These proposals applied to all Core Set reporting: Child, Adult, and Health Home. We solicited comment on how best to provide technical assistance to support States in reporting on all populations as well as on how long States may need to be able to report on all Medicaid, CHIP, and Health Home program beneficiary populations.

Comment: We received several comments supporting full mandatory reporting for all populations. However, many comments about these proposals noted concerns and challenges with reporting for specific populations of beneficiaries, such as those who are dually eligible for Medicare and Medicaid; those whose Medicaid or CHIP coverage is limited to payment of premiums and/or cost sharing, which may include those with private insurance; and those who receive services through Tribes and Tribal Organizations. We also received comments encouraging CMS to consider allowing States the ability to identify specific populations where reporting is difficult due to unique State circumstances.

Response: Although the majority of comments addressed concerns with including specific discrete populations in reporting of the Child and Adult Core Sets, we continue to believe that the intention of the statute is to provide the most comprehensive quality information on as much of the population as possible. Our view is that Congress' requirement for a mandatory reporting regime emphasizes their intent to ensure that all Medicaid and CHIP populations are aware of the quality of care in their state. Therefore, we have revised § 437.15(a)(4) of this final rule to require State reporting of mandatory Child and Adult Core Set measures for all Medicaid and CHIP beneficiaries, including those enrolled in fee-for-service and managed care, unless the Secretary specifies in annual guidance that the population is not required to be reported in accordance with § 437.10(b)(5) or CMS grants a State exemption for the population for one or more Child or Adult Core Set measures in accordance with § 437.15(a) of this rule. This differs somewhat in approach from the proposed rule, in which subregulatory guidance would identify populations for which States would be required to report; however, the final rule provisions are generally consistent with those commenters who supported comprehensive reporting of quality information for all Medicaid and CHIP populations, and with the proposed rule preamble's discussion of the proposed policy for the Child and Adult Core Sets. Rather than using subregulatory guidance to identify the populations for which States must report the Child and Adult Core Sets, as we proposed, we will instead use the guidance to identify specific difficult-to-report populations which will be, for a given reporting year, optional for states to include in reporting of the Child and Adult Core Sets.

With respect to the Health Home Core Sets, for the following reasons, we have determined that States with section 1945 or 1945A health home programs must report on all beneficiaries enrolled in the applicable health home program or programs, with no exceptions. Reporting on *all* populations served in health home programs will provide us with more accurate and comprehensive data that will help inform us of the effect of the health home benefits on coordination of care and aid us in identifying ethnic, racial and socioeconomic disparities. Also, reporting on all beneficiaries allows improved analysis of the quality of services rendered to persons enrolled in health home programs; such reporting can be utilized as a tool for the Annual Core Set Measures Workgroup when evaluating how a measure is contributing to the overall CMS mission of quality improvement for all populations served. Additionally, States will have Health Home Core Set measure data on all populations enrolled in the applicable health home from their health home providers, which are required to provide it to the State as a condition of payment under sections 1945(g) and 1945A(g) of the Act. Since the requirement for providers to report the data collected at the program level to States has been in effect from the beginning of both benefits, most states that have implemented the 1945 health home benefit have been voluntarily reporting on the health home core set for all populations. The 1945A health home benefit has not been in effect long enough to have data on a reporting cycle. Additionally, the population enrolled in health home programs is usually small and easily identifiable through existing data collected at the program level. Therefore, we have added § 437.15(a)(5) to the final rule, to require State reporting of sections 1945 and 1945A Health Home Core Sets measures for *all* beneficiaries enrolled in an approved health home program. This includes those beneficiaries that received Medicaid-covered health home services in FQHCs, RHCs, and facilities operated by IHS, Tribes and Tribal Organizations, and Urban Indian Organizations, if the beneficiary who is enrolled in the applicable health home program received Medicaid-covered health home services in one of these settings during the measurement period. Because reporting on the Health Home Core Sets is required for all beneficiaries enrolled in an approved health home program, we also have revised § 437.10(b)(5) and (c) of this final rule to specifically reference only the Child and Adult Core Sets. The revisions to § 437.10(b)(5) required us to remove the wording, ''as described in paragraph (b)(5) of this section'' from § 437.10(b)(6) as annual reporting guidance on attribution rules applies to the Child, Adult, and Health Home Core Sets.

We address concerns about the feasibility of Child and Adult Core Sets reporting for specific populations in the final rule in two ways. First, because we recognize that there are certain populations for which all States potentially face difficulties in obtaining data, we are revising § 437.10(b)(5) and (c) of this final rule to provide that we will use the annual subregulatory guidance to identify specific populations which will be optional (that is, not mandatory) for States to include in reporting of the Child and Adult Core Sets for a given reporting year. For example, all States that commented on the proposed rule (including those States that currently participate in the Medicare-Medicaid Data Sharing program) requested more time to obtain, link, and analyze Medicare FFS claims and Part D events data. Further, States do not have access to the Medicare Part C data required to report on dually eligible beneficiaries who have enrolled in Medicare Advantage. Given these concerns with data access and experience, this could be an example of a population that the Secretary may exempt in subregulatory guidance issued prior to mandatory reporting. We note that these data access concerns do not impact the States' ability to report on Health Home Core Set measures since these measures do not require Medicare data. As stated previously, States will have Health Home Core Sets measure data on all populations enrolled in the applicable health home from their health home providers, which are required to provide it to the State as a condition of payment under sections 1945(g) and 1945A(g) of the Act. In addition, all the measures in the 2023 and 2024 section 1945 Health Home Core Set as well as all of the measures under consideration for the section 1945A Health Home Core Set can be reported using administrative claims data. Therefore, reporting on all populations for the Health Home Core Sets should not pose an excessive burden on States in the absence of any exceptions.

Second, as set forth in §§ 437.10(b)(5)(i) and 437.15(a)(4) and (6) of this final rule, we allow States to request a 1-year exemption from reporting for specific populations for one or more Child and/or Adult Core Set measures where those populations have not already been exempted by the Secretary for that year in the annual subregulatory guidance. The State would be eligible for such a 1-year exemption if it demonstrates to CMS that, despite reasonable efforts, it is not able to obtain access to data required to report for the population; for example, that it is unable to obtain needed third party data or to finalize a necessary data-sharing agreement between parties before the reporting deadline. The State must request the exemption from us by September 1st of the applicable reporting year, the exemption would be only for that year's reporting, and it would apply only to the specific population for which the State receives an exemption. We do not expect that this population-based exemption process will create an avenue for states to request an exemption from reporting one or more measure(s) in their entirety as most states are already reporting the majority of Core Sets measures for most of the beneficiaries in Medicaid and CHIP. The State will be required to explain why this exemption is necessary and provide a reasonable timeline of the actions underway to resolve the data access issue. In addition, as previously stated in this final rule, the State must demonstrate to us that it has made a reasonable effort to obtain the required data by the reporting deadline. We plan to respond to the State's request before the close of the mandatory reporting period to ensure that the State has time to complete reporting by December 31st. If we deny a State's request for exemption, the State will be expected to include the relevant population in that year's annual Child and Adult Core Sets reporting. Additionally, a State may re-apply in subsequent years to extend an exemption that has been granted. As stated in § 437.10(b)(5)(i), annual subregulatory guidance will provide information about how States can request an exemption.

Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters supported the requirement that States include populations that are harder to report in Core Set reporting, as outlined in the proposed rule, including those who are dually eligible for Medicare and Medicaid, those who use long-term services and supports, people with substance use disorders, and people in FFS Medicaid, including in States that enroll most people in managed care.

Response: We thank these commenters for their support of required reporting for these populations.

Comment: Multiple commenters requested additional clarification from CMS on how States should allocate beneficiaries who experience gaps in coverage or who are enrolled in multiple plans during the reporting period. Specifically, in some States, commenters noted that FFS enrollment is temporary until a beneficiary selects a managed care plan. In other States, FFS populations may comprise a very small percentage of total Medicaid enrollment. The commenters recommended that CMS consider whether the inclusion of the beneficiaries temporarily enrolled in FFS in Core Set reporting is an appropriate use of significant State resources.

Response: As discussed in section II.D.3. of this final rule, we interpret sections 1139A and 1139B of the Act to require reporting of *all* beneficiaries covered by Medicaid and CHIP for the Child Core Set, and to require reporting for the behavioral health measures in the Adult Core Set of *all* beneficiaries covered by Medicaid. Additionally, as discussed previously in this section of this final rule, we are requiring in this final rule that reporting for the Health Home Core Sets include *all* beneficiaries enrolled in the applicable health home program. Attribution of performance and quality data poses challenges for the health care field, and Medicaid and CHIP in particular, as it requires striking a balance between the person-centered goal of measuring quality of care for a beneficiary regardless of delivery system and feasibility for providers, plans, health systems, and States. Our intent in implementing mandatory reporting requirements is for the data collected to be as inclusive of all beneficiaries as possible. However, when developing annual guidance, we will consider what distinctions between delivery systems are meaningful, being mindful of short-term transitions.

