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transforming health through information and technology™

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Donald Rucker, MD
National Coordinator for Health Information Technology
US Department of Health and Human Services
330 C Street, SW
Washington, DC 20201

Dear Dr. Rucker:

On behalf of the Healthcare Information and Management Systems Society (HIMSS), we are pleased to provide comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the Request for Information Regarding the 21st Century Cures Act Electronic Health Record (EHR) Reporting Program. HIMSS appreciates the opportunity to leverage our members' expertise in offering feedback on this request for information (RFI), and we look forward to continued dialogue with ONC on this and other programs involving implementation of the healthcare information and technology provisions included in the 21st Century Cures Act (Public Law 114 -255).

As a mission driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research, and analytics to advise global leaders, stakeholders, and influencers on best practices in health information and technology. Through our innovation companies, HIMSS delivers key insights, education, and engaging events to healthcare providers, governments, and market suppliers, ensuring they have the right information at the point of decision.

As an association, HIMSS encompasses more than 73,000 individual members and 655 corporate members. We partner with hundreds of providers, academic institutions, and health services organizations on strategic initiatives that leverage innovative information and technology. Together, we work to improve health, access, as well as the quality and cost-effectiveness of healthcare. Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, United Kingdom, the Middle East, and Asia Pacific.

Overall, HIMSS appreciates ONC's proactive approach in this RFI to engage stakeholders and create a public, transparent process to establish the reporting criteria associated with the EHR Reporting Program. We are encouraged by ONC's efforts to ensure all stakeholders have more information on the functionalities and differences between health IT products and are fully informed about industry trends on business process decision-making.

Our comments are focused on the areas in the RFI where the HIMSS is best suited to provide a response:

Cross-Cutting Topics

HIMSS believes there is significant knowledge to be derived from collecting health IT comparison information. We have many years of experience to share as a reference point for the types of information we think purchasers would pursue.

As a baseline, we recommend that ONC re-evaluate the list of comparison tools identified thus far through its market research in Appendix A of the RFI. Many of these tools are no longer active, while others are limited in the data they provide. In our experience, creating a resource that is useful to a broad range of purchasers is beneficial, but difficult to maintain.

In terms of rural or underserved ambulatory and small practices, those settings would benefit most from low to no-cost comparison tools. Additionally, it would be best to promote websites that provide information related to practice size, specialty, etc., to ensure that consumers can easily identify applicable technologies and tools, and the needs of the majority of consumers can be met.

In addition, it would be useful if ONC were to collect information from providers on the specific features of an EHR and other clinical systems that directly contribute to providers' ability to meet requirements for value-based payment and/or quality improvement programs through the Centers for Medicare & Medicaid Services (CMS). This would allow providers to be better informed if they would be able to use the system "as is", or if they would need to (a) upgrade the system, (b) switch to another system, or (c) configure or customize the system in a way that changes the original or intended use.

ONC's Health IT Dashboard is a great resource and provides a number of datasets, including the ability to see which providers have successfully attested and the certified EHR technology (CEHRT) they utilized. This is an example of information that is publicly available, though few in the public healthcare consumer sector are aware of its existence. HIMSS also proposes that it would be helpful for decision makers to know which optional quality and reporting measures are being successfully attested to in order to design their own specific measure sets.

Finally, the greater availability of state-level data could be another mechanism to help drive comparison data. HIMSS supports establishing more federal-state sharing arrangements to capitalize on this additional data source.

