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June 28, 2021

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1752-P
Submitted electronically http://www.regulations.gov

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care
        Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed
        Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting
        Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals;
        Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the
        Medicare Shared Savings Program

Dear Administrator Brooks-LaSure:

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide
input on the FY2022 Hospital Inpatient Prospective Payment Systems notice of proposed
rulemaking (NPRM).

AMIA is the professional home for more than 5,500 informatics professionals, representing
frontline clinicians, researchers and public health experts who bring meaning to data, manage
information and generate new knowledge across the health and healthcare enterprise. As the voice
of the nation's biomedical and health informatics professionals, AMIA plays a leading role in
advancing health and wellness by moving basic research findings from bench to bedside, and
evaluating interventions, innovations and public policy across settings and patient populations.

We are gratified that CMS has proposed in this NPRM to require reporting of four of the measures
associated with the Public Health and Clinical Data Exchange Objective of the Promoting
Interoperability Program. The COVID-19 public health emergency has shown a bright light on the
deficiencies of our nation's public health infrastructure. As long-time proponents of proposals to
emphasize public health reporting in Promoting Interoperability, we view this set of proposals as an
excellent step toward improving real-time, electronic data exchange from hospitals and providers to
public health agencies.

We are further pleased to see CMS recognize through a request for information (RFI) on digital
quality measures (dQMs) that the utilization of health IT should be an enabler of quality care, rather
than an end unto itself. It is for this reason that we continue to believe that rather than attempting to
solidify Promoting Interoperability's numerator/denominator construct as dQMs by 2025, CMS
should instead transition to, or at least develop the option of, rewarding eligible hospitals and CAHs

for reporting hospital-developed improvement activities ("Inpatient Improvement Activities) that necessarily leverage certified health IT (CEHRT)

Below we offer additional comments and recommendations in response to select questions and RFIs in the proposed rule. We hope our comments are helpful as you undertake this important work. Should you have any questions or require additional information, please contact Scott Weinberg at scott@amia.org or 240-479-2134. We thank CMS for the opportunity to comment and look forward to continued dialogue.

Sincerely,

Patricia C. Dykes, PhD, RN, FAAN, FACMI
AMIA President and Chair, AMIA Board of Directors
Program Director Research
Center for Patient Safety, Research, and Practice
Brigham and Women's Hospital

(Enclosed: Detailed AMIA Comments regarding CMS' FY22 IPPS NPRM)

Proposed EHR Reporting Periods in CY 2023 and CY 2024

For CY 2023, CMS proposes to continue the EHR reporting period of a minimum of any continuous 90-day period for new and returning participants in the Medicare Promoting Interoperability Program. For CY 2024, it is proposing an EHR reporting period of a minimum of any continuous 180-day period for new and returning participants in the Medicare Promoting Interoperability Program.

AMIA Comments: AMIA agrees with CMS's reasoning in the NPRM and supports the continuation of this flexibility that will allow more eligible hospitals and CAHs to successfully participate in the PI Program in CY 2023. Further, we support increasing the number of days in the reporting period for CY 2024. The 90-day reporting period flexibility was previously warranted, but we believe that as participants have gained more experience with EHR and reporting, the number of days should be increased. While we also believe that the effect on provider burden will be minimal, we strongly encourage CMS to monitor the effect of a 180-day reporting period on workflow and provider burden.

Proposed Changes to the Query of Prescription Drug Monitoring Program Measure under the Electronic Prescribing Objective

CMS is again proposing to make the Query of PDMP measure optional in CY 2022, while increasing its associated bonus points from 5 points to 10 points.

AMIA Comments: AMIA supports the proposal to make the Query the PDMP measure optional for another year. In previous years, we did not believe such a measure should be required until certified health IT (CEHRT) supported it. We recommended that CMS work closely with ONC and its Certification Program to ensure standards are adopted by health IT to enable functionalities in support EHR-PDMP integration. We nonetheless note, as does the NPRM, the recent progress in the availability of both standardized APIs and updated standards for e-prescribing within CEHRT.

