

September 9, 2024

Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

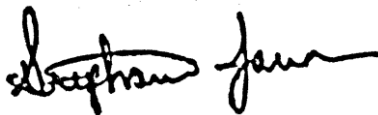
Dear Administrator Brooks-LaSure,

On behalf of our 29 member companies, the HIMSS Electronic Health Record (EHR) Association appreciates the opportunity to provide feedback to CMS on the *Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (CMS-1807-P)*.

The EHR Association is dedicated to improving the quality and efficiency of care through innovative, interoperable health information technology (IT) adoption and use. In doing so, we are committed to working toward a healthcare ecosystem that leverages the capabilities of EHR and other health IT to efficiently deliver higher-quality care to patients in a productive and sustainable way.

We appreciate this opportunity to provide CMS with the following detailed comments and look forward to continued collaboration toward improved patient care.

Sincerely,



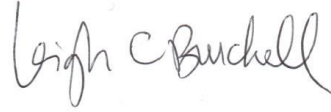
Stephanie Jamison
Chair, EHR Association
Greenway Health

AdvancedMD	Elekta	Greenway Health	Netsmart	Sevocity
Altera Digital Health	EndoSoft	Harris Healthcare	Nextech	STI Computer Services
Athenahealth	Experity	MatrixCare	NextGen Healthcare	TruBridge
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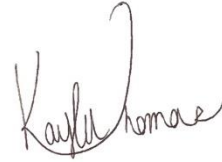
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Established in 2004, the Electronic Health Record (EHR) Association is comprised of 29 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

Electronic Health Record Association

Feedback to CMS on the Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (CMS-1807-P)

CY 2025 MVP Development and Maintenance

Development of New MIPS Value Pathways (MVPs)

We are proposing the inclusion of six new MVPs titled: Complete Ophthalmologic Care; Dermatological Care; Gastroenterology Care; Optimal Care for Patients with Urologic Conditions; Pulmonology Care; and Surgical Care.

The EHR Association appreciates CMS's efforts to enhance the Quality Payment Program through the introduction of new MIPS Value Pathways (MVPs) for various specialties. While we understand the goal of moving away from traditional MIPS participation, we would like to see more flexibility within MVP support. Currently, vendors are required to support all quality measures within an MVP in order to be allowed to claim that they support that MVP for providers. However, there may be instances in which a vendor does not support a specific quality measure for various reasons. We request that CMS allow vendors to support an MVP even if they do not support every quality measure within it.

MVP Maintenance Updates to Previously Finalized MVPs

Through the MVP maintenance process, we are proposing to consolidate the previously finalized Optimal Care for Patients with Episodic Neurological Conditions MVP and the Supportive Care for Neurodegenerative Conditions MVP into a single consolidated neurological MVP titled Quality Care for Patients with Neurological Conditions MVP.

The EHR Association supports the proposed consolidation of the Optimal Care for Patients with Episodic Neurological Conditions MVP and the Supportive Care for Neurodegenerative Conditions MVP into a single Quality Care for Patients with Neurological Conditions MVP. We believe that this consolidation is beneficial from a development perspective, as it simplifies the process and reduces potential confusion for providers. Streamlining these pathways into a unified MVP is a positive step towards making participation more straightforward and effective.

Measures Proposed for Use in the APP Quality Measure Set and APP Plus Quality Measure Sets

We are proposing a phased approach to establish the APP Plus quality measure set over four years. By the CY 2028 performance period/2030 MIPS payment year, the APP Plus quality measure set would consist of the measures currently contained in the APP quality measure set and five additional quality measures from the Universal Foundation measure set. We are proposing to phase in these new measures over time to allow for both the eCQM and, for Shared Savings ACOs, Medicare CQM collection types to be developed and become available.