Data Reported by Health IT Developers vs. End-Users

Since the transmission of data is so critical to the functioning of an EHR, HIMSS would like to see the EHR Reporting Program tool provide information on how successful a product is transmitting usable information to an outside system (i.e. health information exchange, another EHR, or to another provider outside of a given provider's network). Another potential data point

related to information sharing is whether the developer or the provider put sufficient policies and procedures in place to mitigate any sort of risk related to information blocking. HIMSS also suggests that this program provide information related to if the developer is using recognized, updated, best practice standards as noted in the [Interoperability Standards Advisory.](#)

Moreover, HIMSS thinks that a compilation of data points on the number of client sites, electronic prescriptions filled, Continuity of Care Document (CCD) exchanges, application programming interface (API) calls, and apps in the developer's app store, could also be valuable information to those acquiring CEHRT. However, this data must be tied to, and cross-referenced with, specifics like specialty, practice size, etc., to ensure this data is kept in the necessary context.

The most useful approach to developing reporting criteria in making technology acquisition, upgrade, or customization decisions is to focus on outcomes as opposed to process. Understanding how providers, as well as patients, have benefited in their experience with a given product or working with a given developer is more critical than fully understanding the process used to get there. Encapsulating information on improvements in outcomes would be useful information to report on, and help support the broader health system's efforts in the shift to value-based delivery.

[HIMSS Analytics](#) data could also contribute valuable information to this reporting effort. In 2006, HIMSS released the HIMSS Analytics Electronic Medical Record Adoption Model ([EMRAM](#)) to incorporate methodology and algorithms to automatically score hospitals around the world relative to their EMR capabilities. Our eight-stage (0-7) model measures the adoption and utilization of electronic medical record (EMR) functions. As organizations move closer to achieving a near paperless environment that harnesses technology to support optimized patient care, they move to higher stages. HIMSS Analytics has many resources and information that may be helpful to incorporate into the reporting program.

There are also public websites that have compelling information for health IT acquisition decision makers, including KLAS, Blackbook, and Leapfrog. However, the majority of decision makers currently get their data through requests for information and reference site visits. Reference site visits and access to rank and file staff primarily drive the transparency of feedback, with most of that feedback being anecdotal. The power of anecdotal feedback is invaluable to the process of selecting health IT products at the facility level.

A variety of data is also already available via the [Certified Health IT Product List (CHPL)](#), including subjective usability task ratings, and other health IT comparison websites that are useful in reporting criteria from both the developer and end-user to inform health IT comparisons. Safety enhanced design and usability related information that the CHPL charts provide include aggregated information with regards to the individuals who participated in the testing, the number of participants, their gender, education level, etc. but it would be more helpful to aggregate and compare information related to the results of the testing for so that end users would have a method to more quickly and efficiently compare the usability metrics across applications. Currently to compare five different products, an end-user would have to read through five different Safety Enhanced Design (SED) reports. Given the effort that both health

IT developers and ONC-Authorized Certification Bodies (ACBs) expend to provide this information, this data could be even more useful to end-users should additional education and dissemination efforts be made to help consumers understand how to access and interpret the data.

Non-conformities for certified products are currently published on the CHPL but an end-user has no idea as to the severity of a particular non-conformity without drilling down in the record to find a brief description of the issue. The community would benefit if information related to product non-conformities were published to provide a snapshot of the number of open and closed non-conformities per vendor, average time to close, as well as a scale or ranking to represent and differentiate the severity of various non-conformities found.

Additional, useful information such as product specific specialty and domain is currently found within a CHPL record's "Additional Information" section under "Developer Identified Targeted User." Currently, this information is reported on optionally, and not readily apparent to end-users who seek further information specific. HIMSS recommends exploring what additional questions may be helpful to include per medical specialty and practice size. After collection of the data, it could then be published on the [Health IT Playbook](#) site.

User-Reported Criteria

The reduction of additional burden on clinicians is critical to having a successful EHR Reporting Program, and HIMSS strongly encourages the continued use and repurposing of data already reported for various federal programs. We believe that a statistically viable amount of patient data should be centralized and made available via the Health IT Playbook. Within that website, a webpage could be created with links to the various comparison tools. HIMSS strongly encourages using existing data sources and educating the healthcare industry about the availability of the data and helping them understand how to interpret it, as well as including easily accessible links to these data sources. Overall, ONC should allow the creation of new data sources to be driven holistically by market need.

