October 17, 2018

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National Coordinator for Health Information Technology
Office of the National Coordinator (ONC)
U.S. Department of Health & Human Services

Submitted electronically at: http://www.regulations.gov

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

Dear Dr. Rucker:

On behalf of the 4,000 U.S. hospitals and more than 165,000 other providers and organizations in the Premier healthcare alliance (Premier), we are pleased to submit these comments in response to the Office of the National Coordinator's (ONC) Request for Information (RFI) Regarding the 21st Century Cures Act (Cures) Electronic Health Record (EHR) Reporting Program. The Premier healthcare alliance, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive and largest healthcare databases in the industry. Premier works with its members on utilizing informatics, analytics, and data to improve care quality and patient safety, while achieving cost efficiencies. With integrated data and analytics, collaboratives, supply chain solutions, and advisory 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.

In the comments below, we summarize Premier's longstanding support for interoperability across the healthcare continuum, offer general observations and recommendations about the RFI and provide comments in response to several of ONC's specific questions about the EHR Reporting Program.

Ongoing Support for Interoperability

Premier healthcare alliance supports efforts to transform healthcare through the power of data and health information technology (IT). It is essential to address ongoing interoperability challenges so that providers can improve care delivery, patient safety and performance, and to drive operational efficiencies. Premier continues to advocate for, develop and implement innovative solutions to achieve open data access across health IT systems and technologies to support the industry's value-based care transition across the care continuum. Members of the Premier healthcare alliance need robust, scalable, and interoperable health IT systems and electronic health records (EHRs) to improve clinical decision making and deliver improved outcomes. Interoperability will enable systems to move beyond simply recording data in EHRs toward integrating and combining data to streamline analytics on supply chain, financial, public and population health and clinical care for evidence-based decision-making.

Without connectivity across the care continuum, data collection is fragmented and does not provide the total picture necessary for healthcare providers to deliver informed, coordinated care. Further, the movement towards value-based care and alternative payment models has created an even greater imperative for health information exchange and interoperability. Advanced payment models such as ACOs and bundled payments involve participation by multiple providers, suppliers and sometimes payers who are at risk for the cost and quality of care of their patients. Coordinating the care of patients requires

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the ability to access and aggregate information from different EHRs and health information technology applications across multiple facilities and care settings.

Premier healthcare alliance strongly supports the development and implementation of an efficient and effective infrastructure for health information exchange across the care continuum. Hospitals, health systems and clinicians continue to make significant investments in certified EHRs. Providers need comprehensive, up-to-date, understandable and usable information so that they can make more informed decisions about system acquisition, maintenance, reliability, and functionality.

Scope of the RFI

The 21st Century Cures Act (Cures) requires the development of an Electronic Health Record Reporting Program and explicitly requires vendor reporting about health information technology usability, interoperability, and security. Providers need reliable, robust and transparent information about EHRs' usability, functions and interoperability, thus timely implementation of this Cures provision is critical and long overdue. Premier believes that the EHR Reporting Program provides an opportunity for ONC to go beyond simply providing data that helps users make more informed decisions about EHR acquisition, upgrade, enhancement and/or replacements. We urge **ONC to leverage the EHR Reporting Program to collect and curate comparative information to improve CEHRT interoperability, usability, safety and security in the real world.**

The RFI states that "the term "certified health information technology (IT)" includes the range of potential technologies, functions, and systems for which HHS has adopted standards, implementation specifications, and certification criteria under the ONC Health IT Certification Program. We **urge ONC to consider the dynamic nature of the health IT technology and regulatory environment as it develops and implements the EHR Report Program**. Specifically, the development, implementation, and adoption of technical, vocabulary and content standards, implementation specifications and certification criteria change over time; the number and types of "certified health IT" changes and the overall ONC Health IT Certification Program evolves. Certified health IT includes full EHRs (base EHR functionality) as well as modules (some of which when combined together may provide base EHR functionality). We support the EHR Reporting Program required reporting criteria enumerated in Cures: security, usability and user-centered design, interoperability, conformance to certification testing, and other factors necessary to measure the performance of EHR technology.

