



October 17, 2018

Don Rucker, M.D.
National Coordinator
Office of the National Coordinator for Health Information Technology
330 C Street, SW
Washington, DC 20201

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

Dear National Coordinator Rucker:

On behalf of the American College of Physicians (ACP), I am pleased to share our feedback on the Office of the National Coordinator for Health Information Technology's (ONC's) Request for Information (RFI) Regarding the 21st Century Cures Act Electronic Health Record (EHR) Reporting Program. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Since the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act, ACP has been committed to helping our members with the adoption, implementation, and effective use of EHRs. In 2010, ACP cofounded AmericanEHR Partners¹ with Cientis Technologies – a free web-based “consumer-reports” for EHRs that is open to the public and helps practices find an EHR system that meets the unique demands of their practices. AmericanEHR collects data on EHR systems by surveying physicians, nurse practitioners, and physician assistants in collaboration with their professional associations. The information is presented on the site through a comparison engine and ratings system, which allows clinicians to view individual product and benchmark ratings as well as filter the ratings based on practice size and specialty. ACP members find AmericanEHR to be a useful tool when “shopping around” and gathering more information on EHRs but experience has shown that

¹ AmericanEHR website: <http://www.americanehr.com/Home.aspx>

publishing this type of vendor-specific usability information, even within a user-friendly, clear format, is not translating into better, more usable, safer, and interoperable products.

The 2016 EHR Comparison Report to Congress² summarized results from a market analysis of the existing EHR comparison tools, including AmericanEHR, and concluded that collectively these resources are still not meeting the needs of the clinician end users. The majority of the available resources depend on customer-reported information and have not had the leverage needed to push health IT developers to improve the usability of their systems. Promoting transparency and providing useful information on available EHRs and health IT products to help practices select, implement, and effectively use health IT has long been a priority of the College and we fully support the aim of 21st Century Cures in requiring health IT vendors to report on certain aspects of their products as a condition of certification. Requiring vendors to report on key elements of usability, security, and interoperability will add value to the information already available for comparing EHRs, and ONC – through the EHR Reporting Program – has the opportunity to further promote transparency in the health IT marketplace to address the needs of clinicians.

21st Century Cures provided ONC with the opportunity to expand on the reporting criteria called out in the legislation, and as ONC works to fill the gaps within the existing comparison resources, ACP recommends ONC focus their efforts on developing criteria around how fully implemented EHRs function in real-world settings with real patient data. Once an EHR system is purchased and implemented, smaller ambulatory practices do not have the support or flexibility to then shop around for an entirely new system if it is not meeting their needs. This is due to the significant costs and the substantial amount of time it takes to implement EHR systems as well as the time to roll out any system upgrades, including effectively deploying the new technology, staff training, and workflow adjustments – all leading to potential risk to patient health if not done properly. Not to mention the issues and time it takes to obtain patient data and migrate that data to an entirely new system. Having vendors report on how their systems function in real-world settings with real-world clinical variables at play, will not only provide more useful information for the end user or “acquisition decision maker” but also provide a better mechanism for holding health IT vendors accountable for developing truly usable products and drive market competition.

The following contains specific feedback on ONC’s EHR Reporting Program Criteria Categories:

User-Reported Criteria:

Drawing from experiences with AmericanEHR, collecting user data through extensive annual surveys was time-consuming and labor intensive but clinicians were willing to provide the information because they found value in the content. ONC should strive to make user reporting as streamlined and seamless as possible and the most important way to encourage reporting is to configure the process so that the users reporting data see the value in the process and

² Report to Congress: Report on the Feasibility of Mechanisms to Assist Providers in Comparing and Selecting Certified EHR Technology Products, April 2016:

https://www.healthit.gov/sites/default/files/macraehrpct_final_4-2016.pdf

content of what they are reporting. This will require a feedback loop that benefits end user reporters. Finally, if these attempts fail to achieve the desired participation, carrots such as public recognition could be used – or the Centers for Medicare and Medicaid Services (CMS) could provide bonus points through the Merit-based Incentive Payment System (MIPS) for those that submit data to the EHR Reporting Program. ONC should engage with patients and other users of health IT to better understand how to encourage them to participate in the EHR Reporting Program.

In order not to duplicate existing work within the EHR comparison market, the government-sponsored EHR comparison tool should compile and present all existing EHR comparison data in a user-friendly format and remove the need to add more reporting burden on the end-user clinicians. If certain existing comparison data is not publicly available, ONC should work to provide these resources free of cost to smaller ambulatory practices that do not have the resources to conduct their own market research.

