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June 3, 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:

Health Level Seven (HL7) International 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.

HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related interoperability standards, including Fast Healthcare Interoperability Resources (FHIR) and Consolidated Clinical Document Architecture (C-CDA). HL7 is comprised of more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

All of us at HL7 are well aware of the congressional deadline to propose interoperability measures by July 1. Nonetheless, we strongly believe that developing detailed interoperability assessment and measures is premature. Any implementation at this time could potentially create unintended burdens for healthcare providers without the guarantee of improved patient care. HL7 recommends reassessing these efforts after the industry gains experience under the program. We believe that this will help inform the development of more effective measurements and allow the opportunity for multi-stakeholder input. However, we have also included below responses to each of the specific questions included in the RFI.

Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at **cjaffe@HL7.org** or 734-677-7777. We look forward to continuing this discussion and offer our assistance to ONC as it seeks to measure progress toward nationwide interoperability.

Sincerely,

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Charles Jaffe, MD, PhD
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| ONC Request for Information Regarding Assessing Interoperability for MACRA | | |
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| General HL7 comments:<br><br>The Congressionally mandated deadline to propose interoperability measures does not recognize the critical timeframe of clinical care process re-engineering. And, therefore the potential to take advantage of this newly available capability for interoperability and achieve improved outcomes, is significantly diminished.<br><br>Counting and reporting transactions is insufficient to accomplish MACRA's goals. Implementing the measures proposed in the RFI could create unintended burdens for healthcare providers without the guarantee of improved patient care. HL7 recommends focusing less on counting transactions and more on discerning which data transactions lead to improved patient care. These transactions should be the focus of interoperability measurements. These transactions can only be discovered after the industry gains experience under the program. This may be accomplished by surveying program participants to help identify which data exchanges led to improved patient care, followed by a self-assessment of their level of interoperability in these areas.<br><br>HL7 is concerned that the term "subsequent use" can be broadly interpreted and we recommend ONC put forth a precise definition. For example, the subsequent use for an order provider's system receiving a result would be different than a secondary data use, e.g., research. Direct patient care settings will be more concerned about immediate use, while researchers may be more concerned about longer-term uses. | | |
| | ONC Question | HL7 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?<br><br>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 | HL7 Recommendation:<br><br>No. The measurement should encompass the full team of professionals and caregivers who provide care to an individual. It may be appropriate to add or expand some measurements incrementally over time as experience is gained. Interoperability measurement should be in sync with the ONC Interoperability Roadmap to help measure progress in a unified and cross-referenced way. |

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| | 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. | |
| 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? | **HL7 Recommendation**:<br><br>HL7 believes that interoperability should not be limited to exchanges between eligible professionals, although it is possible that a separate set of measures may be defined for these individuals.<br>Information exchanged across all care team members should be included, as this will contribute to improved care delivery. |
| 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? | HL7 Recommendation:<br><br>While these aspects of interoperability may adequately address the exchange and use components of section 106(b)(1) of the MACRA, HL7 is concerned about the apparent focus on transaction volume.<br><br>Instead, we propose that the focus be on discerning which data transactions lead to improved patient care.<br><br>The provider is the most appropriate source to identify which data is useful, regardless of whether they fully incorporate the data received (see our other concerns with counting, e.g., medication reconciliation).<br><br>See HL7 General Comments for more information. |
| 4 | 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? | HL7 Recommendation:<br><br>Per HL7's comments above, no. The measurement should encompass the full range of health IT, not just certified EHR technology. |
| ONC's Available Data Sources and Potential Measures: Measures Based upon National Survey Data | | |
| | ONC Question | HL7 Response |
| 5 | Do the survey-based measures described in this section, which focus on measurement from a health care provider perspective | HL7 Recommendation:<br><br>HL7 believes that reconciliation addresses the initial aspects of use, but not overall value (i.e., measuring reconciliation |


