



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; Medicare Access and CHIP Reauthorization Act of 2015; Request for Information Regarding Assessing Interoperability for MACRA

AGENCY: Office of the National Coordinator for Health IT (ONC), HHS.

ACTION: Request for information.

SUMMARY: In section 106(b)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. No. 114–10, enacted April 16, 2015), Congress declares it a national objective to achieve widespread exchange of health information through interoperable certified electronic health record (EHR) technology nationwide by December 31, 2018. Section 106(b)(1)(C) of the MACRA provides that by July 1, 2016, and in consultation with stakeholders, the Secretary of Health and Human Services (HHS) shall establish metrics to be used to determine if and to the extent this objective has been met.

ONC intends to consider metrics that address the specific populations and aspects of interoperable health information described in section 106(b)(1)(B) of the MACRA. ONC is issuing this RFI to solicit input on the following three topics: (1) measurement population and key components of interoperability that should be measured; (2) current data sources and potential metrics that address section 106(b)(1) of the MACRA; and (3) other data sources and metrics ONC should consider with respect to section 106(b)(1) of the MACRA or interoperability measurement more broadly.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on June 3, 2016.

ADDRESSES: In commenting, refer to file code ONC xxxx. Because of staff and resource limitations, ONC cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word.

2. By regular mail. Please allow sufficient time for mailed comments to be received before the close of the comment period. You may mail written comments to the following address: Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention, *RFI Regarding Assessing Interoperability for MACRA*, 330 C Street, SW, Room 7025A, Washington, DC 20201. Please submit one original and two copies.

3. By express or overnight mail. You may send written comments to the following address: Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention, *RFI Regarding Assessing Interoperability for MACRA*, 330 C Street, SW, Room 7025A, Washington, DC 20201. Please submit one original and two copies.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following address: Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention, *RFI Regarding Assessing Interoperability for MACRA*, 330 C Street, SW, Room 7025A, Washington, DC 20201.

If you intend to deliver your comments to this address, contact 202-205-8417 in advance to schedule your arrival with one of our staff members. Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Enhancing the Public Comment Experience: We will make a copy of this document available in Microsoft Word format in order to make it easier for commenters to access and copy portions of the RFI for use in their individual comments. Additionally, a separate document will be made available for the public to use to provide comments. This document is meant to provide the public with a simple and organized way to submit comments and respond to specific questions posed in the RFI. While use of this document is entirely voluntary, we encourage commenters to consider using the document in lieu of unstructured comments or to use it as an addendum to narrative cover pages. We believe that use of the document may facilitate our review and understanding of the comments received. The Microsoft Word version of this RFI and the document that can be used for providing comments can be found on ONC's website (<http://www.healthit.gov>).

FOR FURTHER INFORMATION CONTACT:

Talisha Searcy, Office of Policy, Evaluation & Analysis, ONC, 202-205-8417,
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Vaishali Patel, Office of Policy, Evaluation & Analysis, ONC, 202-603-1239,
vaishali.patel@hhs.gov

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: A person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered to be proprietary. We will post all comments received before the close of the comment period at <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of a document at Office of the National Coordinator for Health Information Technology, 330 C Street, SW, Room 7025A, Washington, DC 20201.

Contact Talisha Searcy, listed above, to arrange for inspection.

I. Background

Overview of MACRA Section 106(b)(1)

In section 106(b)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. No. 114–10, enacted April 16, 2015), Congress declares it a national objective to achieve widespread exchange of health information through interoperable certified electronic health record (EHR) technology nationwide by December 31, 2018. Section 106(b)(1)(C) of the MACRA provides that by July 1, 2016, and in consultation with stakeholders, the Secretary of Health and Human Services (HHS) shall establish metrics to be used to determine if and to the extent this objective has been met. Section 106(b)(1)(D) of the MACRA provides that if the Secretary determines that this objective has not been achieved by December 31, 2018, then by December 31, 2019 the Secretary shall submit a report to Congress that identifies barriers to this objective and recommends actions that the Federal Government can take to achieve it.

The Secretary of HHS will delegate authority to carry out the provisions of section 106(b)(1) of the MACRA to the Office of the National Coordinator for Health Information Technology (ONC). ONC is committed to advancing interoperability of health information and has developed a roadmap with stakeholder input, entitled *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap* (Interoperability Roadmap), which lays out the milestones, calls to action and commitments that public and private stakeholders should

focus on achieving.^{1,2} The Interoperability Roadmap also specifies that ONC will report on the nation's progress towards interoperability.

