June 17, 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 our 30 member companies, the HIMSS Electronic Health Record (EHR) Association is pleased to offer our comments on the FY23 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) Prospective Payment System and Proposed Policy Changes Proposed Rule (CMS-1771-P). We appreciate this opportunity to provide input on CMS' efforts to facilitate interoperability and to reduce clinician burden by focusing on high-value reporting measures.

EHR Association member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable health information technology.

We offer the following considerations regarding the proposed rulemaking.

Sincerely,

Hans J. Buitendijk
Chair, EHR Association
Cerner Corporation

David J. Bucciferro
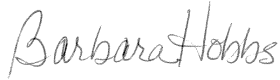Vice Chair, EHR Association
Foothold Technology

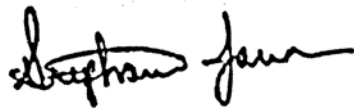**HIMSS EHR Association Executive Committee**

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Electronic Health Record Association

Comments on the FY23 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) Prospective Payment System and Proposed Policy Changes Proposed Rule (CMS-1771-P)

Reduction of Hospital Payments for Excess Readmissions

Seeking comment on updating the [Hospital Readmissions Reduction Program] to incorporate provider performance for socially at-risk populations.

EHR Association Response

There are several important terms that should be codified for clarity and ease of implementation by providers and software developers. For example, before CMS can impose adjustments to a hospital's reimbursement based on performance for socially at-risk populations, it must clearly define what is considered a "socially at-risk population" and specify what reporting would be required in support of the update. Exactitude is critical.

Codification of these definitions and new reporting requirements must be implemented and supported by health IT developers, which requires time to develop, test, and deploy. In regard to this goal, EHR Association recommends CMS adopt standard data definitions for social determinants of health risk areas and risk screeners, such as those currently being developed by HL7's Gravity Project, once those standards are balloted and finalized. We advise against promulgating requirements for the exchange or reporting of SDOH data prior to the availability of those consensus-based standards – historically, we have seen that when ONC or CMS have taken a non-standards-based approach to attempt to speed exchange, and then applied a standards requirement in future rulemaking, it has led to confusion, inefficient and burden-intensive exchange and/or reporting efforts, and the application of significant resources required to redo software development. Instead, we suggest that CMS focus on maximizing SDOH data that is already captured by and reportable from certified EHRs.

Hospital Inpatient Quality Reporting (IQR) Program

(2) Screening for Social Drivers of Health beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination
(3) Screen Positive Rate for Social Drivers of Health beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination

EHR Association Response

The EHR Association fully agrees with the importance of screening for and sharing SDOH data across healthcare and community-based organizations to improve patient outcomes. The Association has urged Congress to improve general access to screening tools, which is currently limited due to intellectual property limitations, and fund initiatives to support a closed-loop patient referral process to connect patients to community resources that help address SDOH

needs. General access to named standard screening tools, such as PRAPARE, The EveryOne Project, and Health-Related Social Needs Screening Tool, would help define what it means to "screen positive," which would be necessary for consistent reporting. Without the clarity offered by standard screeners, CMS' proposed reporting timeline beginning in CY 2023 is not feasible.

While a standard screener is necessary for accurate reporting, we remind CMS that EHR developers would need sufficient time to incorporate screening and reporting tools fully into EHR systems. In the long term, standardization of SDOH screening data will be crucial, but regulators will need to allocate the required time and resources to build the necessary infrastructure.

(4) Cesarean Birth electronic clinical quality measure (eCQM) with inclusion in the measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination
(5) Severe Obstetric Complications eCQM with inclusion in the measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination

EHR Association Response
The proposed 2023 timeline for adding these eCQMs to the measure set is much too fast, especially when considering the requirement to certify these measures. The soonest this would be feasible is 2024.

Further, the EHR Association expresses concern regarding the ambiguity created by the introduction of new eCQMs as CMS has expressed a goal to transition to Digital Quality Measures (dQMs). Can you clarify whether eCQMs, in effect, represent a subset of dQMs– particularly when used to represent individual provider organization performance? Does CMS envision eCQMs and dQMs would both be required going forward (a concept we have indicated in past rule-making would be tremendously burdensome for the software community to support)?

(6) Hospital-Harm—Opioid-Related Adverse Events eCQM (NQF #3501e) beginning with the CY 2024 reporting period/FY 2026 payment determination

EHR Association Response
More information is necessary to evaluate this proposed additional measure, such as clarity regarding which opioids CMS seeks to be included in calculations of "opioid-related adverse events." Is that measure to be based on prescription history within that provider's EHR, or more broadly from a state PDMP? Or is it to reflect patient-reported or test-deduced opioid use?

We are proposing changes to current policies related to eCQMs and hybrid measures: (1) A proposal to modify the eCQM reporting and submission requirements to increase the number of eCQMs to be reported beginning with the CY 2024 reporting period/FY 2026 payment determination

EHR Association Response

The EHR Association appreciates a period of 18-24 months for the development necessary to implement changes. We agree that the increase in the number of eCQMs to be reported seems reasonable.