To what degree would all eligible hospitals and CAHs be prepared to report on the current attestation-based Query of PDMP measure in the near future? What additional considerations would need to be addressed before transitioning to a performance-based version of the measure?	There are three variables that factor into an eligible hospital's readiness to report on the Query the PDMP measure: the state of the EHR, the specific state PDMP's readiness, and the level of integration with the e-prescribing infrastructure and platform. We note that hospitals who are using up-to-date CEHRT should be able to meet this measure easily and routinely. While we could support making this measure required in the near future, we do not support transitioning the measure to a performance-based one and urge CMS to keep the measure attestation-based.
Would changes to the Query of PDMP measure be necessary to accommodate other technical approaches that may be implemented	We recommend adding an attestation statement to the measure as to whether other systems were used to obtain prescription data.

in the future, such as exchange of information with a PDMP or with multiple PDMPs using HL7® FHIR®?	
What, if any, exclusions should be made available as part of the measure's specifications with regard to eligible hospitals and CAHs?	We do not believe there should be exclusions for this measure.
When will State PDMPs be ready to effectively exchange data with provider systems using HL7® FHIR® to support this measure? What are the most common standards and approaches used to access PDMP data through provider systems currently?	We note that APIs have been activated in some PDMPs, but we do believe they are widely used yet.
What technical considerations exist for intrastate vs. interstate PDMP queries? How could health information exchange networks play a role in expanding access to PDMP data? In what ways could FHIR® applications be supported to safely share PDMP data within a clinician's workflow?	Health information exchanges (HIE) have strong potential in expanding access to PDMP data. However, while many, if not most state PDMPs can access data from other states, the ability of HIEs to provide controlled substance prescription and fill data (depending on state) remains to be seen. These interfaces are not FHIR-based at present, and an effort to convert well-functioning PDMP query-response interfaces to FHIR does not appear to us to be a top priority.

Proposed Changes to the Provide Patients Electronic Access to Their Health Information Measure Under the Provider to Patient Exchange Objective

CMS is proposing to, beginning in CY 2022, modify the Provide Patients Electronic Access to Their Health Information measure to require eligible hospitals and CAHs to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely and using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT. The proposed requirement would include all patient health information from encounters on or after January 1, 2016.

AMIA Comments: AMIA supports this proposal, including the proposed January 1, 2016 look-back date. We appreciate CMS's efforts to align the date with the date of service start date finalized in the Patient Access and Interoperability final rule.

Health Information Exchange Objective: Engagement in Bi-directional Exchange Through Health Information Exchange (HIE)

CMS is proposing to add a new HIE Bi-Directional Exchange measure to the HIE objective as an optional alternative to the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health

Information measure. This measure would be reported by attestation and would require a yes/no response.

AMIA Comments: AMIA supports the inclusion of the proposed optional HIE Bi-Directional Exchange measure and is gratified to see that CMS is proposing that this measure be reported by attestation, requiring a yes/no response. We have argued previously[1] that CMS should be charting a course towards ending numerator/denominator measurement and we see this measure as another step in that direction.

We further applaud CMS for the proposal that to successfully attest to this measure, the eligible hospital or CAH must use the capabilities defined for CEHRT to engage in bi-directional exchange via the HIE. We believe that the eligible hospital or CAH's CEHRT should be integrated with the HIE for purposes of bidirectional information exchange and the clinicians can engage in such exchange without leaving the EHR environment. Thus, we fear that the third attestation statement that, "Using the functions of CEHRT to support bi-directional exchange with an HIE." is not specific enough. As currently written, it may even allow for the use of non-integrated HIEs that are easy to join, but do not support information exchange in a practical sense. We therefore recommend that certain specific CEHRT certification criteria be mentioned as being involved in the exchange of data via an HIE, such as the API criteria, the transition of care criterion, or the clinical information reconciliation and incorporation criterion, as defined by the 21st Century Cures Act final rule.

Finally, we note that that there is no consensus opinion on what an "HIE" is. One approach may be to allow eligible clinicians to select from a CMS-approved list whether they participate in open, regional HIEs, or vendor-specific or private HIEs, such as Epic's CareEverywhere (recognizing its potential limitations in exchanging data with open or regional HIEs). Further criteria could state that any other eligible hospital in the attesting clinician's medical service area must also be able to exchange their data via the HIE if they choose to do so.

CMS should also support the eHealth Initiative or the Strategic Health Information Exchange Collaborative (SHIEC), which is a national collaborative representing HIEs and their strategic business and technology partners. We further welcome CMS's commitment in the NPRM to explore ways to provide further guidance and/or update this measure to align with the use of health information networks that participate in the Trusted Exchange Framework and Common Agreement (TEFCA) in the future. CMS should continue to engage with the Sequoia Project, the recognized coordinating entity named by ONC to create the Common Agreement component of the TEFCA.