ONC is issuing this RFI to solicit input on the following three topics, which are described in the comments section (Section II) of the RFI:

- (1) Measurement population and key components of interoperability that should be measured;
- (2) Current data sources and potential metrics that address section 106(b)(1) of the MACRA; and
- (3) Other data sources and metrics ONC should consider with respect to section 106(b)(1) of the MACRA or interoperability measurement more broadly.

II. Solicitation of Comments

Scope of Measurement: Defining Interoperability and Population

In order to establish metrics that will assess whether, and the extent to which, widespread exchange of health information through interoperable certified EHR technology nationwide has occurred, ONC needs to first define the scope of measurement.

Section 106(b)(1)(B) of the MACRA describes key components of interoperability that should be measured and the population that should be the focus of measurement. Section 106(b)(1)(B)(ii) of the MACRA defines interoperability as the ability of two or more health information systems

¹ *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Version 1.0.*
<https://www.healthit.gov/policy-researchers-implementers/interoperability>

² *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap – Version 1.0,*
BuzzBlog.

<http://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/interoperability-electronic-health-and-medical-records/connecting-health-care-nation-shared-nationwide-interoperability-roadmap-version-10/>

or components to: (1) exchange clinical and other information and (2) use the information that has been exchanged using common standards to provide access to longitudinal information for health care providers in order to facilitate coordinated care and improve patient outcomes. We believe appropriate metrics should address both of these aspects of interoperability. Section 106(b)(1)(B)(i) of the MACRA defines “widespread interoperability” as interoperability between certified EHR technology systems employed by meaningful EHR users under the Medicare and Medicaid EHR Incentive Programs and other clinicians and health care providers on a nationwide basis.

ONC intends to consider metrics that address the specific populations and aspects of interoperable health information as described above and in section 106(b)(1)(B) of the MACRA. Thus, ONC plans to assess interoperability among “meaningful EHR users” and clinicians and health care providers with whom they exchange clinical and other information—their exchange partners. Note that the exchange partners do not have to be “meaningful EHR users” themselves. Additionally, ONC plans to measure interoperability by identifying measures that relate to both exchange of health information as well as use of information that has been exchanged using common standards. More specifically, ONC seeks to measure the interoperable exchange and use of information by examining the following: electronically sending; receiving; finding (e.g., request or querying); integrating (e.g., incorporating) information received into a patient’s medical record; and the subsequent use of information received electronically from outside sources.

ONC expects that the scope of the metrics established pursuant to section 106(b)(1)(C) of the MACRA will support overarching interoperability measurement. However, ONC recognizes the need to measure interoperability across populations and settings beyond those specified by section 106(b)(1)(B) of the MACRA. The last chapter of the Interoperability Roadmap details ONC's plans for measuring interoperability across a variety of populations and settings, including proposed measures and accompanying timeframes.³

In summary, under section 106(b)(1)(B)(i) of the MACRA, ONC believes the scope of the measurement should be limited to “meaningful EHR users” and their exchange partners. ONC believes this should include eligible professionals, eligible hospitals, and critical access hospitals (CAHs) that attest to meaningful use of certified EHR technology under CMS' Medicare and Medicaid EHR Incentive Programs. ONC would measure interoperability for section 106(b)(1)(B) of the MACRA by assessing the extent to which “meaningful EHR users” are electronically sending, receiving, finding, integrating information that has been received within an EHR, and subsequently using information they receive electronically from outside sources. Thus, this RFI focuses on obtaining input on measures that address these aspects of interoperability for the specified populations. Although this RFI seeks to obtain input on proposed measures that address section 106(b)(1)(B) of the MACRA, ONC also plans to measure interoperability across a variety of settings and populations, as well as barriers to interoperability in order to evaluate progress for the Interoperability Roadmap.

³ *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Version 1.0.*
<https://www.healthit.gov/policy-researchers-implementers/interoperability>

ONC is requesting input regarding the provisions of section 106(b)(1) of the MACRA. Below are a specific set of questions related to those provisions.

Questions: We would appreciate comments you may have in response to some or all of the questions below. We also welcome any additional comments related to Section 106(b)(1) of the MACRA that you may want us to consider.