Comment: Multiple commenters supported a phased-in approach to the inclusion of populations in mandatory reporting but provided different recommendations about the approach CMS should take. One commenter recommended that CMS collect feedback from affected and interested parties on the most feasible reporting timeframe for specific populations. Another commenter requested that States have the flexibility to make the decisions about phasing in reporting of populations that are challenging to report on a timeframe that is feasible for each State. One commenter recommended that phasing in reporting for any given population should be limited to no more than 3 years, while others noted that 2 to 5 years is the minimum amount of time needed. One commenter recommended that CMS extend the phase-in period beyond 5 years, proposing up to 7 years to phase in fully reporting all measures for all populations. Several commenters recommended allowing more time before CMS phases in mandatory reporting for other populations, such as dually eligible beneficiaries; recommendations varied from as soon as 3 years to 10 years.

Response: Commenters had varying preferences regarding the amount of time that we should provide for phasing in mandatory reporting on specific populations; some commenters recommended that we give States the flexibility to decide what populations they are able to report on, based on their unique circumstances. While reporting on standardized populations will help us achieve data consistency across States and provide actionable data to identify disparities and support efforts to improve the quality of health care, we recognize, based on the range of years supported in public comments, that the ability of States to report on the Child and Adult Core Sets for certain populations may vary, and there are unique circumstances which may result in States' inability to report on certain populations in a given year. As discussed previously in this final rule, we have revised § 437.10(b)(5) and (c) to specify that the Secretary will identify in annual guidance the populations for which States may voluntarily, but are not required to, report the Child and Adult Core Set measures for a specific year. As further discussed previously in this final rule, this same flexibility is not needed for the Health Home Core Sets due to the ready availability of provider data, small population size, and ease of measure calculation. In §§ 437.10(b)(5)(i), 437.15(a)(4), and (6) we also added an opportunity for States to request a 1-year exemption from reporting mandatory populations for the Child and Adult Core Sets for one or more Child or Adult Core Set measures if the State demonstrates an inability to obtain access to data required to report on the measure(s) for the population—for example, if a State is unable to obtain a necessary data-sharing agreement between parties before the reporting deadline. We will consider renewing exemptions for specific populations on an annual basis. Additionally, we revised § 437.15(a)(4) to specify that mandatory reporting would include both fee-for-service and managed care delivery systems unless the population is otherwise specified by the Secretary pursuant to § 437.10(b)(5) or the State has received an exemption. We will work collaboratively with States to provide the technical assistance and reporting guidance necessary to support improvements in reporting for certain populations.

We have also revised §§ 437.10(b)(5), (c), and 437.15(a)(4) of this final rule to specifically reference only the Child and Adult Core Sets. This is because, as discussed previously, under this final rule, Health Home Core Set reporting must include reporting on all beneficiaries enrolled in an approved health home program.

Comment: Multiple commenters noted concerns with accessing claims data for beneficiaries who may be enrolled in Medicaid only for premium assistance programs. Multiple commenters requested that CMS provide clarification that the rule would not apply to individuals who have both Medicaid coverage and private insurance coverage, as the Medicaid agency would not have access to claims information from the member's private plan.

Response: We agree with the commenters that reporting Child and Adult Core Set measures for beneficiaries whose Medicaid or CHIP coverage is limited to payment of private insurance premiums and/or cost sharing may be challenging, as States currently do not have consistent access to data needed from the liable third-party payer, and as discussed previously in this final rule, we are revising § 437.10(b)(5) such that the Secretary will identify in annual guidance populations for which States may, but are not required to, report the Child and Adult Core Set measures. We will work with States to determine reporting feasibility and the technical assistance needed for mandatory Child and Adult Core Sets reporting on such beneficiaries, and will update reporting guidance and mandatory reporting requirements based on these assessments. Reporting for populations who are dually eligible for Medicare and Medicaid is discussed below. We further note that the process for delaying reporting under § 437.10(b)(5) does not apply to the Health Home Core Sets as discussed previously in this final rule. As discussed previously, States are expected to have the data they need to report on the Health Home Core Sets from health home providers, and therefore, are not expected to experience the challenges in reporting for beneficiaries whose Medicaid or CHIP coverage is limited to payment of private insurance premiums and/or cost sharing discussed above.

Comment: Several commenters opposed mandatory State reporting for the dually eligible population and suggested that CMS should be the responsible party for reporting on the dually eligible population as Medicare is the primary payer for most benefits and services for these beneficiaries. A few commenters recommended that CMS should limit mandatory State reporting for dually eligible beneficiaries to delivery systems or measures where the State is directly accountable. One commenter recommended limiting reporting to States that operate Statewide, fully-integrated models for dually eligible beneficiaries (for example, fully integrated dual eligible special needs plans), and one commenter recommended limiting reporting on Core Set measures for dually eligible beneficiaries to measures for which the State is directly accountable so that the quality reporting on dually eligible beneficiaries is reflective of the payer of services.

Response: We recognize the concerns about States' ability to report on the dually eligible population when States are not the primary payer for most health care services for this population. We disagree that States should not report on all dually eligible individuals in the States' reporting of Core Sets measures. Dually eligible individuals experience the health care system and incur health outcomes as individuals, regardless of whether Medicare or Medicaid pays for the service. The purpose of the Child and Adult Core Sets is to measure the overall national quality of care for beneficiaries, which is not limited to services reimbursed by Medicaid or CHIP. The main goal of the health home programs is to improve health outcomes for beneficiaries through care coordination that is intended to better link primary, behavioral health, and long-term services and supports for beneficiaries served by the health home program. The Health Home Core Sets will be used for ongoing monitoring and evaluation purposes across all State health home programs to measure this goal. As discussed previously, States are expected to have the data they need to report on the Health Home Core Sets from health home providers and therefore are not expected to experience challenges in reporting for dually eligible individuals. We recognize that States must obtain, link, and analyze Medicare data in order to report the Child and Adult Core Sets of measures for fee-for-service beneficiaries, and that States do not have access to encounter data for Medicare Part C (Medicare Advantage), and we expect to phase in required reporting of Child and Adult Core Set measures for dually eligible beneficiaries. We will include information, including available technical assistance, on mandatory Child and Adult Core Sets reporting for this population in annual reporting guidance. Since all States that commented on the proposed rule, including those States that currently participate in the Medicare-Medicaid Data Sharing Program, requested more time to obtain, link, and analyze Medicare data, we will work with States and interested parties to identify the timeframe for which mandatory Child and Adult Core Sets reporting for dually eligible beneficiaries will be required. Additionally, we will continue to assess whether we can use T–MSIS or other alternative data sources to calculate Child, Adult, and Health Home Core Sets measures on behalf of States.

Comment: Several commenters expressed concern about access to and the availability of assistance with using the Medicare FFS claims and Part D events data that are needed to report on dually eligible beneficiaries and were concerned that States would require extensive resources to utilize the data. They further commented that CMS is disadvantaging States, as this data is very difficult to obtain and out of their control. A few commenters encouraged CMS to facilitate State participation in the Medicare-Medicaid Data Sharing Program. A commenter recommended CMS establish a standardized data license/sharing agreement to facilitate Medicare data requests for the dually eligible population.

Response: Since 2011, we have provided States access to Medicare FFS claims and Part D events data for dually eligible beneficiaries, including dually eligible beneficiaries whose Medicaid or CHIP coverage is limited to payment of premiums and/or cost sharing (also known as partial-benefit dually eligible beneficiaries), free-of-charge via the Medicare-Medicaid Data Sharing Program. Information on the Medicare-Medicaid Data Sharing Program, including how to request data and the standard data sharing agreements, is available through the State Data Resource Center. We acknowledge that not all States currently request Medicare claims and events data, and that those States that do not currently request Medicare claims and events data may need additional time to request and effectively utilize these data. We also acknowledge that the Medicare-Medicaid Data Sharing Program does not currently make available Medicare Part C encounter data, as discussed in the response below. Since all States that commented on the proposed rule, including those States that currently participate in the Medicare-Medicaid Data Sharing Program, requested more time to obtain, link, and analyze Medicare FFS data, and in light of the systematic Medicare Part C data access challenges, we anticipate that the Secretary's subregulatory guidance issued under § 437.10(b) may specify that mandatory Child and Adult Core Sets reporting will not be required initially for dually eligible beneficiaries. This approach will address concerns for States that are not currently requesting Medicare claims and events data, providing them additional time to gain familiarity with the available claims and events data. Subregulatory reporting guidance will also consider care delivery systems and data availability. Specific to Health Home Core Sets, States collect data from the provider at the program level for this population to inform the health home measures, and therefore the health home measures do not rely on Medicare claims data. Health home programs are an optional State benefit, and there is the possibility that a dually eligible beneficiary could be enrolled in both Medicare and a State health home program if the dually eligible beneficiary has full Medicaid coverage (that is, a ''full-benefit dually eligible beneficiary''). If a full-benefit dually eligible beneficiary is enrolled in both a State health home program and Medicare, the provider would submit data for health home measures to the State, and the State would include this population in Health Home Core Sets reporting. We will consider implications of data access when reviewing measures for possible addition to the Health Home Core Sets in future years.

Information on the Medicare-Medicaid Data Sharing Program, including on how to request data and the standard data sharing agreements, is available at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/StateAccesstoMedicareData* or by contacting the State Data Resource Center at *https://www.statedataresourcecenter.com/home/contact-us.* We will take under advisement the commenters' recommendations on additional technical assistance and resources for using Medicare FFS data, and we will consider Medicare data availability and ease of use when determining the Child and Adult Core Sets reporting schedule for the dually eligible population in general.

