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September 7, 2023

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 31 member companies, the HIMSS Electronic Health Record (EHR) Association appreciates the opportunity to provide feedback to CMS on the *Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule, and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program* (CMS–1784–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,

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Chair, EHR Association
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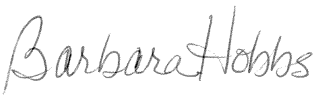

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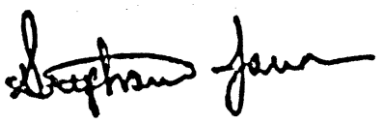

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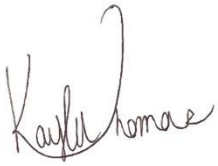

Kayla Thomas
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Established in 2004, the Electronic Health Record (EHR) Association is comprised of 31 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the 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.

ACO Transition to Electronic Clinical Quality Measures Reporting

The EHR Association recognizes and continues to promote the importance of working toward true EHR-based, electronic clinical quality measures (eCQMs) for Accountable Care Organizations (ACOs) and across the entire quality measurement environment, and applaud CMS' commitment to continuing to support ACOs in the transition to all payer/all patient eCQMs/Merit-Based Incentive Payment System (MIPS) CQMs and in the transition to digital quality measurement reporting.

In collaboration with provider stakeholders, the EHR Association has identified the following challenges faced by ACOs attempting to implement eCQM – many of which are relevant to MIPS on a smaller scale.

Challenges in Data Collection

- Certain segments of Health Information Technology (health IT) lack the capability to generate necessary data (due to uncertified systems or paper-based processes).
- Some health IT components are certified but not to the required ACO measures and therefore cannot produce the required ACO measures.
- Health IT can generate the measures, but doing so is often time or cost prohibitive.
- Utilizing the "smoking gun" approach (only generating data for patients qualifying for the measure) to calculate qualification might limit data availability for patients who only qualify across different systems.
- Aggregating data from all relevant sources necessitates awareness and coordination.

Challenges in Data Integration

- Establishing a central repository for comprehensive data integration requires significant additional hardware and processing capacity that ACOs do not have today. Because ACOs often span multiple organizations and care for a significant volume of patients (regardless of their ACO attribution status), they will need to invest in new data center capacity to centrally aggregate, deduplicate, and process patient data for the purposes of quality reporting.
- Patient matching across diverse data sources introduces challenges, especially because different systems include and format key demographic information differently. Additionally, CMS's QRDA I specification supports a limited number of identifiers that can be used for matching. This results in significant manual burden to deduplicate patient populations for accurate reporting.
- The absence of a standardized ambulatory QRDA I implementation guide leads to variations in implementation across different systems.

Challenges in Data Validation

- CMS's methodology and baseline for determining data completeness is unclear, so ACOs and others lack insight into whether they are submitting appropriately complete data.

Proposed Solutions

- Transitioning to dQMs or FHIR would allow the challenges above to persist.
- Allowing more time would aid in addressing some of these challenges.
- Greater flexibility could be offered by lowering the data completeness threshold.
- Incorporating additional demographics in the data (QRDA I or FHIR) may improve patient matching and support deduplication. We suggest CMS consider introducing extra demographic criteria in their CMS Implementation Guide or QRDA I specifications to enhance patient matching accuracy.

Reporting the Medicare CQMs

The EHR Association appreciates the flexibility offered to ACOs as CMS proposes to revise the quality reporting and quality performance requirements to allow Shared Savings Program ACOs the option to report quality measures under the Alternative Payment Model Performance Pathway (APP) on only their Medicare beneficiaries through Medicare Clinical Quality Measures (CQMs).

Proposals to Align CEHRT Requirements for Shared Savings Program ACOs with MIPS

The EHR Association consistently supports synchronization across regulatory programs. As such, we appreciate CMS' efforts to align certified electronic health record technology (CEHRT) requirements for Shared Savings Program ACOs with MIPS. However, it appears the proposal for Shared Savings Program ACOs differs from the proposal for other Advanced Alternative Payment Models under the Quality Payment Program (QPP), as the Shared Savings Program ACO proposals require attestation to the Promoting Interoperability (PI) category and the QPP proposals do not. We suggest alignment between the two to require PI attestation across the board.

