



September 7, 2018

The Honorable Seema Verma  
Administrator, Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1693-P  
Submitted electronically <http://www.regulations.gov>

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide input on the CY2019 Physician Fee Schedule 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 supports PI Program alignment for eligible clinicians and hospitals**

AMIA is pleased that CMS has chosen to align the MIPS ACI, now referred to as Promoting Interoperability Program, with requirements recently finalized for hospitals as part of the FY19 IPPS rule. For example, AMIA appreciates the decision to finalize the required use of 2015 Edition CEHRT beginning in CY 2019 in the IPPS rule. We view this as foundational for improved interoperability, patient data access, and better usability. Thus, we strongly support the agency's proposal to extend this requirement to eligible clinicians (ECs) in this NPRM. See [page 12](#) for more.

**AMIA supports development of MIPS Priority Sets to end numerator/denominator-driven measurement**

As was the case with the CY 2019 IPPS NPRM, we encourage CMS to use this rulemaking as a pivot point to think more critically about how to achieve the dual goals of (1) burden reduction and (2) advanced use of health IT. While we appreciate CMS' efforts to harmonize PI Program requirements across inpatient and outpatient settings, CMS must chart a course towards an end to numerator/denominator-driven measurement. The CMS proposal for MIPS public health priority sets (MIPS Priority Sets), may present such an opportunity. AMIA fully supports CMS efforts to develop MIPS Priority Sets, and we posit that policy development in this direction could one day

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supplant the disparate performance categories, for those ECs who choose such an option. See [page 26](#) for details on how Priority Sets should be established.

### **AMIA supports E/M guideline reform to improve documentation burdens**

As it relates to proposed changes to E/M visit documentation requirements, AMIA and the informatics community have a history of leadership in commenting on EHR documentation challenges in the E/M era.<sup>1,2</sup> AMIA supports both the use of MDM and time as alternative means to determine appropriate level of E/M visit. However, we note that determining levels of MDM is a convoluted and complex task under current guidelines. This complexity must be addressed with an eye towards how IT and informatics can be leveraged so the simplicity of these solutions can be realized. Commentary begins [page 7](#).

### **E/M guideline reform must be facilitated by informatics to reduce documentation burden**

Absent the NPRM's discussion – and presumably CMS' current thinking – is the role technology can play to decrease documentation burden through passive “behind the scenes” data collection, facilitated through EHRs and other health IT. For example, EHRs currently register when a lab test has been viewed, and current technology can easily capture and provide audit data for how various aspects of an EHR is being used. The proposed E/M reforms must be supported through focused and well-resourced efforts to leverage these current functions and develop emerging functions, such as natural language processing, medical device data, voice recognition software, and the use of sensors to capture clinical activity. Acknowledging that these and other informatics tools are still early in development, CMS should support pilots and otherwise incentivize efforts meant to use these kinds of technologies and evaluate their use for documentation purposes. See [page 6](#) for more.

### **CMS must combine MIPS Quality and Cost metrics to incentivize value**

Incentives drive outcomes. To drive value, QPP must reward value, which is defined as quality divided by cost. While QPP recognizes quality and cost, the QPP composite score does not most reward those ECs who deliver the highest value to beneficiaries. Rather, the composite score incentivizes ECs to reduce cost to receive higher composite scores without regard to the impact on quality. To drive value, CMS should reward value by modifying the MIPS scoring methodology to ensure that those ECs who have the optimal ratio of quality/cost receive the highest composite scores.

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.

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<sup>1</sup> Cusack CM, Hripesak G, Bloomrosen M, et al. The future state of clinical data capture and documentation: a report from AMIA's 2011 Policy Meeting. *J Am Med Inform Assoc.* 2013 Jan 1;20(1):134-40. PubMed PMID: 22962195

<sup>2</sup> Payne TH, Corley S, Cullen TA, et al. Report of the AMIA EHR-2020 Task Force on the status and future direction of EHRs. *J Am Med Inform Assoc.* 2015 Sep;22(5):1102-10. PubMed PMID: 26024883

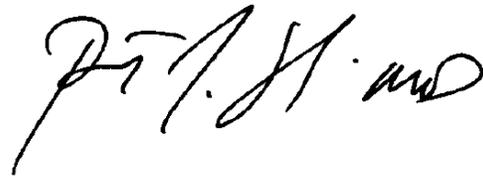
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We hope our comments are helpful as you undertake this important work. Should you have questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at [jsmith@amia.org](mailto:jsmith@amia.org) 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' CY19 PFS NPRM)*

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## **Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services**

CMS is proposing to pay separately for a newly defined type of physicians' service furnished using communication technology. This service would be billable when a physician or other qualified health care professional has a brief nonface-to-face check-in with a patient via communication technology, to assess whether the patient's condition necessitates an office visit.

CMS is additionally proposing to create specific coding that describes the remote professional evaluation of patient-transmitted information conducted via pre-recorded "store and forward" video or image technology. CMS notes that this service is distinct from the brief communication technology-based service described above in that this service involves the practitioner's evaluation of a patient-generated still or video image, and the subsequent communication of the resulting response to the patient, while the brief communication technology-based service describes a service that occurs in real time and does not involve the transmission of any recorded image.

Finally, CMS is proposing to create a new code for "Interprofessional Internet Consultation," for services conducted through telephone, internet, or electronic health record consultations. In creating these new, separately-payable codes, CMS hopes to encourage efficient and effective resource utilization by minimizing unnecessary visits. Further, making separate payment "for interprofessional consultation undertaken for the benefit of treating a patient will contribute to payment accuracy for primary care and care management services."