Comment: Multiple commenters supported provision of technical assistance to States on inclusion of those dually eligible for Medicare and Medicaid and recommended that CMS provide open-source tools, opportunities for shared learning, assistance in developing data infrastructure, guidance on how to link Medicaid and Medicare data, data infrastructure, model analysis with T–MSIS data, and standardized Medicare data packages tailored to Core Set analysis. A commenter recommended considering the work of the NQF Measure Application Partnership (MAP) Dual Eligible Beneficiaries Workgroup when considering measures for the Core Sets and data availability.

Response: We plan to provide technical assistance on Child, Adult, and Health Home Core Sets reporting for dually eligible beneficiaries and will take these ideas into consideration when developing technical assistance resources and learning opportunities.

Comment: Several commenters were concerned about the lack of available Medicare Part C encounter data. These commenters explained that States cannot report on dually eligible beneficiaries enrolled in Medicare Part C without these data.

Response: We recognize that we do not currently make available Medicare Advantage data to States free-of-charge via the Medicare-Medicaid Data Sharing Program. We are looking into how to address this issue. We do not intend to require that States report Child and Adult Core Set measures on dually eligible beneficiaries enrolled in Medicare Part C (that is, in Medicare Advantage) until such data are available. Specific to Health Home Core Sets, States collect data from the provider at the program level for this population to inform the health home measures, and therefore the health home measures do not rely on Medicare claims data. We will consider implications of data access when reviewing measures for possible addition to the Health Home Core Sets in future years.

Comment: One commenter expressed concern with reporting of Medicaid FFS beneficiaries in their State, as they may not meet continuous enrollment requirements for quality measurement. Another commenter noted that there is a significant burden for including Medicaid FFS beneficiaries in State-wide reporting of hybrid measures.

Response: The purpose of the Child and Adult Core Sets, as suggested by sections 1139A and 1139B of the Act, is to measure the overall national quality of care for beneficiaries, monitor performance at the State level, and improve the quality of health care. The main goal of the health home programs is to improve health outcomes for beneficiaries through care coordination that is intended to better link primary, behavioral health, and long-term services and supports for beneficiaries served by the health home program.[47] [48] The Health Home Core Sets will be used for ongoing monitoring and evaluation purposes across all State health home programs to measure progress towards this goal. While we recognize the additional burden to States that may not currently include Medicaid FFS beneficiaries in their reporting, in order to improve the quality of care delivered to all beneficiaries, States must include in reporting the entire population covered by Medicaid and CHIP (or served by the applicable health home program), including Medicaid FFS beneficiaries, except to the extent the Secretary exempts a population from reporting for Child and/or Adult Core Sets measures in annual guidance or grants a state exemption for a specific population for a specific reporting year, as discussed in detail previously in this section. We have revised § 437.15(a) accordingly. The vast majority of measures on the Core Sets (84 percent of the 2023 and 2024 Child Core Set and behavioral health measures on the Adult Core Set can be calculated using administrative claims or survey data. One hundred percent of the 2023 and 2024 section 1945 Health Home Core Set as well as 100 percent of the measures under consideration for the section 1945A Health Home Core Set) can be calculated using administrative claims data. We are assessing the resources and technical assistance to support States in using other data sources more widely. In order to be included in Core Set reporting, beneficiaries must still meet enrollment requirements for quality measurement, which are established by the measure stewards for each measure and based on a beneficiary's continuous enrollment in Medicaid and CHIP. Additionally, for Health Home Core Sets a beneficiary must also be enrolled in an approved health home program. FFS or other beneficiaries who do not meet the enrollment requirements for a given measure would not be included in a State's report.

Comment: One commenter suggested CMS test the validity of mandatory measures that have been expanded to include additional populations, specifically populations that may be more difficult to include, prior to public reporting, and that CMS ensure that risk adjustment models of mandatory measures are robust enough to provide fair comparisons when including expanded populations. This commenter further recommended that CMS work with measure developers to evaluate the fit of the risk adjustment models for mandatory measures prior to reporting results publicly to ensure they generate meaningful information and allow for fair comparisons.

Response: We anticipate that our Core Set reporting guidance will align with measure steward technical specifications with regard to defining the populations included in the measure and to risk adjustment. If the measure steward includes risk adjustment for a measure on the Core Sets, we will include risk adjustment for that measure. We work with measure stewards to adapt measures for State level reporting and provide appropriate reporting guidance. The issue of validity testing of mandatory measures is outside the scope of this rulemaking.

Comment: Several commenters noted that decisions about whether to submit health care data necessary to calculate Core Set measures for beneficiaries receiving care from Indian Health Care Providers (IHCPs) rest with the Tribes and Tribal Organizations, and any CMS rules about data completeness must respect Tribal sovereignty and Tribes' decisions about whether to submit health care data. One commenter noted that the addition of health care facility data from IHS, Tribes, and Tribal Organizations would require significant technical assistance and funding from CMS to facilitate the development of needed infrastructure to support these providers' readiness to capture required data elements, and to assist with data transmission.

Response: We understand that Tribes and Tribal providers take seriously their role in protecting the confidentiality of American Indian/Alaska Native (AI/AN) data and note that State Core Set data is de-identified before it is submitted to us for Core Set reporting. We also recognize that States enter into individual contractual and data use agreements with Tribes and Tribal providers that may affect the availability of Tribal data for Core Sets reporting. States might choose to require their Medicaid providers to report certain data to the State as a condition of receiving Medicaid payment, if doing so would help the State comply with the Core Sets reporting requirements. We strongly encourage States to consult with Tribes and to coordinate with IHS, and Tribes and Tribal Organizations, to discuss reporting of Child and Adult Core Set measures regarding the services provided by IHS and Tribal health care providers in their State. Collaborative relationships between government entities and Tribes are essential to responsible and effective data use and to understanding and addressing the gaps in these data,[49] which limit analyses that support public health decision-making in AI/AN communities.[50] Any delay of reporting data for AI/AN beneficiaries will impede efforts to improve health outcomes for these populations, and we encourage Tribes to report Core Set data to their respective States to help improve the quality of their State's Medicaid program, and ultimately the quality of health care provided to AI/AN individuals.

As discussed previously in this final rule, States are required to report Child and Adult Core Sets quality measure data for all populations, unless a population is identified as optional in annual subregulatory guidance to be issued by CMS, and States may request a 1-year exemption from reporting mandatory populations for one or more measures on the Child and Adult Core Sets if the State demonstrates an inability to obtain access to data, which may include for example, an inability to obtain needed third-party data or to finalize a necessary data-sharing agreement between parties before the reporting deadline. Moreover, this final rule requires States and health home providers to report data on all populations enrolled in the applicable health home. If Tribes or Tribal Organizations are providing section 1945 or section 1945A health home services, sections 1945 and 1945A of the Act require them to report data to the State as a condition of payment for these health home services, as discussed in more detail previously in this final rule.

E. Application of the Child and Adult Core Sets to CHIP

As discussed in section II.E. of the proposed rule, in §§ 437.15(b), 457.700 and 457.770 we proposed the following requirements for CHIP programs: to require that separate CHIPs report on all measures in the Child Core Set in

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[47] *https://www.medicaid.gov/resources-for-states/medicaid-state-technical-assistance/health-home-information-resource-center/index.html.*

[48] *https://www.medicaid.gov/resources-for-states/medicaid-state-technical-assistance/health-home-information-resource-center/1945a-health-home-resources/index.html.*

[49] *https://aspe.hhs.gov/reports/gaps-strategies-improving-american-indianalaska-nativenative-american-data#TOC.*

[50] *https://www.gao.gov/products/gao-22-104698.*

accordance with the requirements outlined in the proposed rule and include all CHIP beneficiaries in State reporting, including pregnant individuals receiving child health assistance coverage for the duration of pregnancy in States that elect to provide coverage through the group known as the 'unborn option'. Separate CHIP programs are encouraged, but not required, to report on the measures in the Adult Core Set.

We received public comments on the application of mandatory reporting to CHIP, and in general, commenters supported the proposed process. We are finalizing these provisions with revisions to §§ 437.15(b)(1) and 457.770(c) as discussed in section II.E.1. of this final rule. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters supported CMS' proposal, in section II.E. of the proposed rule, to include pregnant individuals receiving coverage under CHIP, including those provided CHIP child health assistance for the duration of pregnancy (also referred to as the ''unborn option''), in the mandatory reporting requirements for the Child Core Set, if the pregnant individual meets the age parameters for the measures. One commenter requested guidance on whether States would be required to report quality measures for pregnant individuals receiving coverage through the option to extend special CHIP child health assistance for the duration of pregnancy and whether States would be required to include this population in Adult Core Set reporting.

Response: We appreciate the support from these commenters. We are finalizing the mandatory reporting requirements as proposed in § 457.770(a) to require States to include this population of CHIP beneficiaries when reporting on quality measures in the Child Core Set. States that provide coverage for the duration of pregnancy under CHIP would be required to include this population in reporting of the Child Core Set if the participants meet the age parameters for the measures referenced in § 457.770(a) of this final rule. Reporting on the Adult Core Set is encouraged, but voluntary, for beneficiaries enrolled in CHIP in § 457.770(b) of this final rule.

Comment: One commenter recommended that individuals receiving coverage under CHIP should also be included in reporting for any measures from the Adult Core Set that the State reports on for their CHIP population.

Response: 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 a result, States are encouraged, but not required, to report on the measures in the Adult Core Set for beneficiaries in separate CHIP programs as per § 457.770(b) of this final rule.

