

September 14, 2021

Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
Office of the National Coordinator (ONC)
U.S. Department of Health & Human Services
Washington, DC

Re: Request for Comments Regarding Proposed Health IT Developer Measures in the 21st Century Cures Act Electronic Health Record Reporting Program

Submitted electronically EHRfeedback@urban.org

Dear Dr. Tripathi,

The Premier healthcare alliance (Premier) appreciates the opportunity to respond to the Office of the National Coordinator for Health Information Technology's (ONC) request for comments on the proposed measures for Health Information Technology (health IT) Developers as part of the Electronic Health Record (EHR) Reporting Program as established in Section 4002 of the 21st Century Cures Act (Cures).

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,400 U.S. hospitals and health systems and approximately 225,000 other providers and organizations to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide.

Providers need reliable, robust, and transparent information about EHRs' usability, functions and interoperability, thus timely implementation of the Cures provision for the EHR Reporting Program is critical and long overdue. Below we present our overarching recommendations and include additional comments on some specific proposed measures for your consideration.

Overarching Recommendations

EHR Reporting Program Goals and Objectives. Cures requires the development of an Electronic Health Record Reporting Program (Program) and explicitly requires vendor reporting about "security, usability, user-centered design, interoperability, conformance to certification testing, and other factors necessary to measure the performance of EHR technology." The proposed health IT developer measures are a good start but insufficient as they do not explicitly address the factors required by Cures. The proposed measures focus on the use (not usability) of EHRs and not on data that captures Cures' required product capabilities, functionality, and performance. We note that while ONC's proposed measures are organized into five domains, it is not clear how these domains fulfill Cures' requirements. **We urge ONC to explicitly identify how its proposed measures address usability, security, and user-centered design.** Furthermore, we urge ONC to consider unintended consequences, such as additional provider reporting or administrative burdens that could result from measures requiring data about providers' use of EHRs.

Additionally, we urge ONC to strengthen certification and EHR Reporting Program requirements to ensure that providers can more easily meet various federal regulatory requirements and to further align compliance dates and requirements with its federal partners. For example, CMS' FY 2022 inpatient prospective payment system (IPPS) rule finalized the requirement for hospitals to use certified EHR

technology that is updated consistent with the 2015 Edition Cures Update and clarified that certified technology must support the reporting requirements for all available electronic clinical quality measures (eCQMs). The CMS rule also mandates that hospitals and health systems attest to reporting on four public health measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting). However, the 2015 Edition Cures Update does not require EHR vendors to provide public health reporting functions (including access to third-party apps via open APIs). These unaligned requirements and compliance dates often result in additional provider administrative or reporting burdens.

Provide information about EHRs' functionality and performance. The EHR Reporting Program should focus on products becoming more effective at supporting interoperability, patient treatment and care coordination rather than just meeting ONC certification (CEHRT) requirements or addressing CMS program requirements. Premier urges ONC to require EHR vendors to demonstrate interoperability, usability, security, safety, and their platforms' conformance to standards as part of more robust certification, real world testing, and surveillance programs and publicly report product functionality and performance data. Examples of EHR vendor reported data that should be collected include:

- Timeliness of adoption and implementation of data and interoperability standards and version adherence¹
- Availability of and access to patient- and provider-facing third-party applications (i.e., numbers and types of third-party applications that can be and are integrated with the legacy EHRs; numbers and types of third-party applications in the vendors' sandbox or "app" store)²
- Ability for providers to integrate and implement any third-party application of their choosing
- Functions that advance improvements in usability, user-centered design, security, and interoperability
- How EHRs meet CMS and other federal reporting and administrative programs
- EHR compliance with the Safety Assurance Factors for EHR Resilience (SAFER) Guides

Data collected during EHR certification and from real-world testing should be leveraged and integrated into the EHR Reporting program. We urge ONC to establish **a stronger focus on patient safety-related usability, EHR training and transparency on EHR vendors' cybersecurity practices, as well as cost transparency.** EHR vendors already track and record many data points used for CMS reporting, so these data are readily available for the EHR Reporting Program.