**AMIA Comments:** AMIA applauds CMS for recognizing the increased digitization of healthcare delivery and thus proposing to reimburse providers accordingly. We view these policies as addressing long-standing Medicare reimbursement barriers to widespread adoption of virtual care tools meant to reach more patients in more places, especially those in underserved and rural areas.

However, we have specific concerns related to the context of these new virtual care codes. We raise three specific issues that CMS should consider, including clinical effectiveness, patient authentication, and proliferation of data silos derived from telehealth applications.

### *Clinical Effectiveness*

Health IT should always serve to enhance clinical effectiveness. Regarding CMS' consideration of whether audio-only telephone interactions would be sufficient to qualify for reimbursement, AMIA cautions that such a question is specialty-dependent, and the clinical effectiveness of virtual care may be affected as a result. For example, a psychiatrist may only require audio-only interaction for some of her patients, while a dermatologist might require live-video for his. A CMS-prescribed addition of live-video for a psychiatric visit would not only be unnecessary for some patients, but it could also make such services less accessible to older individuals or individuals without smartphones or computers at home. It is often these individuals where care coordination and check-ins are most important.

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On the other hand, voice-only interactions are not sufficient for all settings and may even lead to lower quality of care. In one study of a direct-to-consumer telemedicine service, where about 80 percent of first-time visits are conducted via voice telephone, providers were less likely to order diagnostic testing and had poorer performance on appropriate antibiotic prescribing for bronchitis.<sup>3</sup> AMIA thus agrees with CMS that the brief telecommunication visit should only apply to established patients of the individual or the practice. However, we do not support the same restrictions for new patients regarding the proposed remote evaluation code.

Given that the “brief communication,” code is not intended to be a thorough evaluation, but a quick “check-in” to determine if a patient should schedule a more comprehensive visit, this restrictive policy on new patients makes sense. A similar restriction on remote evaluations could unduly inhibit the use of such codes for rural and community-based settings

In the spirit of health IT enhancing clinical care, AMIA also believes that it would be inappropriate for CMS to apply frequency limitations on the use of virtual check-in codes. There are some circumstances, again depending on specialty, where a provider may legitimately need to check in with a patient several times per week, or even several days in a row. Since these would likely be complex patients, CMS should not look to restrict access to patients, but rather give providers the freedom to utilize virtual check-ins as they see fit. We note that CMS has existing mechanisms to identify billing fraud. Placing constraints on virtual check-in billing frequency would primarily penalize individuals who are doing appropriate outreach to take appropriate care of patients. Furthermore, such restrictions would present a significant burden and need for more complex IT and billing algorithms.

#### *Patient Authentication*

AMIA raises concerns regarding the accuracy of patient identification for the proposed “remote evaluations” code. One study of the quality of direct-to-consumer teledermatology companies found that of the 16 companies examined, “[n]one asked for identification or raised concerns about pseudonym use or falsified photographs” that were sent to evaluating physicians.<sup>4</sup> CMS must ensure that its auditing processes include oversight of how ECs ensure that patients who initiate a remote encounter are who they say they are. This is especially important if CMS finalizes the proposal to make these services available to new patients.

#### *Proliferation of Data Silos*

AMIA additionally cautions that while patients, especially those in underserved areas, may see benefits from these telehealth services, we run the risk of creating more health IT silos in the care

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<sup>3</sup> Lori Uscher-Pines, Andrew Mulcahy, David Cowling, Gerald Hunter, Rachel Burns, and Ateev Mehrotra. Access and Quality of Care in Direct-to-Consumer Telemedicine. *Telemedicine and e-Health* 2016 22:4, 282-287

<sup>4</sup> Jack S. Resneck Jr, MD; Michael Abrouk; Meredith Steuer, MMS; et al. Choice, Transparency, Coordination, and Quality Among Direct-to-Consumer Telemedicine Websites and Apps Treating Skin Disease. *JAMA Dermatol.* 2016;152(7):768-775. doi:10.1001/jamadermatol.2016.1774

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continuum as telehealth applications proliferate. Whenever possible, remote evaluations and brief communications should be conducted within the EC's existing health IT.

**AMIA Recommendations:** AMIA recommends that CMS proceed with new codes for “brief communications,” “remote evaluation,” and “interprofessional consultation.” We do not support the restrictions placed on new patients for remote evaluations, but see value in such restrictions for brief communications, especially given the new interprofessional consultation code. Finally, we recommend that CMS reconsider its proposal to bundle virtual visits with E/M visits that occur seven days prior to the virtual check-in. Bundling would add to the complexity of the billing rules and the provider burden, as the provider’s office would have to determine whether a charge was or was not related to the prior service. This would then require additional specific codes or modifiers.

### **Documentation Changes for Office or Other Outpatient E/M Visits and Home Visits**

CMS is proposing several changes to E/M visit documentation and payment, to apply only to the office/outpatient E/M code set initially (99201-99215). The changes that would allow practitioners to choose either Medical Decision Making (MDM) or time as a basis to determine the appropriate level of E/M visit, in addition to using the current framework specified under the 1995 and 1997 guidelines.

### **General Comments**

During the 2011 AMIA Policy Meeting focused on the future of clinical data capture and documentation, AMIA concluded that “there is a need to transform the way we capture and document clinical care,” but that reimbursement policies provide “little incentive to explore alternative data capture or documentation practices. Although our observations have been echoed by other professional organizations,<sup>5,6</sup> we are well-positioned to comment on the impact current E/M coding approaches have had on EHRs efficiency and usability, cognitive load, and other factors at the heart of informatics practice.