We offer the following comments about some of the required reporting criteria:

- *Interoperability.* Premier believes that it is essential to enact policies to require interoperability standards in EHRs so that providers can access data from any EHR system and unlock the true potential of coordinated, high-quality, cost-effective healthcare. In prior submissions to ONC, Premier expressed support for having criteria that certified health information technology would need to meet (via demonstration not only self-attestation) to be considered interoperable and standards that set forth the categories and domains of interoperability for EHR vendors.[1] [2]
- *Usability and user-centered design*. Premier urges ONC to continue efforts to develop tools for usability testing and evaluation and to ensure that EHR developers incorporate user-centered design principles into their product lifecycle. [3] [4] We also recommend that ONC's EHR Reporting

[1] Premier comments on ONC Interoperability Roadmap April, 2015 https://www.premierinc.com/transforming-healthcare/healthcarepolicy/hit-privacy/
[2] Premier MTIC comments to JASON task force September, 2014 https://www.premierinc.com/transforming-healthcare/healthcarepolicy/hit-privacy/
[3] Turf. EHR Usability Toolkit. https://sbmi.uth.edu/nccd/turf/
[4] University of Maryland's Human-Computer Interaction Lab. http://www.cs.umd.edu/hcil/sharp/

Program leverage ongoing work addressing usability and potential patient safety issues. [5] [6] [7] [8] [9] [10] [11] [12]

- *Security.* As part of the 2015 Certification Criteria[13], ONC noted that it had adopted "a new, simpler, straight-forward approach to privacy and security certification requirements for Health IT Modules certified to the 2015 Edition" and recommend that ONC revisit that decision. Given ongoing concerns about healthcare industry security challenges, threats and vulnerabilities[14], Premier recommends that ONC leverage existing techniques and research [15] [16] to further develop and implement specific reporting criteria for EHR security.

Premier recommends that ONC first **focus the EHR Reporting Program on obtaining vendor data about certified EHRs in ambulatory and inpatient settings and those EHRs that are used to fulfill CMS and other federal reporting and administrative programs, especially the Promoting Interoperability Programs.** Additionally, we recommend that **ONC establish reporting criteria for certified products that meet the "base" EHR definition.**[17] We urge ONC to require a common set of required reporting criteria to be reported by EHR vendors and to add setting-specific criteria (such as for small and rural providers; long-term post-acute care (LTPAC); behavioral health; and pediatrics) as appropriate.

Timeline for Implementation

Achieving interoperability across the care continuum and ensuring data availability at the point of care and within the clinical workflow must be a top ONC priority. To help providers select and measure performance of EHR products, Cures requires that the EHR Reporting Program include product features and capabilities. Implementation of this Cures requirement is long overdue. We are concerned that during the public ONC informational webinar about the RFI, ONC indicated that its timeline to implement the EHR Reporting Program was at least two years. **Premier believes that the proposed two-year implementation timeline is inconsistent with Cures' intentions and non-responsive to providers' immediate needs.** Providers need reliable, robust and transparent information about certified EHRs. **Premier urges ONC to accelerate its timeline to implement the EHR Reporting Program.** We recommend that ONC **incrementally implement the EHR Reporting Program,** to allow time for pilot testing (across various provider settings and users) of proposed criteria. We urge ONC to ensure broad information dissemination as the Program is developed and implemented and offer ongoing stakeholder awareness and education about the EHR Reporting Program.

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[5] https://www.nist.gov/programs-projects/health-it-usability
[6] https://www.nist.gov/sites/default/files/documents/2017/05/09/NISTIR-7804.pdf
[7] https://healthit.ahrq.gov/sites/default/files/docs/citation/EHR_Usability_Toolkit_Background_Report.pdf
[8] https://healthit.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/examples/usability
[9] http://www.bordamed.com/attachments/EHR_Usability.pdf
[10] https://www.pewtrusts.org/~/media/assets/2016/08/usability_conference_fs.pdf
[11] https://www.pewtrusts.org/en/research-and-analysis/reports/2018/08/28/ways-to-improve-electronic-health-record-safety
[12] https://academic.oup.com/jamia/article/20/e1/e2/692244
[13] https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base
[14] https://www.phe.gov/preparedness/planning/CyberTF/Pages/default.aspx
[15] Kruse, C. S., Smith, B., Vanderlinden, H., & Nealand, A. (2017). Security Techniques for the Electronic Health Records. Journal of Medical Systems, 41(8), 127. http://doi.org/10.1007/s10916-017-0778-4
[16] Fernández-Alemán JL(1), Señor IC, Lozoya PÁ, Toval A. J Biomed Inform. 2013 Jun;46(3):541-62. doi: 10.1016/j.jbi.2012.12.003. Epub 2013 Jan 8. Security and privacy in electronic health records: a systematic literaturereview..
[17] https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base

