Charles N. Kahn III
President and CEO

October 17, 2018

Don Rucker, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program

Dear Dr. Rucker:

The Federation of American Hospitals (FAH) appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology's (ONC) *Request for Information (RFI) Regarding the 21st Century Cures Act Electronic Health Record (EHR) Reporting Program*. The FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay, rehabilitation, long-term acute care, psychiatric, and cancer hospitals in urban and rural America, and they provide a wide range of acute, post-acute, and ambulatory services.

The FAH continues to believe in the potential of health information technology (health IT) to improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. As we have noted in previous comment letters, the *Health Information Technology for Economic and Clinical Health (HITECH) Act* catalyzed broad adoption of EHRs, but the use of such technology has not yet achieved the quality and efficiency goals desired by stakeholders across the health care sector. The inability of EHRs to both exchange and use information is a significant barrier to achieving these goals. Congress recognized this barrier in enacting numerous policies in the *21st Century Cures* Act, including the EHR Reporting Program. The FAH appreciates ONC's efforts to develop and implement this Program and offers the below comments in response to the RFI.

Focus of the EHR Reporting Program

As drafted, the RFI envisions the primary focus of the EHR Reporting Program as providing comparative information to "those acquiring health IT in making health IT acquisition, upgrade, or customization decisions."[1] While a comparative, "consumer reports" model may be somewhat useful for ambulatory and small practice settings, even those settings have already acquired their health IT and are now trying to make those systems work more effectively and efficiently in their practices. Thus, the EHR Reporting Program could be most impactful by focusing on post-acquisition/post-implementation surveillance and improvement of certified technology, as discussed in more detail below.

Ongoing In-the-Field Surveillance of CEHRT

There is a significant need for ongoing, in-the-field surveillance to improve the functioning and use of certified health IT. While there are current regulatory requirements for Authorized Certification Bodies (ONC-ACBs) regarding in-the-field surveillance and maintenance of certification of health IT,[2] the requirements are currently only being implemented for reactive (e.g., complaint-based) surveillance. The regulations regarding randomized surveillance[3] are currently subject to "enforcement discretion," and ONC has stated it will not "audit ONC-ACBs for compliance with randomized surveillance requirements or otherwise take administrative or other action to enforce such requirements…."[4]

The lack of randomized, in-the-field surveillance leaves a significant gap in the ability to determine real-word conformance to certification testing and maintenance of certification, as well as to improve health IT capabilities related to security, interoperability, and usability. At a minimum, the FAH urges ONC to look to the in-the-field, randomized surveillance regulatory requirements as a starting point from which to build the EHR Reporting Program. The FAH also encourages ONC to look beyond the current requirements to develop a more robust, collaborative surveillance and improvement model. Specifically, this model should involve an independent testing/accreditation body that would examine the use of health IT in the field and provide feedback to both health IT vendors and the health care providers who utilize those products.[5]

The FAH strongly urges ONC to be mindful of the burdens such a surveillance program places on health care providers in terms of time and costs and take all necessary steps to minimize such burdens. This includes collaborating with federal partners to determine if any current testing/accreditation programs can be effectively utilized for EHR Reporting Program purposes to avoid additional, potentially duplicative workplace disruptions for health care

[1] 83 Fed. Reg. 42915 (August 24, 2018).
[2] 42 CFR 170.556.
[3] 42 CFR 170.556(c).
[4] ONC Program Guidance #17-02 (September 21, 2017) https://www.healthit.gov/sites/default/files/ONC_Enforcement_Discretion_Randomized_Surveillance_8-30-17.pdf.
[5] This independent body could be a testing organization, such as the ONC-ACBs, or an accreditation organization, such as those currently used by the Centers for Medicare & Medicaid Services (CMS) to determine compliance with CMS regulations.

providers. ONC can also limit burden by ensuring that health care provider participation in the EHR Reporting Program surveillance is *voluntary*, with appropriate incentives to encourage participation. Such incentives could include: a bonus under the Promoting Interoperability Programs for hospitals; and a Merit-Based Incentive Payment System (MIPS) bonus and/or credit for activities in the Promoting Interoperability or Improvement Activities performance categories for clinicians and groups. Additionally, as the EHR Reporting Program is focused on certified health IT, not on health care providers, feedback to providers should not be punitive in nature. Instead, FAH members encourage a collaborative approach where the testing/accreditation body provides recommendations for providers to improve their utilization of health IT.

FAH members also generally favor a collaborative approach between the testing/accreditation body and health IT vendors, with the joint goal of improving the capabilities of the technology. However, while we believe this is the most effective method to catalyze improvements in health IT, ONC must ensure the EHR Reporting Program provides robust audits of certified health IT products in real world scenarios and requires public reporting of the outcomes of those audits, including deficiencies and corrective actions. As health care providers may utilize the same – or similar – technology, public reporting of deficiencies and corrective actions will raise awareness among providers of potential issues within their own health IT systems. This is especially true for deficiencies affecting safety and/or security, which should be publicly reported immediately and for which vendors should bear responsibility to both notify their customers and correct across their health IT products.

