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October 17, 2018

Don Rucker, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: EHR Reporting Program Request for Information
330 C Street NW
Washington, DC 20201

Submitted online at https://www.regulations.gov/

SUBJECT: HHS-ONC-2018-022 – Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program

Dear Dr. Rucker:

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), representing more than 4,000 neurosurgeons in the United States, we appreciate the opportunity to comment on this request for information (RFI) regarding the Electronic Health Record (EHR) Reporting Program.

The EHR Reporting Program was established under Section 4002 of the 21st Century Cures Act (Cures Act) and is intended to provide publicly available, comparative information on certified health information technology (HIT) that will inform the purchasing and implementation decisions of certified HIT users. The Cures Act requires that these reporting criteria specifically address security, interoperability, usability and user-centered design, and conformation to certification testing, as well as other categories as appropriate. The Cures Act also suggests several other categories for consideration, including, but not limited to: enabling users to order and view results of laboratory tests, imaging tests, and other diagnostic tests; exchanging data with clinical registries; accessing and exchanging data from medical devices, health information exchanges, and other health care providers; and accessing and exchanging data held by federal, state, and local agencies. Importantly, the statute also requires that ONC establish these reporting criteria through a public, transparent process that reflects input from developers and end users of certified HIT. This RFI represents a first step toward developing these criteria and implementing the statute.

Overall, the AANS and CNS support the mission of the EHR Reporting Program, which is to provide better information about the quality of EHR systems for those making decisions about HIT acquisition, upgrades, and customization. We strongly believe that EHR vendors should be held accountable for their products' functionalities, performance and cost. We are particularly interested in criteria that focuses on interoperability, including information blocking and other barriers that limit data exchange between EHRs and clinical data registries. Organized neurosurgery's NeuroPoint Alliance (NPA) has multiple clinical data registries, including the Quality Outcomes Database (QOD) qualified clinical data registry (QCDR), which have yet to achieve seamless data exchange with EHRs. The AANS and CNS

are also interested in criteria to ensure that EHR functionalities sufficiently meet the clinical practice needs of a variety of clinician types, including specialists. Currently, EHRs can be in full compliance with federal certification criteria without offering functionalities that are relevant to specialists.

Below, the AANS and CNS offer comments on specific reporting criteria:

1. End-user experiences: Data reported by HIT end-users (i.e., clinicians and patients) are critical to obtaining unbiased accounts of how EHRs are functioning in practice. End-user experiences are critical to assessing subjective categories, such as usability and user-centered design. User reported data could also help assess interoperability as it is experienced by a variety of providers and in varying settings. We strongly encourage ONC to adopt mechanisms that permit end-user data to be searchable or grouped by type of clinician and setting so that those considering an EHR can see how well it functioned for those in situations similar to their own. We also believe that a sufficient number of experiences reported from surgical sub-specialists should be included in the sample. End-user data should capture providers in teaching and non-teaching hospitals, and include house staff (i.e., residents), who are often the primary users of the EHR in teaching hospitals.

2. Interoperability: Interoperability seems to be the area where there is the greatest discrepancy between what EHR vendors purport to be capable of and what they can actually achieve in most practice settings. At a minimum, a certified EHR should be able to exchange documents with other health care providers including operative reports, DICOM-based imaging, and laboratory data. Poor information exchange due to limited interoperability leads to inappropriate decision-making, unnecessary duplication of tests, and lower value care. For surgeons, in particular, imaging reports are insufficient, and original DICOM-based imaging is often essential for appropriate decision-making and surgical planning, particularly when a patient's care is transferred to a specialist. It is critical that EHR reporting address these specific elements of interoperability.

   To address some of these ongoing issues, we urge ONC to develop common, open-source logic models, implementation profiles, and standards to allow for the ease of sharing data. For example, EHR vendors and clinical data registries maintain data in different logic models, implementation profiles, and standards that create additional barriers for aggregating data. If EHRs were required to implement certain open source logic models, implementation profiles, and conform the data to Health Level Seven International (HL7) standards, EHRs could transmit data to registries in a more efficient and cost-effective manner. Developing these models, profiles, and standards is critical to enabling registries to aggregate sufficient data, achieve meaningful results, and extrapolate such results to improve the quality of care. Whether EHRs actually implement such logic models, implementation profiles, and standards would also be useful information for comparing EHR vendors within the interoperability category.