- 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.
- 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? Section 1848(q) of the Social Security Act, as added by section 101(c) of the MACRA, requires the establishment of a Merit-Based Incentive Payment System for MIPS eligible professionals (MIPS eligible professionals).
- 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?

- 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?

ONC's Available Data Sources and Potential Measures

ONC is considering using a combination of the data sources to evaluate interoperability from two different perspectives: (1) by provider, based upon the proportion of “meaningful EHR users” exchanging information with other clinicians and health care providers and subsequently using electronic health information that has been exchanged; and (2) by transactions (e.g., volume of exchange activity), based upon the proportion of care transitions and encounters where information is electronically exchanged and used. ONC’s currently available data sources that will enable evaluation from these two perspectives include: (1) national survey data from key stakeholder organizations and federal entities; and (2) CMS’s Medicare and Medicaid EHR Incentive Programs data. We describe these data sources further below.

ONC recognizes that its currently available data sources might not be sufficient to fully measure and determine whether the goal of widespread exchange of health information through interoperable certified EHR technology has been achieved. ONC’s currently available data sources are largely limited to eligible professionals, eligible hospitals, and CAHs as defined under the current Medicare and Medicaid EHR Incentive Programs. Therefore, ONC is requesting input on these measures and data sources, and is requesting feedback on additional national data sources which may be available for this purpose.

Measures Based upon National Survey Data

ONC is considering using nationally representative surveys of hospitals and office-based physicians to evaluate progress related to the interoperable exchange of health information from the health care provider perspective. ONC collaborates with the American Hospital Association (AHA) to conduct the AHA Health IT Supplement Survey and with the National Center for Health Statistics (NCHS) to conduct the National Electronic Health Record Survey of office-based physicians. Both surveys have relatively high response rates and convey health care providers' perspectives on exchange and interoperability (e.g., proportion of health care providers exchanging and subsequently using health information that has been exchanged). The survey measures electronic exchange with "outside" providers not part of their organization. The measures of electronic exchange specifically exclude e-fax, scanned documents or other forms of unstructured data. In addition, multiple years of survey data will be available for both populations, which will support examining trends. However, these self-reported data are subject to potential biases, do not reflect all types of health care providers, and do not report on transaction-based measures of exchange activity.

Using these national survey data, ONC is considering the following measures below for both hospitals and office-based physicians.

- Proportion of health care providers who are electronically sending, receiving, finding, and easily integrating key health information, such as summary of care records. This can

be a composite measure (engaging in all four aspects of interoperable exchange) or separate, individual measures.

- Proportion of health care providers who use the information that they electronically receive from outside providers and sources for clinical decision-making.
- Proportion of health care providers who electronically perform reconciliation of clinical information (e.g. medications).

Based upon data collected in 2014, approximately one-fifth of non-federal acute care hospitals electronically sent, received, found (queried) and were able to easily integrate summary of care records into their EHRs.⁴ Similar data for office-based physicians will be available in 2016. Starting in 2015 for hospitals and 2016 for office-based physicians, the surveys will also collect information on the subsequent usage of information that is received from outside sources. These data will be available in 2016 and 2017 for hospitals and office-based physicians, respectively. Given that the response rate of survey items that assess the use of information from outside sources is unknown, an alternative measure to assess downstream use of information that is exchanged relates to reconciliation of clinical information. The reconciliation measure has been available since 2014 for office-based physicians. For hospitals, the survey has assessed capability to electronically conduct reconciliations since 2014; the survey has not assessed whether hospitals have used that functionality. If this measure were to be selected, this new measure would have to be added to the 2016 hospital survey, which would be available in 2017.

⁴ Charles D, Swain M Patel V. (August 2015) *Interoperability among U.S. Non-federal Acute Care Hospitals*. *ONC Data Brief, No. 25* ONC: Washington DC.
https://www.healthit.gov/sites/default/files/briefs/onc_databrief25_interoperabilityv16final_081115.pdf

ONC could also use data from national surveys to evaluate whether hospitals and office-based physicians are unable to widely share and use health information, and to identify what barriers to interoperable exchange exist. This would provide contextual information regarding whether interoperability is progressing as expected. For example, in 2014, hospitals reported a number of barriers they faced in exchanging and using interoperable health information.⁵

Questions

- 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?
- 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)?
- 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?