Comment: One commenter requested guidance on whether CMS would give States the option to report by combining the Child Core Set State-level data and section 1945 health home program data.

Response: We will provide technical assistance and further details on how small population sizes should be handled through our reporting guidance. Under this final rule, data would be reported separately at the health home program level for the Health Home Core Sets and the State level for the Child and Adult Core Sets. Given these different denominators for these obligations, we do not plan to combine these reporting requirements.

Comment: One commenter noted that their State enrollment under the special CHIP child assistance option for pregnant individuals is very low and reporting on it will have little impact on the overall rate. Another commenter noted that many individuals who receive special CHIP child assistance for pregnant individuals would not meet the eligibility requirements for reporting, such as receiving CHIP for the duration of the pregnancy or age requirements, and as such, collection of the data may not be a good use of data resources.

Response: While the special CHIP child assistance for pregnant individuals is reflective of a very specific and relatively small population, we believe it is important to gather data for as many populations as possible. In some cases of small population sizes, core set measure data would not be reported separately, but would be included in reports of larger populations. We will provide technical assistance and further details on how small population sizes should be handled through our reporting guidance. We will follow data suppression policies for measure stewards in addition to our Cell Size Suppression Policy such that if sample sizes are too small, data will not be publicly reported to avoid a potential violation of privacy.[51]

Comment: One commenter encouraged CMS to adhere to measure steward specifications and urged that if CMS expands the denominator beyond those specifications, such as including individuals without 12 months of data, CMS should assess the validity and actionability of the measures.

Response: We will take this feedback into consideration when developing Core Set reporting guidance. We will provide technical assistance and further details on enrollment requirements for inclusion of beneficiaries in Core Set reporting through our reporting guidance. In order to be included in Core Set reporting, beneficiaries must still meet enrollment requirements for quality measurement, which are established by the measure stewards for each measure and 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 making measure adaptations, we work closely with measure stewards to develop reporting guidance and to make as few adaptations to the technical specifications as possible.

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

As discussed in section II.D.4. of the proposed rule, in §§ 437.15(b) and 457.770(c), we proposed 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). We also proposed that reporting guidance would include attribution rules, to specify in which program (Medicaid or CHIP) a State would count a child who transitioned between programs within a reporting period.

In response to comments received, we have revised §§ 437.15(b)(1)(i) and (ii), and 457.770(c), to specify that States with separate CHIP programs report on the Child Core Set measures in two categories instead of three as originally proposed: (1) separate CHIP (Title XXI) and (2) Medicaid inclusive of CHIP-funded Medicaid expansion (Titles XIX and XXI). Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters supported the proposed rule proposal to require adherence to the same reporting guidance for Medicaid (funded through Title XIX and Title XXI) and separate CHIP programs, and recommended that the proposed language at § 437.15(b) be revised to clearly articulate that States with a separate CHIP program report on

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[51] CMS Cell Suppression Policy: *https://www.hhs.gov/guidance/document/cms-cell-suppression-policy.*

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). Several other commenters recommended that CMS simplify the reporting categories to instead only require reporting on two categories for Medicaid inclusive of CHIP-funded Medicaid expansion (Titles XIX and XXI) and separate CHIP (Title XXI).

Response: In response to public comment, we have revised §§ 437.15(b)(1)(i) and (ii), and 457.770(c), to specify that States with separate CHIP programs will be required to report on the Child Core Set measures in two categories, instead of three as originally proposed. The category of Medicaid inclusive of CHIP-funded Medicaid expansion includes all Medicaid enrollees, regardless of whether they are funded by Title XIX or XXI. We will aggregate the separate CHIP and Medicaid inclusive of CHIP-funded Medicaid expansion data to create the Medicaid and CHIP combined category, alleviating the burden on States to create and report that data. We believe the change from the three originally proposed reporting categories to the two reporting categories described previously in this final rule maintains the intent of the proposed rule.

Comment: Several commenters did not support separate reporting of children in Medicaid and CHIP. They thought that it added little value and would result in an additional reporting burden, as combined reporting more closely aligns with how services are provided. Instead, one commenter recommended combining reporting for Medicaid and CHIP, and using attribution to determine to which program beneficiaries should be assigned. One commenter recommended CMS allow aggregate reporting to align with current State practices, while another commenter asked if separate or combined reporting of CHIP could be determined at the State level.

Response: Separate CHIP programs have different service requirements than Medicaid. Therefore, we expect that results for certain measures could vary within States for separate CHIP and Medicaid. We believe these differences are important to document, and therefore are maintaining the requirement at §§ 437.15(b) and 457.770(c) that States with a separate CHIP report separate CHIP data separately from Medicaid data. Meanwhile, we have updated the reporting categories to incorporate both Title XIX and Title XXI-funded Medicaid under one category to reduce State burden and to reflect the fact that the source of funds (Title XIX or Title XXI) providing the Federal match for a child enrolled in Medicaid does not impact which or how services are provided. We will also aggregate the separate CHIP and Medicaid data to obtain the combined Medicaid and CHIP results, rather than requiring States to report the combined results, to reduce State burden.

Comment: One commenter suggested that any separate CHIP reporting should be limited to administrative measures that are in the control of MCOs.

Response: The Core Sets are State-level and health home program-level reporting programs, not managed care or health plan-level reporting programs. One of the goals of mandatory reporting is to provide inclusive data on quality and performance for all beneficiaries, regardless of delivery system. We will provide technical assistance to address the needs of States and State partners to report the Core Sets.

Comment: Several commenters noted that if States were required to report results for Medicaid and CHIP separately, a separate CAHPS survey for CHIP would be required. Multiple surveys would result in significant cost increases, require additional time to implement, and increase the potential for insufficient sample sizes.

Response: We will take this feedback into consideration as part of the guidance process that is discussed in the rule. Section 2108(e)(4) of the Act requires states to collect and report CAHPS survey results for Title XXI CHIP programs (see CHIPRA section 402(a)(2)) as part of their annual reports to the Secretary. Reporting CAHPS survey results separately currently is encouraged for voluntary Core Set reporting, and several States successfully do so. We note that previous CMS guidance outlines how States can sample and report CHIP and Medicaid results separately for CAHPS.[52]

Comment: One commenter supported the proposal that CMS include attribution rules in reporting guidance for counting children who move between Medicaid and separate CHIP. One commenter recommended that States be required to include children that meet continuous enrollment criteria in reporting for CHIP, as is required for Medicaid reporting and enrollment criteria, in order to allow for better comparisons. This commenter requested a separate population category for enrollees transitioning from Medicaid to CHIP if CMS were to require reporting on this group, noting that combining these data for children who transition between programs would be burdensome. Multiple commenters acknowledged the need to include children in Child Core Set reporting who transition between Medicaid and CHIP in order to promote consistency and prevent duplicative reporting. Some commenters raised concerns that inconsistencies in Medicaid and CHIP requirements could make it difficult to combine these two groups for reporting.

Response: We plan to provide detailed guidance about attribution rules in the annual reporting guidance required under § 437.10(b), as finalized in § 437.10(b)(6) of this rulemaking with minor changes. We note the importance of capturing data for the population of children who transition between Medicaid and CHIP, given the implications of insurance churn on health care quality.

Comment: One commenter noted that some States with small separate CHIP programs may have difficulty reporting on their CHIP population and requested technical assistance and support from CMS to address data collection and calculation challenges.

Response: We appreciate these comments and concerns and will provide technical assistance to meet the needs of States and State partners.[53]

F. Ensuring Compliance With the Mandatory Reporting Requirements

As discussed in section II.F. of the proposed rule, in § 437.20, we proposed to require that States submit a Medicaid SPA attesting that the State agency would report on the Child, Adult, and Health Home Core Sets in accordance with the requirements in the final rule. 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. With these attestations in the State plan, we would have authority under section 1904 of the Act to withhold Federal Medicaid payments, in whole or in part, if an agency fails to comply with the Medicaid reporting requirements.

We also proposed changes to § 433.112 which 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

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[52] Fact Sheet 2012: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/cahpsfactsheet.pdf.*

[53] Technical Assistance Fact Sheet: *https://www.medicaid.gov/medicaid/quality-of-care/downloads/tafactsheet.pdf.*

transactions standards under 45 CFR part 162, and the health information technology standards under 45 CFR part 170 subpart B to the Core Sets.

We received public comments on compliance requirements, and in general, commenters supported the proposed process. We are finalizing these provisions with a minor wording change to § 437.20(a) to clarify that reporting on Health Home Core Sets measures applies to all populations served by the health home and other minor wording changes to clarify cross-references within the same subpart. Below is a summary of the public comments we received regarding this section and our responses.

Comment: Several commenters supported the proposed standards that States must meet to qualify for enhanced Federal matching funds for Medicaid systems and encouraged the Secretary to use this authority to enforce compliance with mandatory reporting of the Core Set measures. One commenter asked for more information on Federal matching funds for systems.