Improvements to the Certified Health IT Products List (CHPL)

While the FAH believes the overall focus of the EHR Reporting Program should be on post-acquisition/post-implementation surveillance, there are actions ONC can take to improve the CHPL website for health IT consumers. Such ideas include: requiring vendors to list the geographic locations and provider types where they have already integrated around health information exchanges (HIEs) so that those acquiring, upgrading, or customizing health IT can leverage work that has already been done; and requiring vendors to provide information on the cost of health IT upgrades and interfaces so that consumers have some insight into the costs associated with maintenance and use of their health IT tools. While the FAH urges ONC to conduct listening sessions with providers across the country for additional ideas to improve the utility of the information on the CHPL website, some initial ideas are provided below.

Regarding usability and user-centered design, ONC should require health IT vendors to publicly report the makeup of their usability and user-centered design committees (e.g., how many people were on the committee; how many were doctors, nurses, etc.), how many hours the committee met, and whether there was any testing of the health IT system by clinicians before deployment.

Regarding interoperability, ONC should require health IT vendors to publicly report the names of the State departments of health with which they have interfaced; the names of the vendors with which they have interfaced and the number of transactions in the previous six-

month or 12-month period; the APIs the vendor utilizes; and the applications with which the vendor has tested and/or certified.

Additionally, ONC should require additional publicly-posted security information, such as a standardized assessment of each vendor's adherence to privacy and security best practices. Large hospitals and health systems ask for security information beyond what is publicly available and then often do their own "scoring" of the vendor against a nationally-recognized security framework, such as the National Institute of Standards and Technology (NIST) Cybersecurity Framework and/or the HITRUST CSF Assurance Program. This process is time consuming, expensive, and often beyond the capabilities of many smaller facilities and practices. Instead, ONC should require EHR vendors to undergo a third-party assessment of their compliance with privacy and security best practices – and then publicly post those results. This would also appropriately place the burden of such compliance on EHR vendors and reassure providers that the health IT products they are purchasing (or have purchased) are secure.

The information discussed above to improve the CHPL website for consumers should only be applicable to commercially-available certified health IT products. Internally-developed and utilized certified health IT products – those that health care providers have developed for their own hospitals and facilities – should not be subject to the EHR Reporting Program requirements because they are not commercially available and thus there is no need to compare them to other certified health IT products.

Criteria for the EHR Reporting Program Categories

The *21st Century Cures Act* requires the EHR Reporting Program to address the following five categories: security, interoperability, usability and user-centered design, conformance to certification testing, and other categories, as appropriate, to measure the performance of certified EHR technology. The foundation to assess certified technology on the required categories is meaningful, measurable data. In determining what data is needed to successfully implement the surveillance model described above, the FAH urges ONC to avoid new and/or duplicative reporting requirements for health care providers by collaborating with CMS to determine what currently-reported data could be used for the EHR Reporting Program. ONC should also collaborate with CMS to determine what CMS requirements under the Promoting Interoperability Programs are driving health IT design and updates and may be inadvertently diverting from technology capabilities that support safe, efficient health information exchange.

The FAH also encourages ONC to look to data that can be generated and reported automatically by health IT systems. The use of automated data would dramatically reduce the burden of participation by health care providers. For example, regarding usability and user-centered design, automated data could measure the average number of "clicks" it takes a clinician to perform a function (e.g., order a test, submit a prescription) and average amount of time it takes a clinician to perform a function. Regarding safety, automated data could measure the frequency of orders that cannot be correctly placed, the frequency of duplicate records for the same patient, and the frequency of required software patches and updates. And regarding interoperability, automated data could measure the number of transactions (i.e., exchange of health care information) between the system and an HIE and the cost associated with those

transactions. As the technology improves, the systems should also be able to automatically determine what type of information is exchanged (e.g., summary of care record, encounter continuity of care document, procedure notes, etc.).

In addition to the data sources detailed above, the FAH encourages ONC to look to existing public and private sector frameworks to help in the development of criteria for the EHR Reporting Program. For example, the term "usability" means different things to different stakeholders and is in need of a commonly-accepted framework against which to judge certified health IT. Again, the FAH recommends that ONC explore NIST publications related to usability as a starting point for usability criteria.[6]

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The FAH appreciates the opportunity to comment on the RFI. We look forward to continued partnership with ONC as we strive to advance the use of health IT to improve our nation's health care system. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1500.

Sincerely,

[6] *See* https://www.nist.gov/programs-projects/health-it-usability.