Proposal for Shared Savings Program ACOs to Report Medicare CQMs

The EHR Association appreciates CMS's endeavor to support ACOs in their transition to digital quality measure reporting, as evidenced by the proposal for the Medicare CQMs for ACOs Participating in the Medicare Shared Savings Program. However, we would like to express concerns regarding the proposed criteria for determining the appropriate Medicare CQM population. Because the proposed criteria differ from the current assignment methodology, it introduces unnecessary complexity, potentially leading to confusion in identifying the appropriate Medicare ACO population. We suggest that using the existing CMS-provided ACO population base would create less confusion.

Furthermore, the timing aspect presents a challenge, as the proposal's focus on claims during the measurement period could lead to discrepancies due to claims reporting delays of up to a year. We strongly advocate for a streamlined transition by combining the new Medicare CQM assignment methodology with the existing approach, which would mitigate potential challenges and ensure a smoother implementation process.

MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program ACOs - Request for Information (RFI)

We believe CMS' proposal to align quality measures in the Adult Universal Foundation with measures used for evaluation in the Medicare Shared Savings Program addresses the importance of meaningful specialist participation in ACOs and the need for comparable quality data across specialties within the Medicare Shared Savings Program. The alignment of quality measures in the Adult Universal Foundation with those used for evaluation in the program is a step in the right direction, acknowledging the distinctive specialties within ACOs and the relevance of specialty-specific quality data. This approach appropriately highlights the unique aspects of ACOs while fostering consistency and fairness in quality assessment.

To enhance specialist reporting of MVPs within Shared Savings Program ACOs, the EHR Association suggests making a broader array of specialist MVPs accessible. Additionally, we recommend reconsidering the quantity of Quality Clinical Data Registry (QCDR) measures in each MVP, which tends to be larger than other measures and can limit measure selection. Requiring a Qualified Registry to support every quality measure within an MVP could potentially impede their ability to effectively support the MVP and consequently hinder their clients' participation. Addressing these concerns would likely foster greater specialist engagement and contribute to a more effective and inclusive reporting process.

When evaluating ACOs for quality performance based on reporting quality measures within MVPs, the EHR Association reiterates the potential challenges arising from the requirement for QCDRs to support all measures within an MVP. This could inadvertently place undue burden on these entities, especially if a small number of measures within the MVP were not historically supported or aligned with client needs. A more flexible approach that allows for customized measure support could mitigate such concerns and enable more accurate and relevant quality performance assessment within the ACO framework.

The EHR Association is in favor of applying the proposed Shared Savings Program scoring policy for excluded APP measures if MIPS quality measures in MVPs are excluded, as outlined in section III.G.2.f. of the proposed rule. We believe that maintaining consistency between programs is always the best practice.

Proposal to Rescind § 414.94

The EHR Association supports CMS's proposal to indefinitely pause the AUC program for re-evaluation. We remain steadfast in our commitment to the program's overarching goal of enhancing patient safety and reducing healthcare costs by curbing unnecessary imaging studies – and have collaborated with healthcare providers and stakeholders to support the program's successful deployment. However, we appreciate the recognition of the need for a workable implementation approach.

EHRs offer sophisticated capabilities to present timely clinical decision support information to providers, including by integrating with external systems and content providers to leverage the latest professionally validated clinical guidelines. As CMS re-evaluates the AUC program's implementation, we

stand ready to contribute insights on how automated tools in the EHR can support CMS's goals of implementing the program in a manner that does not increase provider burden.

Proposed revisions to Certified Electronic Health Record Technology Definitions in Regulatory Text

The EHR Association is supportive of the statements from CMS that updates to certification criteria by ONC do not automatically become effective and applied to requirements for the use of CEHRT in the PI and APP programs, and that CMS will continue to determine when new or revised measures requiring CEHRT would be incorporated into relevant programs taking into account implementation time and readiness. We believe this is a critical consideration for providers and their respective developers to avoid negative outcomes from rushed development and implementation of new capabilities impacting the provision of patient care.

However, we are concerned that this focus specifically on new measures requiring the use of updated CEHRT ignores updates providers would need to implement for criteria that are part of the CEHRT definition regardless of any directly associated measurement – particularly those under the Base EHR definition. Since the CEHRT definition (both current and updated as proposed in this NPRM) directly references the Base EHR definition at 45 CFR 170.102, any such criteria would be updated as part of the Base EHR definition as of a date defined by ONC, and therefore also updated automatically as part of the CEHRT definition given the direct citation. There are multiple such Base EHR criteria that are proposed to change as of a date (January 1, 2025, for most) in ONC's HTI-1 NPRM.

