INFORMATICS PROFESSIONALS. LEADING THE WAY.

June 25, 2018

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1694-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 2019 Rates; Proposed Quality Reporting Requirements for
Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR)
Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible
Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting
Requirements; and Physician Certification and Recertification of Claims

Dear Administrator Verma:

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide
input on the FY2019 Hospital Inpatient Prospective Payment Systems proposed rule.

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.

AMIA is generally supportive of the balance envisioned through this NPRM to both provide
flexibilities through reduced reporting burdens and to encourage continued investment in improved
information technology (IT) for patient care. For example, AMIA views the required use of 2015
Edition CEHRT beginning in CY 2019 as foundational for improved interoperability, patient data
access, and better usability. So too do we view the continuation of a 90-day reporting period for the
Promoting Interoperability (PI) Program and the introduction of a new scoring methodology to the
PI Program as critical policy changes that will enable hospitals to better work towards the goal of
more efficient and seamless care coordination.

As this program enters its fourth iteration – the first substantial iteration of this administration – we
feel it necessary to highlight lessons learned from the literature thus far and recommend a set of
actions that will better enable hospitals to leverage ongoing investments in health informatics for
patient care and evolve this program to meet the changing needs of both regulators and industry.

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A review of recent literature indicates that the incentives related to Meaningful Use (MU) achieved significant gains in accelerating adoption of EHRs among hospitals eligible for incentives compared to ineligible hospitals.[1] Evidence also suggests that the contours of MU programmatic requirements positively impacted the provision of quality and safe patient care.[2,3,4] However, as the program grew more complex, perceived benefits waned from Stage 1 to Stage 2,[5] and satisfaction with EHRs has not kept pace with clinicians' expectations.[6]

While AMIA has championed federal efforts to digitize care delivery through incentive payments, increasingly we have grown weary of prescriptive requirements for clinicians and a lack of resources for the Federal Health IT Certification program, which provides the technical underpinnings of the program. An AMIA Task Force issued a set of recommendations in 2015 articulating ways in which MU and Certification program should evolve.[7] Among the numerous recommendations was a declaration that, "Changes in reimbursement regulations should support novel changes to and innovation in EHR systems."[8]

As stated in the EHR 2020 Task Force report, "reimbursement requirements influence and are integrally intertwined with EHR design," and CMS has an opportunity to think differently now that the program no longer affords hospitals positive incentives.

AMIA recommends CMS chart a course towards an end to numerator/denominator-driven measurement through the Promoting Interoperability Program (PI Program). Designing technology according to the imperative of capturing a numerator and denominator for tasks as varied and complex as clinical care has been a drag on this program and a glaring flaw to its logic model. 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

[1] Adler-Milstein J, Jha AK. HITECH Act Drove Large Gains In Hospital Electronic Health Record Adoption, Health Affairs 2017 36:8, 1416-1422 https://doi.org/10.1377/hlthaff.2016.1651

[2] Levine DM, Healey MJ, Wright A, et al. Changes in the quality of care during progress from stage 1 to stage 2 of Meaningful Use, Journal of the American Medical Informatics Association, Volume 24, Issue 2, 1 March 2017, Pages 394–397, https://doi.org/10.1093/jamia/ocw127

[3] Furukawa MF, Spector WD, Limcangco MR et al. Meaningful use of health information technology and declines in in-hospital adverse drug events, Journal of the American Medical Informatics Association, Volume 24, Issue 4, 1 July 2017, Pages 729–736, https://doi.org/10.1093/jamia/ocw183

[4] Jones SS Rudin RS Perry T Shekelle PG. Health information technology: an updated systematic review with a focus on meaningful use. Ann Intern Med. 2014;160(1):48–54.

[5] Holman GT, Waldren SE, Beasley JW, et al. Meaningful use's benefits and burdens for US family physicians, Journal of the American Medical Informatics Association, Volume 25, Issue 6, 1 June 2018, Pages 694–701, https://doi.org/10.1093/jamia/ocx158

[6] Meyerhoefer CD, Sherer SA, Deily ME, et al. Provider and patient satisfaction with the integration of ambulatory and hospital EHR systems, Journal of the American Medical Informatics Association, , ocy048, https://doi.org/10.1093/jamia/ocy048

[7] Payne TH, Corley S, Cullen TA, et al. Report of the AMIA EHR-2020 Task Force on the status and future direction of EHRs, *Journal of the American Medical Informatics Association*, Volume 22, Issue 5, 1 September 2015, Pages 1102–1110, https://doi.org/10.1093/jamia/ocv066

[8] Ibid. pg. 1104

threshold parameters enabled by a numerator/denominator compliance schema created dozens of fluctuating requirements leading to short-term workarounds and administrative burden. And perhaps most insidious, numerators and denominators required by MU have negatively impacted the design and usability of EHRs while subsequently demanding byzantine changes to clinical workflow.

AMIA recommends CMS abandon the construct of measure reporting in favor of an activity-based approach, which will enable organizations to demonstrate clinically meaningful use of health IT for their specific patient populations and priorities without forcing novel enactment strategies. Such an 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 are like 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. Further, we envision IIAs would:

- Rely on 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;
- Involve a high percentage of all clinicians that care or patients in facility; and
- Be posted publicly for purposes of transparency.

AMIA recommends CMS initiate a broad and inclusive conversation regarding the contours and additional characteristics of acceptable IIAs. 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. We would encourage this program to be optional, initially, beginning 2021. Guidance from CMS, along with clear requirements for implemented (e.g. "turned on") functionality will be important.

In addition to these long-term programmatic changes, AMIA recommends CMS:
- **Proceed with requiring 2015 Edition CEHRT in 2019**
  - Requiring adoption, implementation, and upgrade to the latest functionality is prerequisite to achieve the many goals projected by the PI Program.
- **Avoid adding requirements not currently supported by 2015 CEHRT, while maintaining CEHRT functionality for measures being retired**
  - The combined measure for *Support Electronic Referral Loops by Receiving and Incorporating Health Information* will prove more difficult than anticipated, and risks introducing errors due to immature electronic reconciliation functionality; we recommend CMS proceed with the current requirements represented by the two, separate measures supported by CEHRT.
  - Ensure that retired patient engagement measure functionalities for secure messaging, patient education, and patient-generated health data remain functionalities of CEHRT moving forward.

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- **Allow use of any CCDA document-level template during referrals/transitions of care**
    - We note that this new level of flexibility may complicate interoperability efforts over the near-term by introducing new levels of optionality and it will require substantial work between health information exchange partners to calibrate standard operating procedures regarding which documents are expected for specific transfers/referrals.
- **Better support public health reporting**
    - We do not support the proposal to limit reporting to Syndromic Surveillance (plus one additional option) and we do not support the proposal to remove that Public Health and Clinical Data Exchange measure in the future. Rather than lower the requirements for public health reporting, AMIA recommends that CMS should carry forward a variation of the Stage 3 requirements.
- **Consider support for/development of a national testing infrastructure for eCQMs**
    - eCQMs continue to be a major challenge due in large part to exclusion criteria, reliance on data not part of the Common Clinical Data Set, and the lack of consistent testing procedures across measure stewards and implementers of eCQMs. A national testing infrastructure would enable more rapid dissemination of more generalizable eCQMs.
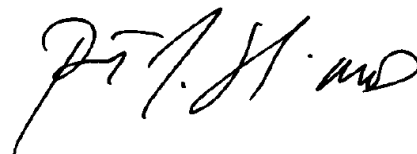
Below, we provide specific comments for the proposals in this NPRM. We urge the agency to consider our comments and criticisms as constructive, and with the aim of helping CMS move toward a more desirable, holistic approach of improving care through robust use of health IT and other informatics tools.

We hope our comments are helpful as you undertake this important work. Should you have questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291. We look forward to continued partnership and dialogue.

Sincerely,

Douglas B. Fridsma, MD, PhD, FACP,
FACMI
President and CEO
AMIA

Peter J. Embi MD, MS, FACP, FACMI
AMIA Board Chair
President & CEO
Regenstrief Institute

(Enclosed: Detailed AMIA Comments regarding CMS' FY19 IPPS NPRM)

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Hospital Inpatient Quality Reporting (IQR) Program

For the CY 2019 reporting period/FY 2021 payment determination, CMS is proposing to extend the same eCQM reporting and submission requirements as FY2018, which requires hospitals to report one, self-selected calendar quarter of data for four self-selected eCQMs.

AMIA Recommendation: AMIA generally supports reducing reporting burden and therefore supports the continuation of this policy finalized in FY2018. However, as we have previously noted in our comments to the CY2018 Updates to the Quality Payment Program proposed rule, there may be cases where individual eCQMs have value, even if topped out, or that there may be a risk of "back sliding" due to a shift in resources from topped-out measures to a new eCQM(s).[9] AMIA recommends that CMS monitor and evaluate how behaviors may change when eCQMs are removed through the process CMS finalized in its FY2015 IPPS final rule. There is some evidence that suggests removing certain technological and practice interventions leads to a reduction in desired clinical behavior.[10, 11]

Proposed Changes to the Medicare and Medicaid EHR Incentive Programs (now referred to as the Medicare and Medicaid Promoting Interoperability Programs)

The FY2018 IPPS final rule allowed health care providers in the Medicare and Medicaid EHR Incentive Programs (now PI Programs) to use either the 2014 or 2015 Edition of CEHRT, or a combination of both Editions, in 2018. CMS is proposing that beginning with the EHR reporting period in CY2019, the 2015 Edition of CEHRT will be required.

AMIA Recommendation: AMIA enthusiastically supports CMS's proposal to require use of 2015 Edition CEHRT in 2019 and agrees that this upgrade will better support interoperable exchange of health information and improve clinical workflows. AMIA encourages CMS to use the regulatory tools at its disposal to encourage adoption of future editions of CEHRT, as well.