3. Usability and user-centered design: The poor usability of many EHRs remains the primary complaint of many providers. It is essential that ONC's reporting criteria measure not only the ability of EHR vendors to exchange electronic health information, but also the usability of the exchanged information. However, certain aspects of usability are subjective and likely vary by type of provider and practice setting. It is critical that data regarding usability are obtained from a wide variety of end-users, including surgical sub-specialists in a variety of practice settings (large and small, urban and rural, teaching and non-teaching). Any end-user data should be grouped or searchable by provider type so that those making HIT decisions can view ratings and reviews by practitioners similar to themselves and in similar settings. Customizable structured data entry (i.e., for operative reports and other notes), as well as care pathways (i.e., order sets and decision support), are EHR features with the greatest potential to measure and improve the quality of care while simultaneously making EHRs

more palatable to providers. Usability reporting should, therefore, address the ease and flexibility of customizing these EHR tools.

4. Clinical data registry exchange: EHR reporting should specifically address the ability of EHRs to exchange information with clinical data registries. Clinical data registries are a critical and necessary tool for measurement of health outcomes and quality improvement, and a growing number of clinicians are using QCDRs as a more relevant mechanism for satisfying reporting requirements under the Merit-based Incentive Payment System (MIPS). However, there is an ongoing and fairly widespread inability to exchange information with EHR vendors that hampers the ability of registries to conduct more thorough analyses for quality improvement purposes, resulting in smaller sample sizes and skewed results.

   The principal impediment to integration of EHR data into clinical data registries is that some EHR vendors refuse to share their data with registries or are charging their customers or registries excessive fees for access to data in a readable format (whether directly or through a requirement that the clinician purchase intermediary software owned by the EHR). It would be helpful for clinicians to know which EHR vendors are able to submit, edit, and retrieve data from registries, as well if a fee is charged, how much, and/or whether the vendor requires intermediary software systems to perform these functions. EHR vendors also should specifically report for which, if any, CMS-approved QCDRs they support data collection and submission of data to CMS for purposes of quality reporting mandates. End-users (i.e., clinicians and their QCDR vendors) should also have an opportunity to report on the ability (or inability) to submit data from EHRs to QCDRs in practice and any details about those experiences. All of these data should be made available to the public so that clinicians can make well-informed decisions about EHR investments and so registries have a better sense of which EHR vendors are more "registry-friendly."

   As we expressed in other recent comment letters to CMS, we also oppose proposals to remove the Public Health and Clinical Data Exchange objective from the Promoting Interoperability performance category of MIPS and from the Inpatient Hospital Promoting Interoperability Program. Although these measures are not perfect, they at least help to shed light on the feasibility of data exchange between EHR vendors and clinical data registries, which is an aspect of interoperability that continues to pose significant challenges and is otherwise not monitored in any standard way.

   Overall, we strongly urge ONC to prioritize the inclusion of the "submitting, editing, and retrieving data from registries, such as clinician-led clinical data registries" category in the EHR Reporting Program. Clinical data registries play an essential role in promoting quality of care. QCDRs and other clinical outcomes data registries provide timely and actionable feedback to clinicians on their performance, speeding and enhancing quality improvement opportunities. They also allow for more meaningful, patient-centered, statistically valid and timely inter-practice and national benchmarking.

5. Patient-reported outcomes: EHR developers should report which, if any, publicly available patient-reported outcomes instruments are available in their systems. Both patients and clinicians also should have an opportunity to report on the usability of patient-reported outcomes platforms in the EHR system.

6. Electronic copies of health information: Clinicians and patients should have an opportunity to report on the ability of EHRs to provide the patient or an authorized designee with a complete copy of their health information from an electronic health record in a computable format.

7. Accessing and exchanging data from medical devices: EHR developers should maintain an accurate list of any medical devices with which an EHR is capable of accessing and exchanging data.

8. Reporting burden: It is important that data be collected in a manner that is representative and timely without creating or increasing burden on clinicians. The program should be consumer driven, and end-users who chose to report should be recognized for their time. Caution also should be exercised to ensure that a representative sample is polled.

   There are multiple existing mechanisms through which CMS and ONC can collect feedback from clinicians about their experience accessing and using EHR technology. For example, CMS could expand the MIPS Promoting Interoperability (PI) Hardship Exemption application to allow clinicians to provide more detailed, plain text explanations of barriers that prevent them from accessing or using an EHR in a meaningful manner. The current hardship exemption application contains only checkboxes and does not allow clinicians to describe what is stopping them from meaningfully using an EHR. Clinicians should have the option to provide these more detailed explanations in their application to help CMS better understand factors that continue to impede EHR use. However, it should not be a mandatory component of the application. We also recommend that CMS offer automatic, full PI category credit to clinicians who engage in a study regarding ongoing EHR barriers, similar to how CMS currently offers Improvement Activity category credit to clinicians who participate in the "Burdens Associated with Reporting Quality Measures" study.

The AANS and CNS appreciate the opportunity to provide feedback on ongoing barriers and potential solutions to effective EHR implementation. If you have any additional questions or would like to discuss any of these issues in more detail, please feel free to contact us.

Sincerely,

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