September 30, 2020

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
Submitted electronically http://www.regulations.gov

Re: Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Administrator Verma:

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide input on the CY2021 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 strongly supports CMS's expansion of reimbursement for telehealth and other communications technology during the current public health emergency (PHE). These services have been incredibly valuable during COVID-19 and we recommend that some of them should continue once the PHE ends. We also continue to support the MIPS Value Pathways (MVP) framework and welcome the proposed new bi-directional health information exchange measure. Below we offer additional insights and observations from our clinical informatics community on these topics.

Telehealth and Other Services Involving Communications Technology Proposals

AMIA continues to support CMS's efforts to reimburse providers for providing various telehealth and other services that utilize communications technology. The change in these policies is

addressing a long-standing barrier 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 clinical effectiveness and patient safety in response to CMS inquires on potential new coding.

MIPS Value Pathways Proposals and Digital Quality Measures

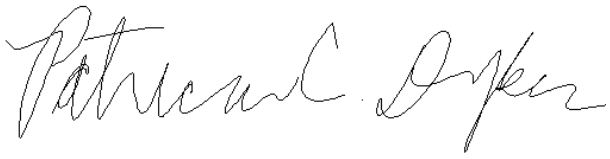
AMIA also continues to support the goals of the MVP framework to align and connect measures and activities across the Quality, Cost, Promoting Interoperability, and Improvement Activities categories. We are especially gratified to see CMS include support for digital quality measures (dQMs) as a potential new guiding principle of the framework. We view the addition of this principle as an important step towards assessing clinicians on how they use certified health IT to drive quality improvement. While we strongly support the addition of this principle, we urge CMS to go further in making health IT use an enabler, not an end unto itself. As CMS continues to refine the MVP framework, AMIA suggests that it do so by:

- Dissolving the current numerator/denominator, measurement/objective structure of the Promoting Interoperability performance category entirely;
- Not only supporting, but requiring, that all participants of the MVP framework possess certified health IT and demonstrate use of such through reporting dQMs and specified Improvement Activities (IAs). Participants should be given wide latitude in deciding which dQMs they should report.

Improving interoperability can still be a core objective of CMS payment policy, but rather than measuring process indicators, the MVP framework provides CMS an opportunity to measure the outcome of interoperability through dQMs and certified health IT-enabled IAs. Additionally, this approach will relieve overburdened clinicians from regulatory reporting requirements and enable them to develop more efficient workflows absent considerations of how to capture numerator/denominator measures. The true opportunity to transform MIPS is to focus MVPs on a combination of quality measures and Improvement Activities that would not be possible without the use of certified health IT.

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 Scott Weinberg, Public Policy Specialist at scott@amia.org or (240) 479-2134. We look forward to continued partnership and dialogue.

Sincerely,



AMIA | American Medical Informatics Association
4720 Montgomery Lane, Suite 500 | Bethesda, Maryland 20814

September 30, 2020

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

(Enclosed: Detailed AMIA Comments regarding CMS' CY21 PFS NPRM)

AMIA | American Medical Informatics Association
4720 Montgomery Lane, Suite 500 | Bethesda, Maryland 20814

Telehealth and Other Services Involving Communications Technology

CMS is proposing to add more services to the Medicare telehealth list on a Category 1 basis. It is further soliciting comment on services added to the Medicare telehealth list during the public health emergency (PHE) for COVID-19 that CMS is not proposing to add to the Medicare telehealth list permanently or proposing to add temporarily on a category 3 basis.

CMS is also seeking comment on whether it should develop coding and payment for a service similar to the virtual check-in, but for a longer unit of time and with an accordingly higher value. It is seeking input from the public on the appropriate duration interval for such services and the resources in both work and PE that would be associated with furnishing them. It is also seeking comment on whether separate payment for such telephone-only services should be a provisional policy to remain in effect until a year or some other period after the end of the PHE, or if it should be PFS payment policy permanently.