AMIA was surprised to see a lack of CMS commentary on the role technology can play to decrease documentation burden through passive “behind the scenes” data collection, facilitated through EHRs and other health IT. We see great promise in the use of such technology to both reduce clinical documentation burden and improve billing precision. For example, EHRs currently register when a lab test has been viewed, and current technology can easily capture and provide audit data for how various aspects of an EHR is being used. The proposed E/M reforms, discussed further below, must be supported through focused and well-resourced efforts to leverage these current

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<sup>5</sup> Kuhn T, Basch P, Barr M, Yackel T; Medical Informatics Committee of the American College of Physicians. Clinical documentation in the 21st century: executive summary of a policy position paper from the American College of Physicians. *Ann Intern Med.* 2015 Feb 17;162(4):301-3. PubMed PMID: 25581028.

<sup>6</sup> Erickson SM, Rockwern B, Koltov M, McLean RM; Medical Practice and Quality Committee of the American College of Physicians. Putting Patients First by Reducing Administrative Tasks in Health Care: A Position Paper of the American College of Physicians. *Ann Intern Med.* 2017 May 2;166(9):659-661. PubMed PMID: 28346948.

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functions and develop emerging functions, such as natural language processing, medical device data, voice recognition software, and the use of sensors to capture clinical activity. Acknowledging that these and other informatics tools are still early in development, CMS should support pilots and otherwise incentivize efforts meant to use these kinds of technologies and evaluate their use for documentation purposes.

*MDM as a basis to determine appropriate level of E/M visit.*

As part of its proposal to allow practitioners to document based on MDM alone, Medicare would only require documentation supporting straightforward medical decision-making measured by minimal problems, data review, and risk (two of these three). CMS further proposes to allow practitioners to rely on MDM in its current form to document their visit, and CMS also solicits public comment on whether and how guidelines for MDM might be changed in subsequent years.

**AMIA Comments:** AMIA supports the use of MDM as an option for practitioners to determine appropriate level of E/M visit. We note that for many practitioners MDM is the heart of their documentation, including the application of ancillary information and diagnostics towards a differential diagnosis. However, we note that determining levels of MDM is still a convoluted and complex task under current guidelines.

**AMIA Recommendation:** To achieve the simplicity sought by this proposal, AMIA recommends CMS reduce the three-element MDM framework (Risk, Number of Diagnosis, and Data) to two, or even a single element. In addition to the proposed documentation requirements for MDM, we propose that practitioner participation in an interdisciplinary treatment plan that is documented elsewhere in the record should suffice (duplicate documentation should not be required).

Further, specialty societies should be encouraged to develop a list of possibilities that would place a service at a given MDM level regardless of how many problems, for example, existed. This would permit clinicians and auditors to use a straightforward checklist in determining MDM levels.

*Time as a basis to determine appropriate level of E/M visit*

CMS is also soliciting public comments on the use of time as a framework for documentation of office/outpatient E/M visits, where Medicare would require the practitioner to document the medical necessity of the visit and show the total amount of time spent by the billing practitioner face-to-face with the patient.

**AMIA Comment:** AMIA supports the use of time as an option for practitioners to determine appropriate level of E/M visit. Allowing different practitioners in different specialties to document the factor(s) most important to them would be a vast improvement over the current state if time alone is used for the E/M visit.

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**AMIA Recommendation:** AMIA recommends this approach should be documented with a history of present illness or interval history, an examination and an assessment/plan, either in the note or in an interdisciplinary plan of care.

CMS is interested in feedback as to whether the 1995 and 1997 guidelines contain adequate information for practitioners to use in documenting visits under its proposals, or whether these versions of the guidelines would need to be supplemented in any way. CMS is also interested in public comments on practitioners' ability to avail themselves of these choices with respect to how they would impact clinical workflows, EHR templates, and other aspects of practitioner work.

**AMIA Comment:** As stated above, we support the new flexibilities and reforms proposed as options for practitioners to document their clinical encounters. These approaches would be straightforward to implement in current EHRs and would drastically reduce documentation burden, provider burden and costs of coders and other administrative personnel related to billing/coding.

**AMIA Recommendation:** AMIA recommends CMS proceed with the options proposed for E/M documentation changes.

#### *Removing Redundancy in E/M Visit Documentation*

CMS proposed to expand flexibilities for certain parts of the history for established patient by only requiring practitioners to focus their documentation on what has changed since the last visit or on pertinent items that have not changed, rather than re-documenting a defined list of required elements such as review of a specified number of systems and family/social history. CMS proposes that for both new and established patients, practitioners would no longer be required to re-enter information in the medical record regarding the chief complaint and history that are already entered by ancillary staff or the beneficiary. The practitioner could simply indicate in the medical record that they reviewed and verified this information.

**AMIA Comments:** AMIA supports these proposed flexibilities regarding certain parts of the history for established patients and regarding chief complaint and history that are already entered by ancillary staff or the beneficiary. As we noted<sup>7</sup> in response to the 2018 PFS NPRM, "some of the information that is relevant to the diagnosis and treatment of patients may, in some instances, be most effectively entered by other members of the care team, captured automatically by devices or other information systems, or captured and entered by patients themselves."<sup>8</sup> We believe that ancillary staff whether this should include health professional students (e.g., medical students, NP students, PA students, clinical psychology students), as well with appropriate review, correction, and verification by billing clinicians.

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<sup>7</sup> <https://www.amia.org/sites/default/files/AMIA%20Response%20to%20CMS%202018%20PFS%20NPRM.pdf>

<sup>8</sup> 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

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**AMIA Recommendation:** AMIA recommends CMS proceed with the proposals for expanded flexibilities and we recommend CMS look to simplify the current MDM framework as described previously.