Proposed Revisions to the EHR Reporting Period in 2019 and 2020

As was finalized in 2018, CMS is proposing the EHR reporting periods in 2019 and 2020 for new and returning participants attesting to CMS or their State Medicaid agency would be a minimum of any continuous 90-day period 2019 and 2020, as well. CMS wants to ensure that providers have the opportunity to thoroughly test their systems and make adjustments in order to successfully attest for the EHR reporting periods in CYs 2019 and 2020. In addition, health care providers may need extra time to fully implement and test workflows with the 2015 Edition of CEHRT, as well as the below

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[9] https://www.amia.org/sites/default/files/AMIA-Response-to-CMS-QPP-Year-2-NPRM.pdf
[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4510234/
[11] https://www.ncbi.nlm.nih.gov/pubmed/9370504

proposal to require use of an API to incorporate patient data in the Provide Patients Electronic Access to Their Health Information measure.

AMIA Recommendation: Again, AMIA agrees with CMS's reasoning, and supports the continuation of this flexibility that will allow more eligible hospitals and CAHs to successfully participate in the PI Programs.

Proposed Scoring Methodology for Eligible Hospitals and CAHs Attesting Under the Medicare Promoting Interoperability Program

CMS is proposing a new performance-based scoring methodology with fewer measures, and moving away from the threshold-based methodology that it currently uses. The performance-based scoring methodology would apply to eligible hospitals and CAHs that submit an attestation to CMS under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY2019. This would include "Medicare-only" eligible hospitals and CAHs as well as "dual-eligible" eligible hospitals and CAHs. A minimum composite score of 50 would be required to avoid a penalty. If CMS does not finalize a new scoring methodology, it would maintain the current Stage 3 methodology with the same objectives, measures and requirements, but CMS would include two new proposed opioid measures, if finalized.

AMIA Recommendation: AMIA welcomes the new proposed scoring methodology for the PI Program. Not only does the proposed scoring methodology bring the program into further alignment with the MIPS scoring methodology, but it provides further flexibility to hospitals by doing away with the current Stage 3 "all or nothing" methodology. While we are supportive of this methodology, we caution CMS to avoid replicating the current MIPS construct, which is proving more difficult than expected to track metrics and adjust processes before summary statistics are calculated and submitted.

As applied to our recommendations for PI Program measures, articulated further below, we believe that the minimum composite score of 50 adequately allows room for hospitals to successfully comply, so long as each required measure requires submission of at least one in the numerator. Our recommendations on the following proposed measures require a slight revision to the points allocation (see Table 1 below):

- *Query of Prescription Drug Monitoring Program (PDMP);*
- *Verify Opioid Treatment Agreement;*
- *Support Electronic Referral Loops by Receiving and Incorporating Health Information;* and
- *Public Health and Clinical Data Exchange.*

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Table 1: CMS Proposed, AMIA Recommended PI Program Measures & Points Allocation

Objective	Measure(s)	Maximum Points (CMS proposal)	Maximum Points (AMIA recommendations)
e-Prescribing	e-Prescribing	10 points	5 points
	Bonus: Query of Prescription Drug Monitoring Program (PDMP)	5 points bonus	5 points bonus
	Bonus: Verify Opioid Treatment Agreement	5 points bonus	n/a
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	20 points	Request/Accept Summary of Care: 10 points
			Clinical Information Reconciliation: 10 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points	40 points
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting (Required) \n\n Choose one or more additional: Immunization Registry Reporting Electronic Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Electronic Reportable Laboratory Result Reporting	10 points	Syndromic Surveillance Reporting, Immunization Registry, and Reportable Lab Results (Required) \n\n Choose one or more additional: Electronic Case Reporting, Public Health Registry Reporting; Clinical Data Registry Reporting \n\n 20 points

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Proposed Measures for Eligible Hospitals and CAHs Attesting Under the Medicare Promoting Interoperability Program

CMS is proposing to remove six measures from the current Stage 3 reporting requirements. Two of the measures – *Request/Accept Summary of Care* and *Clinical Information Reconciliation* – would be replaced by the *Support Electronic Referral Loops by Receiving and Incorporating Health Information* measure, which combines the functionalities and goals of the two Stage 3 measures it is replacing. Four of the measures – *Patient-Specific Education; Secure Messaging; View, Download or Transmit; and Patient Generated Health Data (PGHD)* – would be removed because, according to CMS, they have proven burdensome to health care providers in ways that were unintended and detract from health care providers' progress on current program priorities.

AMIA Comment: While AMIA recognizes the burdens placed on hospitals to report the four measures proposed for removal, we wish to convey that the functionalities developed in support of these measures are not universally disliked/unhelpful.

AMIA Recommendation: AMIA supports the removal of the four measures proposed by CMS as long as the functionality for such actions remains available for use.

Additional comments on the specific measures continue below.

Measure Proposals for the e-Prescribing Objective

CMS has identified two new measures which align with the broader HHS efforts to increase the use of PDMPs to reduce inappropriate prescriptions, improve patient outcomes, and promote more informed prescribing practices. The two measures are: (1*) Proposed Measure: Query of Prescription Drug Monitoring Program (PDMP)* and (2) Proposed Measure: *Verify Opioid Treatment Agreement.*

Proposed Measure: Query of Prescription Drug Monitoring Program (PDMP)

The intent of the Query of the PDMP measure is to build upon the current PDMP initiatives from Federal partners focusing on prescriptions generated and dispensing of opioids. CMS acknowledges many hospitals will likely need to manually enter data into CEHRT to document the completion of the query of the PDMP action and that these hospitals may also need to conduct manual calculation of the measure. CMS further acknowledges that for those hospitals that have achieved successful integration of a PDMP with their EHR, this measure may not be machine calculable, for instance, in cases where the hospital follows a link within the EHR to a separate PDMP system. Finally, CMS indicates that for the purposes of meeting this measure, there are no existing certification criteria for the query of a PDMP. As stated, CMS is seeking comment on whether ONC should consider adopting standards and certification criteria to support the query of a PDMP, and if such criteria were to be adopted, on what timeline should CMS require their use to meet this measure.

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AMIA Comment: AMIA appreciates this line of inquiry from CMS, and views the *Query of PDMP* measure as an exemplary application of health IT in pursuit of a worthy outcome. However, we also view this proposal as a microcosm of what has plagued the EHR Incentive Payment Program for much of its history: it seeks to nationalize a prescriptive activity by leveraging health IT at a granular level which has not been demonstrated in-production among even a regional cohort of stakeholders. While we acknowledge a degree of benefit for this approach early in the nation's journey towards digitized care, we question the same approach at this juncture.

For example, a 2017 study looking at the feasibility of implementing prescription drug monitoring programs and other clinical decision support for opioid risk mitigation in a military health care setting outlined numerous challenges with implementing a PDMP.[12] These challenges included (1) complex decision-making around opioid prescribing and monitoring, (2) varied knowledge and use of existing clinical informatics, and (3) general concerns about the feasibility of implementing a military-based PDMP in their context due to time and work burden, provider licensing, and complexity of integration.

According to a systematic review of factors affecting use of prescription-related electronic decision supports,[13] it should be easy to access and use, compatible with existing IT systems and workflows, supported by initial and ongoing training that accounts for variation in providers' baseline knowledge, and accessible by multiple members of the care team, beyond only physicians. Additionally, we note that such integration should not be cost prohibitive.

Unfortunately, most hospitals must navigate largely proprietary systems and standards to view PDMP data that is usually not integrated into the EHR, but rather viewable through an external prescription database. Instead, prescribers should be able to directly query the PDMP so that it both prominently displays which controlled substance is prescribed and records the information automatically, without additional steps, passwords, etc. on the part of the prescriber.

AMIA Recommendation: AMIA recommends that CMS finalize a policy that makes *Query of PDMP* optional in FY2019 and revisit the status of adoption during the 2019 rulemaking cycle to determine if it should become required in 2020. Further, we recommend CMS task ONC with adopting standards and certification criteria to support the *Query of a PDMP* as informed by a pilot study before requiring such a measure as part of this program. Were CMS to embark on an aggressive timeline, we believe 2021 would be a reasonable goal to include this measure.

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[12] Finley EP, Schneegans S, Tami C, et al. Implementing prescription drug monitoring and other clinical decision support for opioid risk mitigation in a military health care setting: a qualitative feasibility study, J Am Med Inform Assoc. 2018;25:515–522

[13] Moxey A, Robertson J, Newby D, et al. Computerized clinical decision support for prescribing: provision does not guarantee uptake. J Am Med Inform Assoc. 2010;17:25–33.

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Proposed Measure: Verify Opioid Treatment Agreement.

The second proposed measure, *Verify Opioid Treatment Agreement*, is for eligible hospitals and CAHs to identify whether there is an existing opioid treatment agreement when they electronically prescribe a Schedule II opioid using CEHRT if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days. CMS is seeking public comment on the challenges and concerns associated with opioid treatment agreements and how they could impact the feasibility of the proposal.

AMIA Comment: AMIA believes that this measure may present particular challenges for facilities that use opioid treatment agreements in the context of a 42 CFR Part 2 licensed program, as the data sharing restrictions placed by Part 2 rules complicate the feasibility of this measure immensely. Additionally, we note these agreements are more commonly used by outpatient programs where use of EHRs may not be as common. Thus, the potential benefits of looking for an opioid treatment agreement are likely to be modest.

AMIA is also concerned about the data and available evidence regarding the efficacy of opioid treatment agreements in general and potential negative effects of their use. One systematic review from 2014 noted that while some studies showed an apparent benefit relative to a lack of treatment agreements, these were small and poorly designed studies.[14] Another study showed that about one third of individuals with a treatment agreement were dropped from the treatment site for not abiding by the agreement, even on items not necessarily related to opioid use (e.g., having positive urine screens for substances such as marijuana).[15] Perhaps unsurprisingly, those with a past history of substance use were more likely to be discharged due to not adhering to the agreement.[16] Consequently, while well-intended, this measure may have unintended consequences of reducing the receipt of medical care by individuals with opioid use disorder.

