

Child and Adult Core Set Annual Review Workgroup: Measures Suggested for Removal from the 2025 Core Sets

Measure Information Sheets April 2023



Table of Contents

Care of Acute and Chronic Conditions

Use of Opioids at High Dosage in Persons Without Cancer (OHD-AD)	2
Concurrent Use of Opioids and Benzodiazepines (COB-AD)	9
Behavioral Health Care	
Screening for Depression and Follow-Up Plan: Ages 12 to 17 (CDF-CH) and Age 18 and Older (CDF-AD)	6
Dental and Oral Health Services	
Topical Fluoride for Children (TFL-CH)	2
Experience of Care	
Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Health Plan Survey 5.1H, Child Version Including Medicaid and Children with Chronic Conditions Supplemental Items (CPC-CH) and Adult Version (CPA-AD)	27



Care of Acute and Chronic Conditions



CHILD AND ADULT CORE SET REVIEW WORKGROUP: MEASURES SUGGESTED FOR REMOVAL FROM THE 2025 CORE SET

Measure Information	
Measure name	Use of Opioids at High Dosage in Persons Without Cancer (OHD-AD)
Description	The percentage of beneficiaries age 18 and older who received prescriptions for opioids with an average daily dosage greater than or equal to 90 morphine milligram equivalents (MME) over a period of 90 days or more. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice or palliative care are excluded.
Measure steward	Pharmacy Quality Alliance (PQA)
NQF number (if endorsed)	2940
Core Set	Adult Core Set
Core Set domain	Care of Acute and Chronic Conditions (Note that CMS moved the OHD-AD measure from the Behavioral Health Care domain to the Care of Acute and Chronic Conditions domain for the 2023 and 2024 Core Set Updates.)
Meaningful Measures area	Chronic Conditions
Measure type	Process
If measure is removed, does it leave a gap in the Core Set?	Three Workgroup members (WGMs) suggested this measure for removal and none indicated that removing it would leave a gap in the Core Set.
	Response 1: One WGM indicated that the risk of opioid use is an important topic but does not feel that this measure fully addresses this issue.
	Responses 2 and 3: Two WGMs stated that the existing <i>Use of Pharmacotherapy for Opioid Use Disorder</i> (OUD-AD) measure addresses treatment for opioid use disorder in the Adult Core Set.
Has another measure been proposed for substitution (new or existing measure)?	None of the WGMs who suggested the measure for removal suggested a replacement. One WGM stated that reporting on opioid prescribing is a requirement under the Drug Utilization Review (DUR) Board requirements. 1,2,3
Is there another related measure in the Core Set?	Use of Pharmacotherapy for Opioid Use Disorder (OUD-AD)
Use in other CMS programs	The measure is included in CMS's Medicare Part D quality program and is publicly reported as a Display Measure. ⁴



FFY 2023 Technical	Specifications
Ages	Age 18 and older as of January 1 of the measurement year.
Data collection method	Administrative.
Denominator	 Beneficiaries who meet all of the following criteria: Two or more prescription claims for opioids medications on different dates of service and with a cumulative days' supply of 15 or more days during the measurement year. An Index Prescription Start Date (IPSD) on January 1 through October 3 of the measurement year. An opioid episode of 90 or more days during the measurement year. Exclude days' supply that occur after the end of the measurement year. The prescription can be for the same or different opioids. If multiple prescriptions for opioids are dispensed on the same day,
Numerator	 calculate the number of days covered by an opioid using the prescriptions with the longest days' supply. If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply. Any beneficiary in the denominator with an average daily dosage ≥ 90
	morphine milligram equivalent (MME) during the opioid episode.
Exclusions	 Exclude beneficiaries who met at least one of the following during the measurement year: Hospice. Cancer Diagnosis. Sickle Cell Disease Diagnosis. Palliative Care. The exclusion criteria are for beneficiaries with a diagnosis code for cancer or sickle cell disease during the measurement year. Their initial diagnosis may have occurred previously; however, the diagnosis code for cancer or sickle cell disease must be present during the
	measurement year for the beneficiary to be excluded.
Continuous enrollment period	The measurement year with one allowable gap, as defined below.
Allowable gap	No more than one gap in continuous enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the beneficiary may not have more than a 1-month gap in coverage (i.e., a beneficiary whose coverage lapses for 2 months [60 consecutive days] is not considered continuously enrolled).



Reasons for Removal Noted by Workgroup Member(s)

Minimum Technical Feasibility Criteria

None identified by the WGMs.

Actionability and Strategic Priority

One WGM pointed out that states struggle with how to interpret the results of this measure and often question at what level the measure is actionable.

Another WGM noted that policy and practice changes following the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain have reduced opioid prescriptions. The WGM stated that the opioid epidemic is no longer driven by prescription opioids, but by heroin, illicitly manufactured fentanyl, and other drugs, and the AMA and others are calling for a shift in focus. The WGM suggested that some of the actions providers may take to improve performance on the OHD-AD measure may put patients at significant risk of harm or death.

The WGM also noted that research examining adverse outcomes of opioid discontinuation have accumulated, and that the CDC and FDA have acknowledged the risks of opioid tapering. The WGM stated that it is rare for opioid-naïve patients to be started on high-dose opioids; OHD-AD targets chronic users, and the measure may motivate providers to (1) refuse to accept new patients on high-dose opioids, (2) discontinue or taper opioids too rapidly or with inadequate collaboration from patients, or (3) dismiss patients from their practice.

The WGM cited a 2021 study that found "among patients prescribed stable, long-term, higher-dose opioid therapy, tapering events were significantly associated with increased risk of overdose and mental health crisis." After opioid tapering, patients had 9.3 overdose or withdrawal events per 100 person-years and 7.6 mental health crisis events per 100 person-years (compared to 3.8 and 4.3, respectively in patients who did not undergo opioid tapering). The WGM commented that the OHD-AD measure may exacerbate health disparities by gender and among people with mental health conditions, including an increased risk of suicide associated with opioid taper or discontinuation.

Other Considerations

One WGM suggested this measure for removal from the Adult Core Set to support implementation of CDC's 2022 Clinical Practice Guideline for Prescribing Opioids for Pain, and to allow for maximum flexibility and care for the treatment of patients living with pain. The WGM noted that a standardized population-level measure on prescription opioid dosages may not adequately capture the individualized nuance that evidence-based pain care necessitates. The WGM added that CDC is developing new clinician education and communication materials that will be released throughout 2023, and they are also engaging with professional organizations to support implementation and develop tailored materials.