### **Appropriate Use Criteria for Advanced Diagnostic Imaging Services**

On January 1, 2020, the AUC program will begin with an educational and operations testing period and during this time CMS will continue to pay claims whether or not they correctly include AUC consultation information. Ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2020; and furnishing professionals must report the AUC consultation information on the Medicare claim for these services ordered on or after January 1, 2020, including the following: (1) the qualified CDSM consulted by the ordering professional; (2) whether the service ordered would or would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional).

When the AUC consultation is not performed personally by the ordering professional, CMS proposes the consultation may be performed by auxiliary personnel incident to the ordering physician or non-physician practitioner's professional service.

Since they did not finalize a proposal in the CY 2018 PFS final rule, CMS proposes in this rule to use established coding methods, to include G-codes and modifiers, to report the required AUC information on Medicare claims. This will allow the program to be implemented by January 1, 2020. They will consider future opportunities to use a unique consultation identifier (UCI) and look forward to continued engagement with and feedback from stakeholders.

**AMIA Comments:** AMIA supports the use of computer-based decision support to guide ordering as an exemplar of how informatics tools and applications can assist clinicians at the point-of-care. Thus, we are pleased that in addition to the establishment of a voluntary period through 2019, CMS intends on moving forward with the AUC program in 2020. Given the complexity of this program, the voluntary period in the interim is appreciated. Regarding the use of G-codes and modifiers, AMIA is still concerned<sup>9</sup> these coding methods will add layers of complexity, so we urge CMS work to improve how this data is captured and conveyed for purposes of this program.

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<sup>9</sup> AMIA Response to the CY 2018 PFS proposed rule:  
<https://www.amia.org/sites/default/files/AMIA%20Response%20to%20CMS%202018%20PFS%20NPRM.pdf#page=5>

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## **eCQM Reporting Requirements for EPs under the Medicaid Promoting Interoperability Program for 2019**

CMS proposes that the eCQMs available for Medicaid EPs in 2019 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2019 performance period.

CMS requests comments on whether in future years of the Medicaid Promoting Interoperability Program beyond 2019, they should include all e-specified measures from the core set of quality measures for Medicaid and the Children’s Health Insurance Program (CHIP) (the Child Core Set) and the core set of health care quality measures for adults enrolled in Medicaid (Adult Core Set) (hereinafter together referred to as “Core Sets”) as additional options for Medicaid EPs.

**AMIA Recommendation:** AMIA supports the CMS proposal to include e-specified measures from the Core Sets as part of eCQM reporting options for Medicaid EPs. Further, we support the CMS proposal to identify which of the available measures are high priority measures for Medicaid EPs.

## **Proposed Revisions to the EHR Reporting Period and eCQM Reporting Period in 2021 for EPs Participating in the Medicaid Promoting Interoperability Program**

CMS proposes that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program would be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. Similarly, they propose to change the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program to a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021.

**AMIA Recommendation:** AMIA supports this reporting timeline.

## **Proposed Revisions to Stage 3 Meaningful Use Measures for Medicaid EPs**

### *Proposed Change to Objective 6 (Coordination of Care through Patient Engagement)*

CMS understands that Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging), under Stage 3 for EP Objective 6 are the largest barrier to successfully demonstrating meaningful use, especially in rural areas and at safety net clinics. Therefore, they propose to amend the rule such that the thresholds would remain 5 percent for 2019 and subsequent years. They invite comments on this proposal.

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### *Proposed Change to the Syndromic Surveillance Reporting Measure*

CMS also established in the Stage 3 final rule that the syndromic surveillance reporting measure for EPs was limited to those who practice in urgent care settings CMS believes that public health agencies that set the requirements for data submission to public health registries are in a better position to judge which health care providers can contribute useful data. Therefore, they propose to amend EP Objective 8 (Public health and clinical data registry reporting), Measure 2 (Syndromic surveillance reporting measure), restricting the use of syndromic surveillance reporting for meaningful use only to EPs practicing in an urgent care setting. They propose to include any EP defined by the state or local public health agency as a provider who can submit syndromic surveillance data. CMS invites comments on this proposal.

**AMIA Recommendation:** AMIA supports keeping the thresholds for Measure 1 and Measure 2 of the Meaningful Use Stage 3 EP Objective 6 at 5 percent for 2019 and subsequent years. Longer-term, CMS should better align Medicaid MU requirements with those of their MIPS and Hospital counterparts participating in the Promoting Interoperability Program. Further, we support the changes proposed by CMS for EP Objective 8 (Public health and clinical data registry reporting), Measure 2 (Syndromic surveillance reporting measure), restricting the use of syndromic surveillance reporting for meaningful use only to EPs practicing in an urgent care setting.

### **CY 2019 Updates to the Quality Payment Program**

CMS requests comments on its proposals for the 2022 MIPS payment year and future years, where the performance period for the quality and cost performance categories would be the full calendar year (January 1 through December 31) and the performance periods for the improvement activities and Promoting Interoperability performance categories would be a minimum of a continuous 90-day period within the calendar year.

MIPS eligible clinicians and groups must submit data on at least six measures including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure.

CMS is proposing to specify that MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or the eCQMs must submit data on at least 60 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2021.

#### *Request for Comments*

CMS is proposing to remove bonus points for improvement activities that may be applicable to the Promoting Interoperability performance category, but recognizes the need to continue incentives for CEHRT. Therefore, CMS is seeking comment on potentially applying high-weighting for any improvement activity employing CEHRT.