AMIA Comments: Health IT should always serve to enhance clinical effectiveness and patient safety. Regarding CMS's consideration of whether to develop additional coding for audio-only telephone interactions during and even beyond the PHE, AMIA cautions that such a question is specialty-dependent, and the clinical effectiveness of virtual care may be affected as a result. CMS recognized this when it granted a waiver for behavioral health and education services – which in many cases can be effectively administered via audio-only – to be furnished in this manner.[1] However, 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.[2]

If CMS does develop coding for audio-only visits similar to a virtual check-in code, then we urge CMS to be consistent with those codes and permit audio-only "virtual check-in" codes only when the billing practice has an established relationship with the patient.

Transforming MIPS: MIPS Value Pathways

CMS is proposing updates to further refine the guiding principles of MVPs to include the patient voice, subgroup reporting, and a fifth principle related to promoting digital performance measure data submission. In addition, CMS has proposed criteria for stakeholders to follow as they work to develop MVP candidates.

AMIA Comments: AMIA supports the proposed additional guiding principles. Further, we agree that the meaningful use of certified EHR technology to support care coordination and electronic health information exchange should be a key structural part of any MVP. We also agree that interoperability is a foundational element that applies to all clinicians, regardless of MVP. Given these views on the importance of certified EHR technology and interoperability, we are strongly supportive of the proposed fifth Principle, "MVPs should support the transition to digital quality measures." As we understand them, digital quality measures (dQMs) are quality measures that leverage health information from interoperable systems, including certified health IT systems. Incorporating this fifth Principle provides CMS the opportunity to encourage the use of certified

---

[1] https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf

[2] 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

health IT for its own sake, rather than simply measure whether it is being used. At the same, this will help CMS orient MVPs towards the core statutory requirements for successful Promoting Interoperability Program participation: electronic prescribing; quality measurement; and information exchange. It is our that hope that the MVP development process gives stakeholders the widest possible latitude in deciding which dQMs are included the MVPs. We believe that this will help to ensure that the dQMs are not only clinically appropriate, but that they are already implementable in the clinical setting, so that the measure can be collected, reported, and submitted automatically.

While AMIA supports CMS's other proposed guiding principles, as well, we again recommend supplementing Principle 3 by stating explicitly "high priority areas ***of morbidity and mortality***." We urge CMS to establish a consensus process similar to the National Quality Strategy[3] to identify these priority areas.

Finally, AMIA recommends a sixth Principle to ensure that "MVPs should be aligned with CMS policies and programs for inpatient and post-acute care settings." We remind CMS that MIPS eligible clinicians represent but a fraction of all regulated clinicians and organizations. It is important that CMS remains cognizant of how MVPs may impact other payment and quality performance programs and seek to align wherever possible.

MVP Development Criteria
As for the new proposed MVP Development Criteria, we urge CMS to remove "Must include the entire set of Promoting Interoperability measures," and instead emphasize that the included Improvement Activities must utilize certified health IT.

MIPS Performance Threshold Category Measures and Activities

Performance Category Weights
CMS proposes to continue to incrementally adjust the MIPS performance category weights, with the Quality performance category to be weighted at 40% (5% decrease from PY 2020) and the Cost performance category to be weighted at 20% (5% increase from PY 2020); the Promoting Interoperability and Improvement Activities categories will remain the same. CMS further proposes to reduce the MIPS performance threshold for the 2021 MIPS performance period/2023 MIPS payment year from 60 points to 50 points in recognition of the COVID-19 impact on clinicians.

AMIA Comments: We understand that the decrease in the Quality and Cost performance categories' contribution to the final score is statutory. We appreciate CMS's transparency in how both this, and the cost performance category, will be weighted over the next several reporting years. We additionally support lowering the performance threshold to provide flexibility to clinicians impacted by COVID-19.