Core Set Reporting History	
Year added to Core Set	2016
Number of states reporting the measure for FFY 2020	33 states (5 states reported calculating the measure using other specifications, specifically the HEDIS specifications for <i>Use of Opioids at High Dosage</i>)
Was the measure publicly reported for FFY 2020?	Yes (see the following pages for FFY 2020 data)



Is the measure on the Medicaid & CHIP Scorecard?	Yes
Challenges noted by states in reporting the measure for FFY 2020	Data not available (12 states) due primarily to information not collected (7 states). States also noted that the measure is not within the state's strategic quality measures initiative.
Summary of prior Workgroup discussions	This measure was discussed at the 2021 and 2023 Core Set Annual Review meetings, but was not recommended for removal from the Adult Core Set. Note that at the time of the 2021 and 2023 Annual Review meetings, the measure was included in and discussed as part of the Behavioral Health Care domain. CMS moved this measure to the Care of Acute and Chronic Conditions domain for the 2023/2024 Adult Core Sets.
	At the 2021 Core Set Annual Review Meeting, a WGM suggested this measure for removal because it measures how chronic pain is treated and does not reflect performance of the behavioral health care system. During the discussion, other WGMs agreed that, while the measure is not strictly a behavioral health measure, it emphasizes the importance of measuring opioid prescribing and misuse in responding to the opioid epidemic. One WGM indicated that over-prescribing is associated with a number of adverse medical outcomes beyond addiction. Another noted that this is the only measure in the Core Set that makes prescribers and pharmacies accountable for overprescribing, over dispensing, and overuse of opioids.
	At the 2023 Core Set Annual Review Meeting, a WGM suggested this measure for removal because the measure may not be leading to improvements in quality of care and outcomes, and because the opioid epidemic is no longer driven by prescription opioids. During the discussion, a WGM commented that a third of the measures in the Adult Core Set fall under the Behavioral Health Care domain, with four measures focused on opioids, and suggested prioritizing measures that are actionable. However, other WGMs were hesitant to remove the measure because of rising rates of opioid overdoses and deaths during the COVID-19 pandemic.
	Several WGMs noted that OHD-AD measures appropriateness of pain management and integration between pharmacies and providers, rather than opioid abuse. Another WGM commented that although there may be some instances of physicians unnecessarily tapering patients' medications to improve performance on the measure, far more patients will be protected from high-risk doses.
	WGMs suggested that the Workgroup discuss the measure again during the 2025 Annual Review for two reasons. One WGM cited recent changes with CDC's new 2022 Clinical Practice Guideline for Prescribing Opioids for Pain and the shift of the opioid overdose epidemic from prescription opioids to illicit opioids. Another WGM suggested revisiting the measure with a focus on the monitoring that



	occurs under the DUR requirements, which are focused on appropriate prescribing.
Other	The measure steward is considering this measure for retirement for 2025 following the CDC's decision to discontinue updates to the Opioid NDC and Oral MME Conversation File, ⁸ as this source file is necessary to calculate the measure.
	Regarding stratification, the measure steward indicated that they include several variables in their standard measure testing process such as age, sex, and others. Additionally, as part of PQA's commitment to advancing health equity through quality measurement, they are launching a Health Equity Technical Expert Panel to systematically assess a set of variables feasible and appropriate for stratification in PQA measures.

Citations

¹ https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-456/subpart-K.

² https://www.medicaid.gov/federal-policy-guidance/downloads/cib080519-1004.pdf.

³ https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html.

⁴ https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.

⁵ Dowell, Deborah, et al. 2019. No Shortcuts to Safer Opioid Prescribing. *New England Journal of Medicine*, vol. 380, no. 24, 2285–2287. https://doi.org/10.1056/nejmp1904190.

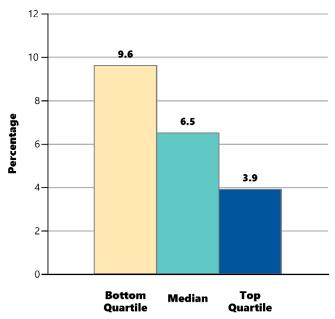
⁶ https://pubmed.ncbi.nlm.nih.gov/34342618/.

⁷ https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm.

⁸ https://www.cdc.gov/opioids/data-resources/index.html.



Percentage of Adults* Without Cancer who Received Prescriptions for Opioids with an Average Daily Dosage Greater than or Equal to 90 Morphine Milligram Equivalents for a Period of 90 Days or More (OHD-AD), FFY 2020 (n = 28 states) [Lower rates are better for this measure]



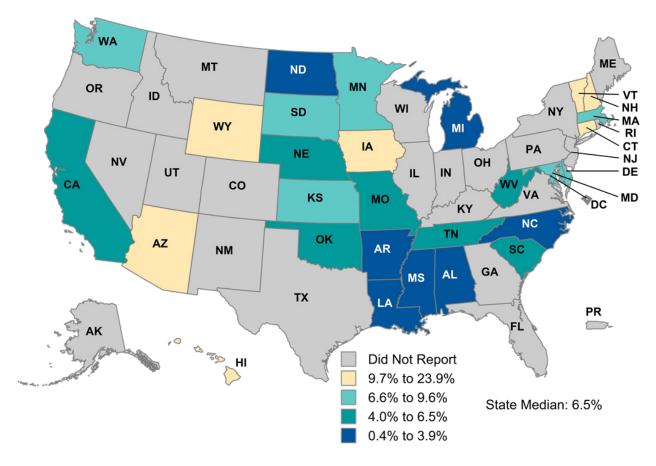
Source: 2021 Adult Core Set Chart Pack, FFY 2020 available at: https://www.medicaid.gov/medicaid/quality-of-care/downloads/performance-measurement/2021-adult-chart-pack.pdf.

Notes: This measure shows the percentage of adults age 18 and older who received prescriptions for opioids with an average daily dosage greater than or equal to 90 morphine milligram equivalents over a period of 90 days or more during the measurement year. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice are excluded. This chart excludes New Jersey, New York, Ohio, Pennsylvania, and Texas, which calculated the measure but did not use Adult Core Set specifications.

* Data displayed in this chart include adults ages 18 to 64 for 26 states and age 18 and older for 2 states.