Usability and Safety of EHRs. Concerns about the usability and safety of EHRs are not new and recognize the interplay between EHR functionality and user implementations. Despite prior recommendations³ to include usability as a core aspect of EHR certification and development ONC has not taken action to develop and implement usability criteria as part of its CEHRT or real-world testing

¹ James Jones, Daniel Gottlieb, Joshua C Mandel, Vladimir Ignatov, Alyssa Ellis, Wayne Kubick, Kenneth D Mandl, A landscape survey of planned SMART/HL7 bulk FHIR data access API implementations and tools, Journal of the American Medical Informatics Association, Volume 28, Issue 6, June 2021, Pages 1284–1287, <https://doi.org/10.1093/jamia/ocab028>

² Wesley Barker, Christian Johnson, The ecosystem of apps and software integrated with certified health information technology, Journal of the American Medical Informatics Association, 2021, ocab171, <https://doi.org/10.1093/jamia/ocab171>

³ Johnson CM, Johnston D, Crowley PK, et al. EHR Usability Toolkit: A Background Report on Usability and Electronic Health Records (Prepared by Westat under Contract No. HHSA 290- 2009-00023I). AHRQ Publication No. 11-0084-EF. Rockville, MD: Agency for Healthcare Research and Quality. August 2011.

processes. Yet, there is increasing research ^{4 5 6 7 8} about the usability and safety challenges of EHRs. In its FY 2022 IPPS rule, CMS requires hospitals and health systems to attest that they have completed an annual assessment of the SAFER Guides. At a minimum, **Premier strongly recommends that ONC adapt the SAFER Guides for use by EHR vendors and implement certification requirements for EHR vendors** to attest to completing an assessment of their technology and product(s) using the SAFER Guides and to report that information publicly as part of the EHR Reporting Program⁹. We also recommend that **ONC continue prior work with NIST** ^{10 11} and formalize approaches and measures to ensure that EHRs are free from critical usability issues.

Leverage ONC's Conditions and Maintenance of Certification and Testing Program(s). The ONC Health IT Certification Program was intended "to provide assurance to purchasers and other users that health IT meets the certification criteria (i.e., has certain functioning capabilities)." We urge ONC to integrate and align the EHR Reporting Program requirements with the conditions and maintenance of certification, testing and surveillance program(s). **We also recommend that ONC continue to implement more robust conditions and maintenance of certification, testing and surveillance processes** to ensure that EHR vendors demonstrate their systems'/platforms' interoperability (ability to send data to and receive data from other EHRs and data sources) and conformance to standards (i.e., explicit conformance to Fast Healthcare Interoperability Resources (FHIR) versioning, resources). The EHR Reporting Program should adapt and leverage data collected by the ONC-Accredited Certification Bodies (ACBs) regarding product conformance to certification criteria and results from real-world testing. Information posted on the Certified Health Information Technology Product List (CHPL) could be incorporated in the Reporting Program.

Dissemination of Comparative Product Information. Providers do not have sufficient information or data to accurately compare products, nor have they been instilled with equitable consumer power to influence EHR market forces and to help ensure an open and competitive marketplace with legacy EHRs. While enabling providers to make better purchasing decisions is an important goal, most providers have already purchased CEHRT.¹² Furthermore, several federal agencies and programs require the use of CEHRT. The EHR Reporting Program should provide transparent information that provides data about product performance to ensure next generation product improvements are based on real-world data. **We urge ONC to provide details about how the data will be collected, reported, and disseminated. We also recommend that the dissemination processes enable a side-by-side comparison across EHR products and measures.**

⁴ <https://www.pewtrusts.org/-/media/assets/2020/04/effective-reporting-could-improve-safe-use-of-electronic-health-records.pdf>

⁵ <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2018.0699>

⁶ Ratwani RM, Hodgkins M, Bates DW. Improving Electronic Health Record Usability and Safety Requires Transparency. JAMA. 2018;320(24):2533–2534. doi:10.1001/jama.2018.14079

⁷ Lisette C. Roman, Jessica S. Ancker, Stephen B. Johnson, Yalini Senathirajah, Navigation in the electronic health record: A review of the safety and usability literature, Journal of Biomedical Informatics, Volume 67, 2017, Pages 69-79, ISSN 1532-0464, <https://doi.org/10.1016/j.jbi.2017.01.005>.

⁸ Aaron Z Hettinger, Edward R Melnick, Raj M Ratwani, Advancing electronic health record vendor usability maturity: Progress and next steps, Journal of the American Medical Informatics Association, Volume 28, Issue 5, May 2021, Pages 1029–1031, <https://doi.org/10.1093/jamia/ocaa329>

⁹ Sittig DF, Singh H. Policies to Promote Shared Responsibility for Safer Electronic Health Records. JAMA. Published online September 10, 2021. doi:10.1001/jama.2021.13945

¹⁰ Lowry, S., Quinn, M., Ramaiah, M., Schumacher, R., Patterson, E., North, R., J., C., M. and P. (2012), (NISTIR 7804) Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records, NIST Interagency/Internal Report (NISTIR), National Institute of Standards and Technology, Gaithersburg, MD, [online], <https://doi.org/10.6028/NIST.IR.7804>

¹¹ <https://www.nist.gov/programs-projects/safety-related-usability-framework>

¹² <https://dashboard.healthit.gov/apps/health-information-technology-datasummaries.php?state=National&cat9=all+data#summary-data>

Additional Comments

Below we offer comments about specific proposed measures and domains.