Provider (user) Burdens

Existing policy levers and incentives continue to unfairly target and penalize providers (i.e., hospitals, health systems and clinicians). Premier believes that EHR vendors should be held accountable for demonstrating and assuring interoperability. Stimulus funding (government supported $30 billion) flowed to EHR vendors, while the penalties and burdens for not implementing certified technology and achieving interoperability remains with providers, creating provider dependence on EHR vendors. Legacy EHR platforms impede and/or do not allow real time data flow to/from EHRs and clinical workflow. Furthermore, EHR vendors retain practical control over clinical data, limiting third party app development and innovation and provider data access.[18] [19]

The RFI poses several questions suggesting that ONC is considering various mechanisms to obtain provider (end user) feedback about EHRs. **Premier does not support any new or additional provider reporting or data collection requirements as part of the EHR Reporting Program.** Rather, we urge ONC to **require EHR vendors to demonstrate interoperability, usability, security and their platforms' conformance to standards**.as part of a more robust certification, testing and surveillance programs (described below in greater detail).

Premier believes that **ONC should minimize any provider reporting requirements outside of data already reported as part of federal programs** (such as Medicare's Promoting Interoperability Program for hospitals and the Quality Payment Program under the physician fee schedule). ONC should consider using self-reported (provider/end user) data from existing national surveys.[20] [21] To obtain user feedback about EHRs, we believe that **subjective product reviews and rankings of certified health IT should continue to be the purview of the private sector – professional and trade associations and professional societies that best understand the needs of their constituents.**[22]

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)." ONC develops the functional and conformance testing requirements for the testing and certification of health IT to the certification criteria, implementation specifications, and standards. **We urge ONC to integrate and align the EHR Reporting Program requirements within the conditions and maintenance of certification, testing and surveillance program(s).**

We also recommend that ONC 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 FHIR versioning, resources).

We **urge ONC to expand and enhance the testing and certification process beyond the initial product submission in order to ensure compliance throughout the life cycle of the product.** As we have stated in response to other ONC and CMS requests for comments and information, Premier believes that CEHRT products should be recertified to a new version of CEHRT shortly after the new version is available; for example, within 12 to 18 months depending upon the complexity of the new CEHRT requirements. Ensuring CEHRT is up to date enables providers to more easily meet CMS and

[18] https://jamanetwork.com/journals/jama/fullarticle/2707668
[19] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4556429/
[20] https://www.cdc.gov/nchs/ahcd/ahcd_products.htm
[21] https://www.cdc.gov/nchs/data/ahcd/2017_NEHRS_Sample_Card.pdf
[22] https://www.healthit.gov/sites/default/files/macraehrpct_final_4-2016.pdf

ONC reporting requirements. We caution that new CEHRT versions should be major revisions that address overarching health IT goals and impact storing, collecting and transferring data. Requiring vendors to regularly recertify to new CEHRT versions with minor changes will be a significant financial burden to providers as vendors often pass on recertification costs to providers.

ONC-Authorized Testing and Certification Body (ONC-ATCB) Certification and Surveillance

ONC-ACBs [23] are required to report information to ONC for inclusion in the open data file that comprises the Certified Health IT Product List (CHPL). ONC adopted new requirements[24] for "in-the-field" surveillance under the ONC Health IT Certification Program to clarify and expand ONC-ACBs' existing surveillance responsibilities by specifying requirements and procedures for in-the-field surveillance. ONC's current surveillance program focuses on responding to complaints and non-conformance with certification criteria to help ensure that certified products and capabilities meet certification requirements, "in-the-field."[25]