Geographic Variation in the Percentage of Adults* Without Cancer who Received Prescriptions for Opioids with an Average Daily Dosage Greater than or Equal to 90 Morphine Milligram Equivalents for a Period of 90 Days or More (OHD-AD), FFY 2020 (n = 28 states) [Lower rates are better for this measure]



Source: 2021 Adult Core Set Chart Pack, FFY 2020 available at: https://www.medicaid.gov/medicaid/quality-of-care/downloads/performance-measurement/2021-adult-chart-pack.pdf.

Notes: This chart excludes New Jersey, New York, Ohio, Pennsylvania, and Texas, which calculated the measure but did not use Adult Core Set specifications.

^{*} Data displayed in this chart include adults ages 18 to 64 for 26 states and age 18 and older for 2 states.



CHILD AND ADULT CORE SET REVIEW WORKGROUP: MEASURES SUGGESTED FOR REMOVAL FROM THE 2025 CORE SET

Measure Information	
Measure name	Concurrent Use of Opioids and Benzodiazepines (COB-AD)
Description	Percentage of beneficiaries age 18 and older with concurrent use of prescription opioids and benzodiazepines. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice or palliative care are excluded.
Measure steward	Pharmacy Quality Alliance (PQA)
NQF number (if endorsed)	3389
Core Set	Adult Core Set
Core Set domain	Care of Acute and Chronic Conditions (Note that CMS moved the COB-AD measure from the Behavioral Health Care domain to the Care of Acute and Chronic Conditions domain for the 2023 and 2024 Core Set updates.)
Meaningful Measures area	Safety
Measure type	Process
If measure is removed, does it leave a gap in the Core Set?	No. The Workgroup Member (WGM) who suggested this measure for removal indicated that removing the measure would not leave a gap in the Core Set. The WGM noted that the <i>Use of Pharmacotherapy for Opioid Use Disorder</i> (OUD-AD) measure assesses treatment for opioid use disorder in the Adult Core Set.
Has another measure been proposed for substitution (new or existing measure)?	No. However, the WGM noted that reporting on opioid prescribing is a requirement under the Drug Utilization Review Board requirements. 1,2,3
Is there another related measure in the Core Set?	Use of Pharmacotherapy for Opioid Use Disorder (OUD-AD)
Use in other CMS programs	The measure is included in CMS's Medicare Part D quality program and is publicly reported as a Display Measure. ⁴



FFY 2023 Technical	Specifications
Ages	Age 18 and older as of January 1 of the measurement year.
Data collection method	Administrative.
Denominator	Beneficiaries with 2 or more prescription claims for opioid medications on different dates of service and with a cumulative days' supply of 15 or more days during the measurement year.
	Notes:
	• Exclude days' supply that occur after the end of the measurement year.
	• The prescription can be for the same or different opioids.
	• If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
	• If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.
Numerator	The number of beneficiaries from the denominator with:
	Two or more prescription claims for any benzodiazepine with different dates of service, AND
	• Concurrent use of opioids and benzodiazepines for 30 or more cumulative days.
Exclusions	Exclude beneficiaries who met at least one of the following during the measurement year:
	Hospice.
	Cancer Diagnosis.
	Sickle Cell Disease Diagnosis.
	Palliative Care.
	The exclusion criteria are for beneficiaries with a diagnosis code for cancer or sickle cell disease during the measurement year. Their initial diagnosis may have occurred previously; however, the diagnosis code for cancer or sickle cell disease must be present during the measurement year for the beneficiary to be excluded.
Continuous enrollment period	The measurement year with one allowable gap, as defined below.
Allowable gap	No more than one gap in continuous enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the beneficiary may not have more than a 1-month gap in coverage (i.e., a beneficiary whose coverage lapses for 2 months [60 consecutive days] is not considered continuously enrolled).



Reasons for Removal Noted by Workgroup Member(s)

Minimum Technical Feasibility Criteria

None identified by the WGM.

Actionability and Strategic Priority

The WGM expressed that a quality measure should incentivize actions that improve the quality of care and health of the patients involved. The WGM suggested that some of the actions providers may take to improve performance on the COB-AD measure may put patients at significant risk of harm or death. In targeting chronic users, the WGM indicated that the measure may motivate providers to (1) discontinue or taper one of these two medications too abruptly, (2) refuse to accept new patients on this combination, or (3) dismiss patients from their practice. The WGM argued that these actions can leave patients without necessary care and precipitate life-threatening withdrawal – life threatening with benzodiazepines but also opioids⁵ – leading patients to do desperate things like seek more dangerous street drugs to relieve intolerable withdrawal symptoms. The WGM explained that such misapplications of the CDC's Guideline for Prescribing Opioids for Chronic Pain in 2016 prompted its authors to advise against these practices that can risk patient health and safety. Thus, the WGM suggests removing COB-AD as it promotes clinical practices that can be potentially fatal for patients while doing little to address their complex needs.

Other Considerations

None identified by the WGM.

Core Set Reporting History	
Year added to Core Set	2018
Number of states reporting the measure for FFY 2020	28 states (all states reported calculating the measure using Core Set specifications)
Was the measure publicly reported for FFY 2020?	Yes (see the following pages for FFY 2020 data)
Is the measure on the Medicaid & CHIP Scorecard?	No
Challenges noted by states in reporting the	Data not available (14 states) due primarily to information not collected (10 states). States also noted:
measure for FFY 2020	The measure is not within state's strategic quality measures initiative
	The state does not require the MCOs to collect data for this measure
	Limited state resources
Summary of prior Workgroup discussions	This measure was discussed at the 2023 Core Set Annual Review Meeting and was not recommended for removal from the Adult Core Set. Note that at the time of the 2023 Annual Review Meeting, the measure was included in and discussed as part of the Behavioral Health



	Care domain. CMS moved this measure to the Care of Acute and Chronic Conditions domain for the 2023/2024 Adult Core Sets.
	A WGM suggested this measure for removal because of concerns around the actions providers may take to improve performance on the measure that may put patients at risk, such as discontinuing or tapering medications, hesitation to serve chronic opioid users, and possible negative patient outcomes.
	During the discussion, a WGM commented that a third of the measures in the Adult Core Set fall under the Behavioral Health Care domain, with four measures focused on opioids, and suggested prioritizing measures that are actionable. However, other WGMs expressed concern about removing the measure due to rising rates of opioid overdoses and deaths during the COVID-19 pandemic. Several WGMs noted that the measure is not intended to capture opioid abuse, but rather measure appropriate pain management and integration between pharmacies and providers.
	The WGM who suggested the measure for removal this year noted that in the conversation last time, the justification for keeping the measure was to focus on the need for appropriate prescribing for pain as opposed to opioid use disorder. However, the WGM suggested revisiting the measure with a focus on the monitoring that occurs under the Drug Utilization Review (DUR) requirements, which are also focused on appropriate prescribing.
Other	Regarding stratification, the measure steward indicated that they include several variables in their standard measure testing process such as age, sex, and other variables. Additionally, as part of PQA's commitment to advancing health equity through quality measurement, they are launching a Health Equity Technical Expert Panel to systematically assess a set of variables that are feasible and appropriate for stratification in PQA measures.