Response: We thank the commenters for their support for our proposal to use these Federal authorities to enforce compliance with Core Set requirements. CMS regulations at 42 CFR part 433, subpart C specify conditions that State Medicaid systems must meet in order for the State's expenditures on mechanized claims processing and information retrieval systems to be matched at the 90 and 75 percent rates described in section 1903(a)(3)(A)(i) and (B) of the Act. These conditions include industry standards described in § 433.112(b)(12), which with the publication of this final rule now include standards and protocols for reporting on the Child and Adult Core Sets and the Health Home Core Sets, as relevant to the specific State Medicaid system or module. Under these regulations, which implement section 1903(a)(3)(A)(i) and (B) of the Act, enhanced FFP is available at 90 percent for State expenditures for the design, development, and installation (including of enhancements) of qualifying State Medicaid systems, and at 75 percent for State expenditures for operations of such systems, once approved by CMS, in accordance with applicable Federal requirements.[54] Furthermore, in accordance with regulations at §§ 433.117 and 433.119, we may not approve replacement State systems or may not reapprove existing State systems if the State does not meet Core Set reporting requirements that are now described in § 433.112(b)(12) and cross-referenced in § 433.116(c), which means that we would not approve or reapprove a Federal matching percentage of 75 percent under section 1903(a)(3)(B) of the Act for such systems.[55]

Additional information about FFP rates for State Medicaid system design, development, and installation (including of enhancements) and operation available under section 1903(a)(3)(A)(i) and (B) of the Act can be found in the Mechanized Claims Processing and Information Retrieval Systems regulations at 42 CFR part 433, subpart C. Separately, under section 1903(a)(3)(A)(iii) of the Act, State expenditures for Medicaid system development and modifications necessary for collecting and reporting on child health quality measures are matched at the State's FMAP rate as defined in section 1905(b) of the Act.

Comment: Some commenters suggested CMS should develop more explicit guidance outlining specific, graduated enforcement mechanisms for States that remain out of compliance with quality reporting requirements, in order to ensure clear enforcement action is taken against States and other entities that fail to comply and encourage State corrective action.

Response: As noted previously in this final rule, States will be required to submit a Medicaid SPA attesting that the State agency will report on the Child, Adult, and Health Home Core Sets in accordance with the requirements in 42 CFR part 437, as finalized in § 437.20. Since States have to attest that they will meet the mandatory reporting requirements, we will be able to withhold Federal Medicaid payments, in whole or in part, from a State that is non-compliant with these reporting requirements in accordance with section 1904 of the Act and implementing regulations at 42 CFR 430.35. We will be able to withhold Federal funds under Title XXI for noncompliance with the reporting requirements for CHIP in accordance with § 457.204 once § 457.770 is codified. The requirement at § 437.20 to submit a SPA does not apply to the CHIP agency. The CHIP State plan already includes an attestation in section 9.4 that ''the State assures it will collect all data, maintain records and furnish reports to the Secretary at the times and in the standardized format that the Secretary requires.'' All States have made this attestation in the current version of their State plan. Graduated enforcement mechanisms for compliance with Core Sets reporting requirements due to issues with State data systems will align with existing CMS policy regarding State corrective action plans.[56]

Comment: Several commenters supported the proposed requirement that States amend their State Plans to indicate that they would report on the Core Sets in order to give CMS clear authority to enforce the Core Set reporting requirements by withholding Federal Medicaid payments under section 1904 of the Act in the event of noncompliance by a State. One commenter requested clarification on the deadline for submission of the SPA.

Response: We appreciate the support for this proposed Medicaid requirement at § 437.20, which we are finalizing as proposed in this rulemaking. We plan to discuss details of changes to the SPA, including the deadline for submission, in annual reporting guidance.

Comment: Several commenters suggested that requiring Health Home programs to submit Core Set measures to the State as a condition of receiving payment, in addition to the State reporting to CMS, is duplicative and redundant.

Response: While we appreciate the submission of these comments, the proposed rule implements statutory reporting requirements that health home providers must meet, as a condition of payment, under sections 1945(g) and 1945A(g)(1) of the Act. If a Health Home provider is submitting all required data into a State-based system that the State is then using to calculate and report the Health Home Core Sets measures to CMS, that would satisfy the statutory requirement for providers under sections 1945(g) and 1945A(g)(1) of the Act.

Comment: A few commenters recommended that CMS change 42 CFR 431.16, which implements section 1902(a)(6) of the Act, to specify that the State plan requirements include the reporting of the Core Sets and underscore the importance of State compliance with Core Sets reporting.

Response: Section 431.16 requires that States comply with all reporting requirements established by the Secretary and that their State plans reflect that the State will do so. Section

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[54] See section 1903(a)(3)(A)(i) and (B) of the Act, 42 CFR 433.15(b)(3) and (4), subpart C of 42 CFR part 433, and State Medicaid Director Letter (SMDL) #22–001.

[55] Medicaid Enterprise Systems Compliance and Reapproval Process for State Systems with Operational Costs Claimed at the 75 Percent Federal Match Rate CIB at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib052423.pdf.*

[56] Medicaid Enterprise Systems Compliance and Reapproval Process for State Systems with Operational Costs Claimed at the 75 Percent Federal Match Rate CIB at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib052423.pdf.*

431.16 does not list any specific reports that States are required to submit, and we do not believe it would be appropriate to single out Core Sets reporting alone. Further, it is not necessary to do so, as the current language of § 431.16 is broad enough to encompass these newly finalized Core Sets reporting requirements (as they pertain to Medicaid), and because § 437.20 of this final rule sets forth the requirement for States to submit a State plan amendment attesting to compliance with the Core Sets reporting requirements.

III. 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 purpose 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.

In our August 22, 2022 (87 FR 51303) proposed rule, we solicited public comment on each of these issues for the following provisions that contain information collection requirements. As stated in section II. of this final rule, we received 93 public comments on the proposed rule, but only one of those comments was related to the rule's collection of information requirements. The comment and our response can be found in section III.C. of this preamble.

A. Wage Estimates

Private Sector, States, and Territories: To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2022 [57] National Occupational Employment and Wage Estimates (*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 other indirect costs (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 ($/hr)	Fringe benefits and other indirect costs ($/hr)	Adjusted hourly wage ($/hr)
Business Operations Specialists	13–1000	40.04	40.04	80.08
Chief Executives	11–1011	118.48	118.48	236.96
Computer Programmers	15–1251	49.42	49.42	98.84
Data Entry/Information Processing Workers	43–9020	18.97	18.97	37.94
General Operations Manager	11–1021	59.07	59.07	118.14
Statistician	15–2041	50.73	50.73	101.46

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 consider the Federal government's contribution to the cost of administering the Medicaid and CHIP programs. The Federal government provides Federal Medicaid funds for medical assistance based on an 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. Section 5101 of subtitle A of title V of division FF of the CAA, 2023 permanently set the FMAP for the four smaller territories (the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) under Medicaid at 83 percent. Puerto Rico's FMAP under Medicaid is statutorily set at 55 percent but has been temporarily increased to 76 percent until September 30, 2027.[58] For each territory, the annual amount of available Federal matching funds is capped. For Medicaid, all States (including the territories) receive a 50 percent Federal matching rate for activities found necessary by the Secretary for the proper and efficient administration of the Medicaid program. As noted previously in this final rule, States may receive higher Federal matching rates for expenditures on certain services and for certain systems improvements, redesign, or operations, up to 90 percent. As such, in considering 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.

Beneficiaries: We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $21.98/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices [59] identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly

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[57] The costs associated with our August 22, 2022, proposed rule differ from the costs in this final rule since the proposed rule used BLS' May 2020 mean hourly wages whereas this final rule uses BLS' 2022 wage estimates.

[58] See section 1905(ff) of the Act.

[59] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//176806/VOT.pdf.*

earnings of wage and salary workers of $1,059[60] for 2022, divided by 40 hours to calculate an hourly pre-tax wage rate of $26.48/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent or $4.50/hr ($26.48/hr × 0.17), resulting in the post-tax hourly wage rate of $21.98/hr.

Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. Information Collection Requirements (ICRs)

The following collection of information requirements and burden estimates were posted for public review and submitted to OMB for review under control number 0938–1188 (CMS–10434 #26 for the Child Core Set and the Adult Core Set and CMS–10434 #47 for the Health Home Core Sets) in association with the August 22, 2022 proposed rule.

Under sections 1139A, 1139B, and 1902(a)(6) of the Act, we have the authority to collect quality metrics on State-specific Medicaid and CHIP programs for 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, in this final rule, we are requiring States that are 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 is intended to 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.

Currently, Child, Adult, and section 1945 Health Home Core Sets reporting is voluntary for States but highly encouraged. Under this final rule, our voluntary annual reporting requirements will become mandatory for States 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).[61] This final rule does not add, remove, or revise any of the existing measures in any of the aforementioned Core Sets. Annual updates to the Core Sets will continue to be made as required by sections 1139A and 1139B of the Act for the Child and Adult Core Sets and this annual update process will also be applied to both Health Home Core Sets as described in section I.C. of this preamble and §§ 437.10(a)(2) and (e). Mandatory reporting of the Child Core Set and behavioral health measures on the Adult Core Set will impact all 50 States, DC, Puerto Rico, Guam, and the Virgin Islands as described in section II.A. of this final rule and in § 437.1. The Health Home Core Sets requirements will 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 (see § 437.1(d)(2)), 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 section 1945 Health Home SPAs.

Under this final 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 final rule. This is due to the mandatory nature of the 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, we have 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 will become mandatory (the Child Core Set measures, behavioral health measures on the Adult Core Set, and the 1945 and 1945A Health Home Core Sets of measures for States with a health home program), two of which we currently report for States and Puerto Rico using alternate data sources. The remaining non-behavioral health Adult Core Set measures will remain voluntary for States to report. The burden to report voluntary measures is not included in this final rule but is submitted annually to OMB for their approval under control number 0938–1188 (CMS–10434 #26). We are currently assessing whether T–MSIS could be used to report any of the remaining measures. If so, this will reduce the number of measures that States will be required to calculate.

