June 27, 2016

The Honorable Andrew M. Slavitt
Acting Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-P
Submitted electronically http://www.regulations.gov

RE: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Acting Administrator Slavitt:

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide input on the Noticed of Proposed Rulemaking (NPRM) regarding implementation of the provisions outlined in the Medicare Access and CHIP Reauthorization Act (MACRA); specifically, the Medicare Quality Payment Program (QPP). This NPRM was published by the Centers for Medicare & Medicaid Services (CMS) in the April 27, 2016 issue of the *Federal Register*.

AMIA is the professional home for more than 5,000 informatics professionals, representing front-line 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 has strong interest in ensuring the QPP is successful for our members and the program encourages responsible use of information technology and other informatics tools to improve healthcare delivery.

We applaud CMS for proposing a set of policies and requirements across the four categories of the Merit-based Incentive Payment System (MIPS) and for Alternative Payment Models (APMs) that clearly incorporate stakeholder feedback and lessons learned from the legacies of the Physician Quality Reporting System, Value-Based Modifier, EHR Incentive Program, and various alternative payment models. **AMIA believes CMS has an unprecedented opportunity to learn which components of these legacy programs will effectively support our healthcare system in moving toward the triple aim, and we strongly recommend that CMS engage medical informatics expertise more broadly to understand how technology should be leveraged to improve care experience, efficacy, and reduce unnecessary expense.**

AMIA has previously recommended that CMS view proposals included in this NPRM as the first in a series that will compose a set of dynamic programs, and we encourage CMS to use the following principles to help guide the final rule, as well as future iterations of the QPP. We have included

specific recommendations, found in the enclosed document, which follow from these principles.

- Use data reporting requirements to learn, not simply to grade.
    - Several activities of the Clinical Practice Improvement Activity (CPIA) Category and the Advancing Care Information (ACI) Performance Category can be, and should, be leveraged to inform a wide array of research questions and policy approaches to some of our most vexing challenges in healthcare, such as diagnosis error and health data interoperability.
- Focus on defining clear, expected outcomes, rather than prescriptive process measures.
    - The ACI Performance Category continues a numerator/denominator paradigm for health IT process measures that is not necessarily associated with improved outcomes, especially if implemented poorly.
- Engage organizations and experts to perform scientifically rigorous, peer-review studies to determine which requirements should be retained in future years.
    - Every Performance Category of MIPS and several aspects of APMs should be subject to robust evaluations, which are themselves subject to expert, independent review.
- Leverage current programs, standards and requirements to enable clinicians to optimize the tools they have to improve care.
    - Stability and consistency, year-over-year, in the Quality and ACI Performance Categories will help clinicians optimize their technology and enable longitudinal tracking of metrics.
- Pay special attention to small practices, which have limited resources, so they are empowered to succeed.
    - We are pleased to learn of additional funding, and we support unique provisions included as part of this NPRM, meant to ensure that small, rural and under-resourced practices are not disadvantaged.
- Develop feedback loops that are accurate, timely and meaningful.
    - We support efforts to close the gap between performance and payment adjustments, which is typically two years, historically.
- Encourage increased data exchange and interoperability whenever possible.
    - CMS should work with its federal agency partners to identify technical standards that would facilitate the exchange of information between third party intermediaries.
- Consider the capacity of the average MIPS eligible clinician (EC) or APM participant to absorb high levels of complexity and change.

Finally, AMIA members express doubt over the ability of MIPS ECs to successfully participate in a full-year reporting period beginning January 1, 2017. Despite our support for much of this NPRM, the level of complexity inherent in these programs has no equal in Medicare, and we suspect it rivals any federal program in aggregate complexity. This complexity will necessitate tremendous amounts of education and dialogue, despite most EC's familiarity with certain aspects of MIPS.

AMIA recommends CMS issue an interim final rule with a comment period to further refine proposed policies based on stakeholder feedback, and we recommend CMS consider a 90- or 180-day reporting period in 2017. Experience with MU has indicated that 90-day reporting

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

periods has benefited clinicians without compromising their commitment to using IT to improve care. Further, CMS has proposed to make clinical improvement activities that occur over 90 days eligible for the CPIA Performance Category. By issuing an interim final rule and shortening the reporting period in 2017, we are confident that more ECs will be successful in the first, critical year of this new paradigm.