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**AMIA Recommendations:** AMIA supports the proposals to maintain the current reporting periods for the MIPS performances categories, as well as the reporting requirement for at least six measures for the quality category, reported on at least 60 percent of the MIPS eligible clinician or group’s patients that meet the measure’s denominator criteria. AMIA supports CMS’ intentions to revisit Improvement Activity (IA) weighting policies, and we see the replacement of bonus points in in the IA performance category for using CEHRT with a high weighting as reasonable. We appreciate CMS’ continued thinking on how to encourage adoption and use of CEHRT through the IA performance category.

### **Promoting Interoperability (PI) (previously known as the Advancing Care Information Performance Category)**

CMS is proposing that beginning with the performance period in 2019, MIPS eligible clinicians must use EHR technology certified to the 2015 Edition certification criteria. CMS is also proposing a new scoring methodology, beginning with the performance period in 2019, to include a combination of new measures, as well as the existing Promoting Interoperability performance category measures, broken into a smaller set of four objectives and scored based on performance. CMS is seeking public comment on the proposed requirement to report on all required measures, or whether reporting on a smaller subset of optional measures would be appropriate. CMS is also seeking public comment on whether these measures are weighted appropriately, or whether a different weighting distribution, such as equal distribution across all measures would be better suited to this program and this proposed scoring methodology.

**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 current functionality. Given the limited number of measures, we support CMS requirements to report on all or receive a zero score.

AMIA additionally welcomes the new proposed scoring methodology for the PI performance category of MIPS. We view the proposed scoring methodology as both bringing the program into alignment with the PI requirements for hospitals and providing flexibility to eligible clinicians to pursue those measures that are more meaningful for their practice and patient populations.

We do not, however, support the implications of the PI performance category score within the larger QPP final score. Rather, CMS should consider a minimum threshold of success, as they have done with the hospitals, that would allow practitioners to receive full credit in the PI performance category. The proposed approach sets an unreasonable bar for ECs, relative to their hospital counterparts.

Our recommendations on the proposed measures require a slight revision to the points allocation (see Table 1 below):

- *Query of Prescription Drug Monitoring Program (PDMP);*

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- *Verify Opioid Treatment Agreement;*
- *Support Electronic Referral Loops by Receiving and Incorporating Health Information;* and
- *Public Health and Clinical Data Exchange.*

*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
	<b>Bonus:</b> Query of Prescription Drug Monitoring Program (PDMP)	5 points bonus	5 points bonus
	<b>Bonus:</b> 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	Choose two of the following: 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)  <u>Choose one or more additional:</u> Electronic Case Reporting, Public Health Registry Reporting; Clinical Data Registry Reporting  20 points

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	Syndromic Surveillance Reporting		
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To reiterate, CMS should consider thresholds to determine PI performance points allocation towards the final MIPS score, rather than a straight percentage.

**Promoting Interoperability Performance Category Measure Proposals for MIPS Eligible Clinicians**

CMS is proposing to remove six measures from the Promoting Interoperability objectives and measures beginning with the performance period in 2019. Two of the measures they are proposing to remove – *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 measures it is replacing. Four of the measures – *Patient-Specific Education; Secure Messaging; View, Download, or Transmit; and Patient-Generated Health Data* – would be removed because they have proven burdensome to MIPS eligible clinicians in ways that were unintended and may detract from clinicians’ progress on current program priorities.

**AMIA Comment:** While AMIA recognizes the burdens placed on ECs 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, similar to those we filed in the 2019 IPPS proposed rule, 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*.

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*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 MIPS eligible clinicians will likely need to manually enter data into CEHRT to document the completion of the query of the PDMP action and that these ECs may also need to conduct manual calculation of the measure. CMS further acknowledges that for those ECs 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.

**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.<sup>10</sup> 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,<sup>11</sup> 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.

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<sup>10</sup> 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

<sup>11</sup> 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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Unfortunately, most ECs 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.

*Proposed Measure: Verify Opioid Treatment Agreement.*

The second proposed measure, *Verify Opioid Treatment Agreement*, is for ECs 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.<sup>12</sup> 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).<sup>13</sup> Perhaps unsurprisingly, those with a past history of substance use were more likely to be discharged due to not adhering to the agreement.<sup>14</sup>

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<sup>12</sup> 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.

<sup>13</sup> 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.

<sup>14</sup> Summers P, Alemu B, Quidgley-Nevaras A. History of drug use predicts opioid treatment agreement violation. *J Opioid Manag.* 2015 Nov-Dec;11(6):501-6.

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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.

**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 EC 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 ECs may use any document template within the CCDA standard for purposes of the measures under the Health Information Exchange objective.

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**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 ECs 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 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.

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**AMIA Recommendation:** AMIA supports CMS’s proposal to allow ECs 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 EC was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the EC 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 ECs 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 EC 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

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CEHRT.<sup>15, 16, 17, 18</sup> 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.

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

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<sup>15</sup> 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.

<sup>16</sup> 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.

<sup>17</sup> 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.

<sup>18</sup> 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

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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.

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 EC 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 EC 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 EC'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 them for actions outside their control. As a matter of programmatic administration, we understand the "at least one patient"

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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.<sup>19</sup> 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.

#### *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 ECs 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.

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<sup>19</sup> <http://syncfor.science/>

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**AMIA Recommendation:** AMIA supports the removal of this measure. Even so, CMS should continue to encourage ECs to provide patient-specific education. There is great value for ECs 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 ECs in ways that were unintended and detract from health care providers' progress on current program priorities.