The EHR Association recognizes the rationale behind CMS's proposal to phase in the APP Plus quality measure set over four years, incorporating additional measures from the Universal Foundation. However, under the proposal APP Plus will require new eCQMs that are only available in the APP Plus measure set. For example, CMS is proposing to create an eCQM and Medicare CQM around Screening for Social Drivers, which is currently a process measure in the Inpatient Quality Reporting (IQR) program and proposed to be added to the Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and the Ambulatory Surgical Center Quality Reporting (ASCQR) programs as a process measure. Similarly, the Adult Immunization Status measure is not currently an eCQM under traditional MIPS, but proposed to be under APP Plus.

We strongly recommend that quality measures made available for reporting in one pathway, such as APP Plus, should be available for use across other pathways as well, such as reporting for traditional MIPS Quality performance category. Restricting the allowable quality measures based on specific pathways could introduce unnecessary complexity and confusion for providers, making it more challenging for them to navigate and select the most appropriate measures for their practice.

Comments are invited on the proposed APP Plus quality measure set and the reporting requirements for Shared Savings Program ACOs. We are particularly interested in feedback on the feasibility of reporting the expanded measure set and its impact on quality measurement.

The EHR Association finds the proposed timeline for increasing eCQM measures within the APP Plus quality measure set to be appropriate, provided that measure specifications are available at least 18 months before the requirement date. This lead time is crucial for ensuring that vendors and providers can adequately prepare for implementation. However, we question the necessity of creating a separate APP Plus pathway instead of expanding the existing APP framework. Building onto the existing APP could streamline processes and reduce potential confusion among providers, making quality measurement more manageable and cohesive.

Scoring for Topped Out Measures in Specialty Measure Sets with Limited Measure Choice

We're proposing to revise our methodology for scoring topped out quality measures in specialty sets with limited measures to address the barriers faced by clinicians due to the scoring cap. Specifically, for the CY 2025 performance period/2027 MIPS payment year, CMS could remove the 7-point cap for certain topped out measures that we would select based on evaluating the factors discussed below. This would allow clinicians who practice in specialties impacted by limited measure choice to be scored according to defined topped out measure benchmarks that do not cap scores at 7 measure achievement points.

We request comment on our proposal to score topped out measures impacted by limited measure choice using specialty-defined topped out measures including the proposed defined topped out measure benchmark.

The EHR Association supports the removal of the 7-point cap for certain topped out measures, particularly in specialty sets with limited measure choices. This adjustment would provide a more accurate reflection of clinician performance in these areas. However, we recommend that this methodology be consistently applied across all MIPS pathways, including APPs, APP Plus, and MVPs. A

uniform approach would help prevent confusion and ensure that clinicians are assessed fairly, regardless of the pathway they participate in.

Promoting Interoperability Performance Category

We propose to amend our policy for treatment of multiple data submissions for the Promoting Interoperability performance category. We are proposing that, for multiple data submissions received, CMS would calculate a score for each data submission received and assign the highest of the scores. We also are proposing to codify this proposal at § 414.1325(f)(2).

We believe this proposal is consistent with our existing policy for treatment of multiple data submissions received in the quality.

We request public comments on this proposal.

The EHR Association is supportive of CMS's proposal to amend the policy for the treatment of multiple data submissions for the Promoting Interoperability performance category. Our past experiences with similar scoring issues suggest that calculating and assigning the highest score from multiple data submissions is a fair and effective approach. We believe this proposal will enhance accuracy in performance assessment and is consistent with the existing policy for the quality category, ensuring equitable treatment across different performance categories.

Improvement Activity Scoring and Reporting Policies

Currently, MIPS eligible clinicians are required to report two high-weighted activities, four medium-weighted activities, or one high-weighted and two medium-weighted activities while MVP participants are currently required to report one high-weighted activity or two medium-weighted activities.

We are proposing that MIPS eligible clinicians who participate in traditional MIPS would be required to report two activities. In addition, we are proposing that MIPS eligible clinicians who are categorized as small practice, rural, in a provider-shortage area, or non-patient facing would now be required to report one activity. We are proposing that these policies would be effective for the CY 2025 performance period/2027 MIPS payment year and subsequent years.

