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September 6, 2022

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 the nearly 30 member companies of the Electronic Health Record (EHR) Association, we are pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the *Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies,* etc. (CMS-1770-P).

The EHR Association's member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Our core objective is to collaborate to improve the quality and efficiency of care through innovative, interoperable health information technology adoption and use.

We appreciate this opportunity to provide CMS with our input and look forward to continued collaboration toward improved patient care.

Our detailed comments follow.

Sincerely,

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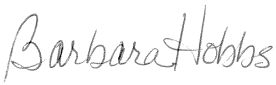

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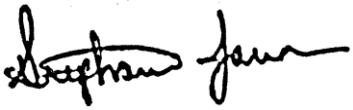

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Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Discarded amounts

Specifically, we propose to require the use of a separate modifier, the JZ modifier, to attest that there were no discarded amounts. To align with the JW modifier policy, the JZ modifier would be required when there are no discarded amounts from single-use vials or single-use packages payable under Part B for which the JW modifier would be required if there were discarded amounts.

The EHR Association strongly suggests additional time be given for the implementation of the required use of a new JZ modifier to be included on all claims for which single-use drug vials or packages payable under Part B are administered with no discarded amounts. For many EHR solutions, adding this modifier will require software modifications or business logic changes to reduce the burden of coding on our clients. The proposed starting date of January 1, 2023, does not offer enough time to ensure that our customers are aware of and able to meet this requirement.

Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs—Request for Information

Potential Future Definition of Digital Quality Measures (dQMs)

We seek comment on this potential future refined definition of dQM and feedback on potential considerations or challenges related to non-EHR data sources. (may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, laboratory systems, prescription drug monitoring programs (PDMPs), instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated data such as a home blood pressure monitor, or patient-reported health data), health information exchanges (HIEs) or registries, and other sources.) Do you have feedback on potential considerations or challenges related to non-EHR data sources?

As CMS evaluates the potential considerations or challenges related to non-EHR data sources and the future refined definition of dQM, the EHR Association emphasizes the cruciality of consistent standards that support data quality and interoperability. It is important to consider that while EHRs are certified to ensure data standardization, other sources of required data will not be. We recommend that all systems contributing to the aggregation of physician quality data should be subject to similar data standardization requirements.

Further, we note that dQMs based in part or in whole on data from non-EHR sources likely involve systems that have not broadly adopted FHIR-based access capabilities. This would likely lead to potentially common challenges with patient matching when source data crosses systems. CMS should

explain what they think the motivation will be for non-certified EHRs or systems other than EHRs to go through the expense of adding such API functionality to their software, as it is unclear to us that such systems will be updated without some form of incentive or mandate.

We strongly suggest CMS consider these dependencies in dQM development and timelines.

The EHR Association seeks clarification regarding the expected protocol for data collection and aggregation. As we move toward dQMs that rely on data not sourced from health IT already inclusive of FHIR-based interoperability functionality but instead from data sources across various health IT systems (including non-certified), it is clear that one data source cannot be reasonably expected to be an aggregator for such data. Also critical is the fact that only data that is clinically relevant to the healthcare provider should be ingested and held within an EHR. **EHRs should not be a required repository or aggregator of data from other sources**.

Data Standardization Activities to Leverage and Advance Standards for Digital Data
We seek comment on the specific Implementation Guides noted previously, additional Implementation Guides we should consider, and other data and reporting components (for example, data vocabulary/terminology, alignment with other types of reporting) where standardization should be considered to advance data standardization for a learning health system.

Including the following existing HL7 Implementation Guides:

- *US Core Implementation Guide;*
- *Quality Improvement Core (QI Core) Implementation Guide;*
- *Data Exchange for Quality Measures (DEQM) Implementation Guide; and*
- *Quality Measure (QM) Implementation Guide.*

We also continue to consider how best to leverage the ONC interoperability certification criteria related to implementing FHIR API technology to access and electronically transmit interoperable data for quality measurement

To advance data standardization for a learning health system, the EHR Association suggests the consistency of data definitions is fundamental to ensuring analysis and interpretations can be applied across the health system. The use of HL7 FHIR and CQL, which depend in large part on the use of industry-standard vocabulary, will substantially contribute to achieving such consistency.

USCDI+ will be necessary, but industry adoption requires adequate timelines. Any use of USCDI+ should have the same supporting availability of interoperability standards and value sets for included data classes and elements that are not a part of the base USCDI version that would be generally available at the time of dQM adoption. The same discipline of supporting standards for the USCDI+ should be maintained for the adopted recognized USCDI versions.