In September 2017, ONC exercised enforcement discretion and noted that it will not, until further notice, audit ONC-ACBs for compliance with randomized surveillance requirements.[26] **We urge ONC to re-consider implementing its audits of ONC-ACBs and/or or implement a similar mechanism to ensure that ONC-ACBs conduct randomized in-field surveillance of certified EHRs.** Premier believes that the implementation of the EHR Reporting Program offers ONC an opportunity to **enhance and refine the in-field surveillance program.**[27] Furthermore, we recommend that **ONC align EHR Reporting Requirements (i.e., usability, security, interoperability and conformance with testing) with the in-the-field surveillance program.**

Adoption and Use of Standards with CEHRT

Nationwide interoperability requires the development, adoption and consistent implementation of data and interoperability standards. Yet EHRs do not uniformly collect, define or present data. A common or core data set is insufficient to achieve interoperability. ONC needs to call for the use of standard clinical terminologies, vocabularies and data formats in addition to agreed-upon data exchange methodologies. **We urge ONC to advance policies (i.e., certification and EHR Reporting criteria) that include specific interoperability standards (transport, syntax, and sematic) along with technical implementation specifications for EHRs.** Significant challenges exist regarding standards such as variability in EHR vendor implementation of standards; insufficiencies in interoperability standards; lack of attention to semantic interoperability standards; and inconsistent use of terminologies and formats. Information that is electronically exchanged from one provider to another should adhere to the same standards, and these standards should be implemented uniformly (within EHRs), in order for the information to be understandable and usable, thereby enabling interoperability.[28]

We urge ONC to continue to **encourage consistent standards implementation, reduce implementation variability, and improve modularity in health data standards for terminology and vocabulary, coding, data content and format, transport, and security**.[29] Lacking such improvements

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[23] https://www.healthit.gov/sites/default/files/policy/2015-11-02_supp_cy_16_surveillance_guidance_to_onc-acb_15-01a_final.pdf
[24] https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base
[25] https://www.healthit.gov/topic/certification-ehrs/surveillance-and-oversight
[26] https://www.healthit.gov/topic/certification-ehrs/onc-acb-surveillance
[27] https://www.healthit.gov/sites/default/files/page/2018-10/SurveillanceResource_1.pdf
[28] ELECTRONIC HEALTH RECORDS Nonfederal Efforts to Help Achieve Health Information Interoperability Report to Congressional Requesters. United States Government Accountability Office. September 2015 https://www.gao.gov/assets/680/672585.pdf
[29] https://dashboard.healthit.gov/strategic-plan/federal-health-it-strategic-plan-goals.php

to the standards, providers will not have the data for true coordinated, high-quality, cost-effective healthcare. **ONC needs to take actions to advance the development, adoption and use of industry-recognized data definitions and data normalization standards,** including the implementation and use of vocabularies, code sets, and value sets. Currently, providers and clinicians are unable to incorporate electronic information received into their EHR due to the limitations of the EHR itself (i.e., incongruent implementation of standards, misaligned standards, semantics, and inconsistent implementation of standards specifications) all hindering data flow and impeding useable and understandable data across EHRs and other health information technologies and systems.

Leverage and Enhance Existing ONC Informational Resources

ONC currently provides a number of disparate resources on its website, including the Health IT Playbook[30]; the Interoperability Standards Advisory (ISA); and the Certified Health IT Product List (CPHL). **We encourage ONC to obtain user feedback about existing ONC-informational resources and then enhance each of these resources so that they are more useful as stand-alone information sources.** ONC could also "combine" existing information in new, more usable and understandable ways to help fulfill the requirements for the EHR Reporting Program.

- ONC's Interoperability Standards Advisory (ISA) The existence of standards and the publication of the ISA does not by itself ensure that application developers and health IT vendors implement and configure their software using the standards. It appears that the ISA is most directly "targeted" to/designed for fairly technical audiences. We believe that a "plain language" version would be helpful to convey the high level concepts and rationale for use across the diverse audiences of non-technical stakeholders. We also recommend that ONC include examples to depict the use of each type of different standard. We believe that "translating" the ISA for non-technical stakeholders using examples most meaningful to each stakeholder type (clinician; researcher; administrator) will help further disseminate information about and use of the ISA.