We are also proposing that MVP participants would be required to report one activity. In the CY 2022 PFS final rule (86 FR 65412 through 65413), we established that MVP Participants submitting MVPs report fewer improvement activities than eligible clinicians reporting traditional MIPS to incentivize and support MVP adoption. We continue to believe that reduced reporting requirements are necessary to support the adoption of and reduce the burden for implementation of MVPs.

The EHR Association supports the proposal to simplify the Improvement Activities (IA) category by removing the weighting of activities and requiring two IAs for MIPS eligible clinicians in traditional MIPS. However, we strongly recommend that this simplification be applied consistently across all pathways.

Specifically, the requirement for one IA in MVPs versus two in traditional MIPS should be aligned, with a single IA requirement for both pathways. This alignment would reduce complexity, enhance consistency across the program, and ensure fairness for participants.

Mandatory Subgroup Reporting for Small Practice TINs

For those clinicians who submitted an MVP for the CY 2023 performance period/2025 MIPS payment year, what practice level barriers did you overcome to successfully submit an MVP? How did you overcome any stated barriers? For those who did not submit an MVP, what key barriers impacted your decision to continue to report traditional MIPS? For those clinicians who participated as a subgroup for reporting an MVP for the CY 2023 performance period/2025 MIPS payment year, we are interested to hear the technological barriers, if any, that impacted the ability to successfully submit subgroup level data. We are also interested to hear feedback from groups on any technical issues with de-aggregating data (specifically, the eCQM quality measure data) at the subgroup level.

One significant barrier to MVP participation is the requirement that third parties must support all quality measures within an MVP. This requirement can be particularly challenging when an outlier quality measure is not supported or requested to be supported by the third party, ultimately preventing the entire MVP from being “supported.” To mitigate this issue, the EHR Association recommends that CMS ensure at least four of every collection type are included per MVP. This would allow EHRs to support the minimum necessary measures, thereby reducing both costs and physician burden.

Additionally, we are concerned about the potential for increased burden with the transition to MVPs, especially without a clear pathway for universal participation before the sunset of traditional MIPS. It is essential that MVPs are designed to serve the entire population of eligible clinicians without adding undue complexity or burden.

As subgroup participation becomes mandatory for multispecialty groups reporting an MVP beginning in CY 2026, how can we balance the increase in burden for groups while allowing comprehensive reporting on the diverse range of services provided by the clinicians in a group? For example, should we consider limiting the number of subgroups that a group must form based on group size and composition? Are there alternative approaches we could consider for setting limits on the minimum and maximum number of subgroups per group TIN?

The EHR Association is concerned that making subgroup participation mandatory or limiting the number of subgroups based on group size and composition will add significant complexity and increase the burden on both vendors and providers. Such requirements could complicate the reporting process and strain resources, particularly in multispecialty groups where diverse services are offered. We recommend exploring alternative approaches that do not mandate subgroups or limit their number, allowing more flexibility in how groups report on the comprehensive range of services provided. This would help to maintain efficiency and reduce the administrative burden on all parties involved.

Request for Information Regarding Public Health Reporting and Data Exchange

Questions for Goal #1: Quality, Timeliness, and Completeness of Public Health Reporting

Should CMS shift to numerator/denominator reporting requirements for current and future measures in the public health and clinical data exchange objective? If so, should CMS prioritize only certain measures for numerator/denominator reporting?

The EHR Association does not recommend moving to a numerator/denominator reporting requirement, as this adds an unnecessary layer that requires additional measurement work and calculations, creating additional burden without adding value for those reporting or those receiving the reports.

New technical approaches such as the use of FHIR APIs to support information exchange with PHAs could enable PHAs to query healthcare provider systems directly, after an initial trigger, rather than solely relying on a healthcare provider to take action to share information. How could performance be measured under approaches such as the use of FHIR APIs to support information exchange with PHAs? Would numerator/denominator reporting be appropriate under such approaches?