Domain: Patient Access

- Patient Access to electronic health information (EHI)
- Sustained Usage
- Privacy Policy

We urge ONC to clarify how the EHR Reporting Program will evolve to reflect revisions or updates to related regulations (for example, changes to the definition of electronic health information; updates to the U.S. Core Data for Interoperability (USCDI)). ONC should clarify how the proposed measures for access to EHI and sustained usage will be used indicate how well EHRs are making data elements available and adopting interoperability standards. The extent to which high levels of patient engagement with their electronic health data will inform their future decisions to use patient-facing apps (such as to submit self-reported data), and premier recommends that ONC further how to integrate patient reported data into EHRs. We note that the privacy policy measure could likely be covered/mandated by ONC certification requirements rather than in a separate reporting program, especially since proposed Numerator 2 inquires if privacy policies align with Cures Act provisions. We recommend that the proposed measure for privacy be removed.

Domain: Public Information Exchange

- Vaccination/Immunizations
- Immunization Forecasts

The need for and ability of EHRs to transmit data from providers to public health authorities became urgent during COVID-19. Data on vaccinations and immunizations is critical if the U.S. is seeking to have centralized vaccination records for COVID tracking or other public health concerns where vaccination is vital to public health. However, we are concerned about the limited availability and potential associated costs of EHR functionality (including by integrating third party applications) to support mandatory public health data reporting between providers and public health authorities.

Integrating and sharing data between various Immunization Information Systems (IIS) is and will remain a challenge. We urge ONC to undertake additional efforts to promote interoperability standards between healthcare providers, independent immunization information systems (IISs) and health information exchanges (HIEs) to align with the standards EHRs must adopt (e.g., FHIR APIs).

Domain: Clinical Care Information Exchange

The proposed measures focus on the (g)(10) standards-based API module and use by clinician-facing applications. This seems to duplicate requirements for Real-World Testing (RWT). Premier recommends that ONC consider how to better leverage data from EHR vendor RWT processes.

Domain: Standards Adoption

We believe that some of the proposed measures appear to duplicate the Real-World Testing program efforts to address the usability and availability of FHIR APIs/profiles and we recommend that ONC address any unintended redundancies. Additionally, we are concerned that the counts of apps using FHIR, number of calls, and breakdown of Core/Non-Core profile usage, while informative, do not go far enough to provide a clear picture of the true availability of FHIR in the real-world.

While some EHRs support FHIR for single-patient use cases, it is not currently a viable method for health systems and practices for transferring their clinical data to third party vendors or submission bodies for population health or analytics use cases. We are concerned about the impact on system/network performance if they use single patient API calls to transmit large volumes of data. Additionally, there are no standard mechanisms to indicate when a patient has updated data (or updated data elements) for a third party to know what has changed or to limit the scope of an API call to reduce the size of the patient resources being requested.

Bulk FHIR is not yet widely adopted and in the cases where it may be supported by EHR vendors, some EHR vendors' practices restrict and limit bulk FHIR access (e.g., weekly), thus compromising data quality, data availability and the providers' ability to synchronize multiple data warehouses. Until the usability and adoption of bulk FHIR improves, it remains a barrier to interoperability and the measures proposed do not directly address these issues.

Conclusion

The Premier healthcare alliance appreciates the opportunity to submit comments regarding health IT developer measures for the 21st Century Cures Act Electronic Health Record Reporting Program. Premier shares the vision of achieving nationwide interoperability to enable an interoperable, learning healthcare ecosystem. Premier hopes our comments are helpful as you continue this important work. Premier stands ready to actively participate in ONC's efforts to develop, finalize and implement the EHR Reporting Program. If you have any questions regarding our comments or need more information, please contact me at blair_childs@premierinc.com or 202.879.8009 or Meryl Bloomrosen, Senior Director, Federal Affairs, at meryl_bloomrosen@premierinc.com or 202.879.8012. We look forward to continued participation and dialogue. Thank you again for providing us the opportunity to provide comments.

Sincerely,



Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance