June 3, 2016

Acting Assistant Secretary
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

Subject: 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

Dear Acting Assistant Secretary DeSalvo:

The American Association of Orthopaedic Surgeons (AAOS) and orthopaedic specialty societies, representing over 18,000 board-certified orthopaedic surgeons, appreciate the opportunity to provide comments on the Request for Information Regarding Assessing Interoperability for MACRA by the Office of the National Coordinator (ONC) for Health Information Technology, and published in the Federal Register on April 8, 2016. The AAOS has been committed to working with ONC in the adoption of electronic health records.

As surgical specialists, we have unique Health Information Technology (HIT) needs and respectfully offer some suggestions to improve interoperability to better reflect the needs of our surgical specialists and their patients and accelerate HIT adoption in the future by orthopaedic surgeons. The AAOS thanks ONC in advance for its solicitation and consideration of the following comments and concerns. We have structured our comments in the order that ONC is soliciting public feedback in the RFI document referenced above.

Scope of Measurement: Defining Interoperability and Population

The focus of measurement should not be limited to “meaningful Electronic Health Records (EHR) users,” as defined (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. The populations and measures should be consistent with how ONC plans to measure interoperability for assessing progress related to the Interoperability Roadmap. For example, consumers, behavioral health, and long-term care providers should be 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. Eligible professionals under the Merit-Based Incentive Payment System (MIPS) and eligible professionals who participate in the alternative payment models (APMs) need certified technology that can process performance measures and exchange normalized data to meet Section 1848(q) of the Social Security Act, as added by section 101(c) of the MACRA, which requires the establishment of a Merit-Based Incentive Payment System for MIPS eligible professionals (MIPS eligible professionals).

The AAOS is concerned that measuring various aspects of interoperability (electronically sending, receiving, finding and integrating data from outside sources, and subsequent use of information electronically received from outside sources) may not adequately address both the exchange and use components of section 106(b)(1) of the MACRA. True exchange of information must be secure, useful, and valuable to the patient and the provider. The reality of the environment is that much of medical documentation outside of laboratory data is unstructured but is important and useful for the care of patients. Much of current medical communication and documentation is not structured. Unstructured data such as narrative and certain types of reports are still important and vital for good patient care and communication. Furthermore, imaging files, for example, comprise essential data for care delivery in certain specialties such as orthopaedics. Although there are established DICOM imaging standards in common use, proprietary extensions and customization, along with data transmission and storage barriers, have perpetuated a high level of friction in the system. This results in the frequent and inefficient duplication of diagnostic imaging studies, and the continued use of physical medium (data discs) that must be manually handled and transported outside the EHR.

Quantitative measures of data exchange should not overshadow the clinical role of high value qualitative data of another type, for example, free-text. Medically informed free-text (e.g. case summaries, operative report descriptions, and decision explanations, etc.) should be preserved and shared in conjunction with more structured data to enhance individualized and holistic patient care amidst the profusion of generic data. Therefore, Application Programming Interfaces (APIs) need to be available not only for structured data but also for various types of unstructured reports that are still vital to good patient care. Exchange and use components should not be limited only to structured data. As the current state of EHR becomes more mature, it will be easier to exchange only structured data. As of now, the installed technology is not ready for prime time and open APIs for the bidirectional free flow of data needs to be encouraged to meet this goal. Metrics on API usage and metrics for exchange of information need to be developed to help define, quantify, and improve interoperability.

It is important to consider measurement of exchange and use of outside certified EHR technology. Certified EHR technology is often based on 50 year old technology. For example, MUMPS database turns 50 this year, which was developed just two years after the fax machine. Current certification standards assume that the current electronic communication and documentation is at a mature state. Thus, there is the potential for entrenched stakeholders
to dismiss innovation and new ideas that could greatly improve patient care and provider communication. Secure bidirectional APIs for the free flow of information is important to break down the walls that lock the data in the various silos. This can be used for improved patient care, performance enhancement and measure, risk assessment, and outcomes.

**ONC’s Available Data Sources and Potential Measures**

EHRs represent only a small subset of patient data in the scattered silos of “meaningful EHR users.” Within the various systems, there exists unstructured clinical documentation, claims data, imaging data, current and past problem lists and many more. There is also data within surgery centers, imaging centers, physicians’ offices, and nursing homes, skilled nursing facilities, and home health agencies that often do not participate as a “meaningful user” under the current Meaningful Use (MU) system.

Since few EHR systems, both ambulatory and enterprise systems, share the same data dictionary, it is almost impossible for the systems to be interoperable locally, as well as nationally. This is true within the same software vendor if the local build is different than the system just on the other side of town or across the state. Unfortunately, clinical documentation for communication and coding for reimbursement are the main drivers of today’s electronic medical record. Metrics for one purpose (i.e. measurement of progress toward a legislative mandate) should not be confused with those for another (i.e. reimbursement bonuses/penalties for providers). There may be separate systems for electronic medical records, coding, revenue cycle systems, data normalization, population health, analytics, and data warehouses.

As far as data collection and options for transfer of both structured and unstructured information, there are many ways to electronically transfer that information. Collected data can be set up as character strings and available for export to any external system with either Open Platforms or an API. Depending on the requirement of the external system (EHR), the collected data can be exported to the external system or to a specific file format (such as XML/HL7/FHIR) that can then be imported directly into the external system. For APIs to be useful, one can take the HL7 system, and add the ability to create other arbitrary fields, tables, and columns so one can handle the differences between systems. HL7 does have a data dictionary. This would also have messages that could be sent back and forth that could implement an API.

AAOS suggests that ONC consider new innovation pathways that can be studied by providers. An innovation pathway could introduce needed change in the current log jam of information focusing on communication between patients, providers, and various health systems. Focusing on the past will limit the advancement of EHR technology and potentially not advance patient care, data, and efficiencies. Providers should be rewarded for use of technology that may
advance patient care that are outside the current certification schema. Certified patient care should not be put in a box that has not changed or improved in decades. Certification should also not lead to mediocrity and the status quo. ONC should consider measurement of exchange and use of processes outside of certified EHR technology if innovation is to be encouraged.

**Measures Based upon National Survey Data**

With regard to the scope and population of interoperability measurement, broader trends in health care delivery would tend to argue in favor of broader measurements. In keeping with the shift from volume to value based reimbursements, the imperative of coordinated care, the movement from process to outcome measures, and the focus on patient centered medicine with shared decision making, interoperability must serve the needs of the wider health care community. And the metrics should encompass this, particularly the inclusion of the patient or “consumer,” in order for interoperable health IT to be self-sustaining.

Survey-based measures that focus on measurement from a health care provider perspective should adequately address the two components of interoperability (exchange and use) as described in section 106(b)(1) of the MACRA. Otherwise, the transaction-based approach could end up without real world interoperability that benefits both providers and patients. The focus needs to move away from measuring clicking radio buttons or check boxes clicks or even claims data. Survey based measures should identify deficiencies and areas of improvements far more than a transaction based approach that sometimes leads to a “garbage in – garbage out” scenario. This information could then be used to achieve significant interoperability. Office-based physicians should be able to serve as adequate proxies for eligible professionals who are “meaningful EHR users” under the Medicare and Medicaid EHR Incentive Programs.

National surveys should be able to provide the necessary information to determine why electronic health information may not be widely exchanged. This would be important for the end users and potentially the patients to provide important input as to the realities of the current state of use. Interoperability measurement using just gross numbers such as the proportion of health care providers exchanging information or the total volume of transactions can potentially obscure underlying deficiencies; the raw data should be appropriately parsed and analyzed. Large integrated medical groups and connected health care systems may generate high numbers suggesting successful interoperability, but these large numbers often belie the reality for providers outside these systems, such as independent physicians in small group practice, particularly those in rural and underserved areas. The care delivery process is only as efficient as its most inefficient part. Because of this, national surveys from both end user providers and patients is needed to determine why electronic health information may not be widely exchanged. The end user experience is not just the physician; the real end user of this
technology is the patient and they should be surveyed, as well. Information on patient usability of their information is a real unknown at this point and a survey would provide important feedback to the vendors and providers.