Modifications to the Public Health and Clinical Data Exchange Objective

CMS is proposing to require four of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the EHR reporting period in CY 2022: Syndromic

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[1] See AMIA's comments on the CY2020 PFS NPRM: https://www.amia.org/sites/default/files/AMIA-Response-toCY2020-PFS-NPRM-Response.pdf

Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting.

AMIA Comments: AMIA enthusiastically supports this proposal. Even prior to the COVID-19 pandemic, we urged[2] CMS to make public health reporting a higher priority. Specifically, we recommended that "CMS evaluate effective priorities for nationwide interoperability between the public and private health sector to enhance coordination of care activities, reduce physician and administrative burden, and best manage the cost of public health." We are thus thrilled that CMS has proposed to elevate these important public health measures. The data collected will be invaluable to tracking disease resurgence, monitoring outbreaks, and determining efficacy of vaccines and their boosters, for both COVID-19 and other public health threats.

We nonetheless urge CMS to use all policy levers at its disposal to elevate the public health objective even more. First, we reiterate our recommendation[3] to increase the total points available for the public health objective from 10 points to 20. CMS has demonstrated its commitment to public health with the proposal to requires all four measures, and this commitment should be reflected in the weighting of the points, as well.

Second, CMS should work with ONC to identify and require adherence to existing standards. Where such standards exist, adherence to them should be required to meet the Promoting Interoperability measures. For example, electronic case reporting could be achieved through participation in eCR Now, or by adhering to the HL7 CDA R2 eICR or FHIR eCR implementation guides, as referenced in ONC optional certification.

Finally, CMS should specify that reporting must also be as complete as possible. In order for them to be able to attest "yes" to actively sending data to a public health agency for the four use cases, providers and hospitals must also attest that the connections send all of the necessary information as part of the established feeds. For example, electronic case and electronic lab reports must include phone numbers, patient address, and race/ethnicity data at a greater than 95 percent completeness. Completeness of race and ethnicity data is critical to support health equity during the COVID-19 response and all reportable conditions. Additionally, complete information on reporter, provider, performing facility, and specimen type is integral to timely public health investigation and follow up. The USCDI can serve as a guidepost for the data that must be included. Attestations to the measures must confirm that they are sending complete data according to the percent selected, which can be verified with audits.

SAFER Guides

CMS is proposing to add a new SAFER Guides measure to the Protect Patient Health Information objective beginning with the CY 2022 EHR reporting period. An eligible hospital or CAH would

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have to attest to having conducted an annual self-assessment of all nine SAFER Guides, at any point during the calendar year in which the EHR reporting period occurs, with one "yes/no" attestation statement accounting for a complete self-assessment using all nine guides.

AMIA Comments: AMIA supports CMS efforts to understand and address patient safety issues that may arise due to use of health IT, and thus supports the inclusion of this measure for CY 2022. We previously supported efforts to promote use of the SAFER Guides and policies to incentivize providers to use them and are thus please with this proposal. We further note that the same notion of incentive should apply to improving providers' cyber hygiene, in addition to health IT safety posture. We reiterate our view that CMS should abandon the construct of measure reporting in favor of an activity-based approach, which would enable organizations to demonstrate clinically meaningful use of health IT for their specific patient populations and priorities, without forcing novel enactment strategies. The approach we envisioned would replace functional measures prescribed by CMS with clinically-relevant Improvement Activities (IIAs), according to both local/regional priority and HHS strategy. We are thus pleased that CMS is proposing making this measures attestation-based.

AMIA believes that health IT safety is a responsibility shared among developers, healthcare organizations, clinicians, patients, and government stakeholders. However, while certain patient safety risks are pervasive across the health sector, others are unique to different providers and healthcare organizations. We recommend applying our approach to IIAs to EHR safety activities, in that healthcare organizations should receive PI Program credit for leveraging their unique EHR safety activities and/or procedures. While we had originally recommended that CMS encourage CMMI to initiate pilots to better understand what systems and controls are needed to support an IIA program, we see the area of EHR safety as a good opportunity to test this concept, as well.

Actions to Limit or Restrict the Compatibility or Interoperability of CEHRT

CMS is proposing to remove from the Promoting Interoperability Program's prevention of information blocking attestation requirement:

- Statement 2: Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: (1) Connected in accordance with applicable law; (2) compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170; (3) Implemented in a manner that allowed for timely access by patients to their electronic health information; and (4) Implemented in a manner that allowed for the timely, secure, and trusted bidirectional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and vendors.)
- Statement 3: Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as

defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.

AMIA Comments: AMIA supports the removal of these attestation statements. We agree with CMS's reasoning that this will lessen confusion for stakeholders who are trying to comply with ONC's information blocking regulations.

Proposed Changes to the Scoring Methodology for the EHR Reporting Period in CY 2022

For CY 2022 and subsequent years, CMS is proposing to increase the minimum scoring threshold from 50 points to 60 points for the Promoting Interoperability Program.

AMIA Comments: AMIA supports this proposal. As CMS notes, nearly 99 percent of participating eligible hospitals and CAHs that reported to the program successfully met the minimum threshold score of 50 points. In CY2019, we similarly agree that experience with CEHRT has only increased and thus warrants a higher score threshold. We reiterate our earlier recommendation that the Public Health and Clinical Data Exchange objective be re-weighted to be worth 20 points. This will help eligible hospitals and CAHs more easily meet the new score threshold during the transition year, while also serving the vital interests of the public health reporting.

Proposed Updates to Certification Requirements for eCQM Reporting – 2015 Edition Cures Update

CMS is proposing to require eligible hospitals and CAHs to use only certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule to submit data for eCQMs, beginning with the reporting period in CY 2023.

AMIA Comments: AMIA supports CMS policies that require use of CEHRT to participate in its programs, and thus supports this proposal. While we have previously supported flexibilities for hospitals and clinicians that had not fully implemented 2015 Edition CEHRT, we strongly believe that providers must upgrade certified EHRs in a timely fashion to sustain and further encourage IT-enabled care delivery.

Request for Information on Additional Objectives or Measures Adopting FHIR®-based API Standards

CMS is seeking comments on its intention to further align Medicare Promoting Interoperability Program measures with approaches utilizing HL7® FHIR® standard Release 4- based API functionality (or the appropriately evolved standard), with the Health Information Exchange as well as the Public Health and Clinical Data Exchange objectives. CMS is interested in public comments on how these two program objectives could be furthered through the use of FHIR®-based API solutions. Specifically, it is interested in the following questions:

How could technical approaches utilizing the FHIR® standard enhance existing data flows required under the public health measures? What are promising FHIR-based approaches to	We recognize that the FHIR API will be required for healthcare organizations in the coming years. To date, however, implementation in Public Health Agencies

public health reporting use cases that ONC and CMS should explore for potential future consideration as part of the Promoting Interoperability program and the ONC Health IT Certification Program?	(PHAs) and their respective systems has been very limited. We note that the FHIR API faces several challenges in PHA implementation, including but not limited to: • Lack of targeted funding of FHIR implementation at PHAs; • The markets for many PHA systems are small and advancing to new standards, like FHIR, without a specific funding initiative will likely be slow; • There is currently no requirement for FHIR API implementation; • There are functional non-FHIR based implementations that would need to be removed and replaced for complete FHIR support; and • The FHIR API by itself does not naturally support the reporting of specific healthcare data to organizations that have limits on the data they need to – and are legally allowed to – receive. There is certainly promise in having a consistent FHIR API available on EHRs. The eCR Now FHIR App[4] already utilizes the EHR FHIR API to convey electronic case reporting capabilities to EHRs that have not already developed them. However, even this implementation currently transforms retrieved FHIR data so that it can be consumed by public health systems. As things currently stand, we anticipate a long path to broad FHIR adoption at PHAs and needs for data transformations for some time to come.
To what degree are PHAs and individual states currently exploring API-based approaches to conducting public health registry reporting? What other factors do stakeholders see as critical factors to adopting FHIR®-based approaches?	A critical issue to explore is the currently limited availability of data through USCDI-compliant EHR APIs. We again stress that emphasis must be placed on expanding USCDI and the APIs to support data classes and data elements important to public health reporting. It is also important to note that the

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[4] https://ecr.aimsplatform.org/ecr-now-fhir-app

	Immunization information systems (IIS) community's preferred transport standard, SOAP/Web Services and the CDC WSDL, is an API, but with V2 rather than FHIR. Any significant changes to interoperability in the immunization community should accommodate the need for long timelines for adoption. Individual IIS have hundreds, if not thousands of data exchange partners they work with, and an internal shift may require those interfaces to change; this is significant work, even if the change is positive or more standards-based.
What potential policy and program changes in CMS and other HHS programs could reduce health care provider and health IT developer burden related to measures under the Health Information Exchange and the Public Health and Clinical Data Exchange objectives?	• Expansion of EHR APIs is critical to accessing the reporting data needed to fully automate Public Health reporting. • IIS and other public health programs need support to create a system of infrastructure like the Reportable Conditions Knowledge Management System (RCKMS), MedMorph, and the Immunization Gateway that programs can use to achieve interoperability more easily and that reduces the burden on providers contributing to and accessing consolidated population-level data. • Finally, the current state of FHIR resources may be inadequate to support CMS's interests, as they relate to outcome measures and public health reporting. Further, pushing to an all-FHIR framework may be limiting in unintended ways. CMS should look to adopt objectives and measures that reflect the desired evolution to FHIR-based reporting, with FHIR-based objectives that complement or augment existing reporting infrastructures. CMS should additionally recognize that the various state and federal public health reporting infrastructures will need to evolve, as well.

Request for Information on a Patient Access Outcomes Measures

June 28, 2021

CMS is seeking comments surrounding changes to the Medicare Promoting Interoperability Program and related efforts which could better target patient access outcomes related to use of patient portals or third-party application(s). This request for information is an opportunity to garner general interest, solicit stakeholder feedback on how to best evaluate issues of patient behavior, and to explore additional key outcome variables to capture for measurement. Specifically, CMS is looking for feedback on the following questions:

What do stakeholders believe would be useful ways to measure patients' access to their electronic health information using health IT methods such as patient portals and/or third-party applications? What actionable figures related to users' medical record behavior, including but not limited to, the frequency of logins, number of messages sent, or lab results viewed could be captured?	We believe that any metrics used to measure patients' access to the electronic health information should be those that research has shown improve health outcomes. These should certainly include patient-generated health data that aid in ongoing care and/or monitoring, such as caloric intake, patient interaction with instructions, appointments made or canceled, prescriptions renewed, and data derived from patient wearable devices. Other actionable figures should include patient portal activation (both from the patient directly and via a proxy) and the presence of training programs and materials for patients to activate patient portals.
How effectively is the Medicare Promoting Interoperability Program currently measuring the use of health IT-enabled processes to improve patient outcomes? What measures in the current program are most relevant to patient outcomes?	We note that the Provide Patients Electronic Access to Their Health Information measure is the only one in the Promoting Interoperability Program that has an explicit patient focus. However, this alone is insufficient to measure patient outcomes. Further, the existing measures are all process measures, so there are no measures that help understand patient outcomes. There is opportunity, however, to document, report, and understand outcomes not only with regards to patient access, but electronic prescribing with associated PDMP query for controlled substances and clinical decision support for all medication orders and prescribing. For example, medication-medication interactions certainly benefits patients, which Leapfrog has shown is measurable and quantifiable.[5]
Should we consider requiring providers to maintain a record of third-party applications which patients have used to access their patient	We believe that this would be a reasonable request of hospitals and CAHs. However, rather than simply "assess[ing] patient usage of

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[5] https://ratings.leapfroggroup.org/measure/hospital/medication-reconciliation

health information through APIs incorporated within certified technology so that this information could be used to assess patient usage of these applications?	these applications," we recommend CMS also focus on third-party apps that follow robust cybersecurity practices, give patients maximum control over their data, and ultimately provide value without provider or EHR vendor disruption. Health systems could work with their vendors to curate a list of third-party applications or maintain their own FHIR server with a list of vetted applications. We also note that the pending Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement[6] proposes to create a separate set of provisions for the right of an individual to direct copies of PHI to a third party. If this is finalized, we expect hospitals to be maintaining a record of such third-party applications anyway. Should CMS create a new requirement to maintain this record for Promoting Interoperability purposes, then it should coordinate compliance timelines with the HHS Office of Civil Rights.
What are specific technologies, capabilities, or system features (beyond those currently addressed in the Medicare Promoting Interoperability Program) that can increase patient utilization of tools to access their health information? How do these technologies and features support improved access or usability within EHR systems and other applications (for instance, alternate authentication technologies that can simplify consumer logon)? How could CMS reward health care providers for higher adoption rates and use of these available technologies?	A major barrier preventing patient utilization of tools to access their health information is lack of digital literacy. We recommend that CMS work with CMMI to create a payment model that incentivizes patient portal use, similar to the Medicare Diabetes Prevention Program.[7] Such a program could require certain Medicare beneficiaries to attend training sessions and demonstrate certain competencies in patient portal use that can lead to improved outcomes. Another option is for CMS to create an alternative measure – or ideally allow an Inpatient Improvement Activity – that can be reported instead of Provide Patients Electronic Access to Their Health Information measure. Such a measure or activity can require the

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[6] https://www.federalregister.gov/documents/2021/03/10/2021-05021/modifications-to-the-hipaa-privacy-rule-to-support-and-remove-barriers-to-coordinated-care-and
[7] https://innovation.cms.gov/files/fact-sheet/mdpp-billpymnfs-2020.pdf

	eligible hospital or CAH to provide culturally competent in-person training in or automated navigation of accessing and using a patient portal or other technologies that can access a patient health information. Overall, patients do and will further utilize tools to access their health information if those tools are easy to use and – most importantly – provide value for them. The requirement for digital literacy is inversely related to usability. CMS's Blue Button project, along with evolving requirements that payers provide FHIR-based access to any patient's health information they host[8] will open access to those data. Further regulatory levers (e.g. Certification, requirements to conform to standards) should be required to optimize the value derived from payer APIs. The continued fragmentation of a patient's health information across payer and provider data systems, as exacerbated by poor or non-existent interoperability remains, however, the major frustration for patients seeking their data.
What are key administrative processes that could benefit from more efficient electronic workflows? How could CMS measure and reward participating eligible hospitals or CAHs for either greater uptake of patient portal access or subsequent health outcomes?	Prior authorization requirements would undoubtedly benefit from more efficient electronic workflows. CMS already recognized this in its Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information proposed rule (CMS-9123-P) from December 2020. We urge CMS to complete its review of this rule and consider ways to address the underlying causes of prior authorization burden.[9]

Request for Information on Clinical Notes

CMS seeking feedback on changes we can make that will better support the goals of the OpenNotes movement to ensure that clinical notes are widely available to patients. Given the implementation of

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[8] https://www.cms.gov/about-cms/obrhi/faqs/faqs
[9] https://www.amia.org/sites/default/files/AMIA-Response-to-CMS-Reducing-Provider-and-Patient-Burden-NPRM.pdf

updates to certified technology, as previously described, that support the Provide Patients Access to their Health Information measure, are there additional changes to this measure, or other program guidance, which could further facilitate ensuring clinical notes are available to patients consistent with the goals of the OpenNotes movement? CMS is also seeking stakeholder feedback on the development of a required and independently scored measure for the Medicare Promoting Interoperability Program to allocate points for the use of "clinical note" types supported by certified health IT. Finally, CMS is seeking comment on the types of clinical notes that are commonly sought, but not easily accessible to patients.

AMIA Comments: We note that under the 21st Century Cures Act information blocking regulations, the eight types of clinical notes outlined in the United States Core Data for Interoperability (USCDI) must be shared free of charge to patients upon request. We thus do not believe there should be an independently scored measure in the Promoting Interoperability Program.

As for other types of clinical notes that are commonly sought, but not easily accessible to patients, pathology and lab results that are not locally available often prove more difficult to access. Additionally, there are varying state laws with regards to who and when one is permitted to access adolescent health information.

Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs – Request for Information

CMS aims to move fully to digital quality measurement by 2025. They also continue to evolve the Medicare Promoting Interoperability Program's focus on the use of certified electronic health record (EHR) technology, from an initial focus on electronic data capture to enhancing information exchange and expanding quality measurement. However, reporting data for quality measurement via EHRs remains burdensome, and its current approach to quality measurement does not readily incorporate emerging data sources such as patient-reported outcomes (PRO) and patient-generated health data (PGHD).