Health IT Developer-Reported Criteria:

As previously discussed in this letter, the “consumer reports” approach to EHR comparison data has not met the needs of end users, specifically ambulatory and smaller practice end users. A contributing factor to this unmet need is that EHR adoption and implementation rates among clinicians are up to 90%,³ and once that EHR system is purchased and implemented, it is difficult to shop around for an entirely new system if it is not meeting their needs. An approach to addressing this lack of leverage within the vendor marketplace is to provide clinicians with information on how EHR systems perform once they are fully implemented and running in a real production environment. Health IT developers should report on real-time production data showing how the fully integrated system works in the real world. This information will help clinicians, specifically smaller ambulatory clinicians lacking the flexibility and resources to “shop around,” better understand the functionalities of the products and hold vendors accountable to develop products that meet the clinician end users’ needs. In order to minimize the burden of reporting, the process should be as automated as possible – these types of automated reporting could include back-end usability testing used by vendors and real-time production data. Any type of automatically generated production data collected in real-time would be the least burdensome approach. However, as ONC further develops reporting criteria for the EHR Reporting Program, time must be given to developers to allow for the needed programming of any required automatic functionality.

Additionally, it would be useful for health IT developers to report on whether they are engaged in collaborations or agreements to adopt uniform processes and standard implementation practices for all aspects of their health IT products. The current administration has shown a commitment to reducing administrative and regulatory burden. To facilitate the elimination, reduction, alignment, and streamlining of administrative burden, all key stakeholders should collaborate in better utilizing existing health IT, as well as develop more innovative approaches to use health IT to reduce burden. With the current negativity towards EHRs, it would be very

³ National Center for Health Statistics, National Health Care Surveys Fact Sheet, May 2018:
https://www.cdc.gov/nchs/data/factsheets/factsheet_nhcs.pdf

useful to know what vendors are doing to simplify clinicians' workload. Much like the information on post-implementation performance, this type of information is not only useful for the end-user but has potential to drive market forces and promote stakeholder collaboration and uniformity of health IT processes and interfaces.

Usability and User-Centered Design Criteria:

Value-based payment arrangements, alternative payment models, as well as the promotion of team-based, coordinated care is changing the way physicians work and health IT developers need to understand this change to provide innovative and useful functionalities. Clinicians need new tools within their EHR including workflow support, data visualization tools, and shared decision-making tools that leverage existing data within the EHR – and remove the need to click through numerous pages and templates to try to find the truly useful and actionable data. As it stands, how our healthcare system measures value is limited to the data currently available within the EHR system (which is insufficient) and clinicians are stuck with workflows designed to generate data largely for the sake of reimbursement, performance measurement, and reporting and not to improve patient care. Health IT vendors need to address and report on how they are improving their systems to support the changing needs of physicians as a way to make EHRs more usable and functional to enhance high-value patient care.

Reporting criteria should include clear examples of how EHRs are addressing currently burdensome, unnecessary, and duplicative tasks – and how they are leveraging data to streamline processes. For example, reporting criteria should include how vendors are more effectively displaying formulary information and automating prior authorization requests. Vendors should also report on how seamlessly they integrate third-party tools and applications into their existing EHR systems. The EHR Reporting Program should require all health IT vendors, not just EHR developers, to report on certain criteria as well. Specifically, vendors who create add-ons for EHRs should report on the ease of use of their products or user interfaces.

The following is a list of specific areas of focus for developing usability reporting criteria:

- **Medication Management and e-Prescribing** – checking patient formulary information, managing drug alert interactions, recording non-prescription medications, receiving a refill request, generating and transmitting an electronic prescription, etc.
- **Capturing and Generating Patient Information** – documenting care plans, documenting a progress note, Evaluation and Management (E/M) coding support, recording family and social history, generating an electronic copy of patient's medical record, generating a useful and readable summary of care report, generating a patient referral letter, etc.
- **Capturing Patient Narrative:** collecting patient-reported outcomes, integrating patient-generated data, etc.
- **Order Management and Tracking** – viewing lab results, viewing radiology images or studies, ordering a lab test, generating list of patients who have overdue test results and flagging overdue tests, etc.

- **Population Management and Public Health Reporting** – generating lists of patients with specific conditions or patients on specific drugs, generating reminders for preventive care, ability to send information or surveillance data to a specialized registry, etc.
- **Data Visualization and Decision Support** – providing context-sensitive clinical decision support, creating automatic reminders, creating templates for specific clinical conditions, editing of reminder rules, supporting text macros, etc.
- **Vendor Tech Support** – directly connecting to vendor IT support (e.g., tech support button within the EHR).

Interoperability Criteria:

ONC discusses using “product integration” as a primary condition of interoperability but it is important to note that integration is just one of myriad elements to assess interoperability and ONC should stay away from trying to simplify or boil down the assessment of interoperability to just one primary condition.

Much of the government’s focus on interoperability measurement is on measuring the actual movement of data from one place to another, which while important, does not really address whether interoperability promotes sharing of meaningful information or measures whether EHR systems help reduce unwarranted tests, diagnostic studies, and improve workflow, care delivery, patient engagement, and clinician satisfaction. When attempting to compare performance on interoperability across certified health IT, ONC should consider measuring frequency in claims data for duplicative testing and diagnostic services among similar risk-adjusted patients, across health IT products, where multiple clinicians provide care. In ACP’s comments on ONC’s Interoperability Standards Advisory⁴, we discuss the importance of addressing the spread of incomplete or inaccurate health information and the need for uniform implementation and management of provenance functionality within EHR systems. Every effort should be made to include reporting requirements focused on how EHR systems address mitigating inaccurate data. Transparency in this area is crucial and health IT vendor-reporting requirements should include questions around implementation and management of provenance functionality as well as questions on whether the system allows for bidirectional communication to correct data shared among clinicians and patients.