Allowing time to collect stakeholder feedback will be crucial in developing the USCDI+ Quality Measures standard and supporting implementation guides using QRDA and/or FHIR resources for quality measure reporting. As a community of EHR developers, we know that the allowed timeline for such programs

should reasonably be at least two years to develop, test, certify and deploy. Additionally, as other non-EHR data sources are being added to dQMs, those developers will also require time and resources to add the necessary APIs for quality measurement. **We request that CMS be mindful of these needs when establishing timelines.**

The EHR Association suggests that for any quality measure to be optimally efficient, it should be sourced from already documented and available data wherever possible. Thus, aligning Quality Improvement Core (QI-Core) with U.S. Core remains important to avoid expressing the same data differently in either mode.

Approaches to Achieve FHIR eCQM Reporting

We previously noted in the CY 2022 PFS final rule (86 FR 65379) the activities we are conducting to begin structuring and reporting eCQMs using FHIR. eCQMs are a subset of dQMs. We consider the transition to FHIR-based eCQM reporting the first step to dQM reporting, and a potential model for how future digital reporting can occur.

To support the transition, we continue to undertake and consider activities necessary for reporting of FHIR-based eCQMs and future dQMs:

- *In the near term, we plan to continue to convert current Quality Data Model (QDM)-based eCQMs to the FHIR standard and test the implementation of measures re-specified to FHIR and submission of data elements represented in FHIR through ongoing HL7 Connectathons.*
- *In the near term, we also plan to develop a unified CMS FHIR receiving system. This system would allow for a singular point of data receipt to be used for quality reporting requirements, and modernization of programmatic data receiving systems to leverage opportunities related to digital data.*
- *We are committed to working with implementers and partners to optimize interoperable data exchange to support FHIR-based eCQM reporting (for example, via FHIR APIs) and eventually other digital quality measures, while ensuring solutions and implementation that require patients to engage with technology also support health equity.*
- *In the near term, we plan to identify opportunities for the public to provide feedback on FHIR-based measure specifications prior to implementation, such as during measure development/conversion activities.*
- *We also plan to identify opportunities for collaboration with vendors and implementers via systems testing of FHIR-based eCQM reporting to ensure involvement in systems development.*
- *Finally, we are exploring venues for continued feedback on CMS's future measurement direction and data aggregation approaches in anticipation of FHIR-based API reporting of eCQMs.*
- *To support both near-term FHIR-based eCQMs and other future dQMs, as noted in section IV.A.4.a. of this proposed rule, we intend to continue engaging with standards development organizations to advance and maintain implementation guides to support the FHIR standard and API reporting of quality measures.*
- *We also anticipate that prior to the implementation of any mandatory FHIR-based eCQM reporting requirements within our quality programs, it would be necessary to undertake voluntary reporting of FHIR-based eCQMs to allow time to learn and enhance systems and processes, both internally and among providers and vendors.*

Generally, our members support the transition to FHIR-based quality reporting but have many questions regarding how this plan will be administered.

We request clarity on implementation timeframes.

- Is the 2025 target date envisioned for beta testing or the full utilization of FHIR-based eCQMs?
- What is the current confidence level of that target date, are further delays likely?
- Will there be a point at which there is a hard stop on eCQM measures after which no new QRDA-based eCQMs will be added and only FHIR measures are offered?

Many providers will not make a change until they are incentivized or required to do so. A prolonged and uncertain transition period requiring developers to simultaneously support both frameworks as changes are slowly adopted by providers would create avoidable additional burden, complexity, and cost. **The EHR Association requests clear transition timelines between eCQMs and dQMs and a commitment from CMS to drive adoption to meet them.**

Once the development of a unified CMS FHIR receiving system is complete, will the current model of annual quality report submissions remain, or will data be requested on a quarterly or perhaps ongoing basis?

Finally, to eliminate confusion regarding the difference between eCQMs and dQMs, the **EHR Association recommends CMS simply defines eCQMs as dQMs that are solely based on EHR data.**

We seek comments on approaches to optimize data flows for quality measurement to retrieve data from EHRs via FHIR APIs, and to combine data needed for measure score calculation for measures that require aggregating data across multiple providers (for example, risk-adjusted outcome measures) and multiple data sources (for example, hybrid claims-EHR measures).