- ONC's Certified Health IT Product List (CPHL). The CPHL lists health IT that have been tested and certified under the ONC Health IT Certification Program. ONC compiles information submitted from ONC-Authorized Certification Bodies (ONC-ACBs) and generates the public List of Certified Health IT products. It appears that the CPHL, is most directly "targeted" to/designed for more technical audiences. While the list was intended to provide "more transparent data about the health IT marketplace can promote competition, discourage information blocking, and make developers accountable to the needs of healthcare professionals and other health IT purchasers," **Premier believes that significant improvements are needed to make this list more robust, user friendly, useful and understandable.**

  The CPHL is a good start but is not a practical nor adequate mechanism for disseminating comparative information about certified EHR products. **ONC should enhance this resource as a fully descriptive and searchable inventory of certified EHRs**. For example, under certification rules established by ONC in January 2016, developers must publicly disclose detailed information about their certified health IT products, including limitations and types of costs that a purchaser or user may encounter in the course of implementing or using the developer's technology.[31] Developers must also make a Transparency Attestation indicating whether they will take additional voluntary actions to increase transparency regarding their products and business practices. While these Transparency Attestations and Developers' Disclosures must be prominently displayed on their websites and in their marketing materials, there is wide variation in what information is provided and how it is formatted and displayed. **EHR vendors should be**

[30] https://www.healthit.gov/topic/safety/selecting-or-upgrading-health-it
[31] https://www.healthit.gov/sites/default/files/policy/2015-11-02_supp_cy_16_surveillance_guidance_to_onc-acb_15-01a_final.pdf

required to report this information in a consistent manner and to update the information regularly. Premier urges ONC to require more consistent and descriptive information about EHR vendors' material limitations and types of costs associated with third party vendor's application integration, demonstration of interoperability, API functionality and app integration capabilities. This will help to ensure an open marketplace, ongoing innovation and a robust app ecosystem.

ONC RFI Questions

ONC invited stakeholder feedback on questions regarding their potential approach. In the chart below we provide brief responses to selected questions.

Comments in Response to ONC RFI EHR Reporting Program	
Existing Data Sources	**Comments**
1. Please identify any sources of health IT comparison information that were not in the EHR Compare Report that would be helpful as potential reporting criteria are considered. In addition, please comment on whether any of the sources of health IT comparison information that were available at the time of the EHR Compare Report have changed notably or are no longer available.	The resources included in the EHR Compare Report vary considerably. We urge ONC to undertake a more comprehensive review of these kinds of resources, including their information collection methodologies; scoring/rating criteria; inclusion/exclusion criteria; targeted audiences; purpose(s) of the materials; update processes/cycles; availability to the public; pricing for the information. ONC should also undertake a thorough environmental scan of other available and potentially applicable resources. We believe that ONC could include descriptive information and links to these types of resources as part of the EHR Reporting Program. However, we do not believe that these [types of] resources sufficiently meet the intent of Cures' provisions for ONC to develop and implement an EHR Reporting Program. Nevertheless, various stakeholders and segments of the healthcare community may be unaware of resources so including them would be beneficial.
2. Which, if any, of these sources are particularly relevant or should be considered as they relate to certified health IT for ambulatory and small practice settings?	Premier asks ONC to consider to what extent it could leverage any information or materials from the Regional Extension Centers (RECs) that were beneficial in helping providers adopt and implement certified health IT. We also suggest that ONC reach out directly to professional and trade associations that represent ambulatory and small practice settings.
3. What, if any, types of information reported by providers as part of their participation in HHS programs would be useful for the EHR Reporting Program (e.g., to inform health IT acquisition, upgrade, or customization decisions)?	See body of letter
4. What data reported to State agencies (e.g., Medicaid EHR Incentive Program data), if	See comments in letter

available nationally, would be useful for the EHR Reporting Program	
Data Reported by Health IT Developers versus End-Users	
5. What types of reporting criteria should developers of certified health IT report about their certified health IT products:	See comments in letter
6. That would be important to use in identifying trends, assessing interoperability and successful exchange of health care information, and supporting assessment of user experiences?	See comments in letter
7. That would be valuable to those acquiring health IT in making health IT acquisition, upgrade, or customization decisions that best support end users' needs?	See comments in letter
8. What types of reporting criteria for health care providers, patients, and other users of certified health IT products would be	See comments in letter
9. What kinds of user-reported information are health IT acquisition decision makers using now; how are they used in comparing systems; and do they remain relevant today?	A variety of information and data sources are used, including first hand discussions with colleagues and other health IT users.
10. What types of reporting criteria would be useful to obtain from both developers and end users to inform health IT comparisons? What about these types of reporting criteria makes them particularly amenable to reporting from both the developer and end user perspective? most useful in making technology acquisition, upgrade, or customization decisions to best support end users' needs?	See comments in letter
User-Reported Criteria	
11. How can data be collected without creating or increasing burden on providers?	ONC should minimize any additional provider reporting requirements outside of data already reported as part of federal programs (such as Promoting Interoperability; QPP). We recommend that ONC rely on self-reported data from national