To remedy this issue, we urge CMS to revise the CEHRT definition in a way that clarifies a date by which such new or revised criteria would become effective for purposes of PI and Quality Payment Program (QPP) program requirements. This could be accomplished by codifying a standard delay from ONC's own effective dates intended for applicability to developers, which would accomplish CMS' goal of not having to revise the CEHRT definition each time criteria are changed by ONC moving forward. We would specifically suggest a standard 12-month delay for this.

MIPS Performance Category Measures and Activities - Promoting Interoperability Performance Category

We understand and generally support CMS efforts to align the performance period for the PI performance category to IPPS requirements. However, although the EHR Association endorsed modifying the EHR reporting period for participating eligible hospitals and CAHs to a minimum of any continuous 180-day period in CY 2025, we advise against transitioning to a 180-day period for eligible clinicians (ECs). Unlike hospitals, ECs often operate with smaller or even non-existent IT departments compared to hospitals. Unlike hospitals, ECs have the alternative of electronically attesting using QRDA 3, introducing complexity in terms of deduplication for a longer duration.

The proposed extended time frame of a 180-day performance period places a burden on providers who are converting between health IT systems mid-year. The importation of PI measures and the deduplication process are not available within PI measures, creating additional and unnecessary work for providers when attesting.

Further, CMS typically does not release PI measure changes for the subsequent year until November. This places a significant burden on both small EHR developers and small physician practices. Given that the final window for data collection comes just about six months after the release of the final Medicare Physician Fee Schedule each year, it is not just challenging – it poses a risk of being unfeasible.

The EHR Association supports modifying the second exclusion for the Query of Prescription Drug Monitoring Program (PDMP) criterion to state that any MIPS-eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period can claim the second exclusion, as proposed. We suggest that CMS add clarity surrounding the situations in which a MIPS-eligible clinician does not electronically prescribe Schedule II opioids or Schedule III and IV drugs, in accordance with applicable law during the performance period, but does write more than 100 permissible prescriptions during the performance period.

Quality Performance Category - Definition of Collection Type

As we consistently support standardization across reporting programs, the EHR Association supports the CMS proposal to amend the definition of the term "collection type" to include the Medicare CQMs for ACOs Participating in the Medicare Shared Savings Program.

Quality Performance Category - (c) Quality Data Submission Criteria

The EHR Association supports the inclusion of this terminology to enhance clarity regarding the requirement to utilize CEHRT for the submission of MIPS quality measures specific to eCQMs. We do, however, recommend that CMS explicitly specify that MIPS-eligible clinicians, groups, Virtual Groups (VGs), Subgroups, and Alternative Payment Models (APMs) opting to report eCQMs must use CEHRT. If a third-party intermediary is chosen for data submission, it should be required to adhere to, at a minimum, the certification requirements outlined in 170.315(C)(1)-(C)(3) for eCQM reporting. While we acknowledge that some third-party intermediaries may not fully meet CEHRT criteria, it is essential that they adhere to the same standards as others when reporting eCQMs. This consistency will ensure uniform and reliable data submission across all reporting entities.

Quality Performance Category - (d) Data Completeness Criteria

The EHR Association expresses reservations regarding the proposal to increase the data completeness criteria threshold to at least 80 percent for the CY 2027 performance period/2029 MIPS payment year.

We understand the desire for more accurate performance assessment and agree that systems should report based on all data contained within them. However, we are concerned about the potential technical challenges associated with this higher threshold for participants who operate in multi-system environments.

Moreover, we question the assertion that increased reporting percentage directly correlates with improved quality outcomes. It is important to note that EHR developers do not selectively choose data for export; instead, all feasible data is exported for the specified reporting year. While using a single developer often achieves a 100% reporting rate, situations involving ACOs with multiple developers and potential limitations in export options might lead to lower completeness thresholds. This, however, does

not necessarily reflect the performance of all entities, as other factors might influence the completeness rate.

Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures - Scoring Flexibility for Changes That Impact Quality Measures During the Performance Period

The EHR Association appreciates CMS for acknowledging the concerns raised by EHR developers and recognizing the challenges associated with truncating measures. The proposal to require measure specifications to include logic for a 9-month performance period alongside the existing 12-month period reflects the agency's intention to provide flexibility. However, we wish to highlight the potential repercussions of this approach. While we agree that a 9-month specification is necessary, offering both 9-month and 12-month specifications would significantly increase the workload for EHR developers. Given the substantial effort required to maintain dual specifications for each measure, our capacity to support the current and potentially additional eCQMs may be compromised. Consequently, the industry's progress could be hindered due to the strain on developer resources. If the primary concern is enabling 9-month reporting, we suggest offering only a 9-month reporting measure specification, starting from January to September. This approach would alleviate the burden on EHR developers and allow them to focus on maintaining the quality and breadth of eCQM offerings.

New Quality Measures Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years - Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults

CMS noted in the IPPS final rule that many commenters did not support the adoption of the Excessive Radiation Dose eCQM. Several concerns raised by commenters were shared by the EHR Association but seem to have been misinterpreted or inadequately addressed by CMS.

The Excessive Radiation Dose measure does not align with the definition of an eCQM. CMS has stated, “We define an eCQM as a measure specified in a standard electronic format that uses data electronically extracted from EHRs and/or health IT systems to measure the quality of health care provided.” This data from Alara does not exist in the EHR system and must be manually entered or triggered for import in some way, or a new interface will need to be created and maintained to allow, as CMS describes, “the hospital to send the data to the EHR for measure calculation.” Any of these options would, in fact, create additional burden – on the users or developers of EHRs. The EHR Association stands by our previous assertion that this measure is not a good fit to be included as an eCQM.

Our greatest concern regarding this measure is that it cannot be calculated within the EHR even when radiology data is stored in the EHR – instead, the entire measure hinges on Alara being able to provide the data needed to calculate the measure. This data is not stored in the EHR and requires extra steps for the healthcare organization to access this third-party system to ensure the data is available. EHR developers may also need to create a new data repository location to store the data for extraction and we do not yet have visibility as to what the format of the data will be.

CMS did not address the EHR Association's request to not require this measure for EHR developers in the IQR program which requires EHR developers to offer all available eCQMs. CMS instead responded that hospitals have the option to self-select and are not required to choose the measure. Without the "eCQM" title, EHRs would not be required to undergo certification for the IQR/PI program and would have the flexibility to choose whether to build new tools in order to offer this measure. However, by requiring this extraordinary eCQM measure for EHRs, CMS is placing a financial and resource strain on EHR developers which is above and beyond the delivery of traditional eCQMs. Instead, we believe this measure – relying on third-party software to be calculated – could be considered a hybrid measure, similar to hybrid measures that use the QDM format and QRDA for reporting but are not considered eCQMs because CMS claims data also is used to calculate these measures.

The EHR Association is also concerned about issues of transparency surrounding the development of this measure. First, CMS noted that the measure was tested across 16 inpatient and outpatient hospitals and a large system of radiology practices, though CMS has not indicated what EHR software was used and whether results were integrated into the EHR – both are important considerations. Similarly, additional transparency is requested regarding a survey administered by Alara Imaging in which respondents are reported to have indicated a small-to-moderate burden for this measure that is similar in level of burden to other measures. It is important to understand which types of measures are referenced – eCQM, chart-abstracted, or registry-abstracted quality measures. Further, respondents indicated that the additional work fell to IT personnel rather than physicians. This is common as physicians would not be expected to execute their own quality reporting. Nonetheless, this process will necessarily create a higher degree of burden if users are required to sign into a third-party software system to upload data and integrate results. Finally, we question the potential conflict of interest created by Alara creating and administering this survey.

There are further concerns regarding a potential conflict of interest for Alara Imaging. CMS noted in the IPPS, "Many commenters did not support the measure due to concerns about the measure developer's relevant expertise and for-profit status, as well as the potential for a conflict of interest due to the measure developer also being the only vendor for the translation software required for the measure." CMS stated that they do not believe there is a conflict of interest because measure reporters can use any software that can complete the calculation. We, however, are not aware of any other vendor who offers this unique software specific to this measure. CMS goes on to say, "If in the future software is more limited [i.e., requires a fee] …CMS will reconsider retaining the measure in CMS programs." This implies CMS understands that there are no other vendors on whom a hospital/clinician could rely to complete the measure. The EHR Association suggests this does appear to be a conflict of interest.