The data fields included in Core Set reporting templates are determined by the measure stewards who own the measures. We are not the measure steward for most measures, and therefore, do not control the actual data fields for most of the measures in the Core Sets. As a result, the templates used for Core Sets reporting will not be published for public comment. Instead, measure stewards implement a separate process for public comment during measure development and measurement updates. We also have recommendations in the CMS Measures Management System Blueprint for a similar process for public comment during measure development.[62]

We are adding SPA preprints to the final rule package under control number 0938–1188 (CMS–10434 #26) for the Child Core Set and the Adult Core Set and CMS–10434 #22, entitled: ''Health Home State Plan Amendment (SPA)'') for the Health Home Core Sets. These preprints were excluded from the proposed rule package, but the contents of the preprints were described under the collection of information requirements, and the burden estimates were included under ICR #1 in the proposed rule. The final rule's preprint does not deviate from those descriptions: ''that the agency would report on the Child and Adult Core Sets in accordance with the requirements in § 437.20(a)'' and that States 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).'' Additionally, we are changing the package under which the Health Home Core Sets SPA preprint is associated from control number 0938–1188 (CMS–10434 #47) to 0938–1188 (CMS–10434 #22, entitled: ''Health Home State Plan Amendment (SPA)''), as this package (CMS–10434 #22) is associated with the health home program State plan requirements. The requirements for the SPA are the same, and the burden set out in the proposed rule is the same as in the final rule (at 54 responses × 1

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[60] *https://fred.stlouisfed.org/series/LEU0252881500A.*

[61] Core Set Measure lists: *https://www.medicaid.gov/medicaid/quality-of-care/index.html.*

[62] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint.*

hour/response = 54 hours total time); only the location is being changed.

Subsequent to the proposed rule we have revised §§ 437.10(b)(5)(i) and 437.15(a)(4) and (6) in this final rule to allow States to request a 1-year exemption from Child and Adult Core Sets reporting for specific populations that have not already been exempted by the Secretary for the year in question in the annual subregulatory guidance. Our assessment of the burden of the exemption request process has been added under ICR #5 (54 responses × 4 hour/response = 216 hours total time). This option is available to all States, and the burden includes all States and Territories subject to mandatory reporting requirements for the Child and Adult Core Sets who may submit an exemption request. As required by the PRA, we will solicit public comment via 60-day and 30-day notices that we will issue in the **Federal Register** separate from this rulemaking document as this voluntary requirement takes effect September 1, 2024.

As noted previously in this rule, we received one public comment related to the collection of information requirements calculation of the burden estimate, which applied to the estimates provided for reporting the Child, Adult, and Health Home Core Sets. The comment, and our response can be found in section III.C. of this final rule.

The burden for reporting voluntary Adult Core Set measures (the measures outside of behavioral health measures) for States to report is not included in this rule's ICR discussions as the mandatory reporting requirements being implemented with this final rule do not apply to the voluntary measures; however, these costs will be included under control number 0938–1188 (CMS–10434 #26). The burden to health home providers for reporting section 1945 and section 1945A Health Home Core Sets data to States is not included in this rule's ICR discussions or under control number 0938–1188 (CMS–10434 #47) as this final rule outlines State requirements to comply with reporting the Health Home Core Sets. The burden to health home providers for reporting the section 1945 and section 1945A Health Home Core Sets along with the development of a Health Home SPA is approved by OMB under control number 0938–1188 (CMS–10434 #22, entitled: ''Health Home State Plan Amendment (SPA)'').

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

The following changes will be submitted to OMB for their approval under control number 0938–1188 (CMS–10434 #26 and CMS–10434 #22). As noted previously in this final rule, we are changing the package under which the Health Home Core Sets SPA preprint is associated from control number 0938–1188 (CMS–10434 #47) to 0938–1188 (CMS–10434 #22, entitled: ''Health Home State Plan Amendment (SPA)'') as this package (CMS–10434 #22) is associated with the health home program State plan requirements.

With the changes outlined in this final rule, the 50 States, DC, Puerto Rico, Guam, and the Virgin Islands that will be subject to the Child and Adult Core Sets reporting requirements will need to submit a single SPA attesting that the agency will 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 will 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 $80.08/hr and a general operations manager 1 hour at $118.14/hr to update and submit the State or territory SPA to us for review. We estimate a one-time burden of 162 hours (54 States and territories × 3 hr/response) at a cost of $15,028 (54 States and territories × ([2 hr/response × $80.08/hr] + [1 hr/response × $118.14/hr])). Taking into account the Federal contribution to Medicaid and CHIP program administration, the estimated State share of this cost is approximately $7,514 ($15,028 × 0.50). CMS is attributing ⅔ of this burden ($5,009 State share and 108 hr) to Child and Adult Core Sets reporting and ⅓ to Health Home Core Sets reporting ($2,505 State share and 54 hr). CMS is attributing additional burden to Child and Adult Core Sets reporting (versus Health Home Core Sets reporting) due to additional effort to coordinate attestation of State Core Sets reporting across State Medicaid and CHIP programs.

TABLE 2—ATTESTATION REQUIREMENTS AND BURDEN UNDER OMB CONTROL NUMBER 0938–1188

[CMS–10434 #26, Child Core Set and the Adult Core Set]

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.20—One-time SPA Submission *	54	54	2	108 (162 hr × ⅔)	Varies	10,019	5,009

* States will be required to submit a 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.

TABLE 3—ATTESTATION REQUIREMENTS AND BURDEN UNDER OMB CONTROL NUMBER 0938–1188

[CMS–10434 #22, Health Home SPA]

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.20—One-time SPA Submission *	54	54	1	54 (162 hr × ⅓)	Varies	5,009	2,505

* States will be required to submit a 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.

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 will be submitted to OMB for their approval 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 FFY 2024. As referenced in section II.A. of this final rule, mandatory reporting of the Child Core Set will be required for all 50 States, DC, Puerto Rico, Guam, and the Virgin Islands. The data collection, as explained in section II.C. of this final rule, will 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.[63] 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.[64] 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: 154 hours at $98.84/hr for a computer programmer to re-program and synthesize the data; 20 hours at $101.46/hr for a statistician to conduct data sampling; 115 hours at $118.14/hr for a general operations manager to analyze the data; 216.5 hours at $37.94/hr for a data entry worker to input the data; and 11.75 hours at $236.96/hr for a chief executive to verify, certify, and approve a State data submission to CMS.[65] We estimate an annual burden of 7,242 hours (517.25 hr × 14 responses) at a cost of $585,689 (14 responses × ([154 hr × $98.84/hr] + [20 hr × $101.46/hr] + [115 hr × $118.14/hr] + [216.5 hr × $37.94/hr] + [11.75 hr × $236.96/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 $118.14/hr for a general operations manager to draft a vendor contract and 2 hours at $236.96/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 $16,559 (14 responses × ([6 hr × $118.14/hr] + [2 hr × $236.96/hr])).

In aggregate, for States with Medicaid expansion CHIP only, we estimate an annual State burden of 7,354 hours (7,242 hr + 112 hr) at a cost of $602,248 ($585,689 + $16,559). Taking into account the Federal contribution to Medicaid and CHIP program administration, the estimated State share of this cost is approximately $301,124 ($602,248 × 0.50).

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: 264.5 hours at $98.84/hr for a computer programmer to collect and synthesize the data; 40 hours at $101.46/hr for a statistician to conduct data sampling; 186.5 hours at $118.14/hr for a general operations manager to analyze the data; 427.75 hours at $37.94/hr for a data entry worker to input the data; and 18 hours at $236.96/hr for a chief executive to verify, certify, and approve a State data submission to CMS. We estimate an annual burden of 37,480 hours (937 hr × 40 responses) at a cost of $2,909,152 (40 responses × ([264.5 hr × $98.84/hr] + [40 hr × $101.46/hr] + [186.5 hr × $118.14/hr] + [427.75 hr × $37.94/hr] + [18 × $236.96/hr])).

Additionally, we expect the new reporting mandate would require vendor contract modifications. We expect the contract modifications to take 6 hours at $118.14/hr for a general operations manager to draft a vendor contract and 2 hours at $236.96/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 $47,310 (40 responses × ([6 hr × $118.14/hr] + [2 hr × $236.96/hr])).

In aggregate, for States with separate CHIPs and States with both Medicaid Expansion and separate CHIPs, we estimate an annual State burden of 37,800 hours (37,480 hr + 320 hr) at a cost of $2,956,462 ($2,909,152 + $47,310). Taking into account the Federal contribution to Medicaid and CHIP program administration, the estimated State share of this cost is approximately $1,478,231 ($2,956,462 × 0.50).

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 $21.98/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 will 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 × 1 survey/yr) at a cost of $2,989 (136 hr × $21.98/hr).[66] In aggregate, for States with Medicaid expansion CHIP only, we estimate an annual beneficiary burden of 1,904 hours (136 hr × 14 States) at a cost of $41,846 ($2,989 × 14 States). We estimate a total of 5,754 beneficiary

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[63] *https://www.medicaid.gov/chip/downloads/chip-map.pdf.*

[64] The Agency for Healthcare Research and Quality is the measure steward for the CAHPS survey (CAHPS health plan database OMB Control No.: 0935–0165).