When reviewing the denominator, we also note that the patient's medication history is not always clearly laid out in the external prescription history. In addition, we do not believe it is standard to download external prescription history into the EHR in a format that allows querying in this type of fashion. Users would need to manually check the external prescribing history and then manually calculate this information with no system level ability to determine if users are identifying applicable patients or not. The burdens to the provider of conducting such calculations may also result in unintended consequences for patients if providers become reluctant to give short-term opioid medications at hospital discharge when appropriate for acute pain or if they are more reluctant to prescribe opioid agonists at discharge in the context of medication-assisted treatment for opioid use disorder.

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[14] Nuckols TK, Anderson L, Popescu I, et al. Opioid prescribing: a systematic review and critical appraisal of guidelines for chronic pain. Ann Intern Med. 2014 Jan 7;160(1):38-47.

[15] Starrels JL, Becker WC, Alford DP, et al. Systematic review: treatment agreements and urine drug testing to reduce opioid misuse in patients with chronic pain. Ann Intern Med. 2010 Jun 1;152(11):712-20.

[16] Summers P, Alemu B, Quidgley-Nevares A. History of drug use predicts opioid treatment agreement violation. J Opioid Manag. 2015 Nov-Dec;11(6):501-6.

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AMIA Recommendation: Given the technical difficulty of this measure and the controversy stated by CMS and observed elsewhere over the efficacy of treatment agreements, AMIA does not support inclusion of this measure in the PI Program. This proposed measure is of limited value, according to available evidence, and we anticipate that complying with this measure will result in wasted time, energy, and provider resources. Lastly, while this measure would be difficult to implement without robust interoperability, we do not understand how this measure promotes interoperability more broadly, as is the stated purposes of the PI Program.

If CMS moves forward with the *Verify Treatment Agreement* measure, there should be a clear consensus over the content of such agreements based on stakeholder feedback, as well as standardization of the requisite sections that should be able to be transmitted electronically. Furthermore, the agreements should be integrated with the PDMP so that users can access both types of information in a single step. Changes to 42 CFR Part 2 to facilitate appropriate sharing of information would also be an essential precursor to requiring this measure.

Proposed Measure: Support Electronic Referral Loops by Sending Health Information

CMS proposes to change the name of the Send a Summary of Care measure to *Support Electronic Referral Loops by Sending Health Information* to better reflect the emphasis on completing the referral loop and improving care coordination. For at least one transition of care or referral, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record. CMS acknowledges that stakeholders have raised concerns that the summary care records shared according to the CCDA standard included excessive information not relevant to immediate care needs, which increased burden on health care providers. Accordingly, CMS is proposing that eligible hospitals and CAHs may use any document template within the CCDA standard for purposes of the measures under the Health Information Exchange objective.

AMIA Comment: AMIA agrees with concerns regarding excessive information contained in summary of care record as dictated by the CCDA standard. We see this proposal as allowing flexibility for localized decision-making between providers who exchange patient data. Further, the option to use other document templates, such as the operative notes, consultation notes, or progress notes, could provide impetus for hospitals to clearly articulate standard operating procedures for common transfers or referrals and, as a result, make the information/document templates that are exchanged more useful and integrated.

Having considered the ideal outcome of this proposal, we note that such a change in policy will likely result in some transfers and referrals missing important information if standard operating procedures are not established among exchange partners. We also note that increasing the number of templates that will satisfy this requirement may cost providers more if vendors charge for each document template as part of their implementation. Further, we reiterate our long-standing concern that CEHRT is tested to send, but not receive, both structured and unstructured data. Much of the current state of CEHRT interoperability can be traced to the Certification Program's lack of

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interoperability testing. We anticipate that this proposal may very well complicate interoperability in the short-term by creating an exponential number of variants across the CCDA's 13 document-level templates. We urge CMS to work closely with ONC and modify the Certification Program accordingly to test that systems can both send and receive individual – and combinations – of CCDA document-level templates.

Retooling the Certification Program to require sending a conforming template *and* receiving all the variations of that conforming template will reduce the cost and burden on the provider, improve provider compliance, and drive vendors to produce simpler and less complex templates. For this policy change to have the intended impact on interoperability, vendors must share in the accountability for interoperable solutions, and CMS must (1) work with standards developers to reduce optionality within the existing templates to simplify implementation and information exchange; (2) test that vendors can send templates that conform to the standard (as they do now); and (3) test that vendors can receive the different versions of the templates that all CEHRT vendors produce. If a vendor can receive all the different versions of the templates, then they will be interoperable with ALL the other certified vendors. Testing would ideally involve a 24x7x365 web-based infrastructure where vendors and providers could iteratively test their ability to compose and send a conforming CCDA-templated document and as well as their ability to receive, display, and reconcile the possible variants of a conforming CCDA-templated document. This work has been done, in part, by claims clearinghouses with X12 5010 billing documents where there exists a constantly-available infrastructure for testing, resulting in more clarity about whether a claim is properly formatted or not.

Requiring this infrastructure as part of testing and certification reduces the burden (and cost) for providers having to pay for each of the variations that they might want to use. We see such a testing scheme as part of shared responsibility for improved interoperability.

AMIA Recommendation: AMIA supports CMS's proposal to allow eligible hospitals and CAHs to use any document template within the CCDA to satisfy this requirement. However, we caution that this new level of flexibility will require substantial work between health information exchange partners to calibrate standard operating procedures regarding which documents are expected for specific transfers/referrals. Further, we recommend that this work must be supported through changes to ONC's Certification Program as described above. Over the longer-term, we hope that this flexibility will lead to better integration and optimization necessary to close the referral loop.

Proposed Measure: Support Electronic Referral Loops by Receiving and Incorporating Health Information

CMS is proposing a new measure, *Support Electronic Referral Loops by Receiving and Incorporating Health Information*: For at least one electronic summary of care record received for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the hospital conducts clinical information reconciliation for (1) medication, (2) medication allergy, and (3) current problem list.

The proposed measure would focus on the result of these actions when an electronic summary of care record is successfully identified, received, and reconciled with the patient record. CMS believes this approach would allow eligible hospitals and CAHs to determine and implement appropriate workflows supporting efforts to receive the electronic summary of care record consistent with the implementation of effective health IT information exchange at an organizational level. Finally, CMS proposes to apply its existing policy for which the hospital determines no update or modification is necessary within the patient record based on the electronic clinical information received, and the eligible hospital or CAH may count the reconciliation in the numerator without completing a redundant or duplicate update to the record. CMS welcomes public comment on methods by which this specific action could potentially be electronically measured by the provider's health IT system – such as incrementing on electronic signature or approval by an authorized provider – to mitigate the risk of burden associated with manual tracking of the action.

CMS also asks for public comment on the impact these proposals may have for health IT developers in updating, testing, and implementing new measure calculations related to these proposed changes. Specifically, CMS wants input on whether ONC should require developers to recertify their EHR technology as a result of the changes proposed, or whether they should be able to make the changes and engage in testing without recertification. Finally, CMS seeks public comment on whether this proposed new measure that combines the Request/Accept Summary of Care and Clinical Information Reconciliation measures should be adopted, or whether either or both of the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures should be retained in lieu of this proposed new measure.

AMIA Comment: We wholeheartedly support the aspirations of this measure. There is very little disagreement that reviewing, reconciling, and acknowledging these three core components of a patient's history are important steps in providing safer, optimal care for patients. Nor is there disagreement that health IT should be used to facilitate this kind of activity. However, clinical information reconciliation continues to present many challenges in practice, especially using CEHRT.[17, 18, 19, 20] Successful reconciliation of clinical information, such as medications, medication allergies, and problem lists using health IT is resource-intensive, time-consuming, requires multidisciplinary collaboration, changes to workflow, standard terminology, and syntax, as well as item provenance attribution.

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[17] Monte AA, Anderson P, Hoppe JA et al., Accuracy of electronic medical record medication reconciliation in emergency department patients. J Emerg Med. 2015; 49 (1): 78–84.

[18] Kwan JL, Lo L, Sampson M et al., Medication reconciliation during transitions of care as a patient safety strategy. Ann Intern Med. 2013; 158 (5_Part_2): 397–403.

[19] Agency for Healthcare Research and Quality, USA, WHO, and the Commonwealth Fund, USA. The High 5s Project—Standard Operating Protocol: Assuring Medication Accuracy at Transition in Care: Medication Reconciliation; Version 3, September 2014. http://www.who.int/patientsafety/implementation/solutions/high5s/h5s-sop.pdf. Accessed May 2018.

[20] Electronic tools to support medication reconciliation: a systematic review. Marien S, Krug B, Spinewine A., J Am Med Inform Assoc., Volume 24, Issue 1, 1 January 2017, Pages 227–240

On the surface, the combining of two existing measures into this new measure makes sense: if providers are already engaged in workflows using CEHRT to accept summary of care documents and, separately, reconciling problems, medications and medication allergies, then this combination measure should be a reasonable progression. Unfortunately, this measure encapsulates three important and fundamental flaws inherent in this program: (1) it manufactures a complex workflow for the purposes of measurement; (2) it positions CEHRT to dictate a set of activities that conflict with how clinicians practice medicine; and (3) it risks becoming an exercise that neither improves interoperability nor care quality. Interoperability could be improved immediately by eliminating optionality in the CCDA standard document templates and allowing vendors and providers to test their products with a web-based testing infrastructure. EHR vendors could then spend their efforts on innovative ways to reconcile interoperable information within their EHR's clinical workflow.

As stated above, a general principle CMS should follow is ensuring that ONC's Certification Program supports all CMS requirements. Existing CEHRT requirements are insufficiently developed for supporting effective and efficient (semi)automated reconciliation, so any measure thereof is likely to compel a clinically ineffective activity. We anticipate that generation of a new numerator/denominator for this measure would require very little work from a development perspective. However, we also anticipate that such development would result in flaws (1) and (2) described above, which would then result in flaw (3).

While much of the technical requirements lie beyond CMS purview, it is important that CMS understand the delta between current clinical reality and what may be envisioned by the PI Program.

AMIA Recommendation: As a practical matter, AMIA supports these activities, but not the combined measure. We recommend that CMS finalize the HIE objective with separate measures: (1) *Request/Accept Summary of Care* and (2) *Clinical Information Reconciliation*, both of which are supported by 2015 Edition CEHRT and have been demonstrated in-production at scale. Questions posed by CMS regarding ways to potentially calculate this measure electronically, as well as questions over recertification, supports our view that the PI Program is not ready for the single measure proposed.

Further, we see the functionality of medication, medication allergy, and problem list reconciliation as successively immature. While medication and medication allergy reconciliation are largely stable due to (1) the adoption of standard terminologies, RxNorm, LOINC, and SNOMED CT, and (2) the process of medication reconciliation being generally integrated into workflows, problem lists do not currently enjoy such characteristics. Problem list reconciliation is immature compared to the other aspects of clinical information reconciliation and require much more manual intervention, thus introducing a greater risk to patient harm.

Even still, medication and medication allergy reconciliation have data use constraints related to workflows and context which complicate when and how to apply the data for both medication and medication allergy reconciliation (see Appendix A for discussion of the sociotechnical interoperability stack). We are also very concerned about the likelihood of error propagation resulting from even these relatively defined tasks.

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We strongly encourage CMS to work with ONC's Certification Program to understand the clinical concerns related to reconciliation and better define applicable standards for clinical information reconciliation, so that deliberate progress can be made in this still disorganized area of interoperability.

Measure Proposals for the Provider to Patient Exchange Objective

Proposed Modifications to Provide Patient Access Measure

CMS is proposing to change the name of the Provide Patient Access Measure to the *Provide Patients Electronic Access to Their Health Information*. This measure would require that for at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department:

- The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information; and
- The eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access 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.

AMIA Comments: We see the *Provide Patients Electronic Access to Their Health Information* measure as a sensible continuation of a vitally important functionality, which underscores the importance of 2015 Edition CEHRT. While there are numerous outstanding questions regarding how the propagation of APIs will impact provider-patient communication, we view this policy proposal as a way to both empower patients and relieve providers from a policy that penalizes hospitals for actions outside their control. As a matter of programmatic administration, we understand the "at least one patient" provision, but wish to make clear our interpretation that providers will be successful in meeting this measure as long as patient data is made available in a timely manner and through APIs that conform to specifications determined by ONC.

AMIA Recommendation: We support this proposal as written. In addition, we recommend CMS work with ONC to ensure that future Editions of CEHRT converge with the basic functionalities of Sync for Science, which enable patients to connect to any third-party application via their patient portals and transfer their data or create an uninterrupted connection.[21] We also encourage CMS to work closely with ONC to ensure that future versions of USCDI capture more of the patient's complete healthcare record, as required by HIPAA, in both structured and unstructured data formats.

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[21] http://syncfor.science/

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Proposed Removal of the Patient Generated Health Data Measure

CMS is proposing to remove the Patient Generated Health Data (PGHD) measure to reduce complexity and focus on the goal of using advanced EHR technology and functionalities to advance interoperability and health information exchange.

AMIA Comments: The removal of the *Patient Generated Health Data* measure is somewhat contentious due to a concern that it will dampen widespread use of such data. However, we also acknowledge that the landscape for PGHD is varied with immaturity of standards, processes, and clinical workflows to be leveraged effectively.

AMIA Recommendation: AMIA supports the removal of this measure, while still recognizing that allowing the transmission of key health data, such as home blood pressure readings, fingerstick glucose levels, and other vitals, is still beneficial to the patient. This functionality should thus remain available within CEHRT. Further we recommend that CMS consider ways to encourage the collection of patient reported outcomes from behavioral health rating scales and other types of rating scales (e.g., quality of life, functional impairment). We note that they are increasingly being incorporated into a number of quality measures. Unfortunately, this data is virtually impossible to capture in most certified systems.

Proposed Removal of the Patient-Specific Education Measure

CMS is proposing to remove the Patient-Specific Education measure as it has proven burdensome to eligible hospitals and CAHs in ways that were unintended and detract from health care providers' progress on current program priorities.

AMIA Comments: While we wholeheartedly support patient education, experience with this measure indicates that CEHRT-delivered educational materials, as necessary for measure calculation, were not uniformly applicable or helpful.

AMIA Recommendation: AMIA supports the removal of this measure. Even so, CMS should continue to encourage eligible hospitals to provide patient-specific education. There is great value for hospitals to provide patient-specific education when impactful, either using resources that are integrated into the EHR or other patient-centered resources.

Proposed Removal of the Secure Messaging Measure

CMS is proposing to remove the *Secure Messaging* measure as it has proven burdensome to eligible hospitals and CAHs in ways that were unintended and detract from health care providers' progress on current program priorities.

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4720 Montgomery Lane, Suite 500 | Bethesda, Maryland 20814

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AMIA Comments: Patients who utilize secure messaging usually do so in the context of an ongoing outpatient relationship with a clinician, rather than with hospitals. AMIA members who support the removal of the *Secure Messaging* measure believe this will allow hospital staff to focus on meaningful and relevant communication with them, rather than on simply messaging to meet this measure. Opponent AMIA members, however, see the requirement as necessary to encourage providers to engage in a more comprehensive patient engagement strategy.

AMIA notes that secure messaging has proven beneficial and useful in some contexts and settings when appropriately integrated into clinician workflow.[22] Further, measures have helped galvanize hospitals around patient engagement and have contributed to increased patient and clinician interest in using these strategies.[23]

AMIA Recommendation: AMIA supports the removal of this measure, but also supports retaining the requirement that CEHRT provide this function.

Proposed Removal of the View, Download or Transmit Measure

CMS is proposing to remove the View, Download or Transmit measure as it has proven burdensome to eligible hospitals and CAHs in ways that were unintended and detract from eligible hospitals and CAHs progress on current program priorities.

AMIA Comments: As this functionality will still be required through the *Provide Patients Electronic Access to Their Health Information* measure, we see no reason to have it remain a standalone measure, subject to numerator/denominator scrutiny.

AMIA Recommendation: AMIA supports the removal of this measure.

Proposed Modifications to the Public Health and Clinical Data Registry Reporting Objective and Measures

CMS is proposing to change the name of the objective to *Public Health and Clinical Data Exchange*. CMS is proposing that eligible hospitals and CAHs would be required to attest to the Syndromic Surveillance Reporting measure and at least one additional measure from the following options: Immunization Registry Reporting; Clinical Data Registry Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Electronic Reportable Laboratory Result Reporting. In addition, CMS intends to propose in future rulemaking to remove the *Public Health and Clinical Data Exchange* objective and measures no later than CY 2022, and is seeking public comment on

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[22] Patel MS, Patel N, Small DS, et al. Change In Length of Stay and Readmissions among Hospitalized Medical Patients after Inpatient Medicine Service Adoption of Mobile Secure Text Messaging. J Gen Intern Med. 2016 Aug;31(8):863-70. doi: 10.1007/s11606-016-3673-7.

[23] Hogan TP, Luger TM, Volkman JE, et al. Patient Centeredness in Electronic Communication: Evaluation of Patient-to-Health Care Team Secure Messaging. J Med Internet Res. 2018 Mar 8;20(3):e82. doi: 10.2196/jmir.8801.

whether hospitals will continue to share such data with public health entities once the *Public Health and Clinical Data Exchange* objective and measures are removed, as well as other policy levers outside of the Promoting Interoperability Program that could be adopted for continued reporting to public health and clinical data registries, if necessary. Lastly, CMS is seeking public comment on whether the Promoting Interoperability Programs are the best means for promoting the sharing of clinical data with public health entities.

AMIA Comments: The long-standing requirements to generate and share public health data through the EHR Incentive Program is an important aspect of the public health data landscape. While we acknowledge difficulties in fulfilling the vision of an integrated clinical and public health data ecosystem, we see the digitization of care delivery as benefiting both patients and populations.

We note a lack of rationale from CMS explaining why Syndromic Surveillance reporting should be the required measure, over the other options. In addition, the language regarding exclusion for Syndromic Surveillance reporting is somewhat ambiguous: it states that if a EH/CAH claims exclusion for *one or both* of the public health measures that the points associated with this measure would be redistributed to the Provide Patients Electronic Access to their Health Information measure instead (emphasis added). It is not clear why exclusion for Syndromic Surveillance reporting should have any effect on the other required public health measure.

Regarding the CMS's proposed removal of the *Public Health and Clinical Data Exchange* objective and measures in future rulemaking, we note that CMS states in the preamble that these registries provide the necessary monitoring of public health nationally and contribute to the overall health of the nation. We believe there is a strong case for transmitting public health data electronically and that every CEHRT should have the capability to do so. While we acknowledge that not every hospital has a public health organization capable of accepting all options in this measure, we suspect that the outcome of removing this measure completely will result in a less functional, less coordinated landscape of public health reporting over time as standards and versions change.

AMIA Recommendation: Rather than *lower* the requirements for public health reporting, AMIA recommends that CMS should carry forward a variation of the Stage 3 requirements. We recommend that the objective be changed to require yes/no attestation to ongoing submission of: Syndromic Surveillance Reporting, Immunization Registry Reporting, Reportable Lab Results and at least one clinical data registry or other public health registry, with the expectation that a clinical registry consists of data from multiple program participants, recognizing the programmatic theme of promoting interoperability. In addition, as the language around exclusion for Syndromic Surveillance is ambiguous, it is necessary to change the language to require a program participant claiming exclusion for syndromic surveillance to engage with another measure option to successfully comply with the measure.

To reiterate: AMIA does not support the proposal and we do not support the proposal to remove that *Public Health and Clinical Data Exchange* measure in the future. Further, we do not believe other CMS programs would better promote the sharing of clinical data with public health entities.

June 25, 2018

Request for Comment - Potential New Measures for HIE Objective: Health Information Exchange Across the Care Continuum

CMS wants to introduce additional flexibility to allow providers a wider range of options in selecting measures that are most appropriate to their setting, patient population, and clinical practice improvement goals. For this reason, CMS is seeking public comment on a potential concept for two additional measure options for the Health Information Exchange objective for eligible hospitals and CAHs.

CMS proposes two new measure concepts: *Support Electronic Referral Loops by Sending Health Information Across the Care Continuum* and *Support Electronic Referral Loops by Receiving and Incorporating Health Information Across the Care Continuum.*

For *Sending Health Information Across the Care Continuum* CMS proposes that for at least one transition of care or referral to a provider of care other than an eligible hospital or CAH, the eligible hospital or CAH creates a summary of care record using CEHRT, and electronically exchanges the summary of care record. For the *Receiving and Incorporating Health Information Across the Care Continuum* CMS proposes that for at least one electronic summary of care record received by an eligible hospital or CAH from a transition of care or referral from a provider of care other than an eligible hospital or CAH, the eligible hospital or CAH conducts clinical information reconciliation for medications, mediation allergies, and problem list.

CMS seeks public comment on whether these two measures should be combined into one measure so that an eligible hospital or CAH that is engaged in exchanging health information across the care continuum may include any such exchange in a single measure.

CMS seeks public comment on whether the denominators should be combined to a single measure including both transitions of care from a hospital and transitions of care to a hospital. CMS is also seeking public comment on whether the numerators should be combined to a single measure including both the sending and receiving of electronic patient health information. CMS is seeking public comment on whether the potential new measures should be considered for inclusion in a future program year or whether stakeholders believe there is sufficient readiness and interest in these measures to adopt them as early as 2019. For the purposes of focusing the denominator, CMS is seeking public comment regarding whether the potential new measures should be limited to transitions of care and referrals specific to long-term and post-acute care, skilled nursing care, and behavioral health care settings.

CMS also seeks public comment on whether additional settings of care should be considered for inclusion in the denominators and if a provider should be allowed to limit the denominators to a specific type of care setting based on their organizational needs, clinical improvement goals, or participation in an alternative payment model. Finally, CMS is seeking public comment on the impact the potential new measures may have for health IT developers to develop, test, and implement a new measure calculation for a future program year.

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AMIA Comments: While we see incorporation of the whole care continuum – including ambulatory, long-term and post-acute care, skilled nursing care, and behavioral health care settings – in support of referral loops as laudable, we offer similar commentary to these proposals as the previous *Supporting Referral Loop* measures. In short, we see these measures as suffering from the same flaws and difficulties facing the other HIE measures. Likewise, we see no reason that these measures will be any more successful at supporting referral loops.

This measure has the added difficulty of contextual factors such as the fact that LT-PAC and SNFs often do not have EHRs, or at least do not have CEHRT. We also note that 42 CFR Part 2 will complicate information exchange with behavioral health programs that are part of the continuum.

AMIA Recommendation: Should CMS proceed with our primary recommendation for *Supporting Referral Loop* measures, we recommend that electronic summary of care records received from a transition of care or referral from a provider of care other than an eligible hospital or CAH count as part of the *Request/Accept Summary of Care* denominator and the *Clinical Information Reconciliation* denominator. This could give CMS a sense of adoption across the care continuum, as well as encourage recipient hospitals to accept and reconcile information received from these settings.

Were CMS to finalize this IPPS NPRM with two separate measures, rather than the combined and revised measure as proposed, summary of care records received from across these settings could be captured and calculated beginning in 2019, as these measures are currently supported by 2015 Edition CEHRT. If CMS does not proceed with our primary recommendation, we would not support the inclusion of these two measure options in the 2019 program year.

If CMS is serious about promoting interoperability within the care continuum, we recommend that CMS focus on the adoption of CEHRT in these settings and look towards fee schedule rules to encourage such adoption. Connecting the care continuum is an important endeavor, but the PI Program and these measure proposals will be ineffective in accomplishing such a goal.

Promoting Interoperability Program Future Direction

CMS believes a focus on interoperability and simplification will reduce health care provider burden while allowing flexibility to pursue innovative applications that improve care delivery. Thus, CMS is exploring the creation of a set of priority health IT activities that would serve as alternatives to the traditional EHR Incentive Program measures. CMS is seeking comment on this concept, as well as welcoming recommendations for other health IT activities through which eligible hospitals could earn credit in lieu of reporting on specific measures. For example, CMS is exploring whether participation in the Trusted Exchange Framework and Common Agreement (TEFCA) should be considered a health IT activity that could count for credit within the Health Information Exchange objective in lieu of reporting on measures for this objective.

CMS is also considering a health IT activity in which eligible hospitals and CAHs could obtain credit if they maintain an open API which allows patients to access their health information through a

preferred third party. This could be the open API maintained to comply with the terms of the TEFCA or a standalone offering as long as the API offers ongoing persistent access to outside parties. Under this approach, an eligible hospital or CAH that attests to making such an open API available for the purposes of ensuring patients have access to their health information would receive full credit for the Provide Patient Access measure under this objective. Finally, CMS is considering developing a health IT activity which would allow eligible hospitals and CAHs to obtain credit under the Public Health and Clinical Data Exchange objective for piloting emerging technology standards.

AMIA Comments: AMIA supports CMS's goals of reducing administrative burden, supporting alignment with the Quality Payment Program, advancing interoperability and the exchange of health information, and promoting innovative uses of health IT. Thus, we are generally supportive of the idea to allow performance and reporting of health IT activities as an alternative to traditional measures. We additionally support the inclusion of TEFCA participation as one such activity, but we note that TEFCA participation is still theoretical and undefined in practice. As we stated in our original comment letter to ONC, we believe that TEFCA can "encourage coordination and harmonization among [...] existing private sector networks, as well as provide opportunities for new networks to emerge."[24] CMS can help encourage the utilization and growth of these new networks by including participation as a qualifying health IT activity.

AMIA also supports the idea, in principle, of giving credit to hospitals if they maintain an open API which allows patients to access their health information through a preferred third party. We would advise CMS to consider both the security and value of APIs that would be eligible under this potential activity.

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[24] https://www.amia.org/sites/default/files/AMIA-Comments-on-Trust-Framework-RFC.pdf

Promoting Interoperability Program Future Direction

In future years of the Promoting Interoperability Program, CMS will continue to consider changes which support a variety of HHS goals, including: reducing administrative burden, supporting alignment with the Quality Payment Program, advancing interoperability and the exchange of health information, and promoting innovative uses of health IT. CMS believes a focus on interoperability and simplification will reduce health care provider burden while allowing flexibility to pursue innovative applications that improve care delivery. CMS is specifically seeking public comments on the following questions:

CMS Questions	AMIA Comments & Recommendations
What health IT activities should CMS consider recognizing in lieu of reporting on objectives that would most effectively advance priorities for nationwide interoperability and spur innovation? What principles should CMS employ to identify health IT activities?	**AMIA Comment:** In comments to CMS in 2016, we stated that payment policies which had been used primarily to encourage adoption, then used to dictate specific uses of health informatics, should be reoriented to learn, not simply to grade. Meaningful Use and its successor programs (PI Program, MIPS, etc.) should abandon the overly prescriptive approach of the past and enable clinicians to receive credit for novel and advanced use of health informatics tools. This would allow CMS to learn about how hospitals are leveraging health IT for patient care, rather than simply grading them on the frequency of their engagement in health IT process measures. As a matter of principle, we believe health IT activities need to be tied to outcomes. For example, the number of times CPOE is used indicates EHR use, but does nothing to indicate how the patient was impacted by the order. And while the *Supporting Referral Loop* measures are more closely tied to outcomes, they do not tell us anything about what such coordination did for the patient. We now have enough adoption and growing experience with health informatics to determine which tools and uses are likely to positively impact patient care. While still in its infancy, the study of health IT as a facilitator, as well as an intervention, to improve patient care has a growing corpus from which to determine how to leverage such tools correctly. These activities need more flexibility than the current approach allows. Specifically, numerator/denominator-driven design has had undue influence on workflows, which have proven far more entrenched than anticipated. Workflows are not immovable, but lasting change only occurs when it's part of a strategic shift, not a government program subject to the whims of yearly rulemaking.

CMS Questions	AMIA Comments & Recommendations
	We also know that hospitals are making progress on multiple dimensions of interoperability. Reimbursement policies and market conditions have encouraged the growth of large, expansive health networks, that must integrate multiple EHRs across inpatient, ambulatory, and other community settings. This has impacted interoperability, both with outside exchange partners, and internally to improve efficiency, cost savings, and care quality. Recent evidence suggest that hospitals exchange more types of information in an intra-system (i.e. within the same organization) manner than inter-system (i.e. between different organizations).[25] This is especially true when there are a number of different inpatient EHR vendors. **AMIA Recommendation:** We recommend CMS evolve the PI Program from a process-measure focused, numerator/denominator-driven reporting program towards a program that empowers hospitals to use health informatics tools in innovative ways and demonstrating that such work has contributed to improved outcomes. We recommend CMS review its catalog of Merit-Based Incentive Payment System program Improvement Activities for the kinds of activities that seek to balance clinical relevance with improved use of health informatics tools. While we see many of the current MIPS Improvement Activities as simple projects with limited scope, we view them as appropriately scaled for small and medium-sized practices. For hospital-submitted Inpatient Improvement Activities (IIAs) we envision larger (in scope and duration), more complicated programs, which would span most (if not all) corridors of the organization. Rather than dictating to clinicians the functionalities necessary for quality patient care, CMS should rely on and monitor IIAs developed by hospitals, addressing priority populations, using health IT. The use of health IT and informatics tools are means to provide better patient care, not an end unto

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[25] Vest JR, Simon K; Hospitals' adoption of intra-system information exchange is negatively associated with inter-system information exchange, *Journal of the American Medical Informatics Association*, , ocy058, https://doi.org/10.1093/jamia/ocy058

CMS Questions	AMIA Comments & Recommendations

	itself. Were CMS to move in the direction of accepting hospital-submitted IIAs, as we recommend above, there are several issues CMS would need to consider. Namely:
	● CMS would need to provide guidance as to an expected level of effort or clearly define the expected outcomes for which IIAs would be focused.
	  ○ CMS should consider single-year and multi-year projects
	  ○ CMS should look towards current large-scale national quality improvement initiatives, or priorities, such as VTE, Sepsis, Readmission Risk, SBIRT, or medication adherence as part of its potential focus.
	  ○ CMS should consider priority areas for hospitals to focus, ensuring that such focus areas are broad: such as patient engagement, promoting interoperability, patient safety and clinical quality improvement.
	  ○ CMS should require that such hospital-driven IIAs involve broad swaths of clinicians who deliver care in their facility, as well as the patients who receive such care.
	● CMS would need to engage with clinical informatics experts who can speak to both the clinical and technical evidence in support of IIAs
	  ○ CMS should ensure that IAs demonstrably improve or achieve the goals for which it was implemented. For example, we know that telehealth has the potential to improve outcomes and lower costs, but does the telehealth IIA proposed by Hospital A achieve improved quality commensurate with CMS expectations?
	  ○ CMS will need to encourage demonstration projects as unforeseen questions surface.
	
	We envision a graduated approach for hospitals who have successfully demonstrated health IT competency as determined through existing Stage 3 / proposed PI Program measures as finalized by this NPRM. We recommend CMS target 2021 to make available IIAs for hospitals who wish to participate, and we encourage CMMI to initiate pilots to better understand what systems and controls are needed to support this program. So too would CMS need to initiate a broad and inclusive conversation regarding the contours and characteristics of acceptable IIAs.

CMS Questions	AMIA Comments & Recommendations
Do stakeholders believe that introducing health IT activities in lieu of reporting on measures would decrease burden associated with the Promoting Interoperability Programs?	**AMIA Comment:** Generally, AMIA has supported the concept of "deeming" in the past to decrease administrative burden associated with reporting requirements for MIPS and its precursor EHR Incentive Payment Programs. **AMIA Recommendation:** Yes, but this support depends on how stakeholders would need to demonstrate/validate their engagement in the health IT activities. If hospitals could design, implement, and report on a series of tailored IIAs, this could align better with and complement the kinds of processes and measures already needed to understand performance, without reporting predetermined numerator/denominator-type measures. Scaling this approach and verifying performance would require attention, but IIAs would provide both flexibility and clinical relevance for hospitals.
If additional measures were added to the program, what measures would be beneficial to add to promote our goals of care coordination and interoperability?	**AMIA Comment:** As has been stated in various other venues, interoperability is too abstract a concept to consider without answering the question "interoperability for what?" Does this question, for example, inquire about the interoperability of key stakeholders such as external labs, radiology, pharmacies, skilled nursing facilities, etc? Or is it focused on improving the interoperability of information contained within the CCDA? **AMIA Recommendation:** Rather than increase the number/kinds of required measures, we recommend CMS evolve the PI Program to decrease the number of measures by tolerating hospital-developed IIAs that leverage CEHRT - as well as functionality that leverages CEHRT (e.g. APIs). In place of measures, CMS should require hospitals: ● Adhere to CEHRT updates and attest that have all the functionalities of CEHRT are "turned on" and ● Adopt/upgrade to new CEHRT within a reasonable, 24-month period. Validation of these actions should be apparent when hospitals submit IIA proposals and results. We note that CMS must demand that CEHRT be closely tied to the USCDI, and it should encourage a predictable

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CMS Questions	AMIA Comments & Recommendations
	schedule of updates to new certification criteria / functionality. A regular cadence of CEHRT updates should be established and provide a floor, set 1 or 2 versions below the most current Edition, depending on update frequency.
How can the Promoting Interoperability Program for eligible hospitals and CAHs further align with the Quality Payment Program (for example, requirements for eligible clinicians under MIPS and Advanced APMs) to reduce burden for health care providers, especially hospital-based MIPS eligible clinicians?	**AMIA Comment:** CMS has made strides towards alignment with MIPS through the proposals of this NPRM, including a new scoring methodology and reduction of measures. We anticipate CMS will make similar (if not the same) proposals through the Physician Fee Schedule and related regulations supporting the implementation of MACRA.

As it relates to Advanced APMs, we see the baseline requirement to use CEHRT as an appropriately calibrated requirement. Given the other systems and controls focused on quality, outcomes, and costs, we do not see need for more prescriptive requirements for health IT in AAPM. Should CMS look to leverage AAPM participation as a health IT activity and subsequently deem hospital participants as meeting the PI Program requirements, we would suggest that one or more IIA be described alongside other AAPM reporting.

AMIA Recommendation: We see value in aligning the PI Program with MIPS Advancing Care Information requirements in the near-term, but would encourage CMS to pursue a different strategy for both ambulatory and inpatient care over the medium and long-terms. We do not think the goal should be to replicate MACRA requirements in the hospital setting. |
| What other steps can HHS take to further reduce the administrative burden associated with the Promoting Interoperability | **AMIA Comment:** We are supportive of many PI Program proposals developed by CMS in this proposed rule, including:
● Shorter (90-day) reporting period;
● Removal / reduction of exclusions to measures, which can have a confounding impact on workflows and IT decision logic; |

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CMS Questions	AMIA Comments & Recommendations
Program?	- Removal of some measures (although bundling of other measures will still prove challenging); and - Removal of "all or nothing" scoring. While supportive of these changes, we are concerned that CMS may be close to the bounds of its ability to impact, indeed, promote interoperability (comments related to the Conditions of Participation RFI notwithstanding). The requirements to engage in prescriptive activities using health IT pale in comparison to the requirements related to CEHRT. CMS is a consumer of ONC's Certification Program, and subject to remarkably similar constraints as hospitals looking to purchase CEHRT to participate in the PI Program. A Stanford/Harris Poll study (Slide 12) showed that the top desire of providers for their EHRs is interoperability. This is not likely unless CMS demands more of CEHRT - especially regarding the ability of CEHRT to interoperate with other CEHRT. As this question asks not "what CMS can do?" but "what HHS can do?" we offer the following: - ONC: Test for interoperability when certifying EHR modules - ONC/NLM: Fund research and development of increasingly granular data specifications - OCR: Better define "designated record set" with input from hospital stakeholders - OCR: Develop capability for CEHRT to "readily produce" patient data in a computable format upon request - ONC: Continue with USCDI development and ensure that CEHRT can generate and exchange requisite data classes - ONC: Address the interoperability of key stakeholders such as external labs, radiology, pharmacies, skilled nursing facilities, etc. We note that these other stakeholders complicate the ability of hospitals to leverage their CEHRT for interoperability, especially with regard to pharmacy systems, PBMS, and third-party lab vendors.

<u>Proposed CQM Reporting Periods and Criteria for the Medicare and Medicaid Promoting Interoperability Programs in CY 2019</u>

For CY 2019, CMS is proposing the same CQM reporting periods and criteria as established in the FY 2018 IPPS final rule, which would be to report one self-selected calendar quarter of CY 2019 data, and the submission period for the Medicare Promoting Interoperability Program would be the 2 months following the close of the calendar year, ending February 29, 2020. For eligible hospitals and CAHs participating only in the Promoting Interoperability Program, or participating in both the Promoting Interoperability Program and the Hospital IQR Program, at least 4 self-selected CQMs from the set of 16 available CQMs must be reported.

AMIA Comments: AMIA supports the continuation of these reporting requirements, which will aid hospitals in their data extraction processes and provide them with flexibility as they fully implement 2015 CEHRT. We believe that this policy supports the ultimate goal of more efficient and seamless electronic collection and submission of quality measures.