AMIA Comments: We appreciate CMS's ambitious goal of moving to full digital quality measurement by 2025. CMS rightly notes that the Promoting Interoperability Program's focus should be the use of certified electronic health record (EHR) technology to improve patient outcomes, rather than measurement of the use of the technology. Further, we are pleased that CMS seeks to promote the standardized aggregation of patient level data across multiple health care systems for quality improvement.

We reiterate our position that CMS phase out required numerator/denominator-driven measurement through the Promoting Interoperability Program. However, if CMS intends to move towards a FHIR-based electronic measure construct, then we recommend that that it augment and enable such digital quality measurement by permitting focused activity-based approaches (as we specify below) that place emphasis on data necessary to construct the new measures. We believe that it would be a mistake to continue designing technology exclusively according to the imperative of capturing a numerator and denominator for tasks as varied and complex as clinical care. Aside from a bevy of analyses comparing functionalities across settings and geographies, it is not clear what

actionable insights have been derived from much of the MU administrative data. The threshold parameters enabled by a numerator/denominator compliance schema created dozens of fluctuating requirements leading to short-term workarounds and administrative burden.

Further, we note another issue with numerator/denominator-driven measurement is how to score a given institution if the only data available is artifactual patient data left behind from multiple contacts with several disparate health care systems.

We believe that an activity-based approach will enable organizations to demonstrate clinically meaningful use of health IT for their specific patient populations and priorities without forcing novel enactment strategies. This approach should replace functional measures prescribed by CMS with clinically-relevant Inpatient Improvement Activities (IIAs) according to both local/regional priority and HHS strategy. IIAs would be similar to the Merit-based Incentive Payment System (MIPS) construct of Improvement Activities for eligible clinicians, yet scaled appropriately – in size, complexity, and impact – for inpatient settings. Ideally, these IIAs would:

- Require the most recent Edition of Certified EHR Technology (CEHRT);
- Align with a small number of broad strategic priorities established by HHS;
- Be hospital-developed with a description of expected data inputs, processing, and action steps, with an assessment of impact;
- Align with the patient care activities of hospitals' credentialed and admitting physicians, who may also participate in MIPS;
- Involve a high percentage of all clinicians that care or patients in facility; and
- Be posted publicly for purposes of transparency

We recognize the difficulty in crafting a program relevant to an array of inpatient settings across the country, so we further recommend that pilots be initiated through the CMS Innovation Center (CMMI) to understand what systems and controls are needed to support this program. As part of its dQM goal, we recommend CMS aim to establish an IIA option for eligible hospitals or CAHs by 2025.

Definition of Digital Quality Measures

CMS previously noted dQMs use "sources of health information that are captured and can be transmitted electronically and via interoperable systems." In this RFI, they seek input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores. They also note that dQMs are intended to improve the patient experience including quality of care, improve the health of populations, and/or reduce costs.

CMS also seeks feedback on how leveraging advances in technology (for example, FHIR APIs) to access and electronically transmit interoperable data for dQMs could reinforce other activities to support quality measurement and improvement.

Do you have feedback on the dQM definition?	We request clarification on whether CMS

| | intends to develop its own software to perform measure calculations. If so, then we believe that defining dQMs as "a software that processes digital data" will cause confusion among stakeholders, when the results of such software are what is primarily desirable. We recommend a separate definition of "dQM software" and a new definition of dQMs as, "measures that emphasize the use of data available in EHRs, gathered in the routine process of care."

We note that data from other health IT systems may still be required to augment EHR data. Further, data used to compile quality measures should be able to be queried in its native environment in a computable and semantically interoperable fashion. We thus affirm that access to multiple data sources, rapid cycle feedback allowing data from non-local sources to inform local clinical decision support and population health care gap identification, and alignment of programmatic requirements across all actors generating, acquiring, or hosting personal health information, will better support outcome measurement and improvement. |
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| Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcome more specific comments on the attributes or functions to support such an approach of deploying dQMs. | While we believe that FHIR-based APIs are promising, CMS should be aware that not all quality measures are available via FHIR. True quality measures, as opposed to measures that are easy to capture but only measure a small aspect of quality such as immunization status, are not currently all available through FHIR. FHIR-based data management, access, and interoperability should be seen as evolutional, augmenting and improving the extensive and complex legacy data infrastructures implemented across every aspect of healthcare today. Presently, CMS's quality and outcome improvement programmatic objectives cannot be supported by FHIR alone. |