Caution should be taken in scenarios such as this in which data is being pulled for quality measurement. For example, chart corrections or other updates that take place after a one-time data pull could result in inaccurate data collection. **We recommend that any data flow approach should also allow EHRs to push data to maximize accuracy.**

There is further concern that pulling data through current FHIR APIs may impact operational use and performance for providers. Asynchronous methods should be considered/permitted, including pushing the relevant data or a subscription method to indicate when the data set is ready to be picked up.

Approaches to Achieve FHIR eCQM Reporting.
We are seeking feedback on the following as described in section IV.A.4.d. of this proposed rule:
++ Are there additional venues to engage with implementors during the transition to digital quality measurement?
++ What data flow options should we consider for FHIR-based eCQM reporting, including retrieving data from EHRs via FHIR APIs and other mechanisms?
++ Are there other critical considerations during the transition?

Considering the concerns raised above with using current FHIR APIs, we repeat our previous recommendations that **CMS should work closely with the data source vendors to find optimum methods to share appropriate data**. This process need not be continuous, synchronous queries, but instead should include transmission of defined data sets on set intervals that can ensure data quality.

We also request clarification as to whether CMS expects single and/or bulk APIs to be central to this effort.

We encourage CMS to continue to engage with the EHR Association to gain additional helpful information based on our collective experience working with healthcare providers and further discuss the optimal approach to the development of dQMs. We welcome the opportunity to continue partnering to advance the goal of digital measurement.

MVP Development and Reporting Requirements

Proposed New MVPs

Through our established development processes for new MVPs (85 FR 84849 through 84856), we aim to gradually develop MVPs that are relevant and meaningful for all clinicians who participate in MIPS. We are proposing five new MVPs.

It is concerning that very few of the seven existing and five proposed MVPs can be reported using exclusively eCQMs, given the significant resources that have gone into developing this quality measurement approach. **The EHR Association urges CMS to leverage the investments that the provider community has made in advanced, interoperable Health IT by offering four or more eCQMs in each MVP.** This will reduce the burden on provider organizations and health IT developers by limiting the amount of rework necessary when disparate reporting mechanisms are required within a given MVP.

More generally, we believe it is late to be adding MVP measures for 2023, especially if they will not be finalized until Nov/Dec 2022 with an expectation that they would become effective in January 2023. November or December finalization is too late for developers to develop, test, and deploy successfully to clients.

The Implementation Guide for MVPs is directed toward clinicians, not Health IT developers, and much detail is missing from a developer perspective. CMS should develop assets and processes that are geared toward developers to allow us to support clinicians. **We repeat our request that CMS establish a predictable implementation timeline that releases all necessary details one year in advance of the implementation of an MVP itself.** MVPs are new, complex programs that require sufficient time to properly understand, create, test, and deploy.

Subgroup Reporting

Definitions of a Single Specialty Group and a Multispecialty Group

We propose to modify the definition of a single specialty group at §414.1305 to state that a single specialty group means a group that consists of one specialty type as determined by CMS using Medicare Part B claims. We also propose to modify the definition of a multispecialty group at § 414.1305 to state that a multispecialty group means a group that consists of two or more specialty

types as determined by CMS using Medicare Part B claims. We seek public comment on these proposals and request comment on additional data sources CMS could use to determine a group's specialty type or types.

We generally support the proposals and **recommend CMS provide a tool or API to allow provider organizations a means to determine if a TIN has been categorized as a single specialty or multi-specialty group.**

Subgroup registration requirements

Propose that an individual eligible clinician, as represented by a TIN-NPI combination may register for no more than one subgroup within a group's TIN

The EHR Association has no concerns regarding proposed subgroup registration requirements but **suggests that clinicians' registration information carry forward from the previous year by default, rather than require repeat registration selection each year.**

Selection of MIPS Quality Measures

MIPS Quality Performance Category Health Equity Request for Information

As we consider the possible future inclusion of additional health equity measures in MIPS in future years, we seek public comment on the following questions in order to better understand the type and structure of health equity measures that would be appropriate for the implementation in MIPS.

As CMS and ONC work to identify nomenclature to be used for SDOH and health equity quality measurement, **the EHR Association again stresses the need for consistent value sets and nomenclature from one quality forum to the next**. It is also critical that reporting requirements not precede the availability of standards-based data approaches currently under development, even where we understand the eagerness at CMS to see progress in this critical area.

Assessing the Collection and Use of Self-reported Patient Characteristics

How important is it to use a standardized tool with coded questions and data elements to collect self-reported patient characteristics across clinicians and practices and what challenges and limitations are present without the use of a coded and standardized instrument?

Again, consistency is crucial for collecting and comparing any reported measures. While having various assessment tool options could be perceived as beneficial because it would allow providers flexibility to choose a tool that best meets the needs of their organization and patients, **the use of a consistent value set for assessment outcomes will be necessary to enable effective interoperability.**

Is the proposed quality measure, "Screening for Social Drivers of Health," appropriate for use in the foundational layer of MVPs? If so, then such inclusion would require most or all eligible clinicians to screen for social drivers of health during patient encounters.

We support the need to evaluate the quality of care for patients with social risk factors and the value of understanding the status of health and health care equity. As such, we support the collection of the

proposed SDOH quality measure. However, given that this measure is brand new, we do not recommend making it a part of the foundational layer at this time. Instead, the **EHR Association suggests a period of adjustment to allow providers to become familiar with this screening practice before incurring penalties if issues arise, pushing out a more mandated approach until one or two years later.**

Assessing Patient-Clinician Communication

We are considering the development of a patient-reported outcome measure that assesses the receipt of appropriate language services and/or the extent of clinician-patient communication. We are seeking feedback on the feasibility and usefulness of such a measure(s). If we developed such measure(s), it may be considered for the foundational layer of MVPs.

Please see the response above regarding the use of brand-new measures as foundational layers of MVPs. **The EHR Association suggests a period of adjustment to allow providers to become familiar with this patient-reported measure incurring penalties.**

Developing Quality Measures that Address Amputation Avoidance in Diabetic Patients
Request for Information

We may also consider the development of a composite quality measure. Would the single measures comprising the composite be appropriate? Why or why not? What would be the benefits and/or unintended consequences of a composite quality measure concept?

Quality measures should offer a positive impact to clinical users and their facilities through the opportunity for improvements in patient care and operational efficiencies. Aggregation across multiple stakeholders and measures diminishes that benefit by diluting accountability because combined scores make it difficult to identify who is responsible for improvements and limit the ability to manage performance on the measure. To achieve maximum accountability and usefulness, **the EHR Association recommends that domains should be calculated and reported separately, with a single outcome per measure.** Merging domains creates unnecessary complexity and diminishes the utility of the measure, as it limits clinical users' ability to monitor and improve their performance without the transparency of clearly identifying the action being measured and which domain failed.

Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians
Changes to the Query of Prescription Drug Monitoring Program Measure under the Electronic Prescribing Objective

Beginning with the performance period in CY 2023, we are proposing to require MIPS-eligible clinicians to report the Query of PDMP measure (which requires reporting a "yes/no" response) for the Promoting Interoperability performance category. We are also seeking feedback on ways CMS can ensure coordination and alignment with varying State requirements for PDMPs.

Varying state regulations dictate which exact data points and the extent to which PDMP-sourced data are allowed to be stored in an EHR, and thus whether this measure can be reported as a performance-based measure. This variability can still be accounted for with the current yes/no attestation method but transitioning to a true numerator/denominator measure in the future would impose burdensome

workflow requirements on clinicians in some states, who would need to attest to each time the PDMP was accessed/reported to/pulled from. **We recommend maintaining a yes/no attestation.**

Proposed Changes to the Query of PDMP Measure to Include Schedules II, III, and IV

Proposed Measure Description: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS-eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.

States currently impose differing requirements regarding the schedule of drugs that must be / can be reported to PDMPs. Federal policymaking must take this variance into account when determining requirements, as the variation clearly undermines the value of the apples-to-apples comparisons that are intended.

Additionally, we request additional detail on drugs to be included in the Query of PDMP measure. For example, not all Schedule III drugs are opioids (e.g., ketamine). Does CMS anticipate that querying would be required for all Schedule III drugs or just opioids?

Health Information Exchange (HIE) Objective: Proposed Addition of an Alternative Measure for Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

We are proposing to add an additional measure through which a MIPS-eligible clinician could earn credit for the Health Information Exchange Objective by connecting to an entity that connects to a QHIN or connecting directly to a QHIN.

Generally, the EHR Association supports any opportunity to offer providers flexibility in meeting measures/objectives. We agree that it would be premature to require hospitals to attest to participation in TEFCA, as it was intended to be voluntary, and the network is not yet facilitating live exchange in production. **Therefore, we support making this a measure option in the HIE Objective.**

Proposed Changes to the Duration of Active Engagement Options

Beginning with the performance period in CY 2023, we are proposing that MIPS-eligible clinicians may spend only one performance period at the Pre-production and Validation level of active engagement per measure and that they must progress to the Validated Data Production level in the next performance period for which they report a particular measure.

Hospitals do not have the sole ability to move from one level of active engagement within the Public Health and Clinical Data Exchange model to the next and cannot control how quickly their state or public health agency is able to work with them to move from testing to production. Therefore, **the EHR Association suggests strongly that it would be inappropriate to hold hospitals accountable for moving from one level of active engagement to the next within a particular reporting period.**

Request for Information on Third Party Intermediary Support of MVPs

Given public comments on the challenges of the current requirement to support all quality measures within an MVP (86 FR 65543), we are requesting input on the following —

Should third-party intermediaries have the flexibility to choose which measures they will support within an MVP?

The EHR Association enthusiastically supports giving third-party intermediaries the flexibility to choose which measures they will support within an MVP. EHRs do not typically support MIPS quality measures; this is the functionality of registries. Further, some registries do not support all eCQM measures. It is necessary that third-party intermediaries be able to select the measures they can support in order to allow them to provide a better solution for our users.

The original policy is too strict and creates limitations in the variety of measures and vendors third-party intermediaries can use, which ultimately makes it harder for clinicians. The ability to fulfill reporting requirements with a vendor of choice should be permitted, even if that includes the use of multiple vendors.

To avoid unnecessarily requiring providers to engage with excessive intermediaries, **the EHR Association recommends a caveat specifying that while an intermediary may select which measures they will support, they must support at least four measures within a submission collection, unless there are less than four of that collection submission type within the MVP**.

Offering at least four of each of the collection and submission types in each MVP would reduce the burden on providers by allowing for flexibility in the choice of submission preference. Current MVP formats also force providers to use a registry, incurring unnecessary additional costs.

Further, we encourage CMS to continue to support the use of eCQMs by not removing eCQMs that are duplicative to MIPS measures, as has happened in past years. **The EHR Association asks that CMS consider bringing back eCQMs that were removed and create new eCQMs that are parallel to the MIPS CQMs so that they will be available to the specialists who want to report without the need for a registry.** This would make things easier for participating providers.

What type of technical educational resources would be helpful for QCDRs, qualified registries, and Health IT vendors to support all measures within an MVP?

In order to support all measures within an MVP, the EHR Association recommends that CMS make all measures available in both eCQMs and MIPS CQMs.

Should we also inquire about the requirements for EHR Vendors who do not serve as 3rd party intermediaries and their responsibility to support MVPs?

The EHR Association would appreciate more information for EHR developers who are not third-party intermediaries. Provided materials currently focus on third-party intermediaries, but there is a lack of clarifying public information regarding EHR developers who are not third-party intermediaries and how that affects their responsibility to their clients. As described above, many of these developers have made investments in eCQM infrastructure required in ONC certification and want to leverage eCQMs to support their customers in MVPs.

Previously Finalized Quality Measures Proposed for Removal in the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

CMS66 proposed removal of Functional Status Assessment for TK Replacement - We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to measure Q470: Functional Status After Primary Total Knee Replacement. The process measure Q375 is only assessing whether pre- and post-assessments were completed; however, outcome measure Q470 requires a certain post-surgical PRO-PM score to meet performance.

The EHR Association does not support the removal of the Functional Status Assessment for TK Replacement measure. CMS states it will be removed because it is duplicative of Q470, but we also have been asking CMS to include more eCQMs in MVPs.

We note that Q470 is included in MVP Improving Care for Lower Extremity Joint repair. Instead of removing this eCQM for being duplicative, we ask CMS to provide more flexibility for providers to choose how to report, *thus increasing participation.* We also want CMS to offer developers options to provide measures to their customers. As stated above, some EHR developers are not third-party intermediaries, and even those who cannot offer all Registry measures.

Please note that the Lower Extremity Joint Repair MVP only offers two eCQMs currently. If this were included in the MVP, developers could offer three eCQMs and would have the option to choose a claims measure to fulfill the set.

As a general rule, we do not support the removal of eCQMs when the only reason is that they are duplicative of MIPS CQMs, given the implications for fewer choices and a more difficult reporting process.