The EHR Association is concerned that the focus on FHIR-based queries indicates a shift from the current push-based reporting system, where data is automatically reported upon the occurrence of a defined event, to a model that relies on a triggered data query following an event notification. Transitioning away from existing, generally effective capabilities without strong justification adds unnecessary costs and resource burdens without delivering clear efficiencies. The current public health infrastructure effectively facilitates the reporting of information from providers and hospitals to the state level, from which it is then conveyed to the federal level. This proposed architectural change risks creating a less efficient reporting mechanism for providers and introduces unnecessary IT challenges, potentially compromising the performance of systems primarily designed to support clinical care. We do not see adequate reasoning to abandon a largely effective reporting infrastructure in favor of a new model that may not be as efficient. Any such changes should be backed by strong, well-founded reasoning.

We recommend a mixed approach: use clearly defined trigger events with associated data requirements to push data at the appropriate time (using HL7 v2, CDA, and/or FHIR-based formats or transport), followed by FHIR-based queries for any additional data that was missed or found to be of additional interest for follow-up investigations.

Furthermore, how to quantify queries in a meaningful way is unclear. For example, are more queries better or worse? What would the denominator be—queries per eCR submitted? The EHR Association suggests that focusing on the ability to query for follow-up data is more suitable than simply counting the number of queries.

Should CMS continue to add measures under the PH and CDE objective to include additional system-specific requirements (for example, vital records)? If so, which ones and why?

The EHR Association supports the inclusion of vital records as a valuable addition to the public health reporting requirements under the Public Health and Clinical Data Exchange objective.

Should CMS create a new measure for each new type of data or use case added to the PH and CDE objective? What are the risks of including too many measures under the objective?

The EHR Association supports addressing all relevant public health reporting and data-sharing requirements through practical and easy-to-calculate measures. As noted in our feedback above, the use of numerator/denominator measures is neither practical nor necessary to gain insight into adoption and to further advance it. Feedback from public health reporting can provide valuable insights to help focus incentives and increase adoption.

Alternatively, should CMS explore ways to group data types and use cases under a more limited set of PH and CDE objective measures? (anecdotal reports suggest that some healthcare providers are attesting to active engagement with PH for the eCase measure if they report cases for at least one notifiable condition (ex. COVID-19)).

The EHR Association requests that CMS clarify the focus of grouping public health reports. Our response would differ if the intent is to group overall report types (e.g., syndromic surveillance plus lab reporting vs. case reporting vs. immunization reports and vital records), rather than if the grouping is intended to be within each type of report (e.g., reportable condition grouping within case reporting and within lab results reporting, and grouping of registry reporting).

We are unconvinced the first approach – the grouping of overall report types – would significantly encourage adoption. However, for certain reports like case reporting, accelerating the adoption of more trigger events, conditions, or other criteria may help encourage step-wise adoption of higher priority events. This would be more applicable for reports with lower electronic reporting adoption rates, such as electronic case reporting, compared to those with higher adoption rates, such as electronic laboratory reporting.

Questions for Goal #2, Flexibility and Adaptability of the Public Health Reporting Enterprise

How can the Medicare Promoting Interoperability Program support or incentivize response-ready reporting capabilities for healthcare providers? What, if any, challenges exist around sharing data with PHAs?

The most important challenges the Medicare PI program can address to support and incentivize response-ready reporting capabilities for healthcare providers are those associated with jurisdiction-specific requirements. While our members provide certified reporting and make the configuration of physical connections simpler, out-of-the-box reports cannot be universally used due to these variations. Therefore, the EHR Association recommends:

- **Standardizing Reporting Requirements:** Encourage the standardization of reporting requirements across jurisdictions to minimize the need for customized adjustments.
- **Providing Technical Assistance:** Offer technical assistance and resources to help healthcare providers adapt their reporting systems to meet specific local requirements efficiently.
- **Incentives for Compliance:** Create incentives for healthcare providers who successfully implement and maintain response-ready reporting capabilities.