Promoting Interoperability
Performance Category Performance Period

[3] https://www.ahrq.gov/workingforquality/index.html

September 30, 2020

CMS is proposing that for the 2023 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period within CY 2021, up to and including the full CY 2021 (January 1, 2021 through December 31, 2021). For the 2024 MIPS payment year and each subsequent MIPS payment year, CMS would establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. This proposal aligns with the proposed EHR reporting period in CY 2022 for the Medicare Promoting Interoperability Program for eligible hospitals and CAHs.

AMIA Comments: AMIA agrees with CMS's reasoning in the NPRM and supports the continuation of this flexibility that will allow more eligible clinicians to successfully participate in the PI Program.

Performance Category Measures for MIPS Eligible Clinicians
CMS is proposing to continue to make the Query of PDMP measure optional, but eligible for 10 bonus points for the Electronic Prescribing objective in CY 2021. In addition, CMS is proposing to change the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information by replacing "incorporating" with "reconciling." Finally, CMS proposes a new optional Health Information Exchange (HIE) bidirectional exchange measure.

AMIA Comments: AMIA supports the proposals to continue to make the Query of PDMP measure optional and increase the maximum points to 10. CMS has correctly surmised that the capabilities of PDMP integration varies greatly by geography and by EHR. This measure should also remain a yes/no measure, rather than a performance measure. We recommend that CMS work closely with ONC and its Certification Program to ensure standards are adopted by health IT to enable functionalities in support EHR-PDMP integration.

We also once again recommend that CMS finalize the Support Electronic Referral Loops by Receiving and (potential) Reconciling Health Information in 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.

AMIA further strongly encourages CMS to double the PI Program points from 10 to 20 for public health reporting and require Syndromic Surveillance Reporting and Immunization Registry Reporting (in addition to the already required Reportable Lab Results Reporting), with the option to choose Electronic Case Reporting, Public Health Registry Reporting; or Clinical Data Registry Reporting as a menu option. Although this is a recommendation we have made for several years, it especially salient during a public health emergency. Reporting to such registries may require significant investments on the provider's part, but had CMS not required minimal public health reporting as part of the last eight years of the EHR Incentive Payment program, we may have had a larger communications gap between the ambulatory setting and public health today.

Finally, AMIA supports the inclusion of the new optional HIE bidirectional exchange measure and is gratified to see that CMS is proposing that this measure be reported by attestation, requiring a

yes/no response. We have argued previously[4] that CMS should be charting a course towards ending numerator/denominator measurement and we see this measure as another step in that direction. We have provided specific feedback on CMS's questions on the proposed attestation statements in table 1 below:

Table 1: CMS Questions with Regard to Proposed HIE Bi-Directional Exchange Measure Attestation Statements

CMS Questions	AMIA Responses
1. Do [the attestation] statements reflect appropriate expectations about information exchange capabilities for eligible clinicians that engage with HIEs capable of facilitating widespread exchange with other health care providers?	We are concerned about the first statement, which requires that the clinician participate in an HIE for "every patient encounter, transition or referral, and record stored or maintained in the EHR." While we believe that a yes/no attestation is appropriate for this measure, there are numerous instances beyond the clinician's control where secure, bi-directional exchange cannot occur for "every patient encounter, transition or referral." There is great variability of HIE capabilities and clinicians may not know all of these capabilities when selecting one. In other cases, a local public HIE may be the only option a clinician has. **Appropriate exclusions should thus be available for this measure if a clinician cannot honestly attest for reasons beyond his or her control.** If CMS wants clinicians to participate in HIEs that have certain functionalities, then it should create a list of eligible HIEs (see question 2 below) that they can choose from to meet the desired criteria. With a CMS list, the EHR could report what HIE it uses, automatically compare it to the CMS list, and answer the question for the physician. This can also help to reduce reporting burden, another important goal of CMS. Furthermore, the first attestation statement describes an action that may not be clinically appropriate for every patient. Newborns, for example, will not have information in an HIE; sending a query regarding them would not only be inappropriate, but add to provider burden. In order to empower providers' clinical judgment, **we recommend that CMS allow for an**