**AMIA Comments:** We note that patients who utilize secure messaging usually do so in the context of an ongoing outpatient relationship with a clinician, rather than with hospitals.<sup>20</sup> AMIA notes that secure messaging has proven beneficial and useful in some contexts and settings when appropriately integrated into clinician workflow.<sup>21</sup> Further, measures have helped galvanize ECs towards patient engagement and have contributed to increased patient and clinician interest in using these strategies.<sup>22</sup>

**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 ECs in ways that were unintended and detract from ECs' 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.

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<sup>20</sup> Shimada SL, Petrakis BA, Rothendler JA, Zirkle M, Zhao S, Feng H, Fix GM, Ozkaynak M, Martin T, Johnson SA, Tulu B, Gordon HS, Simon SR, Woods SS. An analysis of patient-provider secure messaging at two Veterans Health Administration medical centers: message content and resolution through secure messaging. *J Am Med Inform Assoc.* 2017 Sep 1;24(5):942-949. doi: 10.1093/jamia/ocx021.

<sup>21</sup> 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.

<sup>22</sup> 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.

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## 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 MIPS eligible clinicians would be required to submit two of the measures of the clinician's choice from the five measures associated with the objective: Immunization Registry Reporting, Syndromic Surveillance Reporting, Electronic Case Reporting, Public Health Registry Reporting, and Clinical Data Registry 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 whether ECs 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.

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 provider has a public health organization capable of accepting all options in this measure, we suspect that the outcome of removing this measure completely will be 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.

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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.

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 ECs.

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 EC, the EC 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 EC from a transition of care or referral from a provider of care other than an EC, the EC conducts clinical information reconciliation for medications, medication allergies, and problem list.

CMS seeks public comment on whether these two measures should be combined into one measure so that an EC 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

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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.

**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 the EC 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 ECs to accept and reconcile information received from these settings.

Were CMS to finalize this PFS 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.

### **Improvement Activities Bonus Score under the Promoting Interoperability Performance Category and Future Reporting Considerations**

In connection with significant changes to the scoring methodology and measures beginning with the performance period in 2019, CMS is not proposing to continue the bonus for completing certain improvement activities using CEHRT for the performance period in 2019 and subsequent performance periods. CMS seeks comment on other ways to promote the use of CEHRT and invites comments on its decision not to propose to continue the bonus for completing certain improvement activities using CEHRT for the performance period in 2019 and subsequent performance periods.

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Furthermore, CMS intends to consider proposing in future rulemaking MIPS public health priority sets across the four performance categories (quality, improvement activities, Promoting Interoperability, and cost). They intend to develop the first few public health priority sets around: opioids; blood pressure; diabetes; and general health (healthy habits). In this proposed rule, CMS is seeking comments on additional public health priority areas that should be considered, and whether these public health priority sets should be more specialty focused versus condition specific. They are also seeking comment on how CMS could implement public health priority sets in ways that further minimize burden for health care providers, for instance, by offering sets which emphasize use of common health IT functionalities. Finally, they are seeking comment on how CMS could encourage or incentivize health care providers to consider using these public health priority sets

**AMIA Comments:** AMIA strongly believes that CMS must focus its policies to achieve the dual aims of (1) reporting/compliance-related burden reduction and (2) encouraging continued investment and application of informatics to patient care. 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 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.

We view the IA performance category as a tremendous development in innovation for Medicare, as it acknowledges the self-driven culture of learning and continuous improvement that nearly all ECs embrace. This performance category meets clinicians where they are and asks them to demonstrate clinical practice improvements, leveraging the tenets of evidence-based medicine through national guidelines and accepted best practice.

Further, CMS is to be commended for using this category to find mutually-reinforcing efficiencies across MIPS performance categories. This has been demonstrated through the awarding of bonus points awarded for use of CEHRT, and some IAs<sup>23</sup> closely align with quality measures<sup>24</sup> that can be submitted as part of that performance category. While we do not have access to understand the frequency for which these IAs were leveraged, we believe the policy principle is sound.

Insofar as MIPS public health priority sets seek to further integrate the disparate performance categories and promote the use of CEHRT, we see great value in the concept.

**AMIA Recommendation:** AMIA supports the discontinuation of bonus points for completing certain improvement activities using CEHRT for the performance period in 2019 and subsequent

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<sup>23</sup> PSPA 8: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-14985.pdf#page=1471>

<sup>24</sup> Measure 358: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-14985.pdf#page=1349>

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performance periods. We recommend CMS proceed with plans to elevate such IAs with a high weighting in absence of bonus points, over the near term. Eventually, we would like to see CEHRT use fade as a differential factor because it will be ubiquitous and part of the standard of care.

AMIA fully supports CMS efforts to develop MIPS public health priority sets (MIPS Priority Sets), and we posit that policy development in this direction could one day supplant the disparate performance categories, for those ECs who choose such an option. For years, we have been advocates for the Million Heart's initiative,<sup>25</sup> and we have advocated for CMS to view this kind of program – which relies on CEHRT, monitors established eCQMs, and relies on cost control strategies – as a policy direction worth expanding.