- **Facilitating Collaboration:** Promote collaboration between healthcare providers and public health agencies to streamline the reporting process and ensure data is shared effectively.

How can CMS and ONC work with vendors to ensure that provider systems are being continually updated to meet new data needs, such as those in rural areas?

The EHR Association recommends that CMS and ONC create a more efficient and consistent reporting process by aligning on certified implementation guides for specific topics. While USCDI/USCDI+ can help set broad expectations for data, using actual implementation guides offers a more focused and standardized approach. This reduces variability across jurisdictions in terms of methods, techniques, and content. For example, sharing electronic case reporting (eCR) knowledge through certified implementation guides enables source systems to adjust more effectively to new data content. By focusing on these certified standards, CMS and ONC can better ensure that provider systems, including those in rural areas, are consistently updated to meet evolving data needs. USCDI/USCDI+ should still play a role in aligning across certified implementation guides, but the actual standards and implementation guides should remain the primary focus for public health and other use cases.

Questions for Goal #3, Increasing Bi-Directional Exchange with Public Health Agencies

Both CDC's ACD and ONC's HITAC have recommended that CDC and ONC work together to establish certification criteria for public health technologies used by PHAs and implement a coordinated, phased approach to incentivize and eventually require their adoption. How, if at all, could the Medicare Promoting Interoperability Program support or incentivize PHA adoption of certified systems and technologies?

The EHR Association suggests that CMS, CDC, and ONC collaborate to advance the consistent, standards-based adoption of reporting and data sharing/query capabilities using a certification approach. Certification for reporting ensures alignment between senders and receivers regarding format and content, while certification for queries guarantees that data sources are consistent and requesters support certified formats and content.

For PHAs, certification would focus on capabilities where other parties query PHA data, such as immunization histories. Ensuring that queries are properly defined and aligned with authorized purposes is crucial to stakeholders across the healthcare continuum. Therefore, certifying PHAs for their ability to handle such requests effectively adds value. The EHR Association recommends appropriate funding be allocated to PHAs to build infrastructure that supports these capabilities, including standardized tools and algorithms. The availability of implementation centers to support PHAs can further advance improvements in their infrastructure. We encourage CMS to work with the CDC to create incentives for PHAs to adopt the matching criteria that ONC is defining, addressing both sides of the interaction.

How can CMS use the Public Health and Clinical Data Exchange objective to incentivize early adoption of FHIR-based APIs for public health data exchange?

The EHR Association suggests that CMS focus on new "green field" opportunities that benefit from FHIR-based data sharing techniques rather than solely replacing existing HL7 v2 and HL7 CDA-based reporting

mechanisms. Replacing existing systems may require investments greater than the benefits it yields at this time. Instead, targeted enhancements that address missing data and improve data quality can immediately provide substantial benefits in those areas.

We suggest that meaningful data-sharing advancements can be achieved without requiring comprehensive system replacements by:

- **Targeted Enhancements:** Focus on areas where FHIR-based data sharing can address gaps in data quality and completeness.
- **Investigative Queries:** Encourage the use of FHIR for investigative queries to enhance data accessibility and usability.
- **Bulk Data Support:** Support the use of FHIR for bulk data queries by PHAs where needed, allowing large data set queries by providers.
- **FHIR-Based Payloads:** Promote the adoption of FHIR-based payloads, as demonstrated with electronic case reporting (eCR).

Additionally, we note that the collaboration between ONC and CDC through the HL7 HELIOS Accelerator offers a holistic approach to integrating FHIR-based capabilities. This approach focuses on complementing and advancing current capabilities, thereby minimizing the need for costly and immediate replacements of existing systems.

CMS previously finalized the Enabling Exchange under TEFCA measure under the HIE objective for eligible hospitals and CAHs to attest to engaging in health information exchange. Should CMS introduce a similar measure to allow providers to receive credit for the HIE objective by exchanging public health data through participation in TEFCA?