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

	exclusion that use of the HIE was not clinically appropriate for all patients. We additionally appreciate that this measure, while optional, provides clinicians a good opportunity to fulfill Promoting Interoperability requirements by actually relying on the functionalities of certified health IT (CEHRT). Since we have asserted that CEHRT utilization is paramount, **we believe that the attestation statements need to specify that the eligible clinician's CEHRT is integrated with the HIE for purposes of bi-directional information exchange and the clinician can engage in such exchange without leaving the EHR environment.** Finally, many HIEs still require clinicians to log into separate web-based portals to search for and retrieve patient information from other provider organizations. This process is often very disruptive to clinician workflow and can effectively prevent many clinicians from using the HIE – they simply forego the retrieval of data from the HIE unless there is a pressing clinical need. Technical integration with the HIE such that no separate login is required and the current patient context is automatically transmitted to the HIE streamlines the process and makes use of HIE data practical within clinician workflows. Additionally, the eligible clinician's CEHRT should provide data to other users of the HIE automatically, without requiring the clinician or her staff to manually upload information from patients' records. FHIR APIs, for example, could achieve this, as well as automated submission of C-CDA documents upon discharge or ADT messages upon admission. Additional exclusions should be added for clinicians who utilize only the web-portal or Direct Secure Messaging capabilities of HIEs, both of which require manual intervention to send and receive data.
2. How should CMS effectively identify those HIEs that can support the widespread exchange with other health care providers?	We note that there is no consensus opinion on what an "HIE" is. One approach may be to allow eligible clinicians to select from a CMS-approved list whether they participate in open, regional

	HIEs, or vendor-specific or private HIEs, such as Epic's CareEverywhere. Further criteria could state that any other eligible clinician or eligible hospital in the attesting clinician's medical service area must be eligible to also exchange their data via the HIE if they choose to do so. CMS should also coordinate with the eHealth Initiative or the Strategic Health Information Exchange Collaborative (SHIEC), which is a national collaborative representing HIEs and their strategic business and technology partners. Additionally, CMS should engage with the Sequoia Project, the recognized coordinating entity named by ONC to create the Common Agreement component of the Trusted Exchange Framework and Common Agreement (TEFCA).
3. How are eligible clinicians currently using CEHRT to exchange information with HIEs, and do the proposed attestation statements allow for different ways health care providers are connecting with HIEs utilizing certified health IT capabilities?	As we stated in response to question 1, we recommend that the attestation statements need to specify that the eligible clinician's CEHRT is integrated with the HIE for purposes of bi-directional information exchange and the clinician can engage in such exchange without leaving the EHR environment. The third attestation statement that, "I use the functions of CEHRT for this measure" is thus not specific enough. As currently written, it may even allow for the use of non-integrated HIEs that are easy to join, but do not support information exchange in a practical sense. We therefore recommend that certain specific CEHRT certification criteria be mentioned as being involved in the exchange of data via an HIE, such as the API criteria, the transition of care criterion, or the Clinical information reconciliation and incorporation criterion, as defined by the 21st Century Cures Act final rule.

Based on all of our comments above, we recommend a slight revision to the Promoting Interoperability points allocation (see Table 2 below):

Table 2: CMS Proposed, AMIA Recommended PI Program Measures & Points Allocation for 2021

September 30, 2020

Objectives	Measures	Maximum Points	Maximum Points (AMIA recommendations)
e-Prescribing	e-Prescribing	10 points	5 points
	Bonus: Query of Prescription Drug Monitoring Program (PDMP)	10 points (Bonus)	10 points (bonus)
Health Information Exchange OR	Support Electronic Referral Loops by Sending Health Information	20 points	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points	Request/Accept Summary of Care: 10 points
			Clinical Information Reconciliation: 10 points
Health Information Exchange (alternative)	HIE Bi-Directional Exchange	40 points	40 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points	40 points
Public Health and Clinical Data Exchange	<u>Choose two of the following:</u> Immunization Registry Reporting Electronic Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Syndromic Surveillance 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