Citations

¹ https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-456/subpart-K.

² https://www.medicaid.gov/federal-policy-guidance/downloads/cib080519-1004.pdf.

³ <u>https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html.</u>

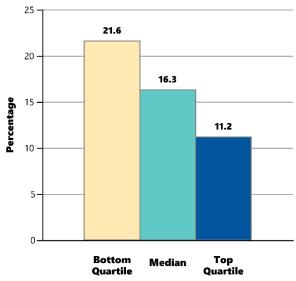
 $^{^{4}\ \}underline{\text{https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData}.$

⁵ James, J.R., Scott. et al. 2019. Mortality After Discontinuation of Primary Care–Based Chronic Opioid Therapy for Pain: a Retrospective Cohort Study. *Journal of General Internal Medicine*, vol. 34, 2749–2755.

⁶ Dowell, Deborah, et al. 2019. No Shortcuts to Safer Opioid Prescribing. *New England Journal of Medicine*, vol. 380, no. 24, 2285–2287. https://doi.org/10.1056/nejmp1904190.



Percentage of Adults* with Concurrent Use of Prescription Opioids and Benzodiazepines for 30 or More Cumulative Days (COB-AD), FFY 2020 (n = 27 states) [Lower rates are better for this measure]



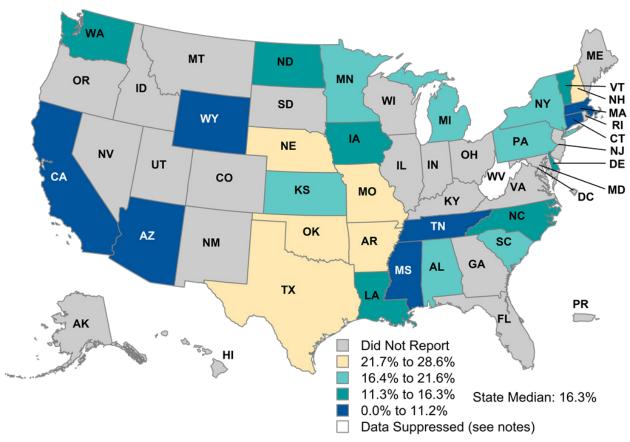
Source: 2021 Adult Core Set Chart Pack, FFY 2020 available at: https://www.medicaid.gov/medicaid/quality-of-care/downloads/performance-measurement/2021-adult-chart-pack.pdf.

Notes: This measure shows the percentage of adults age 18 and older with concurrent use of prescription opioids and benzodiazepines for 30 or more cumulative days during the measurement year. Adults with a cancer diagnosis, sickle cell disease diagnosis, or in hospice are excluded. Data were suppressed for West Virginia due to small cell

* Data displayed in this chart include adults ages 18 to 64 for 26 states and age 18 and older for 1 state.



Geographic Variation in the Percentage of Adults* with Concurrent Use of Prescription Opioids and Benzodiazepines for 30 or More Cumulative Days (COB-AD), FFY 2020 (n = 27 states) [Lower rates are better for this measure]



Source: 2021 Adult Core Set Chart Pack, FFY 2020 available at: https://www.medicaid.gov/medicaid/quality-of-care/downloads/performance-measurement/2021-adult-chart-pack.pdf.

Notes: Data were suppressed for West Virginia due to small cell sizes.

^{*} Data displayed in this chart include adults ages 18 to 64 for 26 states and age 18 and older for 1 state.



Behavioral Health Care



MEASURE INFORMATION SHEET

CHILD AND ADULT CORE SET REVIEW WORKGROUP: MEASURES SUGGESTED FOR REMOVAL FROM THE 2025 CORE SET

Measure Information	
Measure name	Screening for Depression and Follow-Up Plan: Ages 12 to 17 (CDF-CH) and Age 18 and Older (CDF-AD)
Description	CDF-CH: Percentage of beneficiaries ages 12 to 17 screened for depression on the date of the encounter or 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool, and if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter. CDF-AD: Percentage of beneficiaries age 18 and older screened for depression on the date of the encounter or 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool, and if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.
Measure steward	Centers for Medicare & Medicaid Services (CMS)
NQF number (if endorsed)	0418/0418e (no longer endorsed)
Core Set	Both Child and Adult Core Sets
Core Set domain	Behavioral Health Care (Note that CMS moved the CDF-CH and CDF-AD measures from the Primary Care Access and Preventive Care domain to the Behavioral Health Care domain for the 2023 and 2024 Core Set Updates.)
Meaningful Measures area	Behavioral Health
Measure type	Process
If measure is removed, does it leave a gap in the Core Set?	The Workgroup member (WGM) who suggested these measures for removal said that their removal could potentially leave a gap in the Core Sets.
Has another measure been proposed for substitution (new or existing measure)?	No. The WGM who suggested these measures for removal did not suggest a replacement.
Is there another related measure in the Core Set?	No
Use in other CMS programs	 Medicaid Health Home Core Set Merit-based Incentive Payment Systems (MIPS) End-Stage Renal Disease Quality Incentive Program Care Compare Medicare Shared Savings Program Core Quality Measures Collaborative (CQMC)



FFY 2023 Technical Specifications	
Ages	CDF-CH: Ages 12 to 17 on date of encounter.
	CDF-AD: Age 18 or older on date of encounter.
Data collection method	Administrative or electronic health records (EHR).
Denominator	The eligible population with an outpatient visit during the measurement year.
Numerator	Beneficiaries screened for depression on the date of the encounter or 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND, if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter using one of the following codes: G8431 or G8510.
Exclusions	 A beneficiary is not eligible if they have been diagnosed with depression or bipolar disorder. Exclude beneficiaries only if the beneficiaries do not meet the criteria for inclusion in the numerator for a documented reason for not screening for depression due to the following: Beneficiary Reason: Beneficiary refuses to participate. Medical Reason: Beneficiary is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the beneficiary's health status. Situations where the beneficiary's cognitive, functional, or motivational limitations may impact the accuracy of results.
Continuous enrollment period	None.
Allowable gap	Not applicable.