The EHR Association supports the adoption of the Public Health purpose of use in TEFCA, leveraging a common agreement and trust framework to reduce the need for multiple connection configurations and point-to-point data-sharing agreements. However, we have some concerns about the current use cases being considered that involve FHIR, as these may lead to unnecessary architectural changes or may be ahead of the FHIR adoption pace under TEFCA and HL7 HELIOS.

We believe that participation in TEFCA for the exchange of public health data should be incentivized under the HIE objective if it enables new capabilities that are not otherwise available. We do not support a shift to TEFCA simply for the sake of change if it does not yield any additional benefits or capabilities for public health agencies (PHAs). However, if TEFCA can facilitate new and valuable capabilities, such as more efficient or advanced data-sharing processes, these advancements should indeed be recognized and rewarded.

For example, if TEFCA enables more effective investigative follow-up queries by PHAs through FHIR-based access after the receipt and analysis of lab reports or case reports, such enhancements should be acknowledged within the HIE objective. Similarly, leveraging TEFCA's common agreement and trust framework to streamline and improve the exchange of public health data—thereby reducing the need for multiple point-to-point data-sharing agreements—should also be incentivized.

While we support the adoption of the Public Health purpose of use in TEFCA, we also urge caution in requiring a shift from established communication methods like XDR and Direct-based reporting to QHIN-brokered reporting unless these new methods offer clear advantages. The EHR Association suggests utilizing the full set of available capabilities within the TEFCA framework to support public health data exchange, ensuring a flexible and efficient integration process that maintains high standards of interoperability.

Questions for Goal #4, Eliminating Reporting Burden for Healthcare Providers

Under the current Public Health and Clinical Data Exchange objective, which measures, or other requirements result in the most administrative burden for MIPS eligible clinicians?

Any measure that requires data not captured in routine care documentation, or that adds new data requirements unrelated to the current data flow, result in the most significant administrative burden for eligible clinicians. Such measures create significant challenges for health IT developers, who must develop additional data collection processes, and for providers, who must collect this data and adjust their workflows accordingly. Simplifying these measures to align with existing documentation practices and data flows would help reduce this administrative burden.

How can the Medicare Promoting Interoperability Program balance robust Public Health and Clinical Data Exchange objective requirements with our desire to reduce burden on MIPS eligible clinicians?

To balance robust Public Health and Clinical Data Exchange objective requirements with the desire to reduce the burden on eligible providers, the EHR Association suggests ensuring consistency between ONC certification requirements and PHA requirements. Implementing a PHA-focused certification program that aligns with the standards referenced by ONC can substantially reduce unnecessary variations.

How can new technical approaches to data exchange with PHAs, such as the use of FHIR APIs, reduce burden for MIPS eligible clinicians? What are potential barriers to achieving burden reduction as these new approaches are implemented?

The increased availability of FHIR-based APIs for querying data presents tremendous opportunities for more efficient data access. However, it's important to balance this with the appropriate use of query-based approaches and avoid moving everything to this model. Focusing on suitable use cases, such as investigative follow-up queries upon receipt and analysis of ongoing reports, will be key to achieving this balance. One of the main challenges will be ensuring the appropriate use of these APIs and identifying the use cases that can now be effectively addressed, such as the investigative queries mentioned. The participation of PHAs in TEFCA will be critical to supporting these use cases at scale.

Additionally, the rapid expansion of case reporting, facilitated by common agreements through APHL, eHealth Exchange, and Carequality, highlights the power of a national network in accelerating adoption. Flexibility will be essential, and we urge CMS to work with ONC to provide the necessary flexibility to determine when to use the common agreement and trust framework versus when data should flow through QHINs.

With the opportunity to use TECCA to rapidly expand PHA access to relevant data, variations across jurisdictions, particularly in privacy rules, present a critical challenge. Deciding when to share or not to share data will be complex, not only for provider-PHA data sharing to include any data exchange involving different privacy rules across jurisdictions of the source and the recipient of the data.