<u>Request for Comment</u>

CMS is seeking feedback on challenges related to eCQM use. Specifically, it is inviting comment on the following:
- What aspects of the use of eCQMs are most burdensome to hospitals and health IT vendors?
  - There are two main barriers to electronic quality measurement: exclusions and data availability. The number and kinds of exceptions/exclusions to CQMs create the most burden for hospitals and health IT vendors. In addition, many CQMs are not developed based on the data that is available / generated during the routine delivery of care. These twin issues drive manual abstraction and create enormous burden.
- What program and policy changes, such as improved regulatory alignment, would have the greatest impact on addressing eCQM burden?
  - Alignment across payers and regulatory requirements for consensus measures would deliver more harmonized eCQMs.
  - Another important aspect of the current eCQM experience is the incredible time and effort needed to test eCQMs. Despite CEHRTs capacity to generate eCQMs, it seems as though every site needs to engage in burdensome and resource-intensive testing. CMS should consider ways that it could facilitate the testing of eCQMs through shared infrastructure, so that individual settings can have a more streamlined experience.
- What are the most significant barriers to the availability and use of new eCQMs today?
  - Significant barriers to the availability and use of new eCQMs stem from the current measure development process. AMIA envisions an improved process that is transparent, consistent, inclusive, and includes a parallel quality assurance mechanism to ensure all measures developed through the process are aligned with a holistic strategy. In conjunction, we wish to see efforts to simplify measure development and

streamline approval processes, including a firm set of selection criteria and strict endorsement processes.[26]

- What specifically would stakeholders like to see us do to reduce burden and maximize the benefits of eCQMs?
  - CMS should encourage the development of evidence-based quality measures based on data elements that already exist in the EHR. This would help to ensure that data can be captured through routine practice, without impairing patient-provider communication. In addition, CMS should develop a measurement tool to better understand the cost/benefit of data collection, when it considers CQMs that need data elements outside the EHR. Finally, CMS should establish a national testing infrastructure for CQMs.
  - Encourage all CQMs used in CMS programs to depend on data supported by the current USCDI and CEHRT. If the eCQM requires data outside the USCDI / CEHRT, then it should not be required for reimbursement.
- How could CMS encourage hospitals and health IT vendors to engage in improvements to existing eCQMs?
  - CMS should look to hospitals' existing quality improvement initiatives, which should become increasingly electronic. For eCQMs that are built into a vendor system, vendors could analyze the data and/or encourage hospitals to share the data for analysis. This would allow fine tuning of required information, as well as provide information on apparent gaps in care when eCQMs are not met for an eligible patient. Such analyses would help in identifying barriers to delivery of care as specified in the eCQM, as well as identifying problems with the eCQM itself.
- How could CMS encourage hospitals and health IT vendors to engage in testing new eCQMs?
  - CMS could also help test new eCQMs by leveraging the creativity that currently exists in hospitals across the country. The agency could do this by creating a "safe harbor" status for organizations that utilize their own vetted quality measurement systems. Such a status would not only advance quality improvement, but it would allow hospitals to utilize improvement practices tailored to their specific setting, without imposing a "one size fits all" policy that may not, in fact, fit at all.[27]
- Would hospitals and health IT vendors be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would explore less burdensome ways of approaching quality measurement, such as sharing data with third parties that use machine learning and natural language processing to classify quality of care or other approaches?
  - As hospital EHR adoption has become nearly universal and wearable device and patient portal use more ubiquitous, there is more information to take advantage of

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[26] See the NCQA: http://www.ncqa.org/Portals/0/HEDISQM/Measure_Development.pdf
[27] McGlynn EA, Kerr EA. Creating safe harbors for quality measurement innovation and improvement. JAMA. 2016;315(2):129-30.

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than ever before. CMS should thus work with stakeholders to establish pilots that will specifically seek to leverage data entered by other members of the care team, captured automatically by devices or other information systems, or captured and entered by patients themselves.[28] Pilot participants should be able to demonstrate quality improvement driven by data that is in many cases, collected outside the four walls of the hospital.

- o AMIA does also support the use of research and pilot projects on use of machine learning and natural language processing as ways to assist in reducing quality measurement burden.

- What ways could CMS incentivize or reward innovative uses of health IT that could reduce burden for hospitals?
    - o As we mention above, hospitals already have innovative quality improvement programs and processes using health IT. CMS should find ways to reward such innovative uses.
- What additional resources or tools would hospitals and health IT vendors like to have publicly available to support testing, implementation, and reporting of eCQMs?
    - o A shared infrastructure to test CQMs would be a tremendously valuable resource.

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[28] Payne T.H., Corely S., Cullen T.A. et al. Report of the AMIA EHR-2020 Task Force on the status and future direction of EHRs. Journal of the American Medical Informatics Association, Volume 22, Issue 5, 1 September 2015, Pages 1102–1110, https://doi.org/10.1093/jamia/ocv066

XII. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid Participating Providers and Suppliers

CMS is specifically inviting stakeholder feedback on the following questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information:

CMS RFI Questions	AMIA Comment & Recommendations
If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?	**AMIA Comment:** It has been our experience that clinicians want to send important data and receive important data, and we acknowledge this isn't occurring consistently. We observe that information blocking may occur for numerous reasons (see Sociotechnical Interoperability Stack in Appendix A). We anticipate that the forthcoming rules by ONC and OIG will be sufficient in stemming the nefarious aspects of information blocking, especially for provider-to-provider exchange. We also suspect that individual patients will benefit from the same regulation, given the history of difficulty in obtaining their records and their lack of agency to address the issue the way a business might. **AMIA Recommendation:** We recommend that CMS garner experience and insights under the Information Blocking rule, once finalized, before deciding to modify COP/CfC/RfPs. Further, we recommend CMS focus its inquiry on provider-to-patient information flows and calibrate its policies to ensure that all entities receiving Medicare funds provide patients 24x7x365 access to their information in a persistent manner and without special effort. We find the concept of "medically necessary information," somewhat abstract and very context-dependent. Should CMS endeavor in this direction, we recommend considering Admission, Discharge, Transfer (ADT) feeds as potential candidates for incorporation into CoPs/CFCs/RFPs updates. Encouraging the generation ADT feeds
Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his	**AMIA Comment:** We do worry about uniform adoption, implementation, upgrade, and ongoing maintenance of CEHRT across settings and geographies. For patient access, implementation of 2015 Edition CEHRT (assuming all functionalities are

CMS RFI Questions	AMIA Comment & Recommendations
or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?	activated) would satisfy this requirement. However, we foresee a need to develop consensus on a standard process that ensures third-party applications can successfully and safely receive, store and transmit clinical information from/to Covered Entities. This process would give assurance to hospitals and patients that such applications are safe and perform as intended. For residents, we understand that their settings of care do not have equally high rates of EHR adoption, as compared to hospitals, so compelling investments in 2015 Edition CEHRT will represent a more costly/difficult undertaking. **AMIA Recommendation:** As stated previously, we recommend CMS garner experience under the bevvy of policy and technical updates expected over the next year before rendering proposals regarding CoPs/CfCs/RfPs. However, should CMS proceed with proposals to amend CoPs/CfCs/RfPs to ensure patient / resident access to his or her health information, we recommend CMS take a differential approach to such requirements, depending on adoption trends across the setting of care (e.g. inpatient, SNF, LT-PAC, etc.). As means to implement these changes, AMIA recommends that any hospital that implements the 2015 Edition CEHRT and successive Editions, while ensuring API functionality (and successor functionalities as appropriate) is activated, would be considered compliant. A regular and predictable cadence of CEHRT updates is necessary for providers to plan for updates. Once normalized, CMS could establish a baseline expectation that hospitals maintain CEHRT, no more than one to two versions behind the most current Edition, depending on update frequency. Annual updates to CEHRT may be less dramatic, thus tolerating use of previous Editions. Given the status of CEHRT adoption among other Medicare- and Medicaid

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CMS RFI Questions	AMIA Comment & Recommendations
	Participating Providers and Suppliers, we suggest lesser requirements. One possibility is to require a Direct account and patient portal for LT-PAC and SNFs, for example. Many post-acute care facilities are acquiring the equivalent of provider EHRs and, overtime, requirements for CMS payment need to include the ability to send and receive standard documents via portals, secure messaging, and APIs. Direct is an insufficient standard for the future, but will suffice until RESTful means (web-based portal access or APIs) are more broadly available.
Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, HIPAA, and implementation of relevant policies in the 21st Century Cures Act?	**AMIA Comment:** It is as-yet-unclear what impact revised CoPs/CfCs/RfPs will have on routine electronic transfer of health information as well as overall patient/resident care and safety. It is equally unclear how implementation of various Cures provisions will impact the landscape. We anticipate that requirements to use 2015 Edition CEHRT will improve the availability of patient information through patient portals, transmission functionality, and propagation of APIs, but the CEHRT requirements need to be augmented: patients need to be able to enter their email address, secure messaging address, or the address of their third-party application into existing CEHRT patient portals, ala the Sync-4-Science initiative, and be able to get automatic updates whenever the EHR receives new information.
What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed	**AMIA Comment:** Simple, straight-forward requirements and well-documented means to achieve any updates to COPs/CfCs/RfPs is necessary. CMS should also conduct an in-depth landscape review of whether and how pervasive any considered updates might be within the setting (LT-PAC, e.g.) of focus. This landscape review should then inform the development of a compliance timeline.

