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May 23, 2016

The Honorable Karen DeSalvo, MD, MPH, M. Sc.
Acting Assistant Secretary for Health,
National Coordinator for Health Information Technology,
Department of Health and Human Services
Attention: ONC 2016-08134
Submitted electronically to: http://www.regulations.gov

Re: Request for Information Regarding Assessing Interoperability for MACRA

Dear Dr. DeSalvo:

The American Medical Informatics Association (AMIA) welcomes the opportunity to submit comments regarding ways the Office of the National Coordinator for Health Information Technology (ONC) should consider implementing Section 106(b)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. No. 114–10). This Request for Information (RFI) was published by ONC in the April 8, 2016 issue of the *Federal Register* at 81 FR 20651.

AMIA is the professional home for more than 5,000 informatics professionals, representing researchers, front-line clinicians 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 members play a leading role in moving basic research findings from bench to bedside; evaluating interventions across communities; assessing the impact of health innovations on health policy; and advancing the field of informatics.

Cognizant of the congressional deadline to develop interoperability measures by July 1, 2016, AMIA strongly recommends that ONC develop a measurement strategy that is patient-centric, and one that can be expanded and refined over time. Our approach would enable ONC to contextualize transaction- and provider-focused data to better understand if clinically relevant data were available to the clinician when and where they were needed. Rather than try to develop measures for the myriad of ways interoperability may be occurring, we recommend an approach that looks to understand where interoperability is needed, and then assess whether or not it is occurring.

Such an approach, described in more detail in Appendix A, would rely on claims data and statistical samples to conduct retrospective reviews, examining if expected interoperable data sharing occurred for patients with health conditions that necessitated receiving care from multiple providers. Using a retrospective review would also enable an assessment of why expected interoperable data sharing did not occur. If the sampling is representative, such an approach should offer insight into the level of interoperability across the nation, and address whether interoperability was in place among providers who share a high volume of patients. This approach would help ONC assess the availability of data and the impact of interoperability where it is likely to influence the care of patients most – among the clinicians and organizations that treat them routinely.

We are not convinced that volume-based measures are the most appropriate primary way to determine the extent of nationwide interoperability, and we are not confident the data sources mentioned in the RFI will be sufficient. However, we recognize that our recommended approach is not likely to be operational by the July 2016 congressional deadline. Therefore, we assume ONC will need to measure interoperability, initially, using the sources identified in the RFI, and we recommend a number of enhancements to inform ONC's near-term approach in Table 1, included as an attachment. We also provide guidance to help ONC better understand the limitations of EHR Incentive Program data.

Finally, we issue a word of caution against the development of new national measures that further burden clinicians as they deliver patient care and divert vendor focus from meeting provider and patient needs. We note that the measurement paradigm developed through the EHR Incentive Program has affected development and usability of health IT, and impacted care workflows in unintended, negative ways. The strength of our recommended approach, based on retrospective reviews, is that it would only require reporting by a very small subset of providers. **We urge ONC to work closely with organizations such as AMIA that can convene clinicians and technology developers to identify expected data sharing patterns and measurement instruments that indicate to what degree we have achieved nationwide interoperability, while avoiding the pitfalls of past approaches.** To this end, we offer our assistance and welcome a prolonged conversation on this important task.

Below, we address individual questions and provide additional context to our priority recommendations. Should you have any 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 continuing this dialogue, and we reiterate our offer to provide assistance to ONC as it seeks to measure our progress toward nationwide interoperability.

Sincerely,

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

Thomas Payne

Thomas H. Payne, MD, FACP
AMIA Board Chair
Medical Director, IT Services, UW Medicine
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Enclosure: AMIA recommendations to specific questions posed by ONC

Table 1

ONC Request for Information Regarding Assessing Interoperability for MACRA		
Scope of Measurement: Defining Interoperability and Population		
	ONC Question	**AMIA Response**
1	Should the focus of measurement be limited to "meaningful EHR users," as defined in this section (e.g., eligible professionals, eligible hospitals, and CAHs that attest to meaningful use of certified EHR technology under CMS' Medicare and Medicaid EHR Incentive Programs), and their exchange partners? Alternatively, should the populations and measures be consistent with how ONC plans to measure interoperability for the assessing progress related to the Interoperability Roadmap? For example, consumers, behavioral health, and long-term care providers are included in the Interoperability Roadmap's plans to measure progress; however, these priority populations for measurement are not specified by section 106(b)(1)(B)(i) of the MACRA.	**AMIA Recommendation:** ONC should focus its measurement on "meaningful EHR users," in the near term, while developing plans to expand this scope to include other cohorts identified in the Interoperability Roadmap. Ultimately, and consistent with our primary recommendations, we suggest ONC develop a patient-centric measurement approach that seeks to determine if the clinically relevant information was available where and when it was needed across the care continuum. We note there are limitations to the primary question related to "meaningful EHR users" and their exchange partners given the ambiguity of "exchange partners" for any given "meaningful EHR user." If this means any potential exchange partner that an EP or EH wishes to share clinical data with, the list is quite extensive, and would span the care continuum and even beyond into social and community services. In the near-term, we urge ONC to pursue an interoperability measurement strategy that focuses on the providers who share the greatest volume of patients, and therefore have the greatest need to engage in interoperable data sharing, and to focus on priority use cases where interoperability could be reasonably expected to be occurring, notably care coordination and patient engagement. CMS claims data can be used to determine which exchange partners, at the dyad-level, share the highest volumes of patients, and whether those dyads engage in interoperable data exchange. This would limit the scope of measurement to a reasonable degree, while also adhering to one of our overarching principles: that ONC prioritize interoperability where it impacts patients the most. Another limitation is that data from this cohort is heavily skewed to those EPs and EHs / CAHs that were successful in Meaningful Use, and says nothing of how interoperable unsuccessful providers are. We also wish to highlight an emerging area for which ONC should consider future work. Current and proposed policies related to the program formerly

		known as Meaningful Use will proliferate the use of application programming interfaces (APIs) and apps. ONC should consider how they wish to measure exchange at the app level, which will become more prevalent as standards emerge, mature and become more ubiquitous. For example, apps will provide a way to have actionable interoperability, such as a shared care plan that can be discussed via shared apps, which could become a new kind of interoperability not currently seen in production. Finally, patient-reported outcomes will likely proliferate as new models of care emerge. ONC should prioritize development / refinement of a framework to capture the extent of interoperable exchange between patients and providers using patient-generated health data.
2	How should eligible professionals under the Merit-Based Incentive Payment System (MIPS) and eligible professionals who participate in the alternative payment models (APMs) be addressed?	**AMIA Recommendation:** Eligible Clinicians (ECs) participating in MIPS should be treated as "meaningful EHR users" for the purposes of measurement scope. Insofar as Qualified Professionals report on measures similar to what is required by the program formerly known as Meaningful Use, they should be treated similarly to ECs.
3	ONC seeks to measure various aspects of interoperability (electronically sending, receiving, finding and integrating data from outside sources, and subsequent use of information electronically received from outside sources). Do these aspects of interoperability adequately address both the exchange and use components of section 106(b)(1) of the MACRA?	**AMIA Recommendation:** Conceptually, yes, those aspects of interoperability adequately address the exchange and use components of section 106(b)(1) of the MACRA. We note there is a difference between capability, integration and use, and assessing the ability to query (find) data will be difficult through volume-based measures.

<table>
<tr><td>4</td><td>Should the focus of measurement be limited to use of certified EHR technology? Alternatively, should we consider measurement of exchange and use outside of certified EHR technology?</td><td>AMIA Recommendation: We urge ONC to focus its initial measurement on certified EHR technology.
However, should ONC accept our primary recommendation, the status of the technology’s certification matters less than whether the relevant data was available and used for the purpose identified, as long as there is adherence to standards for terminology and messaging.
We note the increasing volume of clinically relevant data generated outside the medical institution. Remote patient monitoring and consumer health informatics tools are important sources of information, and should be included in the scope of future measurement efforts.</td></tr>
<tr><td colspan="3"><i>ONC’s Available Data Sources and Potential Measures: Measures Based upon National Survey Data</i></td></tr>
<tr><th></th><th>ONC Question</th><th>AMIA Response</th></tr>
<tr><td>5</td><td>Do the survey-based measures described in this section, which focus on measurement from a health care provider perspective (as opposed to transaction-based approach) adequately address the two components of interoperability (exchange and use) as described in section 106(b)(1) of the MACRA?</td><td>AMIA Recommendation: AMIA supports the use of national surveys provided they elicit information regarding a broader range of data and more specificity with regard to exchange partners in order to determine whether providers are engaging in interoperable data exchange with “none,” “few,” “some” or “all” of the other providers with which they share patients. We also recommend that surveys ask open-ended questions about what clinically relevant data is commonly missing. Further we recommend that surveys frame questions around high-value use cases, such as ED visits and care coordination for patients with multiple chronic conditions. Finally, we recommend that survey instruments explicitly target respondents that spend time in front-line clinical care.
While we see utility in leveraging the national surveys mentioned in this RFI, and encourage ONC to use data from these national surveys, we note two fundamental limitations: (1) the focus of exchange is on the summary of care record, which is important but not inclusive of the full spectrum of relevant information; and (2) we have concern over the target respondent’s ability to provide accurate and detailed information of the sort that is required to reflect degree of interoperability.</td></tr>
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		Information on how often survey participants receive imaging and other studies done at outside institutions would also be helpful. We also note that functional status would be an important addition to surveys as it is key data for transitions, especially to nursing homes and other long-term care settings.
6	Could office-based physicians serve as adequate proxies for eligible professionals who are "meaningful EHR users" under the Medicare and Medicaid EHR Incentive Programs (e.g. physician assistants practicing in a rural health clinic or federally qualified health center led by the physician assistant)?	**AMIA Recommendation:** Information from these groups should be gathered and used to inform ONC measurement of interoperability, and we believe they are an appropriate initial proxy. We again note our preference for an approach that would place patients as the center-point of measurement, avoiding challenges related to identifying various fractionated provider groups.
7	Do national surveys provide the necessary information to determine why electronic health information may not be widely exchanged? Are there other recommended methods that ONC could use to obtain this information?	**AMIA Recommendation:** No, national surveys are not likely to provide adequate information on why electronic health information may not be widely exchanged. One key reason is that it could vary by exchange partner and so, technical issues may be relevant in one situation while workflow issues may be the primary obstacle in another. Differences among patient populations also will affect electronic exchange of health information. We again recommend ONC develop a patient-centric approach to measurement that focuses on a limited number of high-value use cases to determine if clinically relevant data was available, retroactively, and if it was not, use that as the basis to identify the barrier(s). Regardless, national surveys provide ONC with a starting point, and if they were updated as we recommend, they could provide more robust information and supplement more detailed data collection that is likely infeasible on a survey.
ONC's Available Data Sources and Potential Measures: CMS Medicare and Medicaid EHR Incentive Programs Measures		
	ONC Question	**AMIA Response**

8	Given some of the limitations described above, do these potential measures adequately address the "exchange" component of interoperability required by section 106(b)(1) of the MACRA?	**AMIA Recommendation:** Yes, these are rough approximations of national-level data that could indicate "exchange." However, we reiterate our concerns regarding the degree to which MU data is skewed, given the high numbers of providers that have not successfully met program requirements year-over-year. Further, the vast majority of providers attesting to these measures are just above the 10 percent threshold, which is a signal in itself of how difficult connections have been to make across provider boundaries. We also note that organizations define transitions of care differently, and this inconsistency in denominators could have substantial implications for the validity of the measure. The 2014 Edition does not specify what triggers the formation and sending of a Clinical Care Document (CCD), only that the vendor must demonstrate that their EHR can do so. It is not likely that the triggers for CCD creation and transmit are the same across multiple vendors, meaning that the denominators reported as "care transitions" likely include some (but not most) actual transitions and differ depending on the underlying Certified EHR Technology.
9	Do the reconciliation-related measures serve as adequate proxies to assess the subsequent use of exchanged information? What alternative, national-level measures (e.g., clinical quality measures) should ONC consider for assessing this specific aspect of interoperability?	**AMIA Recommendation:** No, this is a poor proxy for many of the same reasons cited above. The numerator and denominator for this measure are ambiguous, especially when it could include a new patient or simply a new summary of care record. We also note that EPs or EHs / CAHs qualifying for exceptions because they have fewer than 100 care transitions obscures whether or not summary of care records were provided. Lastly, medication reconciliation could occur manually, or as a combined electronic and manual process. A provider may simply read an external report and get what she needs, without "reconciling" any information electronically. The broader "clinical reconciliation" measure is probably a better metric, but it will likely suffer from the same shortcomings as the narrower

		"medication reconciliation" measure by not clearly indicating the actual use of the data.
10	Can state Medicaid agencies share health care provider-level data with CMS similar to how Medicare currently collects and reports on these data in order to report on progress toward widespread health information exchange and use? If not, what are the barriers to doing so? What are some alternatives?	n/a
11	These proposed measures evaluate interoperability by examining the exchange and subsequent use of that information across encounters or transitions of care rather than across health care providers. Would it also be valuable to develop measures to evaluate progress related to interoperability across health care providers, even if this data source may only be available for eligible professionals under the Medicare EHR Incentive Program?	**AMIA Recommendation:** We recommend ONC also develop measures to evaluate exchange both across healthcare providers and among providers and health IT applications within the same organization. We agree that one cannot determine with consistency when inter-organizational versus intra-organizational exchange has occurred, and we support development of measures on both.

ONC's Available Data Sources and Potential Measures: Identifying Other Data Sources to Measure Interoperability

	ONC Question	AMIA Response
12	Should ONC select measures from a single data source for consistency, or should ONC leverage a variety of data sources? If the	**AMIA Recommendation:** In the near-term, we recommend ONC use a combination of measures from national surveys and administrative data from federal and state programs, such as the EHR Incentive Program. However, we reiterate our concern that such an approach is not sufficient, and we call on ONC to

	latter, would a combination of measures from CMS EHR Incentive Programs and national survey data of hospitals and physicians be appropriate?	develop a longer-term strategy that focuses on a patient-centric view of interoperability.
13	What, if any, other measures should ONC consider that are based upon the data sources that have been described in this RFI?	**AMIA Recommendation:** Please refer to our response to question 5 on ways surveys should be enhanced. We understand ONC's identified approach as using national surveys (AHA and NCHS) and the following measures from the EHR Incentive program, using MACRA parlance: 1. Patient Care Record Exchange 2. Request / Accept Patient Care Record 3. Clinical Reconciliation These seem appropriate, but they represent crude measures that should be improved upon over time.
14	Are there Medicare claims based measures that have the potential to add unique information that is not available from the combination of the CMS EHR Incentive Programs data and survey data?	**AMIA Recommendation:** Yes. AMIA recommends ONC develop near-term and long-term strategies to incorporate Medicare claims data to supplement identified measures, as well as new measures identified in Appendix A. In the near-term, Medicare claims data could be overlain with EHR Incentive Program data that would allow ONC to characterize the attester in various ways, including by provider type (e.g. academic medical center or community hospital) and it could reveal patient sharing trends between attesters. This kind of analysis would help characterize the level of interoperability among providers that *should be* exchange partners (i.e. where is the greatest need for interoperability), using both claims and EHR Incentive Program data. Another use of claims data is to look for patterns that suggest absence of interoperability. For example, claims data would reveal if the same patient was ordered an MRI or CT scan within a period time or for conditions that are unlikely to need repeat testing.

15	If ONC seeks to limit the number of measures selected, which are the highest priority measures to include?	**AMIA Recommendation:** We recommend ONC focus on measures that capture interoperability across healthcare organizations. While interoperability within organizations is important, exchange across organizations is the larger policy concern.
16	What, if any, other national-level data sources should ONC consider? Do technology developers, HISPs, HIOs and other entities that enable exchange have suggestions for national-level data sources that can be leveraged to evaluate interoperability for purposes of section 106(b)(1) of the MACRA (keeping in mind the December 31, 2018 deadline) or for interoperability measurement more broadly?	**AMIA Recommendation:** We encourage ONC to conduct outreach to HISPs and HIEs directly with such questions, should they not respond to this RFI, as they should be in possession of interesting, if not representative, views of interoperability. For example, HIEs that receive ADT information may be able to calculate the percentage of encounters where HIE was accessed for data. Additionally, some vendors provide functionality to request outside records, which could be monitored. This is neither a widely implemented nor offered functionality, but could be a source of future work.
17	How should ONC define "widespread" in quantifiable terms across these measures? Would this be a simple majority, over 50%, or should the threshold be set higher across these measures to be considered "widespread"?	**AMIA Recommendation:** If ONC uses EHR Incentive Program measures discussed in the RFI and as framed by Congress in the MACRA statute, we urge ONC to define "widespread" as performance on appropriate measures equal to, or more than, 75 percent. This percentage is consistent with other signals of congressionally-defined success in the EHR Incentive Program, and is a reasonable threshold for these discussions. If an accurate assessment of nationwide interoperability is the goal, we do not agree that 50 percent or 70 percent equates to achievement of that goal. We reiterate our concern with volume-based, national measures as the long-term strategy for ONC to understand if we have achieved nationwide interoperability. Creating measures based on the proportion of providers conducting medication reconciliation, for example, is insufficient. Thus,

		creating arbitrary thresholds for such measures will likewise be insufficient.

Appendix A

Below is a proposed alternative to the strategy outlined by ONC in this RFI to measure interoperability. Our alternative approach uses a retrospective review to accomplish the following aims:

- Enable measurement that could determine whether, and to what extent, nationwide interoperability is occurring;
- Develop measures of interoperability without creating burdens on providers and healthcare organizations;
- Prioritize measures that reflect the patient's experience; and
- Focus on care / referral patterns that share high-volumes of patients.

Rather than focus on the kinds of volume-based measures identified by the RFI, we believe a better approach would seek to understand if the outcomes enabled through interoperability had occurred. Such an approach would include a retrospective review, using CMS claims data and statistical sampling to answer the basic question: were clinically relevant data available when and where needed? And if not, why not?

Our proposed strategy would work as follows:

- Target Population for the Review
    - Using current, publicly available CMS claims data, select a set of patients with clinical conditions that would be expected to benefit from well-coordinated care, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease, as well as mental and behavioral health conditions and patients with multiple conditions. These conditions could span chronic care, acute care, long-term / post-acute care and mental/behavioral healthcare use cases.
    - Another population that could be targeted, and may be easier to pursue from a measurement perspective, is provider dyads or provider networks with a high volume of shared patients. Again, currently available CMS claims data could be used to identify providers that have the highest volume of shared patients, under the assumption that it is important to understand the kinds of interoperability that exists between entities sharing, for example 10,000 patients as opposed to only a handful of patients.

- Methodology: Determine Desired Data Flows

  - For each of those identified conditions/providers, define key expected data flows that would likely improve care. The goal is to identify what data should be available to optimize the patient's care, identify how the data were made available, as well as reasons for its unavailability / absence. For example:
    - Were outside lab results available in a timely manner?
      - If so, how were they made available? (e.g. fax, Direct, via HIE, "other")
      - If not, why not? (e.g. lab refused, patient not in HIE, MPI match failure, "other")
    - Were outside images and reports available?
    - Were outside summary records (CCDs) available?
    - Were other providers' notes available?
    - How many records were requested by the Emergency Department and how were they were obtained?
  - For each of these data flows, it would be important to capture the relevant entities and vendors that were involved. For example, if outside labs were available, who was the lab, and who was the EHR vendor. Likewise if data were not available.
  - Another data point to consider would be to ask the patients for their impressions of data sharing.
    - Were they aware of times when their provider did not have data that they expected to be available?

- Methodology: Fielding
  - Select a statistically large enough sample of patients whose care covers the desired measurement domains (e.g., chronic care, acute care LTPAC care) and/or select a statistically representative number of providers with high volumes of shared patients.
  - Distribute a set of questionnaires, administered by trained auditors to get meaningful data at a modest cost.
  - Reviews could be conducted by CMS or third-party organizations, such as the Joint Commission, or be included as part of ONC-Authorized Certification Bodies in-the-field surveillance activities.

Results from this kind of review, could then be aggregated to inform policymakers and stakeholders on the current state of interoperable data sharing, and which aspects of the Interoperability Roadmap need enhancement, including standards, governance and best practices. This review could also supplement what we know about the general performance of certified health IT, the interactions between certified and non-certified health IT, and help clarify the incidence of information blocking.