To help improve the timeliness of the data so there are not significant lags between collection and publication, we suggest centralizing the data within ONC to ensure de-duplication of efforts to minimize provider reporting requirements and reduce publication lags. The timeliness of data is critical as any reporting mechanism needs to ensure that it is using data that reflects current practices so it is maximally beneficial.

In addition, there is a pervasive concern throughout all industries of users providing reviews that are patently false, or by users who have been paid for the review. While it may be difficult to ensure, HIMSS recommends that ONC take steps to verify that the individual is a confirmed end-user of the CEHRT before a review is submitted, possibly while they are using their system. There is a legitimate concern that allowing unconfirmed reviews would require a great deal of burden on the developer to evaluate each review and rebut, when necessary. A first step may be to ensure that the review process is an iterative one, and all stakeholders have the opportunity to submit information, but that developers and providers have the opportunity to respond to and address any potential concerns that are raised.

Categories for the EHR Reporting Program

From the perspective of the end-user, HIMSS believes the priorities for reporting criteria are as follows: (1) usability and user-centered design; (2) security; (3) interoperability; (4) conformance to certification testing; and, (5) safety. These topics are critical for all healthcare stakeholders to understand as they look for distinct, measurable differences between products as well as the various functionalities of health IT products being used across the spectrum of care.

As we prioritize safety, it is critically important to also consider the safety of health IT implementations. In recent years, we have learned more about some of the unintended consequences of health IT, causing additional burden to clinicians, and most importantly, causing actual patient harm attributed to usability, functionality, and programming concerns. Some of these events can be attributed to aspects of any health IT infrastructure which could include errors of commission or omission, which may be caused by technical (hardware/software), human-machine interface, or organizational processes and activities.

To appropriately address safety, we urge ONC to further refine the EHR Reporting Program to address health IT safety factors, particularly in the usability aspects. There are existing efforts that focus on the safety components of health IT implementation and these are programs that shed light on the safety of EHRs and have promoted measures that address these issues. There is an opportunity to leverage the adoption of these tools in the broader health IT community and allow the EHR developers and other healthcare stakeholders to have a common understanding of where the safety opportunities are and together, partner to further ensure that the deployment and optimization of these health IT tools pay close attention to the safety as part of the socio-technical aspects of the health IT project.

We recommend that ONC fully evaluate information from the following programs to review their relevance in the usability and safety aspects of the EHR reporting program:

o [Leapfrog CPOE Tool](#): The Leapfrog Group maintains a tool to test Computerized Physician Order Entry (CPOE). The tool examines the implemented system within hospitals to examine the usability of factors related to medications, such as drug allergy alerts, therapeutic duplication, and dose limits. The tool provides an overall score for CPOE, and 10 subcategories that represent areas where serious adverse events could occur. The tool—which has been endorsed by the National Quality Forum (NQF)—is already widely used and therefore would not introduce a significant new burden on health care providers. Nearly 2,000 inpatient facilities in 2017 used the tool; an ambulatory module of the test is in development and expected to be completed in 2019. While individual sites use the tool, scores at each facility using the same certified EHR may be able to be aggregated. Both the overall score from the Leapfrog test, as well as some of the subcategory scores may be useful, qualitative measures to include the EHR Reporting Program.

o [SAFER Guides](#): ONC's SAFER guides include checklists to assess a wide range of EHR features and includes recommendations for functions that EHRs should possess. The SAFER Guides could be used as a tool to identify some high-priority functions. For example, one SAFER guide on the display of laboratory test data examines whether systems provide context

on the normal range of results and whether the status of orders can be tracked. ONC should examine whether it can identify high-priority functions from the SAFER Guides on which to obtain information, and could indicate which function—or group of functions—are enabled by certified EHRs. Alternatively, the reporting program could indicate whether a certain percent of high-priority areas from SAFER Guides are able to be completed using certified products. For example, the SAFER Guides have recommendations on how to evaluate downtime and functional downtime through automated means. To evaluate this, a test patient medication order is displayed on a workstation every minute for 24 hours; the delay in displaying the order or number of times it isn't displayed could provide information on the lag faced by clinicians when using the system.