**CMS Medicare and Medicaid EHR Incentive Programs Measures**

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 underlying assumption included in 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.

Electronic medical reconciliation for transition of care is one of the most important advances in the use of EHRs. The deficit in many locations is that home health agencies, skilled nursing facilities, hospice, long term care facilities, and others may or may not have electronic medical records. Often if they do, the systems do not talk to each other due to the local system build. The systems are locally configured and not turnkey systems on the market.

A good example would be communicating transitions of care such as a hip fracture. First, the term hip fracture means many things both in claims data where elective hip replacement and hip fracture care fall under the same DRG. Secondly, the term hip fracture in clinical terms means different clinical pathways depending on the type of hip fracture. The clinical term hip fracture means different things to the various providers that interact with the patient, from the primary care physician, the physical therapist, nursing staff, etc. Currently the only common language is ICD-10CM that does possess a granularity that was not available in ICD-9 (See Appendix I for examples on femur and hip fracture).

In addition to reconciliation-related measures, EHRs should be measured to assess interoperability of data for use in performance measures. This should include the ability to pull in any needed claims data, as well as clinical data for any calculations involving any involved numerators and denominators, both for the individual practitioner, as well as a health system. These performance measures should also be exportable through an API embedded in the EHR to a data warehouse or registry both for protected health information as well as deidentified data for aggregation. To summarize, EHRs should be measured in terms of the availability of a dashboard for collection of performance measures, summary aggregation of this data per provider, and then be measured on the ability to export data to a clinical registry, data warehouse, or other database. State Medicaid agencies could share health care provider-level data with CMS much like Medicare currently collects and reports on this data. The issue is
interoperability and the data dictionary of each health information system that is used. Also, there is the ongoing problem of claims data not matching clinical data.

A simple example of non-interoperability is the collection by Centers for Disease Control and Prevention (CDC) of infectious disease surveillance information. State systems have interoperability problems from the county health departments, and state health departments do not necessarily communicate directly to CDC due to disparate systems that do not communicate. The problem again is data normalization at the point of care. Unfortunately, Systematized Nomenclature of Medicine (SNOMED) and ICD-10 are the only languages that are common to EHRs and both have issues of normalizing data. The problem is the collection and codification of the primary data entered at the point of care and the different electronic silos, make it extremely difficult. In Information Technology, a disparate system or a disparate data system is a computer data processing system that was designed to operate as a fundamentally distinct data processing system without exchanging data or interacting with other computer data processing systems. Legacy systems are examples of disparate data systems as are heterogeneous database data systems. A disparate system is often characterized as an information silo because of the data system's isolation from or incompatibility with any other data systems. This problem found in the national disease surveillance system, as well as the current state of Meaningful Use EHRs can be solved through well-developed APIs.

By ensuring that health IT is more open and plug-and-play, the aim is to put the control in the hands of physicians. Patients as well as providers need a powerful program that is much easier to use, lower-burden and that promotes connectivity and innovative technology. Well-constructed APIs will open this plug and play type of applicability to new outside innovative technology, as well as provide transfer of data to regional and national disease registries. These APIs and their system architecture will need to be transparent and this is where measurement of interoperability should occur.

An API has to be based on a common data dictionary in order to be useful. One where entities such as patients, encounters, orders, tests, procedures are common between systems. This common data dictionary does not currently exist. It can be built by using HL7, but that leaves a problem for newer technologies and innovations that need a path to incorporate documents, and data that are not yet fully established. If a standard HL7 is used to define a standard data dictionary, legacy systems will have a lot of work to translate that dictionary to their established dictionaries and enjoy the convenience of a fully integrated HL7 data dictionary. HL7 events, segments, fields, data types and table values need to support new data sets as well as using HL7 messaging. With this, even structured data outside of the MU ecosystem could be included. Limiting data sources to eligible professionals under the Medicare EHR Incentive Program does not help in the continuum of care. There are too many points in the patient’s care continuum that are touched by facilities and providers that are not in or eligible for the incentive program.
Identifying Other Data Sources to Measure Interoperability

Until there is improvement in electronic health records, it is worth considering a single data source for consistency. The only single data source that is found in both eligible and non-eligible providers is ICD-10 CM, ICD-10 PCS, and CPT coding and it is the most granular. Since these are required for billing, this claims data set is ubiquitous among all providers in all settings. In addition, if the Z-code section had more wide use among providers, the risk assessment on claims data could be more complete. Most physicians are not familiar with SNOMED even though it is embedded in their EHRs. When ICD-11 reconciles ICD-10 CM and SNOMED, this would be especially useful for exchange of information since the code sets are the only data key found in all practices and providers of patient care. It would be prudent to return to the original use of ICD coding as disease tracking and communication.

AAOS suggests that the ONC consider procedure codes, diagnostic codes, structured data, unstructured data, and survey data as sources of information with certain structured data sets, code sets, and survey data as the primary data sources. The Z00-Z99 chapter are Medicare claims based measures that have the potential to add unique information. Factors influencing health status and contact with health services of ICD-10 CM as previously discussed by the AAOS would be useful information not found in EHR and survey data. There would need to be an education process to providers since currently most know little of the ICD-10 CM chapter. Wide spread use of these Z codes through the use of incentives will help better define the patient and exchange useful structured data that is codified.

Given the diversity of providers that interact with the patient during a care pathway, end-user survey data seems best given the current technology to move forward interoperability and reporting to Congress on progress on this needed process. This should not be at the institution level since a recent Black Book study demonstrated that there is a wide disparity between the C-suite evaluation of EHR success vs. nursing, physicians, and HIT professionals.

ONC is correct in recognizing that the currently available data sources may 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 needs to define what “outside sources” and “data sources” would be. This request for information does not mention Clinical Data Registries (CDRs) or Qualified Clinical Data Registries (QCDRs) and registries are a big part of data collection and allows for benchmarking, linking measurement to performance improvement and leading to the betterment of overall quality of care. Focus should not be limited to use of certified EHR technology but should also include CDRs and QCDRs. MIPS eligible clinicians are being encouraged to use certified EHR technology along with CDRs and QCDRs.
and therefore ONC should consider measurement of exchange and use outside of certified EHR technology.

AAOS suggests that ONC define widespread to incorporate the patient, the payors, and the providers. The providers and facilities can be spread out across the care episode with many not participating in the current Meaningful Use program. This includes facilities such as ambulatory surgery centers, imaging centers, outpatient physical therapy, home health, skilled nursing facilities, long term care facilities, mental health centers, group practices, hospitals (sometimes more than one), and skilled nursing facilities among others including community organizations such as the Council on Aging. Even among providers that are participating in Meaningful Use, there is poor communication among the facilities since they do not speak a common language or share a data dictionary.

The recommendation to define widespread would be to set it initially at no more than 50% since many of the providers do not provide structured data and those that have structured data sometimes are limited to the walls of their institution. Even a C-CDA messaging while having the advantages of a recognized technology, strong industry standard widely in use, and flexible envelope for extensibility, basis for many exchange solutions, and enforced metadata & context coupling has severe disadvantages that include payload intensity, lots of extraneous parts not handled well, and unforgiving compliance requirements.

Thank you for considering our comments on these important matters. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,

American Academy of Orthopaedic Surgeons (AAOS)
American Association of Hip and Knee Surgeons
American Orthopaedic Foot and Ankle Society
American Orthopaedic Society for Sports Medicine
American Shoulder and Elbow Surgeons
Arthroscopy Association of North America
Cervical Spine Research Society
J. Robert Gladdens Orthopaedic Society
Musculoskeletal Infection Society
Musculoskeletal Tumor Society
Pediatric Orthopaedic Society of North America
Scoliosis Research Society
Society of Military Orthopaedic Surgeons