CMS also noted further concerns "According to commenters, if the software integrates with the EHR, they believe staff time would also be required to build and maintain that integration. Commenters believed that EHR developers would face a burden in developing and configuring new software to support measure reporting. Multiple interfaces and third-party applications might need to be reconfigured and mapped to process radiology data." To which CMS responded by stating, "The software accepts a wide range of FHIR, HL7 formats for EHR data, and DICOM CT radiation dose and image data to decrease burden." We ask if this is intended to insinuate that we (the EHR developers) should be creating new HL7 and or FHIR interfaces from our radiology products to the Alara product to

share data with the software so they can perform calculations and return the necessary data to calculate? And that the creation of new interfaces for EHR developers is without burden?

Finally, express concerns pertaining to potential data breaches, security protocols, and third-party business arrangements for data sharing with Alara. The execution of the Alara Imaging software remains unclear. In two instances within CMS's responses to the measure, CMS indicated that a hospital would access the measure developer's secure portal and run the Alara Imaging Software for CMS measure compliance behind their firewall. Although this suggests being behind the Alara firewall upon signing into the software, CMS further states that the software creates intermediate data elements, which hospitals can then send to the EHR for measure calculations and reporting. However, CMS's explanation about data security does not adequately detail how the software's automatic execution to create necessary data elements and data transmission within the hospital's firewall would occur without a developer-created interface. We urge CMS to provide more clarity regarding the protection of data under the Alara Imaging Software and whether the hospital/clinician signs into Alara and is protected by the Alara firewall – which would necessitate a business agreement – or if the hospital/clinician independently runs Alara software on their own hospital systems.

Previously Finalized Quality Measures Proposed for Removal in the CY 2024 Performance Period/2026 MIPS Payment Year and Future Year

The EHR Association objects to the proposed removal of the Adult Major Depressive Disorder (MDD): Suicide Risk Assessment (CMS161v12), Preventive Care and Screening: Influenza Immunization (CMS 127), and Pneumococcal Vaccination Status for Older Adults (CMS 147) measures, as well as the removal of eCQMs in general. These measures play a significant role in assessing healthcare quality and patient safety. Numerous state ACOs rely on these measures, and our clients have expressed value in reporting on these measures internally.

CMS's emphasis on encouraging EHR adoption and eCQM reporting, along with reducing burden and ensuring data accuracy, contradicts the decision to eliminate eCQMs. In section IV.A.4.f.(1)(d)(i) of this proposed rule, CMS states, “We continue to encourage individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, including small and rural practices, to explore EHR adoption and the reporting of eCQMs to reduce burden and technical challenges to ensure data accuracy as we seek to increase the data completeness criteria threshold.”

We firmly believe that retaining eCQMs is essential for reducing burden, ensuring data accuracy, and improving healthcare quality.

Proposed Partial Removal of Three Previously Finalized Quality Measures as Component Measures in Traditional MIPS and Proposed Retention of These Three Measures for Use in Relevant MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

The EHR Association does not support the Proposed Partial Removal of Three Previously Finalized Quality Measures as Component Measures in Traditional MIPS and Proposed Retention of These Three Measures for Use in Relevant MVPs, as these measures serve as popular care guidelines for our provider clients. While more comprehensive registry-reported measures are available, providers are unlikely to

transition from EHR-based reporting to registry-based reporting solely to maintain reporting of those measures. The cost and inconvenience associated with using a registry, as opposed to leveraging internally stored and managed data, create barriers for those who cannot afford or prefer not to utilize registry services, resulting in the loss of access to crucial care measures for program tracking. This situation forces them to opt for less impactful or desirable eCQM measures to fulfill reporting requirements while being unable to monitor significant population measures due to the presence of a costlier registry alternative. Removing eCQMs in favor of MIPS CQMs or QCDR measures is not a sound approach.

Modifications to Previously Finalized MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

The EHR Association encourages CMS to expand its inclusion of eCQMs for each MVP, thereby enhancing the comprehensiveness and relevance of performance evaluation. In particular, we urge CMS to consider integrating the Addressing Social Needs (ASN) eCQM as it becomes available.