Reasons for Removal Noted by Workgroup Member(s)

Minimum Technical Feasibility Criteria

The WGM suggested these measures for removal because there are challenges in collecting the data and producing reliable results. They noted that some states are more advanced than others and if a state cannot easily access EHR data, their administrative rates make performance appear to be much worse than it actually is.

Actionability and Strategic Priority

None identified by the WGM.

Other Considerations

None identified by the WGM.



Core Set Reporting I	History
Year added to Core Set	2018 (Child Core Set) and 2013 (Initial Adult Core Set)
Number of states reporting the measure for FFY 2020	14 states reported the Child Core Set measure (2 of the 14 states indicated substantial deviations from Core Set specifications) and 15 states reported the Adult Core Set measure (3 of the 15 states indicated substantial deviations from Core Set specifications).
Was the measure publicly reported for FFY 2020?	No
Is the measure on the Medicaid & CHIP Scorecard?	No
Challenges noted by states in reporting the measure for FFY 2020	The primary challenge reported by 21 states is that the data source is not easily accessible, including because information was not collected. Some other reasons that states did not report this measure included: • State resource constraints
	MCOs do not collect or report this measure
	This measure requires data linkage that does not currently exist
	Complete and accurate reporting of this measure is not possible without medical record review
	Providers are not billing the procedure codes identified in the technical specifications that identify both screening for depression and follow-up plan
Summary of prior Workgroup discussions	The CDF-CH and CDF-AD measures were discussed at the 2021 and 2023 Core Set Annual Review meetings. They were recommended for removal at the 2023 meeting, but not at the 2021 meeting. Note that at the time of the 2021 and 2023 Annual Review Meetings, the measures were included in and discussed as part of the Primary Care Access and Preventive Care domain. CMS moved this measure to the Behavioral Health Care domain for the 2023/2024 Core Sets.
	During the 2021 Annual Review, WGMs raised concerns about the feasibility of collecting the data, as reflected by the low numbers of states reporting the measures. The WGMs acknowledged challenges using claims or encounter data to verify that the screening had been completed, a valid tool had been used, and a follow-up plan had been documented. Because of these limitations, states noted that rates using administrative data only are very low and need to be supplemented with medical record reviews. (However, the measures are not specified for the hybrid methodology using medical record reviews.) During the public comment period, several state representatives noted that providers are not billing the codes to reflect the services included in the measure, in part because there is no payment associated with the codes. Thus, obtaining an accurate assessment of screening and follow-up is not possible using the measures' administrative specifications. Despite these challenges, WGMs expressed hesitation about removing
	the CDF-CH and CDF-AD measures from the Core Sets, noting that depression is a highly prevalent condition for both adults and



adolescents, one that significantly impacts functioning. The Workgroup also discussed increasing efforts to integrate behavioral services, such as depression care, into primary care. In addition, WGMs noted that the COVID-19 pandemic has increased the need for mental health services, and screening for depression will be very important to track. Several WGMs shared that their states have incorporated the measures into state-level quality initiatives or value-based payment programs, which may incentivize providers' use of the depression screening encounter codes and improve the completeness of the administrative data used to calculate the measures.

During the 2021 meeting, the Workgroup voted against recommending removal of these measures from the Core Sets and suggested that CMS explore opportunities to leverage EHRs and Health Information Exchanges to support more accurate state reporting.

At the 2023 Core Set Annual Review Meeting, the Workgroup discussed removing the CDF-CH and CDF-AD measures in conjunction with the *Depression Screening and Follow-Up for Adolescents and Adults* measure, which had been suggested as a replacement. During the discussion, many WGMs were outspoken about inclusion of a depression screening measure in the Core Sets and said that it is critical that this gap not be left in the Core Sets if the CDF-CH and CDF-AD measures are removed.

The WGM who suggested the measures for removal said that, on the Child Core Set, the *Child and Adolescent Well-Care Visits* (WCV-CH) measure could fill the gap as it covers screening for psychosocial issues during well-child visits. Other WGMs countered this assertion, as the CDF-CH and CDF-AD measures go a step further by requiring use of a standardized screening tool, which is associated with higher-quality care.

Another WGM added that, unlike WCV-CH, the depression screening measures capture screenings that occur outside of a primary care encounter. Another Workgroup member commented that the CDF-CH and CDF-AD measures were added to the Core Sets in alignment with Medicare and Health Resources and Services Administration (HRSA) programs, and to be mindful of this when deciding whether to keep or remove the measures.

At the meeting, many WGMs did not express strong preferences for either of the depression screening measures under consideration. However, several Workgroup members noted that replacing CDF-CH and CDF-AD with *Depression Screening and Follow-Up for Adolescents and Adults* – which is a HEDIS® Electronic Clinical Data Systems (ECDS) measure – would provide an opportunity for states to shift toward electronic measures. (ECDS includes data from administrative claims, electronic health records, case management systems, and health information exchanges/clinical registries.) (Note that CDF-CH and CDF-AD also are specified as eCQMs.)

Ultimately, the Workgroup voted to recommend removing the CDF-CH and CDF-AD measures from the 2023 Core Sets and replacing them with the *Depression Screening and Follow-Up for Adolescents and*



	Adults measure. However, CMS decided to retain the CDF-CH and CDF-AD measures in the 2023/2024 Core Sets.
Other	CMS recently announced the goal of establishing a Universal Foundation of quality measures that will apply to as many CMS quality-rating and value-based care programs as possible. The CDF measures were included in the preliminary list of adult and pediatric Universal Foundation measures. CMS noted, however, that for Medicaid and CHIP, "any changes to measure sets will be made in partnership with states and other stakeholders."

Citations

¹ Jacobs, D. B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L. A. (2023). Aligning quality measures across CMS — the universal foundation. *N Engl J Med*, doi:10.1056/NEJMp2215539. Available at: https://www.nejm.org/doi/full/10.1056/NEJMp2215539.