Use of FHIR for Current eCQMs

Do you agree that a transition to FHIR-based quality reporting can reduce burden on health IT	Yes, we believe that transition to FHIR-based quality reporting, resulting in standardized

vendors and providers?	elements and data representation and automated data extraction, will reduce complexity and associated vendor and provider burden.
Would access to near real-time quality measure scores benefit your practice?	Yes, consistent with our proposed definition of dQMs above, we believe that it is not enough that a measure be deemed clinically appropriate for endorsement, but the measure also be demonstrably implementable in the clinical setting, balancing value with provider time required during visits, so that the measure can be collected, reported, and submitted automatically. Most importantly, however, near real-time quality measure scores are not as useful as real-time access to interoperable data made accessible to clinical decision support infrastructures.
What parts of the current CMS QRDA IGs cause the most burden?	What causes the most burden is anything that requires work beyond what providers do to take care of patients. For example, providers can review and add a new problem list entry or medication, but unless they click "Problem list reviewed" in their EHR, they continue to see prompts to do so. Annual reviews and mapping of value set elements to local vocabularies adds to the burden, as well.
What could we include in a CMS FHIR Reporting IG to reduce burden on providers and vendors?	The Reporting IGs have become lengthy and complex. CMS should make efforts to improve clarity and reduce complexity. However, any such IG would be dependent on the definition of "quality" for the specific site. This is another reason we believe that eligible hospitals and CAHs should have such leeway by having the option to report IIAs, and that CMS should ideally chart a course towards this participation framework in the long term.
Do you agree that a transition to FHIR-based quality reporting can reduce burden on health IT vendors and providers?	Limiting quality measure to FHIR elements could accomplish alignment. To the extent FHIR resources have been defined, data are then available for either function. Clinical concepts and observations are extremely nuanced and FHIR is still evolving to better capture that nuance. Thus, exclusive use of FHIR may impose limitations on data availability. This is why believe that CMS should permit eligible hospitals and CAHs the option to

	report IIAs.

Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025.

CMS is considering further modernization of the quality measurement enterprise in four major ways: (1) Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; (2) redesign its quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate.

AMIA Comments: If CMS proceeds with this framework, then we recommend it consider a preceding requirement, in that data captured as a by-product of clinical processes needs to be represented in accordance with FHIR standards. This would then make CMS's remaining aims possible. CMS has already expressed such a data capture precedent in its current definition of dQM as data "originating from sources of health information that are captured and can be transmitted electronically via interoperable systems." We note that this may be too limiting to be able to understand and improve some important clinical outcomes.

Leveraging and Advancing Standards for Digital Data and Obtaining all EHR Data Required for Quality Measures via Provider FHIR-based APIs

How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data?	This would be a highly desirable goal, so as to be able to automate the inclusion of such data.
What are possible approaches for testing data quality and validity?	Synthetic patient records, such as those generated through Cypress[10] should be evolved for FHIR-based data. A standard dataset would be captured via usual clinical workflows and then demonstrated to be extracted via the relevant FHIR API.

Redesigning Quality Measures to be Self-Contained Tools

CMS is considering approaches for including quality measures that take advantage of standardized data and interoperability requirements that have expanded flexibility and functionality compared to CMS' current eCQMs. It is considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payers, CMS, and others; calculate measure score(s), and produce reports.

How would this more open, agile strategy for end-to-end measure calculation facilitate broader	This strategy would make the analytic results ("measure components") – either at an

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[10] https://ecqi.healthit.gov/tool/cypress

engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?	individual patient level or in aggregate – available locally in real time so as to inform care, enable identification of care gaps, and be available electronically to clinical decision support infrastructures. We believe that public health reporting and research should similarly benefit.
Do you have feedback on policy considerations for aggregation of data from multiple sources being used to inform measurement?	CMS and ONC should leverage Certification, programmatic requirements, and potentially Medicare Conditions of Participation. Where potentially useful, they should seek Congressional support to engage all participants and evolve towards a common standards-based national information management ecosystem.

Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

What are initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools)?	Rather than a dQM portfolio, HHS as a whole should determine a small number of broad strategic priorities that hospital-developed measures should align with. As the definition of "quality" can be variable, these broad strategic priorities will help guide eligible hospitals and CAHs, while letting them have maximum flexibility in determining how to best improve the use of their health IT to improve quality, as they define it.