o National Quality Forum Report: In February 2016, NQF published "Identification and Prioritization of Health IT Safety Measures." This report identified nine key health IT safety measure concepts that could be adapted into an EHR Reporting Program. For example, the report provides concept ideas on clinical decision support; user-centered design; system downtime; and other areas. This report, which has dozens of measure concepts, should be examined to identify areas where data exist and could be collected to incorporate into the EHR Reporting Program.

o Safety Surveillance Data: ONC's 2016 EHR Compare Report suggests that "safety surveillance data" could be useful if made publicly available. ONC could include summary data on safety surveillance reports for each certified product. Safety surveillance could emerge from information obtained by ONC in conducting its oversight functions, or via the surveillance activities of ACBs. ONC regulations require ACBs to conduct reactive surveillance, which refers to the examination of systems when they become aware of areas that may not conform to certification criteria, including around safety-related functions, such as drug-allergy interaction checks. Similarly, ACBs must conduct random surveillance of systems. The findings from ACB's reactive and random surveillance could be summarized and made available via the reporting program.

Security

Useful reporting criteria that would provide meaningful differences between products would include a summary of enough detailed security-related functionalities and capabilities to evaluate products on a side-by-side basis for: support for role-based user access; support for on-demand audit trails of all end-user activity (edit, view, print, download, email, etc.) for a specific patient and range of date/time; and, support for disclosure audit trails for all data electronically shared (disclosed) outside of the organization for a specific patient and range of date/time. It is also critical that the covered entity has a business associate agreement (BAA) in place with other entities who are doing business with that covered entity.

HIMSS finds that the following would also be useful security and privacy functions that should be considered for incorporation into EHR reporting criteria, as they are beyond those required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the ONC Health IT Certification Program:
o 2-factor authentication

- o Biometrics (do they integrate with devices that use biometric authentication)
- o Encrypted Database features
- o Role-Based Access Control
- o Extensive password protection (complexity + reset frequency) that follows the National Institute of Standards and Technology (NIST) recommendations
- o Audit Trails
- o Store, display, and print patient consent opt-in agreements
- o Custom privacy policy and terms of conditions for portals
- o Payment Card Industry Data Security Standard compliance for credit card transactions

Interoperability

Hospitals and health systems would greatly benefit from comparison data on the exchanging of the complete CCD for a patient. CCDs provide administrative, test results, and medications, as well as allergy data, implantable device information, family and social history, operations, that all contribute to improved patient care across the continuum. Hospitals provide emergency, inpatient, and intensive care, as well as, operating, pharmacy, lab and medical imaging operations for inpatients, while smaller practices may not offer any of these services.

Due to the uniqueness of the reach of hospital services compared with small clinics, it is almost impossible to compare EHRs for these very different healthcare delivery systems. As for health systems, usually it is prioritizing what components of the EHR provide the best efficiency and patient care. The differences in areas or focus and capabilities across the delivery system aligns with the benefits of the comparison tool and the idea of providing information from across a variety of settings.

In addition, integration is one means of assessing interoperability; however, HIMSS thinks it is important not to discount "launching" from either one EHR system to another directly, or web-based platforms (HIEs, etc.) as a valuable measure of interoperability. There are many patient care scenarios that do not require integration of another provider's data, only a knowledge of the information to care for the patient. The forward-looking ability to launch certain data points between EHRs or other health information technologies would provide a more straightforward level of access without integration, and should be considered for inclusion in the reporting criteria

Other domains of interoperability that would be helpful to include focus on the complexities of a product to integrate with others and the product's connectivity to networks such as state-based HIEs, CommonWell Health Alliance or Carequality would be useful for comparative purposes.