The interoperability reporting criteria should also include measures of care coordination and resource use focused on whether or not patients received their data, and did they feel that their doctors received and used their data. The patient perspective is very important and ACP supports exploration as to how vendors could collect and use both patient and family input to improve the design of their systems. This patient input should focus on interoperability features that address the need for patients and caregivers to access and use information from their health records and whether they benefited from sound, seamless care coordination. Additionally, health IT vendors should develop and implement brief customer satisfaction surveys for clinician end users, and ask simple questions about whether needed information

⁴ ACP’s Comments on ONC’s 2018 Interoperability Standards Advisory:
https://www.acponline.org/acp_policy/letters/acp_comments_on_interoperability_standards_advisory_2018.pdf

was accessible and if not, why not. The presence and ease of use of customer satisfaction surveys as well as the results of those surveys (specifically on questions measuring interoperability) should be included in the health IT developer-reporting criteria.

In order to even scratch the surface of how to promote – or even measure – interoperability, ONC needs to be collecting evidence of value as well as evidence of data movement. In all of its reporting criteria development and measurement activities, it is critical that ONC distinguish measurements of interoperability within an organization that shares a common health IT platform from measurements across multiple organizations that do not share a platform. To a large extent, interoperability has been “solved” within some leading health organizations, while interoperability hardly exists at all in interactions among many other organizations. The ACP believes it is beneficial to learn from organizations and vendors in which there are few, if any, remaining interoperability challenges, and to see if care has improved or become more efficient and effective. One approach to better understanding the different venues of interoperability is for ONC to develop case studies to highlight how organizations have achieved improvements in interoperability when they have grown by the purchase or absorption of practices with multiple different technology platforms. These types of case studies might provide the needed insights for larger health care organizations to transition faster to a fully interoperable system.

Conformance to Certification Testing Criteria:

The current certification testing criteria are too simplistic, unrealistic, and easy to game the test to reach the desired goal. ONC’s certification testing criteria need to incorporate and measure activities that reflect real-world care delivery processes. To reiterate our previous recommendation regarding additional reporting criteria necessary for the success of the EHR Reporting Program, ACP recommends ONC focus their efforts on developing criteria around how fully implemented EHRs function in real-world clinical settings with real patient data. Moreover, certification testing and conformance to testing reporting should examine the same health IT product in different installations (e.g., small vs. large practice, primary care vs. subspecialty practice, etc.).

Other Reporting Criteria Categories for Consideration:

Patient Safety

As part of a condition of certification, health IT developers should report on how they address and resolve “near misses.” Vendors are required to report on how they address issues that result in medical errors but information is needed on how the vendor handles issues where the EHR could have caused patient harm but did not.

Cost Transparency

As mentioned in the background information within the RFI, there is a gap in information on base, subscription, and transaction costs associated with the purchase and implementation of EHRs. In developing reporting criteria to promote cost transparency, ONC should consider and distinguish between implementation,

customization, and upgrade costs as well as other add-ons that might be needed once the system is implemented. In some cases, additional costs can come from sources outside of the EHR or health IT vendor such as state-based regulations that require certain add-ons or functionality – and this state-based information should be considered when developing cost transparency reporting criteria. We discuss inclusion of vendor technical support earlier in this letter, but incorporating costs for technical support within this category would be very useful as well.

Quality Reporting and Population Health

Clinicians in smaller ambulatory practices need confidence that their EHR will meet their quality reporting needs. Unlike employed physicians in larger settings, these clinicians are more likely to be the decision makers for selecting reporting options for programs like the Medicare Quality Payment Program. Flexibility in quality reporting options should be considered when evaluating EHRs – they should easily integrate with the multiple reporting pathways (e.g., EHR, CMS portal, qualified registries or Qualified Clinical Data Registries). Ambulatory and small practices do not have the health IT capacity to establish data integration feeds that allow for automated data reporting. Information on whether the health IT product reliably maps to data elements required to populate MIPS measures (specifically electronic Clinical Quality Measures) and/or push out data required to populate measures in standardized file formats is a critical piece to the reporting requirements.

Conclusion

ONC has a critical role in further promoting transparency around needed functionalities within the health IT marketplace. 21st Century Cures provides a good foundation for enhancing the currently available EHR comparison data by requiring reporting on certain criteria as a condition of certification. ONC can expand on this and push vendors to be transparent in what their products provide as well as drive competition to make products more user-friendly. ACP appreciates the opportunity to provide this initial feedback on the development of reporting criteria for the EHR Reporting Program and we hope that you will find value in our response and continue to seek clinical end-user feedback on this very important program. Should you have any questions, please contact Brooke Rockwern, MPH, Associate, Health IT Policy at brockwern@acponline.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia L. Hale MD, PhD". The signature is fluid and cursive, with the first name "Patricia" being the most prominent part.

Patricia L. Hale, MD, PhD, FACP
Chair, Medical Informatics Committee
American College of Physicians