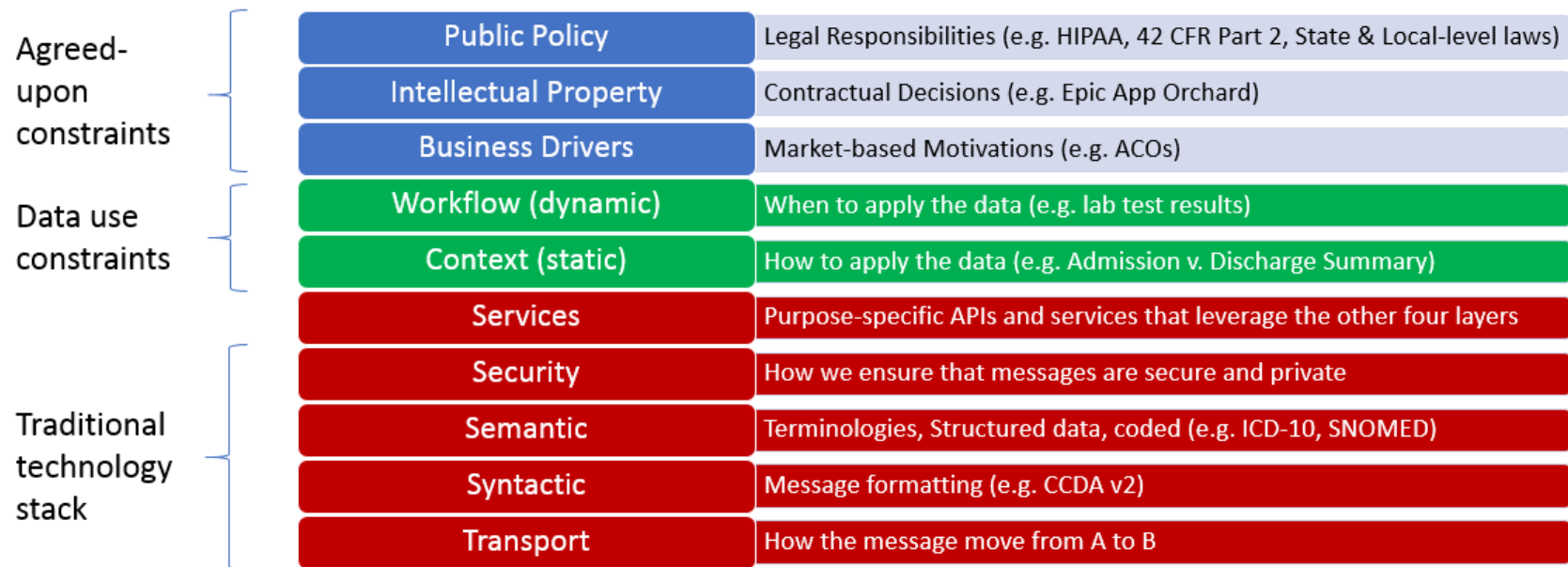| CMS RFI Questions	AMIA Comment & Recommendations
implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?	CMS also needs to coordinate with ONC a regular cadence and process to update CEHRT requirements for use of consensus standards that slowly march forward over the years and give EHR vendors adequate, but not unlimited, time to make the required changes. We reiterate our position that standard message formats, standard document formats, and standard vocabularies, all named, numbered, without optionality, and testable 7x24x365 on a web-based infrastructure should be the goal.
Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?	**AMIA Comment:** It is as-yet-unclear what impact revised CoPs/CfCs/RfPs will have on routine electronic transfer of health information as well as overall patient/resident care and safety. However, if the updates lead to data availability for patients and automatic ADT information, we anticipate positive impacts to patient/resident care and safety.
Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?	**AMIA Comment:** Yes, form, format and manner of receipt of information should accommodate human-readable (non-electronic) information, if requested by the patient / resident. However, such requests from a receiving provider or supplier should diminish overtime, and CMS should monitor the pace of progress to determine when such requests are no longer permissible, except for in rare circumstances (e.g. natural disaster).

CMS RFI Questions	AMIA Comment & Recommendations
Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?	**AMIA Comment:** Yes. We note HIPAA considerations that should be examined above, and we note that differing state- and local-level regulations may facilitate or impede interoperability. We also note that 42 CFR Part 2 regulations have inhibited information flows historically. In comments submitted to SAMHSA in 2016, we stated, "Part 2 regulations have had the effect of erecting a 'brick wall' that blocks information exchange between Part 2 programs and other health system elements. Technically, Part 2 programs can share information with appropriate patient consent or under narrowly defined circumstances (e.g., life threatening medical emergencies) but on a practical level, information exchange is incomplete and infrequent. Logistical barriers and widespread confusion about the regulatory requirements often paralyze organizations from exchanging data or coordinating care with Part 2 programs."[29] (see Appendix B for visual description). **AMIA Recommendation:** We recommend that CMS coordinate with ONC and OCR to (1) better define the HIPAA construct of a Designated Record Set, and (2) translate the HIPAA construct of "readily producible," by way of ONC certification criteria via CEHRT. Over time, the USCDI and CEHRT need to deliver as much or as little of the "Designated Record Set" as a patient requests. Further, we recommend HHS work with Congress to develop a policy solution inhibiting exchange of Part 2 data, while also encouraging the development of more granular data specifications, so that the spectrum of sensitive data – including reproductive, mental health and SUD data is managed in a more comprehensive fashion.

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[29] AMIA Response to SAMHSA Proposed Rule Regarding the Confidentiality of Substance Use Disorder Patient Records. April 6, 2016. Available at: https://www.amia.org/public-policy/amia-response-samhsa-proposed-rule-regarding-confidentiality-substance-use-disorder

## Appendix A: Socio-Technical Interoperability Stack

Agreed-upon constraints	Public Policy	Legal Responsibilities (e.g. HIPAA, 42 CFR Part 2, State & Local-level laws)
	Intellectual Property	Contractual Decisions (e.g. Epic App Orchard)
	Business Drivers	Market-based Motivations (e.g. ACOs)
Data use constraints	Workflow (dynamic)	When to apply the data (e.g. lab test results)
	Context (static)	How to apply the data (e.g. Admission v. Discharge Summary)
Traditional technology stack	Services	Purpose-specific APIs and services that leverage the other four layers
	Security	How we ensure that messages are secure and private
	Semantic	Terminologies, Structured data, coded (e.g. ICD-10, SNOMED)
	Syntactic	Message formatting (e.g. CCDA v2)
	Transport	How the message move from A to B

Our view is that information blocking is the absence of interoperability. Interoperability may not occur for numerous reasons, outlined by category (blue, green, red). Red represents the traditional technology stack, using the Internet Protocol stack as a model. Data use constraints are particular to healthcare and can impact information blocking and/or interoperability. Workflow is a dynamic concept and indicates that data received at the wrong time in the workflow could be perceived as information blocking or negatively impact concepts of interoperability. Context is a static concept, which is to say that data can have different meanings depending on context, and be rendered more or less usable for the task at hand. Public policy, intellectual property, business drivers comprise the top of the socio-technical stack, and may be reasonable or unreasonable inhibitors to interoperability.

Appendix B: 42 CFR Part 2 and Information Exchange
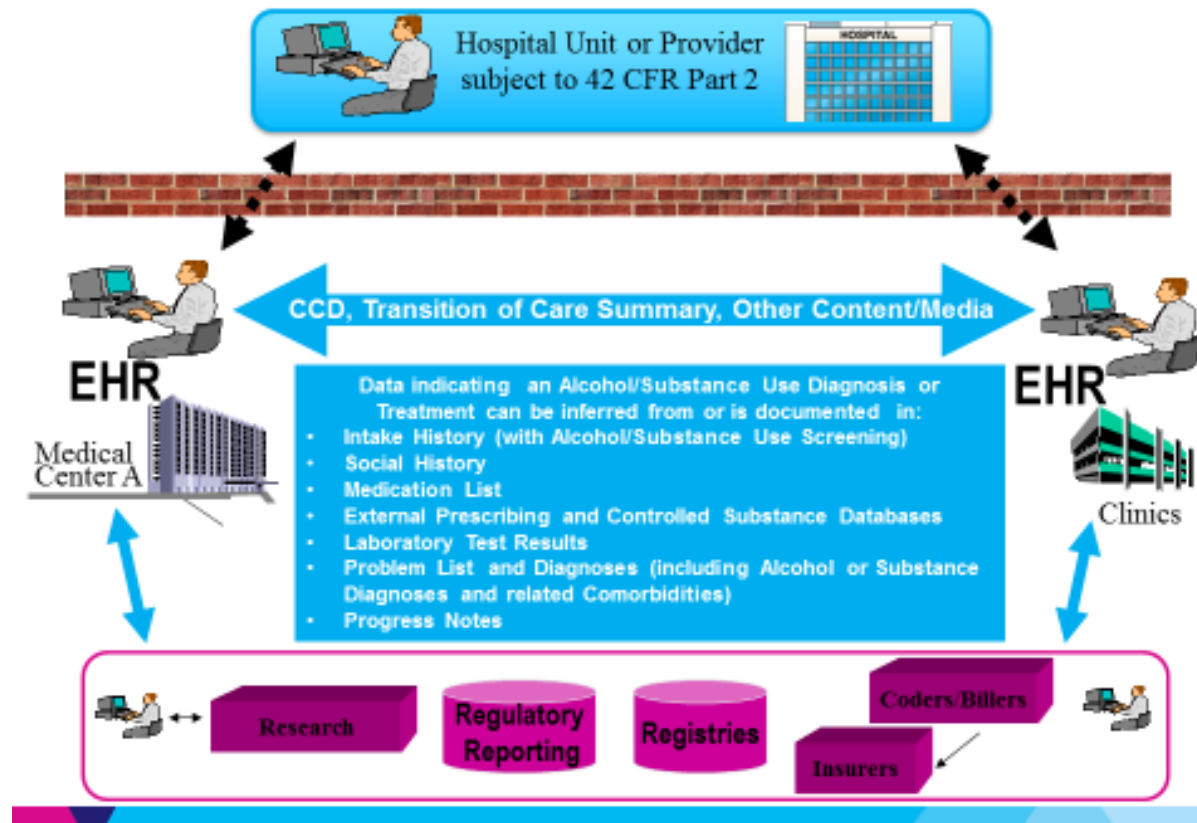
In the current health care delivery system, diagnosis and treatment of SUDs can occur in multiple settings, some of which are subject to 42 CFR part 2 and many of which are not subject to Part 2. As shown in Figure 1, the Part 2 regulations have had the effect of erecting a "brick wall" that blocks information exchange between Part 2 programs and other health system elements. Technically, Part 2 programs

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can share information with appropriate patient consent or under narrowly defined circumstances (e.g., life threatening medical emergencies). On a practical level, however, information exchange is relatively infrequent due to logistical barriers and widespread confusion about the regulatory requirements. Further, many of the same issues are present for behavioral health organizations that treat both mental health and SUDs and are complicated by a set of state laws, rules and guidance for mental health. Figure 1 also shows that goals of 42 CFR Part 2 cannot be met simply by sequestering information and tightly controlling its release from Part 2 programs. Within other elements of the healthcare system, there has always been documentation and exchange of information related to SUDs. However, such data is more readily available with the growth of electronic health records and the increasing emphases on coordination of care and behavioral health integration.