[65] 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.*

[66] Per CAHPS Health Plan Survey 5.1H Guidelines: The sample needs to be large enough to achieve a goal of 411 completed surveys per reporting unit (for example, health plan or State).

responses (14 States × 411 beneficiary responses).

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 × 411 beneficiary responses/State × 2 surveys/yr) at a cost of $5,957 (271 hr × $21.98/hr).[67] In aggregate, for States with combination CHIP programs or separate CHIP program only, we estimate an annual beneficiary burden of 10,840 hours (271 hr × 40 States) at a cost of $238,280 ($5,957 × 40 States). We estimate a total of 32,880 beneficiary responses (40 States × 411 beneficiary responses × 2 surveys/year).

For States to administer the survey, we estimate an ongoing aggregate beneficiary burden of 12,744 hours (1,904 + 10,840 hr) at a cost of $280,126 ($41,846 + $238,280).

TABLE 4—CHILD CORE SET REQUIREMENTS AND BURDEN UNDER OMB CONTROL NUMBER 0938–1188
(CMS–10434 #26, Child Core Set and the Adult Core Set)

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.15—Medicaid Expansion CHIP Programs	14	14	525.25	7,354	Varies	602,248	301,124
§ 437.15—States with combination CHIP programs or separate CHIP programs only.	40	40	945	37,800	Varies	2,956,462	1,478,231
Subtotal: States	54	54	Varies	45,154	Varies	3,558,710	1,779,355
§ 437.15—CAHPS survey: Medicaid Expansion CHIP Programs.	5,754	5,754	0.33	1,904	21.98	41,846	NA
§ 437.15—CAHPS survey: States with combination CHIP programs or separate CHIP programs only.	32,880	32,880	0.33	10,840	21.98	238,280	NA
Subtotal: CAHPS Survey beneficiary	38,634	38,634	Varies	12,744	21.98	280,126	NA
Total	38,688	38,688	Varies	57,898	Varies	3,838,836	1,779,355

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

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

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 FFY 2024. As referenced in section II.A. of this final rule, mandatory reporting of the Adult Core Set will be required for all 50 States, DC, Puerto Rico, Guam, and the Virgin Islands. The data collection, as explained in section II.C. of this final rule, is 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: 115 hours at $98.84/hr for a computer programmer to re-program and synthesize the data; 20 hours at $101.46/hr for a statistician to conduct data sampling; 76 hours at $118.14/hr for a general operations manager to analyze the data; 212 hours at $37.94/hr for a data entry worker to input the data; and 6.5 hours at $236.96/hr for a chief executive to verify, certify, and approve a State data submission to CMS.[68] We estimate an annual burden of 23,193 hours (429.5 hr/response × 54 responses) at a cost of $1,725,730 (54 responses × ([115 hr × $98.84/hr] + [20 hr × $101.46/hr] + [76 hr × $118.14/hr] + [212 hr × $37.94/hr] + [6.5 × $236.96/hr])).

Additionally, we expect the new reporting mandate would require vendor contract modifications. We expect the contract modifications to take 6 hours at $118.14/hr for a general operations manager to draft a vendor contract and 2 hours at $236.96/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 $63,869 (54 responses × ([6 hr × $118.14/hr) + [2 hr × $236.96/hr])).

In aggregate, we estimate an annual State burden of 23,625 hours (23,193 hr + 432 hr) at a cost of $1,789,599 ($1,725,730 + $63,869). Taking into account the Federal contribution to Medicaid and CHIP program administration, the estimated State share of this cost is approximately $894,800 ($1,789,599 × 0.50).

The CAHPS measure is the only mandatory measure on the Adult Core Set which would include a burden on beneficiaries.[69] We estimate it would take 20 minutes (0.33 hr) at $21.98/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 $2,989 (136 hr × $21.98/hr).[70] For States to administer the survey, in aggregate, we estimate an annual beneficiary burden of 7,344 hours (136 hr/State × 54 States) at a cost of $161,406 ($2,989 per State × 54 States). We estimate a total of 22,194 beneficiary

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[67] Per CAHPS Health Plan Survey 5.1H Guidelines: The sample needs to be large enough to achieve a goal of 411 completed surveys per reporting unit (for example, health plan or State).

[68] *https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/adult-health-care-quality-measures/index.html.*

[69] The Agency for Healthcare Research and Quality is the measure steward for the CAHPS survey (CAHPS health plan database OMB Control No.: 0935–0165).

[70] Per CAHPS Health Plan Survey 5.1H Guidelines: The sample needs to be large enough to achieve a goal of 411 completed surveys per reporting unit (for example, health plan or State).

responses (54 States × 411 beneficiary responses).

TABLE 5—ADULT CORE SET REQUIREMENTS AND BURDEN UNDER OMB CONTROL NUMBER 0938–1188
[CMS–10434 #26, Child Core Set and the Adult Core Set]

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.15—(Adult Core Set) States	54 States	54	437.5	23,625	Varies	1,789,599	894,800
§ 437.15—CAHPS Survey (Beneficiaries)	22,194	22,194	0.33	7,344	21.98	161,406	NA
Total	22,248	22,248	Varies	30,969	Varies	1,951,005	894,800

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

The following changes will be submitted to OMB for their approval 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 as the burden estimate for the 1945 and 1945A health home programs is already included in control number 0938–1188 (CMS–10434 # 22). Including the provider burden in this estimate would be duplicative.

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 we rely 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 will 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 final 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. of this final rule, will be required to include: reporting on all mandatory measures following the reporting guidance provided by CMS; all beneficiaries served in each State's relevant health home program; 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 $98.84/hr for a computer programmer to collect and synthesize the data; 52 hours at $118.14/hr for a general operations manager to analyze the data; 6.5 hours at $37.94/hr for a data entry worker to input the data; and 6.5 hours at $236.96/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 $522,792 (40 responses × ([52 hr × $98.84/hr] + [52 hr × $118.14/hr] + [6.5 hr × $37.94/hr] + [6.5 × $236.96/hr])).

Additionally, we expect the new reporting mandate would require vendor contract modifications. We expect the contract modifications to take 6 hours at $118.14/hr for a general operations manager to draft a vendor contract and 2 hours at $236.96/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 $47,310 (40 responses × ([6 hr × $118.14/hr) + [2 hr × $236.96/hr])).

In aggregate, for States with a 1945 health home program, we estimate an annual burden of 5,000 hours (4,680 hr + 320 hr) at a cost of $570,103 ($522,792 + $47,310). Taking into account the Federal contribution to Medicaid program administration, the estimated State share of this cost is approximately $285,052 ($570,103 × 0.50).

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.

TABLE 6—1945 ADULT CORE SET REQUIREMENTS AND BURDEN UNDER OMB CONTROL NUMBER 0938–1188
[CMS–10434 #47, Health Home Core Sets]

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.15—(1945 Health Home Core Set)	40	40	125	5,000	Varies	570,103	285,052

Section 1945A Authority: We anticipate that the section 1945A Health Home Core Set for section 1945A programs would consist of approximately 7 measures. For each respondent with this program, we estimate it would take: 28 hours at $98.84/hr for a computer programmer to collect and synthesize the data; 28 hours at $118.14/hr for a general operations manager to analyze the data; 3 hours at $37.94/hr for a data entry worker to input the data; and 3 hours at $236.96/hr for a chief executive to verify, certify, and approve a State data submission to us. We estimate an annual State burden of 620 hours (62 hr/response × 10 responses) at a cost of $69,001 (10 responses × ([28 hr × $98.84/hr] + [28 hr × $118.14/hr] + [3 hr × $37.94/hr] + [3 × $236.96/hr])).

Additionally, we expect the new reporting mandate would require vendor contract modifications. We expect the contract modifications to take 6 hours at $118.14/hr for a general operations manager to draft a vendor contract and 2 hours at $236.96/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 $11,828 (10 responses × ([6 hr × $118.14/hr) + [2 hr × $236.96/hr])).

In aggregate, for States with a 1945A health home program, we estimate an annual State burden of 700 hours (620 hr + 80 hr) at a cost of $80,829 ($69,001 + $11,828). Taking into account the Federal contribution to Medicaid program administration, the estimated State share of this cost is approximately $40,415 ($80,829 × 0.50).

Note that we anticipate 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.

TABLE 7—1945A ADULT CORE SET REQUIREMENTS AND BURDEN UNDER OMB CONTROL NUMBER 0938–1188

[CMS–10434 #47, Health Home Core Sets]

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.15—(1945A Health Home Core Set)	10	10	70	700	Varies	80,829	40,415

5. ICRs Regarding Optional Request for Exemption From Mandatory Child and Adult Core Sets Reporting for Specific Populations (Child and Adult Core Sets (Part 437, Subpart A))

With the changes outlined in this final rule, the 50 States, DC, Puerto Rico, Guam, and the Virgin Islands that will be subject to the Child and Adult Core Sets reporting requirements will have an opportunity each year to request a 1-year exemption from reporting data for one or more mandatory populations for the Child and Adult Core Sets if the State demonstrates an inability to obtain access to data required to report on the Child and Adult Core Sets in accordance with the requirements in §§ 437.10(b)(5), 437.15(a)(4)(ii), and (6). We have added this option to address concerns about the feasibility of Child and Adult Core Sets reporting for specific populations. A State that needs an exemption must request the exemption from CMS by September 1st of the applicable reporting year, the exemption would be only for that year's reporting, and it would apply only to the specific population for which the State receives an exemption for reporting that population in one or more measures. The State would be required to define the specific population for which exemption from reporting is sought and to which measure(s) the request applies. The State will be required to explain why this exemption is necessary (that is, why the State agency was not able to obtain access to the data required to report on the relevant population) and what actions are underway to resolve the data access problems. In addition, the State must demonstrate to us that it has made a reasonable effort to obtain the required data by the reporting deadline. As discussed previously in this final rule, we will solicit public comment via 60-day and 30-day Paperwork Reduction Act notices that we will issue in the **Federal Register** separate from this rulemaking document before this voluntary requirement takes effect September 1, 2024.