It is important to note that CMS program data is more reflective of how clinicians are using the product, rather than the capabilities of the product. For example, the HIE-related measures reflect whether clients are using CEHRT, but are not necessarily indicative of whether the CEHRT is capable of helping them meet that measure. Many different types of decisions go into the implementation and use of CEHRT, and while a product is capable of a function, the site may simply choose not to use it. The existing CHPL data already shows to which criteria the CEHRT is certified, with those criteria reflecting specific functionalities.

Additional data sources and measures that could be used to compare performance on interoperability could include additional data from regional and state HIEs and data from public and private sources. Although healthcare user and patient experience data can be subjective, it is still important to include that information in comparing products. If a product design is not seen as user and patient-intuitive, it will not be used optimally in facilitating the exchange of data across patient and provider platforms. This data is especially important in determining what specific functionalities may negatively impact use.

For example, the CMS Promoting Interoperability Programs requirement for each EHR to have its own portal and, for the most part, portals do not necessarily share data outside their EHR system. Patients have multiple portals and multiple passwords (hospitals, primary care providers, specialty care providers, etc.). This leads to patient dissatisfaction and patients not using the portals. However, the use of API interfaces to compile data from multiple sources into one healthcare application of the patient's choice will improve the user experience for many patients and should be a component of a reporting program.

Overall, the redefining and streamlining of the Medicare and Medicaid EHR Incentive Programs to the Promoting Interoperability Programs will allow healthcare facilities to better compare EHR systems for future sustainability. Based on a health IT developer's current strategy, facilities can forecast, if the developer is positioned with the appropriate approach, funding, and human resources to implement what is projected to be the next steps in increasing interoperability. The redesigned program has allowed facilities to focus on comparisons instead of comparing multiple components, many of which are no longer required in reporting under the Programs. A comparison of future developer strategy and capabilities on interoperability would be helpful in this case.

Hospitals and Health Systems

The most frequently utilized sources of comparative information are identified on ONC's Health IT Dashboard, including the ability to determine the number of CMS attestations per developer.

Existing information can be found in the transparency disclosures mandated by 2015 Edition CEHRT. While this information is not populating the compare tool on CHPL, bringing more awareness to it by adding it to the CHPL compare tool could be useful. Also the website is not formatted to compare all elements for multiple developers on the screen simultaneously so a website reconfiguration may be warranted. In searching for developers, the user needs to know the "legal" name of the developer; it would also be helpful to be able to search by "brand" or "marketed name".

Additionally, the software that 2015 Edition CEHRT relied upon to achieve certification has recently been removed from the CHPL summary report, making this information more difficult for users to locate.

There is also attestation data reported by developers to their ACBs which is not publicly available, such as encryption and hashing algorithms used to comply with certification criteria. This

comparative information could also be helpful and would not be overly burdensome to procure since it is already collected.

Overall, an ideal online tool for the EHR Reporting Program could best reflect the information needed for hospitals and health systems, ambulatory and smaller provider settings, and overlapping information in developing summary reports or comparison tools. The tool should be electronic, interactive, easy to search, respond quickly and allow users to prepare spreadsheet or other visual depictions (charts, graphs, etc.) online by moving, re-prioritizing, and eliminating data based on a facility's needs.

HIMSS is committed to be being a valuable resource to ONC and the entire community to help implement the 21st Century Cure Act and develop an EHR Reporting Program. We welcome the opportunity to meet with you and your team to discuss our comments in more depth. Please do not hesitate to contact Jeff Coughlin, Senior Director, Federal & State Affairs, at 703.562.8824, or Eli Fleet, Director, Federal Affairs, at 703.562.8834, with questions or for more information.

Thank you for your consideration.

Sincerely,

Harold F. Wolf III, FHIMSS
President & CEO
HIMSS