Dental and Oral Health Services



MEASURE INFORMATION SHEET

CHILD AND ADULT CORE SET REVIEW WORKGROUP: MEASURES SUGGESTED FOR REMOVAL FROM THE 2025 CORE SET

Measure Information	Measure Information	
Measure name	Topical Fluoride for Children (TFL-CH)	
Description	Percentage of enrolled children ages 1 through 20 who received at least two topical fluoride applications as: (1) dental or oral health services, (2), dental services, and (3) oral health services within the measurement year	
Measure steward	American Dental Association (ADA) on behalf of the Dental Quality Alliance (DQA)	
NQF number (if endorsed)	2528 // 3700 // 3701	
Core Set	Child Core Set	
Core Set domain	Dental and Oral Health Services	
Meaningful Measures area	Wellness and Prevention	
Measure type	Process	
If measure is removed, does it leave a gap in the Core Set?	Yes. The Workgroup member (WGM) who suggested the measure for removal indicated that removing it would leave a gap in the Core Set. The WGM suggested the HEDIS <i>Topical Fluoride for Children</i> measure in its place.	
Has another measure been proposed for substitution (new or existing measure)?	Topical Fluoride for Children	
Is there another related measure in the Core Set?	No	
Use in other CMS programs	No other programs listed in CMS's Measure Inventory Tool or reported by the measure steward	



FFY 2023 Technical	Specifications
Ages	Ages 1 through 20 as of December 31 of the measurement year. Report eight age stratifications and a total rate: • Ages 1 to 2. • Ages 3 to 5. • Ages 6 to 7. • Ages 8 to 9. • Ages 10 to 11. • Ages 12 to 14. • Ages 15 to 18. • Ages 19 to 20. • Total ages 1 through 20.
Data collection method	Administrative.
Denominator	The eligible population, which includes children ages 1 through 20 as of December 31 of the measurement year.
Numerator	Numerator for Rate 1 (Dental or oral health services) The unduplicated number of enrolled children who received at least two fluoride applications as dental or oral health services during the measurement year, where there were at least two unique dates of service when topical fluoride was provided. Numerator for Rate 2 (Dental services) The unduplicated number of enrolled children who received at least two fluoride applications as dental services during the measurement year, where there were at least two unique dates of service when topical fluoride was provided. Numerator for Rate 3 (Oral health services) The unduplicated number of enrolled children who received at least two fluoride applications as oral health services during the measurement year, where there were at least two unique dates of service when topical fluoride was provided. Note that numerator 1 is not the sum of numerators 2 and 3. There could be instances where a child is eligible to be included in numerator 1 but not in numerator 2 or 3 (for example, if the child received two topical fluoride applications, one as a dental service and another as an oral health service). There could also be instances where a child is eligible to be included in both numerators 2 and 3 (for example, if the child received two topical fluoride applications as an oral health service and two topical fluoride applications as an oral health service).
Exclusions	None.
Continuous enrollment period	The measurement year.
Allowable gap	No more than one gap in enrollment of up to 31 days during the measurement year. To determine continuous enrollment for a beneficiary for whom enrollment is verified monthly the child may not have more than a single 1-month gap in coverage.



Reasons for Removal Noted by Workgroup Member(s)

Minimum Technical Feasibility Criteria

None identified by the WGM.

Actionability and Strategic Priority

None identified by the WGM.

Other Considerations

The WGM suggested adding a more focused measure for the youngest children who would most benefit from topical fluoride treatments. The WGM also mentioned that a measure that focuses on the youngest children would be easier to implement with providers.

Core Set Reporting History	
Year added to Core Set	2022
Number of states reporting the measure for FFY 2020	Not applicable; measure was added to the 2022 Child Core Set, for which reporting and analysis are still underway.
Was the measure publicly reported for FFY 2020?	Not applicable; measure was added to the 2022 Child Core Set, for which reporting and analysis are still underway.
Is the measure on the Medicaid & CHIP Scorecard?	No
Challenges noted by states in reporting the measure for FFY 2020	Not applicable; measure was added to the 2022 Child Core Set, for which reporting and analysis are still underway.
Summary of prior Workgroup discussions	This measure was recommended by the Workgroup for addition to the 2022 Core Set. The WGM who suggested the measure for addition noted that the measure has a strong evidence base, including evidence that patients who receive two applications of fluoride within a 12-month period achieve significant reductions in caries. In addition, the WGM discussed their experience using the measure as part of the California 1115 Medi-Cal 2020 waiver and DQA's experience calculating the measure using T-MSIS data. They noted that T-MSIS data could potentially be used as an alternate data source to help reduce the burden of state reporting. Much of the Workgroup discussion around the measure involved technical questions about the measure specifications, including the age stratifications integrated into the measure specifications. The WGMs confirmed that the upper range for the measure is children under age 21 in alignment with the population eligible for EPSDT. DQA, the measure steward, also confirmed that the lower age range for the
	measure starts at age 1 because the measure requires at least 12 months of continuous enrollment for a child to be eligible for the measure, and that children under age 1 would not be captured in the numerator



	because the measure requires two fluoride applications within the reporting year.
	The WGM who suggested the measure for addition for the 2022 Core Set commented that provider stratification built into the measure allows states to understand how various components of their system are functioning, as well as how the system is functioning overall. The WGM also added that the age stratifications integrated into the measure specifications help states understand where there are gaps in performance and target interventions accordingly.
	One WGM representing a state Medicaid program noted that they have had difficulty calculating the measure in their state. DQA, the measure steward, noted that they have successfully calculated the measure using T-MSIS data. Two other WGMs representing state Medicaid programs commented that it should be feasible to calculate the measure using claims data. They further noted that they do not have difficulty collecting information on fluoride varnish application using claims.
Other	DQA noted that this measure is included in its State Healthcare Quality Dashboard, which stratifies TFL scores by age, geographic location (rural/urban), sex, race and ethnicity, and language. DQA encourages measure scores to be stratified by beneficiary characteristics and provides guidance for implementing stratifications in its Pediatric Measures User Guide.
	In addition, testing results included measure scores reported with stratifications; these testing results are available in DQA's NQF submissions and can be accessed through the National Quality Forum's Quality Positioning System.
	DQA stated that the primary challenges with the stratification of this measure are common among other Medicaid and CHIP claims-based measures, such as data completeness (for example, race and ethnicity are less likely to be filled in completely than age and sex) and standardized definitions and methodology (for example, disability).
	DQA also noted that the three numerators are designed to be reported together to provide a complete picture of topical fluoride receipt. States may adopt different implementation approaches through the dental delivery system, the medical delivery system, or both. Strategies may also vary by age and examining measure scores by age may be useful.