The process to request an exemption from reporting one or more mandatory populations for the Child and Adult Core Sets will require the state to submit an exemption request to us. We estimate it would take a business operations specialist 1 hour at $80.08/hr to determine which populations the state is unable to report, a general operation manager 2 hours at $118.14/hr to draft an exemption request and 1 hour at $236.96/hr for a chief executive to review, approve, and submit the exemption request. We estimate an annual burden of 216 hours (54 States and territories × 4 hr/response) at a cost of $29,879 (54 States and territories × ([1 hr/response × $80.08/hr] + [2 hr/response × $118.14/hr]) + [1 hr/response × $236.96/hr])). Taking into account the Federal contribution to Medicaid and CHIP program administration, the estimated State share of this cost is approximately $14,940 ($29,879 × 0.50).

TABLE 8—REQUEST FOR EXEMPTION FROM REPORTING SPECIFIC POPULATIONS

[Child/Adult Core Sets only]

Regulatory section(s) under Title 42 of the CFR	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)	Adjusted cost ($) (50% FMAP or FFP)
§ 437.15(a)(6)—Annual Exemption Request*	54	54	4	216 hrs	Varies	29,879	14,940

*States will have the option to submit a request for exemption from reporting one or more mandatory populations. Exemption requests only apply to Child and Adult Core Sets reporting.

C. Summary of Annual Requirements and Annual Burden Estimates

As stated in section II. of this final rule, we received 93 public comments on the proposed rule, but only one of those comments was related to the rule's collection of information requirements.

Comment: One commenter noted that in their experience with the Child and Adult Core Sets, the time to convert the reporting guidance into analytic code is underestimated in the COI (by 3–4 times) and the time to input the data is an overestimate.

Response: As the COI estimate reflects the average costs for all States that are required to comply with mandatory Core Set reporting requirements, it is expected that there will be variation in time estimates experienced by individual States. Upon additional review, we have revised the COI estimate for the Child and Adult Core Sets to reflect the issue raised by this public comment and added additional time to program, synthesize, analyze, and review the data. We are working with States to develop strategies to reduce the burden of implementing reporting guidance and for FFY 2021 reporting introduced a new reporting system to help reduce the burden of Core Set reporting. We will continue to work with States to identify best practices and strategies to further reduce this burden and incorporate this information into reporting guidance and technical assistance materials.

Table 9 sets out our annual burden estimates.

TABLE 9—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	Varies	10,019	5,009
§ 437.15—Medicaid Expansion CHIP Programs	14	14	525.25	7,354	Varies	602,248	301,124
§ 437.15—CAHPS survey: Medicaid Expansion CHIP Programs.	5,754	5,754	0.33	1,904	21.98	41,846	NA
§ 437.15—States with combination CHIP programs or separate CHIP programs only.	40	40	945	37,800	Varies	2,956,462	1,478,231
§ 437.15—CAHPS survey: States with combination CHIP programs or separate CHIP programs only.	32,880	32,880	0.33	10,840	21.98	238,280	NA
§ 437.15—(Adult Core Set)	54	54	437.5	23,625	Varies	1,789,599	894,800
§ 437.15—CAHPS: (Adult Core Set)	22,194	22,194	0.33	7,344	21.98	161,406	NA
Subtotal (#26)		60,990	Varies	88,975	Varies	5,799,860	2,679,164
CMS–10434 #22							
§ 437.20—One-time SPA Submission *	54	54	1	54	Varies	5,009	2,505
Subtotal (#22)	54	54	1	54	Varies	5,009	2,505
CMS–10434 #47							
§ 437.15—(1945 Health Home Core Set)	40	40	125	5,000	Varies	570,103	285,052
§ 437.15—(1945A Health Home Core Set)	10	10	70	700	Varies	80,829	40,415
Subtotal (#47)	50	50	Varies	5,700	Varies	650,932	325,467
CMS–10867							
§ 437.15(a)(6)—Annual Exemption Request *	54	54	4	216	Varies	29,879	14,940
Total	Varies	61,148	Varies	94,945	Varies	6,485,680	3,022,076

* States will be required to submit a 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.

IV. 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), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), 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). Section 3(f) of Executive Order 12866 as amended by Executive Order 14094 defines a ‘‘significant regulatory action’’ as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President’s priorities, or the principles set forth in the Executive Order. OIRA has determined that this final rule is significant, and it was accordingly reviewed by OMB.

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 final 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 final 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 604 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 final rule 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 2023, that threshold is approximately $177 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 August 23, 2023.

List of Subjects

42 CFR Part 433

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 amends 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—

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).

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, treatment, and recovery 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.

§ 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 Child, Adult, and Health Home Core Sets; and update the Child and Adult Core Sets beginning no later than January 1, 2024 and annually no later than January 1 thereafter.

(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; and are feasible for State-level and/or Health Home program level reporting, as appropriate.

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

(4) Not later than September 30, 2025 and annually by September 30 thereafter, collect, analyze, and make publicly available the information reported by States on the Child and Adult Core Sets as described in § 437.15.

(5) Annually, collect, analyze, and make publicly available the information reported by States on the Health Home Core Sets as described in § 437.15.

(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 frequency of reporting for survey-based measures, which will be no more frequent than annually.

(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 may, but are not required to, report the Child and Adult Core Set measures identified by the Secretary under paragraph (b)(1) of this section for a specific year in accordance with paragraph (c) of this section.

(i) Additionally, CMS will include guidance to States on how to request a 1-year exemption from reporting one or more Child and/or Adult Core Set measures for specific populations in accordance with § 437.15(a)(4)(ii) and (6) of this part.

(ii) [Reserved]

(6) Attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population, during the reporting period.

(7) The subset of measures within 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 Child and Adult Core Sets reporting for certain populations of beneficiaries described in paragraph (b)(5) of this section will be voluntary for a specific year, considering the level of difficulty in accessing the data required for such Child and Adult Core Sets State reporting.

(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 consider 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 Home 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.

(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 paragraphs (a)(2) and (a)(4) of this section, the agency—

(i) Must report by December 31, 2024, on all measures on the 2024 Child Core Set and the behavioral health measures in the Adult Core Set;

(ii) In subsequent years, 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);

(iii) 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), 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

(iv) May report on all other measures in the Adult Core Set 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 Child and Adult Core Set measures, the agency is required to report on all Medicaid and CHIP beneficiaries, including those enrolled in fee-for-service and managed care, unless—

(i) The Secretary specifies in annual guidance that the population is not required to be reported in accordance with § 437.10(b)(5); or

(ii) The Secretary grants the agency an exemption from reporting one or more Child and Adult Core Set measures for a specific population in accordance with paragraph (a)(6) of this section.

(5) In reporting on all 1945 and 1945A Health Home Core Sets measures, the agency is required to report on all beneficiaries enrolled in an approved health home program.

(6)(i) The agency may request a 1-year exemption from reporting for a specific population defined by the State for one or more Child and/or Adult Core Set measures if the agency demonstrates that it:

(A) Is unable to obtain access to data required to report the relevant Child and Adult Core Set measure or measures for that population despite making reasonable efforts to do so; and

(B) Has a reasonable timeline of actions underway to resolve data access problems.

(ii) The agency must submit a request for an exemption by September 1st of the applicable reporting year.

(iii) If the Secretary determines that the agency satisfies the conditions set forth in paragraph (6)(i) of this section, the Secretary will approve the exemption only for that year's Child and/or Adult Core Set reporting and the exemption will apply only for the specific population for which the State requests an exemption. If the Secretary determines that the agency does not satisfy the conditions set forth in paragraph (a)(6)(i) of this section, the Secretary will communicate a denial of the exemption request to the agency, and the agency will be expected to include the relevant population in that year's Child and Adult Core Sets reporting.

(iv) The agency may request an exemption to reporting Child and Adult Core Set measures for the same population in accordance with this paragraph in more than one reporting year.

(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) The Medicaid beneficiaries (including those for whom the State claims Federal financial participation under both Title XIX and Title XXI) in the age range to which the measure applies, as per reporting guidance described in paragraph § 437.10(b)(2); and

(ii) The beneficiaries in the State's separate CHIP in the age range to which the measure applies, 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 of this subpart.

(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 all populations served by the health home providers and 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) by removing the period at the end of the paragraph and replacing it with "; and"; and

■ c. Adding 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 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 for individuals enrolled in a separate CHIP separately from individuals enrolled in Medicaid in accordance with § 437.15(b) of this chapter, regardless of whether the State claims Federal financial participation for such Medicaid-enrolled individuals under title XIX or title XXI of the Act.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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