Below, we address specific sections of the NPRM with relevance to the applied informatics community AMIA represents, including various Performance Categories of MIPS and certain aspects of APMs included the Medicare QPP. We also provide input on some requests for comment, proposals meant to prevent information blocking and raise issues related to third-party data submission. However, we first wish to voice concern over the pace and volume of change resulting from this NPRM.

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

Sincerely,

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

Thomas H. Payne, MD, FACP
AMIA Board Chair
Medical Director, IT Services, UW Medicine
University of Washington

Enclosed: AMIA Response to CMS Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model Incentive under the Physician Fee Schedule NPRM

Prevention of Information Blocking and Surveillance Demonstration

AMIA understands the federal government's concerns regarding information blocking, standards adherence and patient access to their health information. However, we believe the proposed attestations – especially statements #2 and #3 – will be difficult to implement, will create wide variation in interpretation among providers and will create great confusion among providers over perceived risk of non-compliance. Further, compliance with statements #2 and #3 is likely to fall outside what the average MIPS EC can control or would be knowledgeable enough to feel confident in attesting.

For instance, most ECs would have no way of knowing whether their EHRs have been implemented in a manner that is consistent with the language in statement #2; most clinicians do not understand the underlying "technologies, standards, policies and agreements" to a degree they could attest without serious reservation – no matter how interoperable their technology.

Despite our support for the spirit of statement #3, it is also problematic. Any provider purposefully failing to respond to a request for information should be held accountable, and patients who encounter obstacles in trying to receive their information should have a path of remediation. However, we believe statement #3 – like statement #2 – will likely create anxiety and confusion among providers, while leaving the identified problems unaddressed.

AMIA Recommendation: Given these views, AMIA believes statements #2 and #3 are untenable, and we recommend CMS finalize only statement #1. Statement #1 most clearly represents the language and intent of what MACRA requires, is likely to avoid misinterpretation as EC attest, and Statement #1 is relatively enforceable.

CMS also proposes to require EPs, eligible hospitals, and CAHs to attest (as part of their demonstration of meaningful use under the Medicare and Medicaid EHR Incentive Programs) that they have cooperated with the surveillance of certified EHR technology under the ONC Health IT Certification Program. Similarly, CMS proposes to require such an attestation from all eligible clinicians under the ACI Performance Category, including eligible clinicians who report on the ACI Performance Category as part of an APM Entity group under the APM Scoring Standard.

We understand this attestation is meant to strengthen surveillance and other oversight of certified health IT, including through expanded in-the-field surveillance and ONC direct review of technology and capabilities. However, we have general concerns with the burden on providers and associated uncertainty that could be imposed by the surveillance attestation. We also question whether such an attestation is necessary, given that in-the-field surveillance is a new activity, and ONC direct review is not yet a legal authority of the Office.

AMIA Recommendation: AMIA does not support this attestation requirement. We believe it is premature to use such a mechanism to address a problem of non-cooperation among providers regarding surveillance when little or no experience would warrant such attestation.

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

MIPS Category Measures and Activities
CMS seeks comments for future rulemaking on whether it should propose requiring health IT vendors, QCDRs, and qualified registries to have the capability to submit data for all MIPS Performance Categories.

AMIA Recommendation: Vendors should certainly have the opportunity to report this data if they are prepared to do so, however we oppose making it a requirement of the QPP. Many vendors have developed solutions tailored to specific areas of healthcare quality and performance improvement, and given the breadth of QPP requirements it would be unreasonable to insist they divert resources from their core business focus in order to satisfy additional programs. Some vendors may wish to pursue such a strategy; however, we recommend CMS not require health IT vendors, QCDRs, and qualified registries to have the capability to submit data for all MIPS Performance Categories at this time.

Quality Performance Category
We support the CMS vision of a future state where clinicians will be using their certified health IT seamlessly to leverage clinical quality measurement to manage patient population with the least amount of workflow disruption and reporting burden. We commend CMS for accepting previous AMIA recommendations to limit the total number of required CQMs, and enable specialty societies to play a more active role in determining which CQMs are most relevant for their scope of practice. AMIA supports both the reduction in required CQMs for the Quality Performance Category, the elimination of the requirements to span domains, the increased focus on outcomes measures, and the establishment of specialty-specific groupings as a means to improve applicability. However, we do wish to highlight some concerns with the proposed path and offer ways to improve the likelihood of success.

Of acute concern is the validity of quality measures used to determine clinicians' performance in this category of MIPS – especially as it relates to electronic clinical quality measures (eCQMs). The experience of our members, and the results of a recent pilot study involving hospitals' use of eCQMs,[1] calls into question whether the majority of proposed process-oriented quality measures are accurate in electronic formats. Further, there does not appear to be a consistent, transparent and widely understood pathway through which paper-based or "registry-only" measures are translated to electronic-based measures, and done in a way that maintains validity.

AMIA Recommendation: To improve the current approach, AMIA recommends that CMS devote more resources to testing both the accuracy of the measure calculation as well as the feasibility of the data collection requirements, and pilot all new eCQMs before their release for use. We further recommend CMS establish a regular cadence of updates/revisions to eCQMs, ensuring adequate time is allowed for implementation of revisions by both the vendor and provider; and ensure that all information and tools located in the eCQI Resource Center are complete and up-to-date. We also

[1] CMS Hospital Inpatient Quality Reporting (IQR) eCQM Validation Pilot Summary. Mathematica Policy Research / Lantana Consulting. 10 June 16. http://bit.ly/28OZv4L

urge that CMS focus on including more e-specified measures in the specialty measure grouping so that clinicians can use their EHRs if they choose to report such measures.

We are also concerned with CMS' plan to update quality measures on a yearly basis, with a November 1 deadline for measures to be required for the next year. Such timing will pose major issues for clinicians and vendors if material changes are made so close to the start of a new year. If the measures on which clinicians are going to be assessed change from year to year, it is difficult to compare year-to-year performance and demonstrate whether we are moving in the right direction. Similarly, if quality measures change from year-to-year, there is a tremendous burden on providers and health IT vendors, including clinical data and other registry sponsors, to incorporate new measures in their respective clinical workflows and health IT systems/registries. We also note that health IT vendors are at a significant disadvantage if they should want to adopt certain QCDR measures that have been developed by the medical specialty societies into their respective EHR systems, given MACRA does not require these measures to be established through notice-and-comment rulemaking.

AMIA Recommendation: AMIA recommends measures be considered in "test/pilot" mode for the first two years they are included in CMS' quality programs, rigorously evaluated for validity and accuracy during the pilot period, and should be maintained for five years following, to ensure the agency has a reasonable understanding of how providers have performed and improved over time, as well as to determine whether CMS' end-points have been reasonably met, with respect to included quality measures. Should the measures be found inadequate, or if performance has met CMS' "topped out" threshold, CMS should propose removal of the quality measure before five years has lapsed.

In addition, it is not clear whether QCDR measures will be required to have e-specifications that would allow vendors to adopt those measures into their respective technologies.

AMIA Recommendation: To avoid concerns regarding uneven opportunities for providers, registries and health IT developers, CMS should require all measures planned for inclusion in its quality reporting programs to include specifications such that any organization that would want to use those measures may do so.

For CMS to realize "a future state where clinicians will be using their certified health IT seamlessly to leverage clinical quality measurement to manage patient population with the least amount of workflow disruption and reporting burden," it stands to reason that the reporting threshold should be lower for QCDRs to encourage its use.

AMIA Recommendation: We urge CMS to reduce the reporting threshold for QCDRs in the final rule to 50 percent, which is consistent with the current reporting threshold for QCDRs in the PQRS program and to also revisit the EHR submission thresholds.

Last, we believe CMS has grossly underestimated the time and resources required to collect and report quality data. Recent data indicates US physician practices spend more than $15 billion annually to report quality measures, and while we support many of the policies in this category, such

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

resources are not sustainable.[2] We urge CMS to conduct a more thorough assessment of the burden imposed by these quality activities, and ensure that new policies are not additive to this already large financial and resource-heavy burden.

Advancing Care Information Category

AMIA has a strong interest in seeing the Advancing Care Information (ACI) Performance Category work for all stakeholders. 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 uses of health IT and other informatics tools. Below, we supply comments on both the mechanics of ACI in the near-term, and recommend ways to refine the strategy over subsequent years.

The implementation of programs established under MACRA affords CMS a unique opportunity to drastically change the direction of the meaningful use (MU) program for clinicians. AMIA appreciates that CMS sought to address clinicians' core concerns with MU, such as removing the "all or nothing" paradigm and reducing the total number of measures. We also commend CMS for developing an innovative approach to scoring this category that simultaneously ensures continued use of a broad set of functionalities, and provides ECs flexibility to focus on functionalities important to their practice and patient populations.

These changes to the mechanics of MU notwithstanding, these requirements constrain provider choice and add unnecessary costs by continuing a form of the "all-or-nothing" approach. Under CMS' proposal, clinicians would be required to meet a "one-patient" threshold for each measure where a numerator/denominator is required, in order to earn any points toward the base score. This proposal means that some MIPS ECs might continue to engage in IT use that is not meaningful to their practice and patient populations. Further, it means health IT vendors and providers may spend inordinate amounts of time and resources on functionalities that must only be used on one patient during an entire reporting period.

Our concerns about insufficient flexibility is further reinforced by CMS' proposal to eliminate exclusions for most proposed measures. Absence of exclusions could result in only a subset of measures being available to a given clinician, meaning she would have to score inordinately higher on other measures reported.

AMIA Recommendation: AMIA recommends that CMS make the following changes to the ACI Performance Category to improve the likelihood of widespread successful participation, thus increasing the digital acumen of our nation's clinicians:

- Allow for exclusions, using criteria similar to what is currently required for the EHR Incentive Program. This option will alleviate burdens for providers who, historically, have not met patient volume for specific measures, such as transitions of care, historically.

[2] Casalino LP, Gans D, et al. "2016 US physician practices spend more than $15.4 billion annually to report quality measures." Health Affairs 35 (3) 1-6 March 2016

- Provide ECs 60 points for meeting all Base Score requirements. This revision will require ECs to implement all ACI capabilities, yet the extra points will provide ECs some additional flexibility with the Performance Score. We anticipate that patient generated health data, request / accept care record and clinical reconciliation will be difficult for many ECs to achieve high percentages, especially in the near-term.
    - Alternatively, CMS could reconsidering their calculation of the Performance Score that currently employs a scale that equates 100% threshold performance to attain the maximum score of 10 points for any given measure. We note that achieving all the Stage 3 thresholds adopted in October 2015 would generate a total ACI score of 80/100 (2017) and 82.5/100 (2018+).

We also note there are different numbers of measures available for those still in Stage 2 in 2017 (6 measures) vs. Stage 3 (8 measures). This complicates, and unfairly disadvantages, ECs reporting Stage 2 measures in 2017 vis-à-vis the Performance Score.

AMIA Recommendation: We urge CMS to take steps, such as revising the scoring per measure for those in Stage 2, to ensure that those still in Stage 2 in 2017 are not unintentionally or unduly disadvantaged by only having access to a pool of 60 points to achieve the maximum of 50 performance points rather than the pool of 80 available to those doing Stage 3. One option would be to allow ECs who are only using 2014 Edition CEHRT to report on the Stage 3 Patient Generated Health Data measure, as this is a measure that notably does not require use of certified technology.

We are also concerned about the timeline from expected release of the Final Rule to when measurement and reporting are to begin for both 2017 and 2018 reporting years. Experience to-date indicates that, in addition to complications related to upgrades and implementation, another large challenges will be in educating ECs about the finalized MIPS and APM requirements. The challenge of such support will be increased by the availability of the new group reporting option and the need to track and report at the TIN/NPI level, with the need for revised measure logic. Such tracking and measurement support will also be challenged by the new ACI scoring model (as well as the expected EC desire to understand how they are doing relative to category and overall scores and benchmarks).

AMIA Recommendation: We urge CMS to be realistic in defining reporting periods in 2017, especially as it relates to the ACI Performance category. We recommend CMS consider a shorter reporting period, of perhaps six months, in 2017 to help accommodate this hugely complex and high degree of change.

Should these recommendations be adopted, we would be more confident in the near-term success of the ACI program; however, we further recommend ways to evolve the program over time.

AMIA Recommendation: AMIA suggests CMS develop a multi-year strategy that shifts toward a more evidence-based, outcomes-driven program that measures end-results stemming from the use of health IT, rather than the process-based measures used today. Further, we request CMS look to

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

better align ACI requirements to reflect how successful APMs use health IT in future iterations of the program.

As an initial step, AMIA recommends CMS fund a robust, peer-reviewed study articulating how the current and proposed approach will continue to meaningfully improve healthcare quality, cost and outcomes. We further request CMS enhance its study efforts with information on "opportunity costs," including the cost of foregone clinical interventions and the types of enhancements delayed or missed by MIPS ECs, resulting from new health IT measures introduced into the program.

Clinical Practice Improvement Activities (CPIA) Category

MACRA defines a CPIA as an activity that relevant eligible clinician organizations and other relevant stakeholders identify as improving clinical practice or care delivery, and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. This category has a maximum of 60 points, which can be achieved through engaging in "medium" or "high" point activities, valued at 10 and 20 points, respectively.

AMIA supports and appreciates the manner and wide variety of potential CPIAs ECs could engage to fulfill and achieve maximum credit for this Performance Category. Similar to the ACI category, we provide below a set of recommendations meant to improve the near-term, and we provide recommendations on the long-term evolution and refinement of the CPIA category.

In 2000, the American Board of Medical Specialties mandated that its 24-member physician boards limit board certification of medical doctors to 10 years. Thus, most current practicing physicians are engaged in Maintenance of Certification (MOC) activities, some of which could count towards CPIA credit in this Performance Category. In addition, there are physicians who are not required to participate in the 10-year recertification cycle who either choose to do so, or who engage in continuing medical education (CME) activities designed to assist physicians in their lifelong commitment to remain competent.

AMIA Recommendation: AMIA strongly supports inclusion of MOC-IV as a potential CPIA for MIPS ECs. Further, AMIA recommends that CMS provide "high" weighting to ECs engaged in MOC-IV activities. Physicians participating in these activities should be given 20-point credit toward the CPIA component because:

- MOC-IV involves significant time and resource investments;
    - Physicians regularly address clinical practice improvement through the analysis of aggregated patient data;
    - They regularly rely on two distinct data pulls and are an example of a cross-sectional study, a scientific study design commonly used in scientific research (if the same patient records are used for both data pulls, the physician is engaging in a cohort study, another commonly used study design);
- Giving "high" credit for MOC-IV would lessen the burden on physicians who are complying with their boards' MOC cycles, which have the same intent as MACRA's CPIAs;

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

- Board MOC requirements already include mechanisms and infrastructure to audit / verify activities and thus should be encouraged by CMS;
- Numerous proposed "high" point activities would be analogous to MOC-IV activities, such as:
    - Collection and follow-up on patient experience and satisfaction data on beneficiary engagement, including development of improvement plan;
    - Use of a QCDR to generate regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations; or
    - Consultation of Prescription Drug Monitoring Program prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription that lasts for longer than 3 days.

AMIA Recommendation: Additionally, AMIA recommends "medium" CPIA weighting for certain CME activities, provided by accredited providers of CME. These CME activities would include:

- Performance Improvement CME, characterized by A) an initial analysis of patient data, leading to the identification of a practice area needing improvement; B) the physician's engagement in educational activities focusing on that area; and C) a second analysis of patient data, demonstrating the impact of this educational pursuit on patient outcomes, with a focus on the identified gap. The PI-CME activity is required to take place over a minimum of three months, and offers 20 credits of CME
- CME activities for which there is a 3-month follow-up survey, in which physicians report the impact of an educational activity on practice.

AMIA Recommendation: Specific to the subspecialty of clinical informatics, of which more than 1,000 have received board certification, AMIA strongly supports efforts made by CMS to put a special emphasis on group, and transdisciplinary CPIAs. Clinical informatics subspecialists can be board certified in any specialty, and thus represent a diverse mix of clinical knowledge. The value of informatics is amplified when groups or teams of clinicians, representing multiple disciplines, work together.

CMS proposes to aid non-patient-facing MIPS ECs and groups, as well as special considerations for small, rural or health professional shortage areas practices by allowing them to report on a minimum of one activity to achieve partial credit or two activities to achieve full credit to meet the CPIA submission criteria (irrespective of the weighting).

AMIA Recommendation: AMIA supports these proposals.

CMS proposes to allow for MIPS eligible clinicians to submit CPIA Performance Category data through qualified registry, EHR, QCDR, attestation and CMS Web Interface submission methods.

AMIA Recommendation: AMIA supports this proposal.

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

CPIA Study

To help better understand the current processes and limitations, CMS proposes to conduct a study on CPIAs and measurement to examine clinical quality workflows and data capture using a simpler approach to quality measures. The study will allow a limited number of selected MIPS eligible clinicians and groups to receive full credit (60 points) for the CPIA category. CMS seeks comment on the study and welcome suggestions on future study topics.

AMIA Recommendation: AMIA supports such a study, particularly from a holistic quality process perspective, and we urge CMS to engage in studies that meet the rigor of peer-reviewed scientific studies. Strategically, we have some concern that introducing a "grab bag" of activities and metrics that have not been proven to have a significant impact will distract clinicians from engaging in activities where evidence has shown care is improved. However, as stated before, we appreciate the flexibility provided by CMS and encourage ongoing evaluation and refinement of potential activities as the program evolves.

We note the importance of ensuring the study design process involve both CEHRT vendors as well as providers and experts in workflow, and focus on ways that health IT can improve outcomes. This and future studies may provide CMS with valid evidence upon which future modifications to the ACI Performance Category could be built. Studies could also be designed to better understand which, and under what circumstances, quality measures led to improved outcomes, leading to improvements in future Quality, Resource and ACI reporting measures.

CPIA Policies for Future Years of the MIPS Program: Proposed Approach for Identifying New Subcategories and New Activities

For future years, CMS proposes to consider the addition of a new subcategory or activity to the CPIA Inventory only when the following criteria are met:

- The new subcategory represents an area that could highlight improved beneficiary health outcomes, patient engagement and safety based on evidence.
- The new subcategory has a designated number of activities that meet the criteria for a CPIA activity and cannot be classified under the existing subcategories.
- Newly identified subcategories would contribute to improvement in patient care practices or improvement in performance on quality measures and resource use Performance Categories.

AMIA Recommendation: We support the criteria as outlined by CMS. For both proposed and new activities, it is important that the CPIAs be clear and unambiguous in terms of what counts for credit, including the needed documentation requirements. We support CPIAs that take advantage of current and emerging health IT capabilities, but recommend CMS focus more on the activity and less on the specific means of achieving the practice improvements.

CPIA Policies for Future Years of the MIPS Program: Request for Comments on Call for Measures and Activities Process for Adding New Activities and New Subcategories

CMS plans to develop a call for measures and activities process for future years of MIPS, where stakeholders may recommend activities for potential inclusion in the CPIA Inventory. As part of the process, MIPS eligible clinicians or groups would be able to nominate additional activities that

CMS could consider adding to the CPIA Inventory. Prospective activities that are submitted through a QCDR could also be included as part of a beta-test process that may be instrumental for future years to determine whether that activity should be included in the CPIA Inventory based on specific criteria noted above.

AMIA Recommendation: We believe this approach makes sense, and we suggest that CMS develop a template designed to ensure that proposed CPIAs are clearly measurable and also that the "value" of the CPIA can be related to an existing CPIA.

CPIA Policies for Future Years of the MIPS Program: Request for Comments on Use of QCDRs for Identification and Tracking of Future Activities

CMS recognizes that QCDRs could enhance the ability of MIPS eligible clinicians or groups to capture and report on more meaningful activities, especially for specialty groups. QCDRs may provide for a more diverse set of measures and activities than are possible to list under the current CPIA Inventory. CMS believes that for future years, QCDRs will be allowed to define specific CPIAs for specialty and non-patient- facing MIPS eligible clinicians or groups through the already-established QCDR approval process for measures and activities.

AMIA Recommendation: We support the use of QCDRs for this purpose, but recommend CMS ensure the validity of such approaches and that CMS develop means to demonstrate measurability and value as stated previously. In general, we also urge that CMS be mindful of the potential complexity of multiple reporting channels.

Alternative Payment Models (APMs)

CMS proposes that an Advanced APM must require at least 50 percent of eligible clinicians who are enrolled in Medicare to use the CEHRT functions (as outlined in the proposed CEHRT definition) "to document and communicate clinical care with patients and other health care professionals." This threshold would be confined to the first QP Performance Period (2017). The threshold for use of CEHRT would increase to 75 percent beginning with the second QP Performance Period (2018).

AMIA Recommendation: First, we support CMS efforts to assess whether eligible clinicians used CEHRT functions "to document and communicate clinical care with patients and other health care professionals," via attestation by the APM entity of its policies for CEHRT use for these functions. If this is the case, we support the attestation approach. Second, while AMIA believes most Advanced APMs would meet these requirements, we also seek additional clarity in how APMs would identify its respective denominator of eligible clinicians. We urge CMS to represent the method for calculating the denominator of eligible clinicians using a mathematical expression as well as how the level of proof required would translate to an entity-level percentage-based measurement.

CMS requested comment on whether it should explore ways to set lower thresholds for entities such as specialty-focused APMs.

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

AMIA Recommendation: We recommend close collaboration with the medical informatics community to address this issue. AMIA members have clinical informatics expertise in numerous specialties, and would be invaluable in developing the most appropriate solution. For example, developing specialty-focused "use cases" may be more likely to result in an understanding of whether these criteria have been met, while also resulting it better policy for specialty-focused APMs. AMIA stands ready to assist CMS with this challenge.

In response to CMS' other questions:

- AMIA believes the definition of CEHRT for Advanced APMs and Other Payer Advanced APMs should be the same and we agree with CMS's proposal and urge that this approach be continued in the out years. As indicated, we also agree with the proposed approach to assess the use of CEHRT by APM entities.
- Rather than asking what health IT functionalities APM participants need to effectively provide care to their patients, CMS should instead focus on program goals and better defining expected outcomes, which would help guide APM entities to identify what technologies that will best meet those endpoints.
- We urge CMS to clearly state what it is trying to accomplish or study before asking how the use of interoperable health IT strengthens and encourages higher quality patient care and more effective care coordination across all APMs.
- AMIA does not believe new health IT standards and certification criteria are needed. Rather, the existing standards need to be recognized and adopted in a consistent manner that does not vary by vendor. Implementation guides promulgated by standards organizations may be most helpful in this regard. We also urge more study on how EHRs affect workflows, both positively and negatively, particularly as workflows are changing due to quality and other reporting/performance requirements.
- AMIA supports additional emphasis on usability and compatibility of electronic data collected by HIEs. We are concerned that HIE data are not always readable by EHR systems. We are also concerned that HIE data, in current exchange formats and without trusted relationships among providers, face limited update by providers receiving information. Meaningful health information exchange requires sending the information, receiving the information, and being able to use the information for patient care.

Third Party Data Submission

One of CMS's strategic goals in developing MIPS includes developing a program that is meaningful, understandable, and flexible for participating MIPS eligible clinicians, which may be accomplished by allowing MIPS eligible clinicians the flexibility of using third party intermediaries to collect or submit data on their behalf. As such, CMS proposes that MIPS data may be submitted by third party intermediaries on behalf of a MIPS eligible clinician or group by: (1) a qualified registry; (2) a QCDR; (3) a health IT vendor; or (4) a CMS-approved survey vendor. Furthermore, CMS proposes that third party intermediaries must meet all the requirements designated by CMS as a condition of their qualification or approval to participate in MIPS as a third party intermediary.

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

AMIA Recommendation: Generally, AMIA supports CMS' proposal; however, we urge CMS to make a few modifications.

First, we note the absence of "hold harmless" provisions to ensure MIPS eligible clinicians would not be subject to penalties under MIPS if a third party intermediary were to have any error rate, and particularly if the intermediary were disqualified, or if they pull out of the market at any point during the reporting period. Similar provisions are included as part of CMS' EHR Incentive Program in the form of hardship exceptions. Specifically, CMS grants hardship exceptions when providers faced extreme and uncontrollable circumstances in the form of issues with the certification of the EHR product or products such as delays or decertification. CMS must include such provisions in the final rule.

Second, we are concerned that some physician practices may have difficulty identifying if and when there is a problem based on their own review of data. We urge CMS to provide guidance and technical assistance so that practices will be able to review their own data and reports to determine if there are errors. CMS might also include language in the final rule that encourages "due diligence" on the part of the physician practice to review their data and reports at periodic intervals. Such guidance might also outline steps the provider should take to contact their health IT vendor if and when concerns are identified. Most of this could be accomplished through subregulatory guidance, but it should be developed in an open and transparent manner, allowing vendors and physicians to contribute to the development of such materials.

Finally, we wish to support CMS' proposal for Targeted Review, as outlined elsewhere in the rule, whereby CMS proposes to adopt a targeted review process under MIPS wherein a MIPS eligible clinician may request that CMS review the calculation of the MIPS adjustment factor and, as applicable, the calculation of the additional MIPS adjustment factor applicable to such MIPS eligible clinician for a year. CMS provides examples of circumstances under which a MIPS eligible clinician may wish to request a targeted review, which includes the following:

> "The MIPS eligible clinician believes that measures or activities submitted to CMS during the submission period and used in the calculations of the CPS and determination of the adjustment factors have calculation errors or data quality issues. These submissions could be with or without the assistance of a third party intermediary."

We believe this is a likely scenario, and urge CMS to finalize this proposal in the final rule.

Health IT Vendors That Obtain Data from MIPS Eligible Clinician's Certified EHR Technology

EHR-based systems are currently required to be considered certified EHR technology for multiple CMS quality programs. CMS proposes to maintain this standard and require EHR-based data submission (whether transmitted directly from the EHR or from a data intermediary) to be certified EHR technology to submit quality measures, advancing care information, and CPIA data for MIPS. In addition, CMS proposes that health IT vendors that obtain data from a MIPS eligible clinician's certified EHR technology, like other third party intermediaries, would have to meet all requirements

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

designated by CMS as a condition of their qualification or approval to participate in MIPS as a third party intermediary.

CMS proposes at 414.1400(a)(2) to expand health IT vendors' capabilities by allowing them to submit data on measures, activities, or objectives for any of the following MIPS Performance Categories: Quality; CPIA; or ACI. CMS further proposes that health IT vendors must be able to do the following:

- For measures, activities, and objectives under the quality, advancing care information, and CPIA Performance Categories, if the data is derived from certified EHR technology, the health IT vendor must be able to indicate this data source.
- Either transmit data from the certified EHR technology or through a data intermediary in the CMS- specified form and manner, or have the ability for the individual MIPS eligible clinician and group to be able to submit data directly from their certified EHR technology, in the CMS-specified form and manner.

AMIA Recommendation: AMIA believes these requirements are reasonable. Nonetheless, we have some concerns. First, we are concerned about the ability of health IT vendors to incorporate mechanisms for reporting the new ACI and CPIA Performance Categories into QRDAs under the current reporting deadlines and without new implementation guides. Second, it does not appear that the latest draft of the HL7 Quality Reporting Document Architecture (QRDA) has incorporated these new categories, which would be essential for facilitating vendor efforts to make software modifications, in our view. Third, once the QRDA is updated to accommodate the MIPS, it will be important for CMS to test and validate the reporting standards related to the inclusion of these new Performance Categories.

Probation and Disqualification of a Third Party Intermediary

CMS proposes a process for placing third party intermediaries on probation and for disqualifying such entities for failure to meet certain standards established by CMS. Specifically, CMS proposes that if at any time it determines that a third party intermediary has not met all of the applicable requirements for qualification, CMS may place the third party intermediary on probation for the current performance period and/or the following performance period, as applicable.

AMIA has reviewed the process and associated criteria and we have some significant concerns. For example, CMS proposes to require a corrective action plan from the third party intermediary to address any deficiencies or issues and prevent them from recurring, which must be received and accepted by CMS within 14 days of the CMS notification to the third party intermediary of the deficiencies or probation. In addition, CMS proposes if the third party intermediary does not submit an acceptable corrective action plan within 14 days of notification of the deficiencies and correct the deficiencies within 30 days or before the submission deadline – whichever is sooner, CMS may disqualify the third party intermediary from participating in MIPS for the current performance period and/or the following performance period, as applicable.

AMIA Recommendation: These timeframes are unreasonably short and we recommend they be extended. It is unreasonable for CMS to expect that a health IT vendor would be able to verify that

a problem exists, identify and troubleshoot the source of the problem, and present a precise solution for correcting the problem, within 14 days. We urge CMS to extend this to 30 days, at a minimum.

With regard to correcting deficiencies, 30 days may be unreasonably short. Depending on the nature of the problem, it can take anywhere from a week to several months to program a software patch, and even longer to correct the problem through a software upgrade. We urge CMS to extend this to 90 days, at a minimum.

Auditing of Third Party Intermediaries Submitting MIPS Data

CMS proposes that any third party intermediary must comply with certain auditing requirements as a condition of their qualification or approval to participate in MIPS as a third party intermediary. Specifically, CMS proposes the entity must make available to CMS the contact information of each MIPS eligible clinician or group on behalf of whom it submits data. The contact information will include, at a minimum, the MIPS eligible clinician or group's practice phone number, address, and, if available, email. Further, CMS proposes the entity must retain all data submitted to CMS for MIPS for a minimum of 10 years.

AMIA Recommendation: While AMIA does not oppose this proposal, we urge CMS to provide important clarification in the final rule. Specifically, CMS should clarify that the audits called for in this section are focused on the accuracy of the health IT vendor and their product, and not on the MIPS eligible clinician. Moreover, the vendor should not be held responsible for the accuracy of data provided or stored by the provider when the vendor would not be in a position to assess the validity of provider data. Thus, any findings related to the audit of the third party submitter would be focused on the vendor only and would not lead to actions affecting the MIPS eligible clinician. Furthermore, any negative findings should not impact the MIP eligible clinician and that they would be "held harmless" from any negative MIPS adjustments or other CMPs under the False Claims Act.

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