Citations

¹ https://www.ada.org/resources/research/dental-quality-alliance/dqa-improvement-initiatives

² https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/dqa/dental-quality-measures/2023-measures/2023 dqa pediatric measures user guide final.pdf



Experience of Care



MEASURE INFORMATION SHEET

CHILD AND ADULT CORE SET REVIEW WORKGROUP: MEASURES SUGGESTED FOR REMOVAL FROM THE 2025 CORE SET

Measure Information	
Measure name	Consumer Assessment of Healthcare Providers & Systems (CAHPS®) Health Plan Survey 5.1H • Child Version Including Medicaid and Children with Chronic Conditions Supplemental Items (CPC-CH) • Adult Version (Medicaid) (CPA-AD)
Description	CPC-CH: This measure provides information on parents' experiences with their child's health care. Results summarize children's experiences through ratings, composites, and individual question summary rates. The Children with Chronic Conditions (CCC) items provide information on parents' experience with their child's health care for children with chronic conditions. CPA-AD: This measure provides information on the experiences of adult beneficiaries with their health care and gives a general indication of how well the health care meets the beneficiaries' expectations. Results summarize beneficiaries' experiences through ratings, composites, and question summary rates.
Measure steward	Agency for Healthcare Research and Quality (AHRQ) Note: AHRQ is the measure steward for the survey instrument in the Child and Adult Core Sets (NQF #0006) and the National Committee for Quality Assurance (NCQA) is the developer of the survey administration protocol.
NQF number (if endorsed)	0006
Core Set	Child and Adult Core Sets
Core Set domain	Experience of Care
Meaningful Measures area	Person-Centered Care
Measure type	Patient Experience
If measure is removed, does it leave a gap in the Core Set?	Yes, the Workgroup member (WGM) who suggested the measures for removal acknowledged that removing any measure reduces information; however, they noted that in this case the costs and challenges of conducting the child and adult CAHPS surveys for a small state seem to outweigh the benefits.
Has another measure been proposed for substitution (new or existing measure)?	No. The WGM did not suggest a measure for replacement, but mentioned that a partial replacement could be achieved through the Mental Health Statistics Improvement Program (MHSIP) survey, or analysis of access, frequency, and timing of services via claims data.



Is there another related measure in the Core Set?	Yes. The Adult Core Set includes the following measures derived from the CAHPS survey: • Flu Vaccinations for Adults Ages 18 to 64 (FVA-AD) • Medical Assistance with Smoking and Tobacco Use Cessation (MSC-AD) Note that the FVA-AD measure is being retired for HEDIS
	measurement year 2023 (2024 Core Set). In addition, NCQA has proposed to retire the MSC-AD measure for HEDIS measurement year 2024 (2025 Core Set). The proposed retirement of MSC-AD is pending NCQA's review of public comments.
Use in other CMS programs	No other programs are listed in CMS's Measure Inventory Tool. However, many CMS public reporting programs include other CAHPS patient experience surveys, such as Hospital CAHPS, Home Health CAHPS, and CAHPS Hospice. More information about the use of CAHPS and other CMS patient surveys in CMS programs is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS .
	In addition, the Home and Community Based Services (HCBS) CAHPS survey is a cross-disability survey for adults receiving long-term services and supports from state Medicaid HCBS programs: https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf .

FFY 2023 Technical	FFY 2023 Technical Specifications	
Ages	CPC-CH: Age 17 and younger as of December 31 of the measurement year. CPC-AD: Age 18 and older as of December 31 of the measurement year.	
Data collection method	Survey	
Denominator	CPC-CH: The survey sample includes beneficiaries age 17 and younger as of December 31 of the measurement year, who were continuously enrolled the last six months of the measurement year, and who were currently enrolled at the time the survey was completed. Note that the sample needs to be large enough to achieve a goal of 411 completed surveys for both the general child (GC) and children with chronic conditions (CCC) populations per reporting unit (e.g., state, health plan, or PCCM program) and at least 100 valid responses on each question.	
	CPA-AD: The survey sample includes beneficiaries age 18 and older as of December 31 of the measurement year, who were continuously enrolled the last six months of the measurement year, and who were currently enrolled at the time the survey was completed. Note that the sample needs to be large enough to achieve a goal of 411 completed surveys per reporting unit (e.g., state, health plan, or PCCM program) and at least 100 valid responses on each question.	



Numerator	CPC-CH and CPC-AD: Four global rating questions reflect overall satisfaction:
	Rating of All Health Care.
	Rating of Personal Doctor.
	Rating of Specialist Seen Most Often.
	Rating of Health Plan.
	Four composite scores summarize responses in key areas:
	Getting Care Quickly.
	Getting Needed Care.
	How Well Doctors Communicate.
	Customer Service.
	A single question reflects experience of care in the following key area: Coordination of Care.
	In addition, item-specific results ("question summary rates") are reported for select questions.
	CCC Items: Three composites summarize satisfaction with basic components of care essential for successful treatment, management, and support of children with chronic conditions:
	Access to Specialized Services.
	Family-Centered Care: Personal Doctor Who Knows the Child.
	Coordination of Care for Children with Chronic Conditions.
	Item-specific question summary rates are reported for each composite question for the CCC population. Question summary rates are also reported individually for two items summarizing the following concepts:
	Access to Prescription Medicines.
	Family-Centered Care: Getting Needed Information.
Exclusions	Exclude beneficiaries who died during the measurement year from the sample.
Continuous enrollment period	The last six months of the measurement year.
Allowable gap	No more than one gap in enrollment of up to 45 days during the continuous enrollment period. To determine continuous enrollment for a beneficiary for whom enrollment is verified monthly, the beneficiary may not have more than a 1-month gap in coverage (a beneficiary whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).