AMIA offers the following to supplement CMS' thinking on future rulemaking for MIPS Priority Sets:

- Allow MIPS Priority Sets to be either specialty focus or condition(s) specific;
- Allow ECs to offer their own MIPS Priority Sets in addition to scoping out CMS-preferred MIPS Priority Sets;
- Both EC-developed and CMS-preferred MIPS Priority Sets should meet the following minimum requirements:
  - Include at least three (3) quality measures related to the specialty focus or specific condition(s)
  - Involve the use of CEHRT (intensity of “use” to be determined)
  - Include at least two (2) IAs that determine whether ancillary improvements resulted from the practice-determined focus
  - Capture and assess costs associated with the MIPS Priority Set activities
- An alternative to this minimum requirement approach would be to have a tiered approach, granting the most robust of MIPS Priority Sets the largest share of the MIPS Composite Score. The minimum requirements stated above would receive a mid-tier MIPS Composite score because it included half of current MIPS requirements. CMS could consider MIPS Priority Sets that include more or fewer MIPS requirements as garnering a lower or higher share of the MIPS Composite Score.

## Public Reporting on Physician Compare

In the CY 2018 Quality Payment Program final rule, CMS finalized a policy to include an indicator on Physician Compare for any eligible clinician or group who successfully meets the Promoting Interoperability performance category, as technically feasible, for all future years. In year 3, CMS is proposing not to include the indicator of “high” performance and to maintain only an indicator for “successful” performance in the Promoting Interoperability performance category beginning with year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019). CMS

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<sup>25</sup> <https://millionhearts.hhs.gov/>

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requests comment on the proposal not to include the indicator for “high” performance in the Promoting Interoperability performance category beginning with year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019). They are also seeking comment only on the type of EHR utilization performance information stakeholders would like CMS to consider adding to Physician Compare. This information would be considered for possible future inclusion on the website.

**AMIA Comments:** AMIA places tremendous value in performance transparency. As such, we would like to see CMS release all appropriate administrative data related to the QPP, not simply a grade – or worse – a binary “pass/fail,” score. Public expenditures belong to the citizens of the US, and CMS should strive to ensure the utmost transparency around cost, quality, and performance.

**AMIA Recommendation:** We support the “successful/unsuccessful” indicator for the PI Program only if the administrative data supporting this indicator is available as a drill down. CMS has been derelict in making public performance data for QPP since the program’s inception. Given the lax requirements that came to define its first 2 years, we accept this state of transparency. However, CMS should not look to extend the current modus operandi into the future. At a minimum, Physician Compare should include PI Program data related to the following measures: eRx; Provide Patients Electronic Access to Their Health Information; and what kind of public health and clinical data exchange they engage.

### **Increasing the CEHRT use criterion for Advanced APMs.**

CMS is exploring opportunities to incorporate the goals of interoperability into the design of alternative payment models (APMs), wherever feasible and appropriate, to further promote the seamless and secure exchange of health information for clinicians and patients. CMS is therefore proposing that, beginning for CY 2019, in order to be an Advanced APM, the APM must require at least 75 percent of eligible clinicians in each APM Entity use CEHRT to document and communicate clinical care with patients and other health care professionals. CMS seeks comment on this proposal.

**AMIA Comments:** AMIA supports efforts to further encourage the use of 2015 CEHRT, and thus supports this proposal, as well.

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. Below, AMIA reiterates its comments submitted to CMS as part of its IPPS NPRM response:

CMS RFI Questions	AMIA Comment & Recommendations
<p>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?</p>	<p><b>AMIA Comment:</b> 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 <a href="#">Appendix A</a>).</p> <p>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.</p> <p><b>AMIA Recommendation:</b> 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.</p>
<p>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</p>	<p><b>AMIA Comment:</b> For patient access, implementation of 2015 Edition CEHRT (assuming all functionalities are activated) would satisfy this requirement. However, we do not anticipate uniform adoption, implementation, upgrade, and ongoing</p>

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CMS RFI Questions	AMIA Comment & Recommendations
<p>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?</p>	<p>maintenance across settings and geographies.</p> <p>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.</p> <p><b>AMIA Recommendation:</b> As stated previously, we recommend CMS garner experience under the bevy 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.).</p> <p>As means to implement these changes, AMIA recommends that any EC 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 ECs 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.</p> <p>Given the status of CEHRT adoption among other Medicare- and Medicaid 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</p>

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CMS RFI Questions	AMIA Comment & Recommendations
	<p>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.</p>
<p>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?</p>	<p><b>AMIA Comment:</b> 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.</p> <p>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.</p>
<p>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 implementation dates for specific participating providers and suppliers, or types of participating</p>	<p><b>AMIA Comment:</b> 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.</p> <p>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</p>

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CMS RFI Questions	AMIA Comment & Recommendations
<p>providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?</p>	<p>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.</p>
<p>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?</p>	<p><b>AMIA Comment:</b> 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.</p>
<p>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?</p>	<p><b>AMIA Comment:</b> 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).</p>