Additionally, we are seeking comments on ongoing ways we can advance digital quality measurement and use of Fast Healthcare Interoperability Resources (FHIR).

EHR Association Response

The EHR Association supports the overall direction toward using CQL, HL7® FHIR®, and FHIR-based APIs to define and report on both quality measures and/or source data for the quality measures. Having a common expression language of these measures and how the source data is made available promotes consistency and re-use of the same data relevant to different purposes, whether across measures or any other interoperability use case using FHIR-based approaches, thus having a consistent systems/data view across all HIT.

We must be more specific about the meaning of "FHIR APIs" that is being contemplated with the transition from the current platform. Using existing FHIR US Core-based APIs may not be an ideal approach, depending on the volume of data being considered and the frequency of access. FHIR Bulk Data may be better suited to avoid taxing organizations' production databases. We also anticipate that the FHIR resources needed to calculate dQMs may go beyond those available through FHIR US Core-based APIs. The complexity further increases as we progress toward dQMs that are not sourced from health IT that already support some level of FHIR-based interoperability but instead from data sources across various health IT (including non-certified), as one data source cannot be reasonably expected to be an aggregator for such data. Lastly, switching from non-FHIR/CQL measure definitions and QRDA reporting formats to direct queries against the source data using FHIR-based APIs does not in itself improve the quality of the resulting measures. Much effort will be necessary to ensure the source data is accurate and complete.

Therefore, we suggest CMS publish a thoughtful, deliberative roadmap that focuses on how source systems can generate the relevant source data set into an agreed-upon FHIR-based format mapping to the source health IT's internal data structures, before attempting to access such data directly through data element level FHIR-based APIs. This approach would also enable more focus initially on data mapping, quality, and completeness, and on patient matching across HIT to ensure data is properly correlated for dQMs beyond EHRs. Thus, starting with dQMs that can be sourced from EHRs, which are already further along the path of FHIR adoption and have data mapped to many of the relevant FHIR resources, would be appropriate. As other health IT solutions advance their FHIR capabilities and patient matching/linking is more thoroughly addressed, other dQMs can be deployed appropriately.

Medicare Promoting Interoperability Program

For CY 2023, we are proposing several changes to the Medicare Promoting Interoperability Program. Specifically, we are proposing: (1) to require and modify the Electronic Prescribing Objective's Query of

Prescription Drug Monitoring Program (PDMP) measure while maintaining the associated points at 10 points beginning with the EHR reporting period in CY 2023

EHR Association Response
Varying state regulations dictate the extent to which PDMP-sourced data and which exact data points 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 attestation method, but transitioning to a true numerator/denominator measure 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.

(2) to expand the Query of PDMP measure to include Schedule II, III, and IV drugs beginning with the CY 2023 EHR reporting period;

EHR Association Response
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.

We further 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? Clarity is important here.

(3) to add a new Health Information Exchange (HIE) Objective option, the Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) measure (requiring a yes/no response), as an optional alternative to fulfill the objective, beginning with the CY 2023 EHR reporting period;

EHR Association Response
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, since it was intended to be voluntary and the network is not yet facilitating live exchange in production, and therefore support making this a measure *option* in the HIE Objective.

(4) to modify the Public Health and Clinical Data Exchange Objective by adding an Antibiotic Use and Antibiotic Resistance (AUR) measure in addition to the current four required measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting) beginning in the CY 2023 EHR reporting period;

EHR Association Response
Conceptually, the EHR Association supports this measure. We would, however, recommend CMS delay implementation by one year, as many hospitals will need to license and implement certified modules.

(5) to consolidate the current options from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective and to require the reporting of active engagement for the measures under the objective beginning with the CY 2023 EHR reporting period

EHR Association Response

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 other public health agency is able to work with them to move from testing to production. Therefore, it would be inappropriate to hold hospitals accountable for moving from one level to the next within a particular reporting period, as it is not within their control.

Solicitation of Comments

++ Do you have feedback on potential considerations or challenges related to non-EHR data sources?

EHR Association Response

We note that dQMs based in part or in whole on data from non-EHR sources likely involve systems that have not advanced far with FHIR-based access capabilities, which could introduce potentially common challenges with patient matching when source data crosses systems. We strongly suggest CMS considers these dependencies in dQM development and timelines.

Data Standardization Activities:
++ Do you have feedback on the specific implementation guides we are considering, additional FHIR implementation guides we should consider, or other data and reporting components where standardization should be considered to advance data standardization for a learning health system?

EHR Association Response

To advance data standardization for a learning health system, we suggest the consistency of data definitions is fundamentally critical to ensure analysis and interpretations can be applied across the health system. The use of HL7 FHIR and CQL, which depends in large part on the use of industry-standard vocabulary, will substantially contribute to achieving such consistency.

Approaches to Achieve FHIR eCQM Reporting
++ Are there additional venues to engage with implementors during the transition to digital quality measurement?