Reasons for Removal Noted by Workgroup Member(s)

Minimum Technical Feasibility Criteria

The WGM noted that while there are coding manuals, the CAHPS instrument properties seem unclear, in terms of pilot data or other data indicating reliability (test-retest, etc.) and validity (predictive, concurrent, face, content and criterion). The WGM also indicated concerns about potential memory or cognitive bias for some survey items, questioning whether the respondent would have sufficient recall and adequate knowledge and understanding to accurately respond to all items. The WGM also noted that demographic differences in states (rural/urban; race and ethnicity; population SES/education level) vary and research shows that often various populations react to survey questions and Likert items differently due to the instrument properties themselves, rather than to actual differences between populations. The WGM commented that they have not seen data exploring potential disparities and response biases by state and evidence that the instrument operates with equity and consistency for various populations.

Lastly, the WGM questioned the financial viability of the CAHPS surveys, noting that they require time, expense, staff expertise, and a contractor to collect per the technical specifications.

Actionability and Strategic Priority

The WGM commented that more information must be provided to indicate that persons of all demographics react, answer, and interpret the items with parity, otherwise the instrument is not appropriate for comparative analyses by demographics. The WGM asked that data about the instruments' reliability and validity be presented with respect to this criterion. The WGM also emphasized their uncertainty about whether self-reported data is reliable and valid enough to use to assess state progress, especially when actual claims data are available.

Other Considerations

The WGM noted that all states may not be able to produce the measure for Core Set reporting within two years of the reporting cycle under review, because it is unclear whether their state will be able to fund and solicit a contractor to complete the adult survey within the allotted two years. It is also unclear whether their state could alternatively develop capacity to conduct the survey internally, with for instance, new hires and/or re-allocations of staff time and expertise.

Another WGM suggested retaining the CAHPS surveys in the 2025 Child and Adult Core Sets but changing the frequency. They indicated that they would like to see the surveys conducted less frequently (e.g., every other year or at the discretion of the state) due to growing concerns around survey fatigue and unwillingness of members to engage in survey efforts. The WGM referenced the increasing difficulty to gather sufficient responses for statistically valid results and noted that while the CAHPS surveys may not quite be at this point, it is becoming increasingly challenging to use the results to drive improvement due to low response rates.

Core Set Reporting History	
Year added to Core Set	2010 (Initial Child Core Set) and 2013 (Initial Adult Core Set)
Number of states reporting the measure for FFY 2020	39 states reported the Child Core Set measure and 36 states reported the Adult Core Set measure (all states reported calculating the measures using Core Set specifications)
Was the measure publicly reported for FFY 2020?	Yes. CMS reported on state data collection efforts; CMS did not report state results (e.g., ratings and composites).



Is the measure on the Medicaid & CHIP Scorecard?	No
Challenges noted by states in reporting the measure for FFY 2020	 Data not available due primarily to budget constraints, data source not easily accessible, and information not collected. States also noted: The state conducts the Adult/Child surveys every other year This measure is not within the state's strategic quality measures initiative at this time The state performed the CAHPS survey. However, the responses associated with the reporting units within the state could not be generalized to a statewide response The state did not conduct a survey for the overall Medicaid population The start date for the CAHPS survey was delayed due to the COVID-19 pandemic
Summary of prior Workgroup discussions	The CAHPS measures were discussed at the 2020 and 2021 Core Set Annual Review meetings and were not recommended for removal. A WGM suggested removing both CAHPS measures from the 2020 Core Sets, citing poor state response rates, the high cost of administering the surveys, and the fact that results may not be comparable across diverse populations. During the Workgroup discussion, many WGMs expressed concern with removing the measures because of the importance of measuring beneficiary experience of care as part of the Child and Adult Core Sets. State representatives commented that they analyze CAHPS data, including by health plan in managed care states, publicly post the findings, and use the results to inform system and health plan performance improvement. A WGM suggested removing both CAHPS measures again during the 2021 Annual Review, citing reasons similar to those provided during the 2020 Review. During the Workgroup discussion, some WGMs indicated that CAHPS response rates are nearing single digits, despite efforts to explore alternative data collection modalities. The Workgroup largely acknowledged and appreciated the concerns expressed about low response rates and the resulting validity of the data. However, many WGMs did not support removing the measures because the surveys provide valuable information about beneficiaries' experience. They noted that removal of the measures would leave a gap in the Core Sets. WGMs strongly urged NCQA and AHRQ to explore options for addressing the methodological issues, especially in the context of mandatory reporting of the Child Core Set and behavioral health measures in the Adult Core Set in 2024.



Other

CMS has been conducting a pilot and providing technical assistance to utilize the CAHPS Database for state reporting of the CAHPS measures. CMS strongly encourages states (or their managed care plans) to submit raw CAHPS data to the AHRQ CAHPS Health Plan Survey Database to increase the completeness of CAHPS data included in the database. More information about participating in the CAHPS Health Plan Survey Database is available at https://www.ahrq.gov/cahps/cahps-database/hp-database/participate.html.

CHIP requirements for CAHPS: Section 2108(e) of the Social Security Act (the Act), as implemented through the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) section 402, requires Title XXI programs to 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."

CHIPRA requires States to submit data that are representative of all children covered by their entire Title XXI program (CHIP Medicaid Expansion, Separate CHIP Program, or Combination CHIP Program). If a state chooses to collect CAHPS data for children in both Medicaid and CHIP, the state must separately sample and submit data for children enrolled in its separate CHIP program to fulfill the CHIPRA requirement. Children in the Title XXI-funded Medicaid Expansion CHIP may be included in the Medicaid sample.

CMS recently announced the goal of establishing a Universal Foundation of quality measures that will apply to as many CMS quality-rating and value-based care programs as possible. The CAHPS overall rating measures were included in the preliminary list of adult and pediatric Universal Foundation measures.² CMS noted, however, that for Medicaid and CHIP, "any changes to measure sets will be made in partnership with states and other stakeholders."

In September 2022, AHRQ convened a research meeting to explore how CAHPS surveys shed light on disparities in patient experience and how improved measurement can advance health care equity. A meeting summary is available at:

https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/news-and-events/events/webinars/virtual-research-meeting-summary-2023.pdf.

Citations

¹ https://www.ncqa.org/about-ncqa/contact-us/public-comments/now-open-hedis-public-comment/.

² Jacobs, D. B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L. A. (2023). Aligning quality measures across CMS — the universal foundation. *N Engl J Med*, doi:10.1056/NEJMp2215539. Available at: https://www.nejm.org/doi/full/10.1056/NEJMp2215539.