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| | (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? | does not necessarily measure value of the interoperability). C-CDA reconciliations may not necessarily improve outcomes or value.<br><br>HL7 recommends focusing on the "proportion of healthcare providers who use the information that they electronically receive from outside providers and sources for clinical decision-making." These participants should be surveyed to determine which data exchanges are not useful to further advance interoperability. |
| 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)? | HL7 Recommendation:<br><br>HL7 believes eligible clinicians, as defined by MIPS, and their related support staff can serve as adequate proxies. HL7 believes that advanced practice nurses and physicians assistants with defined patient responsibilities should definitely be considered as "meaningful EHR users."<br><br>Excluding certain clinicians, responsible supporting staff, patients and medical technicians would negatively impact the measurement of interoperability. |
| 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? | HL7 Recommendation:<br><br>HL7 is not sufficiently familiar with these surveys and thus has no comment. |
| ONC's Available Data Sources and Potential Measures: CMS Medicare and Medicaid EHR Incentive Programs Measures | | |
| | ONC Question | HL7 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? | HL7 Recommendation:<br><br>While the first bullet on page 15 measures movements of data, without value measurement these are not sufficient to measure end-to-end interoperability. Specifically, our concerns with these measures are as follows:<br><br>"Proportion of transitions of care or referrals where a summary of care record was created using certified EHR technology and exchanged or transmitted electronically"<br><br>HL7 believes that this measurement will have limitations similar to those of Meaningful Use<br><br>"Proportion of transitions or referrals and patient encounters |


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| | | in which the health care provider is the recipient of a transition or referral or has never before encountered the patient, and where the health care provider (e.g., eligible professional, eligible hospital, or CAH) receives, requests or queries for an electronic summary of care document to incorporate into the patient's record"<br><br>HL7 believes this measurement is too complex. "Proportion of transitions of care where medication reconciliation is performed"<br><br>Because there is no precise definition of transitions of care, this can easily lead to variations in interpretation, leading to inaccurate measures. |
| 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? | HL7 Recommendation:<br><br>Per our feedback in the general comments, without a precise definition of subsequent use it will be difficult to measure. HL7 suggests evaluating what data is being exchanged across active HIEs that might serve as the appropriate measures. HL7 also suggests surveying providers to determine which transactions lead to improved patient care. |
| 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? | HL7 Recommendation:<br><br>It is unclear how easily state Medicaid data can be used to measure progress toward interoperability. Data is variable across states in terms of scope (financial claim data), definition, and content.<br><br>It is unclear whether state Medicaid agencies have insight into clinical data exchange and whether there is any consistency in reporting.<br><br>Regarding alternatives, see suggestions above. |
| 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 | HL7 Recommendation:<br><br>Yes, though this will be difficult to measure, HL7 believes it would be valuable to seek measures to evaluate interoperability across providers.<br><br>Ideally, encounter or transition of care data within a healthcare provider organization (larger practices, hospitals, etc.) is exchanged or used by a common or shared system(s) based on standards that should already enable cross system data sharing. Therefore, focusing on cross healthcare provider data exchange will help address the larger interoperability questions. |


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| | if this data source may only be available for eligible professionals under the Medicare EHR Incentive Program? | |
| ONC's Available Data Sources and Potential Measures: Identifying Other Data Sources to Measure Interoperability | | |
| | ONC Question | HL7 Response |
| 12 | Should ONC select measures from a single data source for consistency, or should ONC leverage a variety of data sources? If the latter, would a combination of measures from CMS EHR Incentive Programs and national survey data of hospitals and physicians be appropriate? | HL7 Recommendation:<br><br>While a single source is preferable for consistency, to our knowledge no such source exists. HL7 recommends ONC identify or develop a single data source in the long-term. In the shorter term, using a well-controlled core set of common statistics obtained from surveying HIEs and ACOs should be a reasonable solution. |
| 13 | What, if any, other measures should ONC consider that are based upon the data sources that have been described in this RFI? | HL7 Recommendation:<br><br>See response to question 12. |
| 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? | HL7 Recommendation:<br><br>Medicare claims data might be used to determine whether high levels of interoperability correlate with cost reduction. |
| 15 | If ONC seeks to limit the number of measures selected, which are the highest priority measures to include? | HL7 Recommendation:<br><br>The high priority measures should be those which correlate to improved patient care. But it will likely take more experience to identify these. |
| 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 | HL7 Recommendation:<br><br>HL7 recommends that ONC engage directly with HISPs, HIOs and other entities for their input. |


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| | December 31, 2018 deadline) or for interoperability measurement more broadly? | |
| 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"? | HL7 Recommendation:<br><br>HL7 recommends a threshold of 80% to be considered widespread. The value of the information is equally important.<br><br>As stated previously, HL7 recommends that ONC should focus less on transaction volume and more on discerning which data transactions lead to improved patient care.<br><br>Widespread interoperability should ultimately be measured by improved patient care and lowered cost. |

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