CMS Medicare and Medicaid EHR Incentive Programs Measures

CMS Medicare and Medicaid EHR Incentive Program data could potentially be a useful data source as it consists of the population and measures aspects of interoperability as described in section 106(b)(1)(B) of the MACRA. However, there are limitations associated with these data

⁵ *ibid*

for addressing both the exchange and use components of section 106(b)(1) of the MACRA. One primary limitation is that differences exist in how CMS currently receives performance data from each of the Medicare and Medicaid EHR Incentive Programs. Currently, Medicare collects and reports on performance data for each individual eligible professional, eligible hospital, and CAH. However, performance data is not available for each individual Medicaid eligible professional, eligible hospital, or CAH as the Medicaid EHR Incentive Program is operated by the states. Thus, ONC would not be able to evaluate interoperability across individual health care providers or transactions for the Medicaid EHR Incentive Program, unless it obtained these data from each state individually.

Additionally, not all aspects of health information exchange can be measured using the CMS EHR Incentive Programs data. The purpose of this meaningful use objective is to ensure a summary of care record is *sent* to the receiving provider when a patient is transitioning to a new provider. However these data do not assess whether a summary of care record was electronically *received* by the receiving provider.

Based upon CMS EHR Incentive Programs data, ONC is considering the following measures listed below.⁶ These measures could be used to evaluate the exchange and use aspects of interoperability as described in section 106(b)(1)(B) of the MACRA.

⁶ Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017. <https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicare-programs-electronic-health-record-incentive-program-stage-3-and-modifications>

- Proportion of transitions of care or referrals where a summary of care record was created using certified EHR technology and exchanged or transmitted electronically.
- For 2017 and subsequent years, the proportion of transitions or referrals and patient encounters 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.
- Proportion of transitions of care where medication reconciliation is performed.
- For 2017 and subsequent years, the proportion of transitions or referrals received and patient encounters in which the health care provider is the recipient of a transition or referral or has never before encountered the patient, and the health care provider performs clinical information reconciliation for medications, medication allergies, and problem lists.

Reconciliation may include both automated and manual processes to allow the receiving provider to work with both electronic data and with the patient to reconcile their health information. The assumption underlying including this measure is that although some portion of the medication reconciliation processes may be occurring manually, it should be facilitated by the electronic exchange of clinical data, and therefore may serve as an adequate proxy for assessing use of information that is exchanged.⁷

⁷ *Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017.* <https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicare-programs-electronic-health-record-incentive-program-stage-3-and-modifications>. See page 62810.

Questions

- 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?
- 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?
- 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?
- 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?

Identifying Other Data Sources to Measure Interoperability

ONC acknowledges that other data sources might exist that could aid in the measurement of interoperability. For example, other potential data sources are Medicare Fee-For-Service (FFS) claims data as well as performance data from other programs. Section 1848(q)(2)(B) of the

Social Security Act, as added by section 101(c) of the MACRA, describes the measures and activities for each of the four performance categories under the Merit-Based Incentive Payment System (MIPS), which includes meaningful use of certified EHR technology. These measures may also serve as a potential data source for assessing progress related to interoperability for MIPS eligible professionals. As the MIPS Program is implemented, ONC will be assessing whether any measures could be used for this purpose. Additionally, some of the information used to evaluate the performance of eligible professionals who participate in the alternative payment models (APMs) may also help inform progress related to interoperability.

Additionally, ONC is considering use of electronically-generated data from certified EHR technology or other systems, such as log-audit data, or leveraging surveys of entities that enable exchange to evaluate progress related to widespread electronic information exchange and use. ONC recognizes this will require collaboration and coordination with federal entities and stakeholders across the ecosystem including entities that enable exchange and interoperable health information use, such as technology developers, Health Information Organizations (HIOs) and Health Information Service Providers (HISPs).

Overarching Questions

- 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?

- What, if any, other measures should ONC consider that are based upon the data sources that have been described in this RFI?
- 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?
- If ONC seeks to limit the number of measures selected, which are the highest priority measures to include?
- 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?
- 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”?

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

IV. Response to Comments

ONC typically receives a large public response to its published Federal Register documents.

ONC will consider all comments received by the date and time specified in the "DATES" section of this document, but will not be able to acknowledge or respond individually to public comments.

Dated: April 1, 2016.

Karen DeSalvo, MD, MPH, MSc

National Coordinator

Office of the National Coordinator for Health Information Technology

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