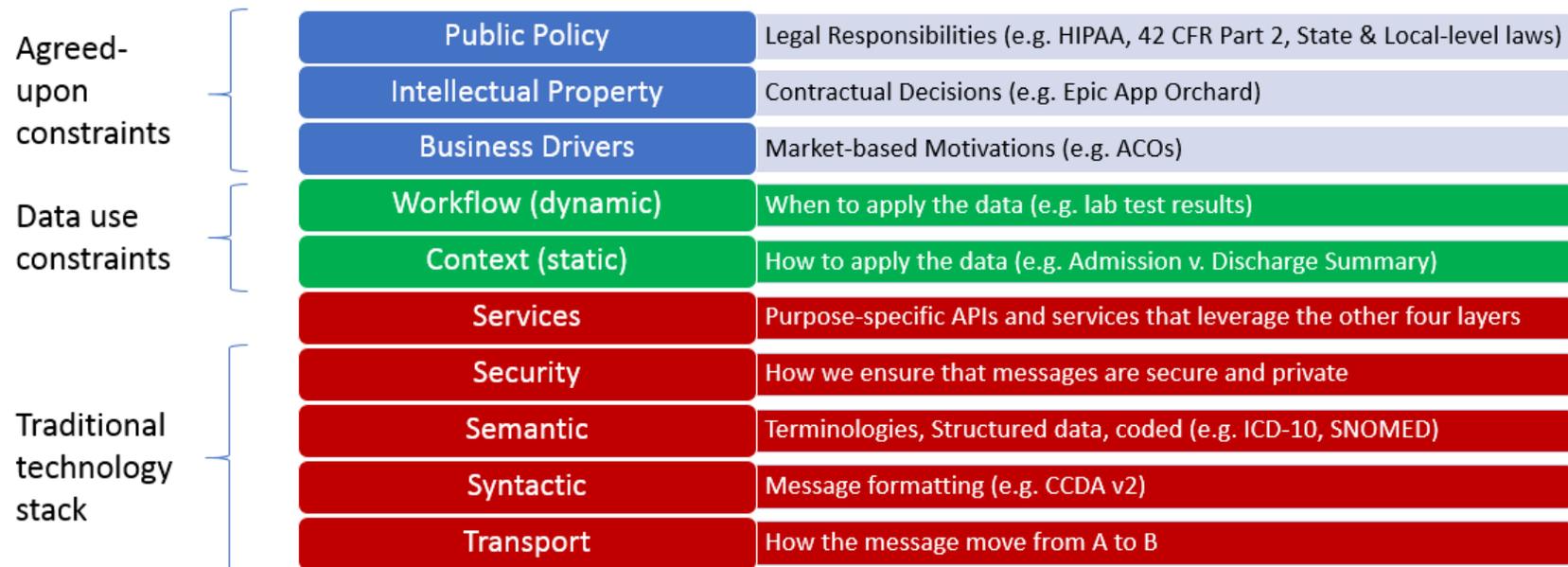
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CMS RFI Questions	AMIA Comment & Recommendations
<p>Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new 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?</p>	<p><b>AMIA Comment:</b> 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.”<sup>26</sup> (see <a href="#">Appendix B</a> for visual description).</p> <p><b>AMIA Recommendation:</b> 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.</p>

<sup>26</sup> 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>

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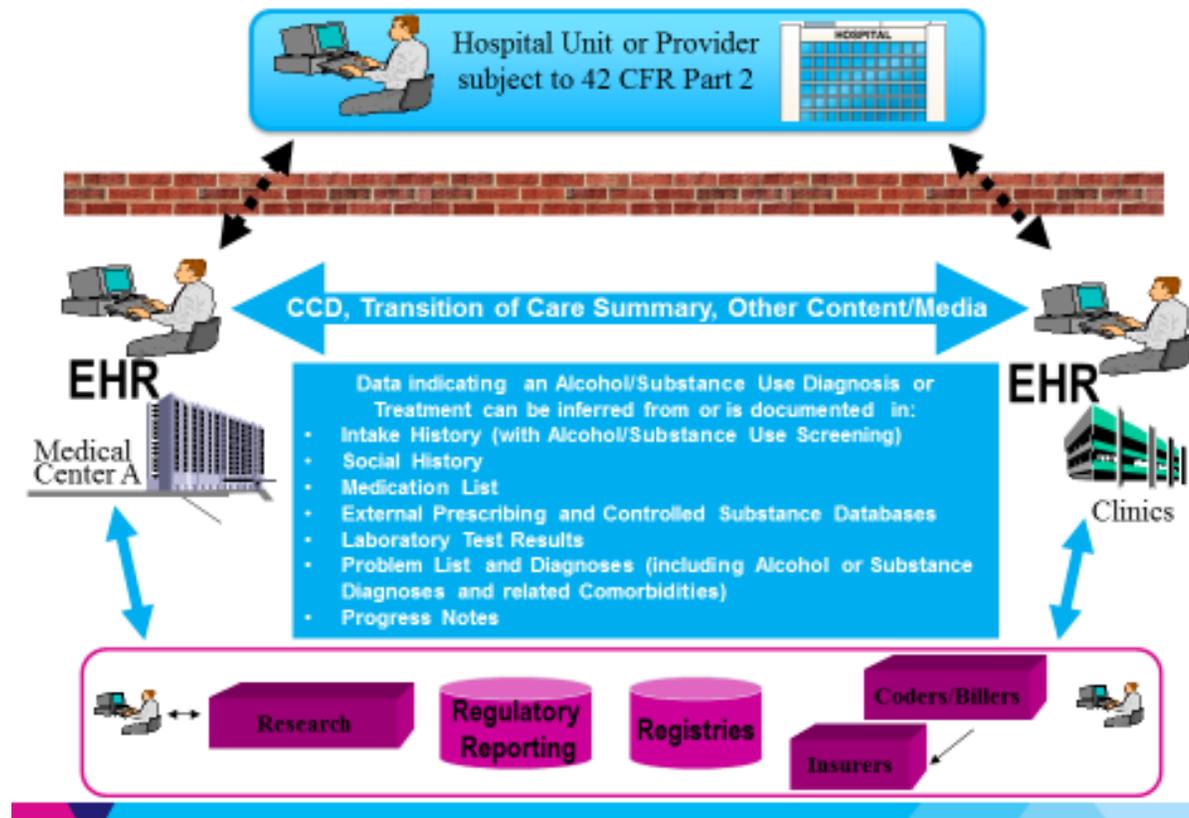
### Appendix A: Socio-Technical Interoperability Stack



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.

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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

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“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). 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.