EHR Association Response

We encourage CMS to continue engaging through Connectathons. We also ask for details on the prioritization of measures. Given timing concerns we began raising in 2021, clear communication regarding prioritization will help ensure adequate time is provided to develop and adopt dQMs in addition to all other FHIR projects.

++ 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?

EHR Association Response

As stated above, The EHR Association supports the overall direction toward using CQL, HL7® FHIR®, and FHIR-based APIs to define and report on both quality measures and/or source data for the quality measures. Having a common expression language of these measures and how the source data is made available promotes consistency and re-use of the same data relevant to different purposes, whether across measures or any other interoperability use case using FHIR-based approaches, thus having a consistent systems/data view across all HIT.

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Advancing the Trusted Exchange Framework and Common Agreement–Request for Information

What are the most important use cases for different stakeholder groups that could be enabled through widespread information exchange under TEFCA? What key benefits would be associated with effectively implementing these use cases, such as improved care coordination, reduced burden, or greater efficiency in care delivery?

EHR Association Response

We note that for treatment purposes, substantial data is already shared through national networks (e.g. Carequality, CommonWell, eHealth Exchange) and in numerous iterations at the local and regional levels. The TEF has the opportunity to further expand on this, particularly for non-treatment use cases, while advancing data sharing beyond document exchange, such as FHIR-based data access. Enabling access to a more complete record enables improved decision-making and care coordination.

What are key ways that the capabilities of TEFCA can help to advance the goals of CMS programs? Should CMS explore policy and program mechanisms to encourage exchange between different stakeholders, including those in rural areas, under TEFCA? In addition to the ideas discussed previously, are there other programs CMS should consider in order to advance exchange under TEFCA?

EHR Association Response

Data sharing for purposes of use beyond medical treatment holds tremendous possibility for advancing the goals of CMS programs and healthcare delivery. While many such capabilities are available through existing national networks, adoption is not as widespread. We suggest that CMS work with ONC and other federal health agencies to identify where the TEF would be uniquely positioned to advance such use cases under the right policy controls. For example, CMS, ONC, and CDC could collaborate to promote the onboarding of state and local public health agencies to exchange via the TEF for case reporting and other public health needs.

We would also suggest that the TEF has the ability to enable new or emergency response means of data sharing if the framework would support the enablement of the use of its common agreement without having to use the QHIN's brokered services. One example is the collaboration between APHL, eHealth Exchange, and Carequality that made it possible to push case reports to APHL without needing to establish separate data-sharing agreements with each provider, instead using existing Direct and IHE XDR standards that did not have to be brokered by QHINs. Such flexibility would enable more rapid responses where time-sensitive gaps need to be filled or the opportunity to explore new innovations that only need to rely on a common agreement and in cases where record location is essential, the record locator services are provided by the QHINs.

How should CMS approach incentivizing or encouraging information exchange under TEFCA through CMS programs? Under what conditions would it be appropriate to require information exchange under TEFCA by stakeholders for specific use cases?

EHR Association Response

The EHR Association suggests that it would only be appropriate to require information exchange under the TEF when it is less expensive or more ideally, free. Many of our customers lack the necessary budget to spend any additional funds on TEF connection or participation, and the industry needs essentially everyone to participate in order for the associated exchange effort to be effective. The Federal government should consider investing in building out the TEF, as well as covering associated costs similar to other critical national infrastructure, if exchange through that mechanism is a priority.

What concerns do commenters have about enabling exchange under TEFCA? Could enabling exchange under TEFCA increase burden for some stakeholders? Are there other financial or technical barriers to enabling exchange under TEFCA? If so, what could CMS do to reduce these barriers?

EHR Association Response

We note that as the TEF is being established with overlapping capabilities with existing national networks, the cost of connecting to multiple networks is a concern. At the time of this RFI, the cost structure is not yet available, thus creating some level of uncertainty. We suggest that CMS work with ONC to help ensure that the TEF is not increasing the cost footprint of national networks, participating providers, or health IT software development partners.

Hybrid Measures: Certification and File Format Requirements

In the FY 2022 IPPS/LTCH PPS final rule, to align with the health IT certification requirements for eCQM reporting, we finalized to require hospitals to use only certified technology that has been updated consistent with the 2015 Edition Cures Update to submit hybrid measure data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years (86 FR 45421). We are not proposing any changes to these policies in this proposed rule.

EHR Association Response

During a recent CMS and EHR Association workgroup call, we discussed the certification requirements of hybrid measures. It is our understanding that CMS does not consider the hybrid measures to be eCQMs and, as a result, EHR developers would not be subject to the certification requirements of eCQMs that specify that all eCQMs must be certified to 170.315 (C1-C3). As we understood from the call, CMS believes there is no certification requirement because there is no measure logic for the electronically-reported portion of the hybrid measures. We ask that CMS verify for the developer community if our interpretation is correct that hybrid measures require the use of 2015 Edition-certified software, but that this is not the case for individual measure certification 170.315 C1-C3 for the 2 hybrid measures CMS 529 and CMS 844 in this final rule.