	surveys and federal reporting requirements. The national surveys include data from office-based physicians, hospitals, individuals and a subset of providers in long-term care settings. Other options for user (provider) data includes leveraging data already provided federal Promoting Interoperability reporting requirements.
12. What recommendations do stakeholders have to improve the timeliness of the data so there are not significant lags between its collection and publication?	See comments in letter
13. Describe the value, if any, in an EHR Reporting Program function that would display reviews from existing sources, or provided a current list with hyperlinks to access them.	Providing a list of currently available comparative data from other [publicly available] resources might be helpful; however, such resources would be inadequate as the EHR Reporting System by themselves.
14. Discuss the benefits and limitations of requiring users be verified before submitting reviews. What should be required for such verification?	See comments in letter
15. Which reporting criteria are applicable generally across all providers? What reporting criteria would require customization across different provider types and specialties, including small practices and those in underserved areas?	See comments in letter
16. For what settings (e.g., hospitals, primary care physicians, or specialties) would comparable information on certified health IT be most helpful? If naming several settings, please list in your order of priority.	See comments in letter
17. How helpful are qualitative user reviews (such as 'star ratings' or Likert scales) compared to objective reports (e.g., that a system works as expected with quantifiable measures)? Which specific types of information are better reflected in one of these formats or another?	See comments in letter

18. How could HHS encourage clinicians, patients, and other users to share their experiences with certified health IT?	As stated in the ONC 2016 report, [32] we believe that subjective product reviews and rankings of certified health IT should continue to be the purview of the private sector – the professional and trade associations and professional societies that best understand the needs of their constituents.
Health IT Developer-Reported Criteria	
19. If you have used the certified health IT product data available on the ONC Certified Health IT Products List (CHPL) to compare products (e.g., to inform acquisition, upgrade, or customization decisions), what information was most helpful and what was missing? If providing a brief list of the information, please prioritize the information from most helpful to least helpful also considering their grouping into categories in Section IV.	See comments in letter
20. Would a common set of criteria reported on by all developers of certified health IT, or a mixed approach blending common and optional sets of criteria, be more effective as we implement the EHR Reporting Program?	We urge ONC to require a minimum set of common data to be reported by EHR vendors.
21. What developer-reported criteria are particularly relevant, or not relevant, to health IT users and acquisition decision makers in the ambulatory and small practice settings?	We urge ONC to require a minimum set of common data to be reported by EHR vendors and to add setting-specific criteria as appropriate.
22. Which criteria topics might be especially burdensome or difficult for a small or new developer to report on?	See comments in letter
23. What types of criteria might introduce bias (e.g., unfair advantage) in favor of larger, established developers or in favor of small or new developers?	See comments in letter
24. In what ways can different health IT deployment architectures be accommodated?	We urge ONC to require a minimum set of common data to be reported by EHR vendors and to add health IT deployment approach- specific criteria if required and as appropriate.

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

For instance, are there certain types of criteria that cloud-based certified health IT developers would be better able to report on versus those who are not cloud-based? How might this affect generating and reporting information on criteria?	
Categories for the EHR Reporting Program	
25. What categories of reporting criteria are end users most interested in (e.g., security, usability and user centered design, interoperability, conformance to certification testing)? Please list by priority.	We believe that each of the required reporting criteria are high priority.
Security	
26. What reporting criteria could provide information on meaningful differences between products in the ease and effectiveness that they enable end users to meet their security and privacy needs?	We urge ONC to leverage efforts underway (such as those undertaken by NIST and the Cyber Security Health Sector Coordinating Council) to identify key priority reporting criteria for security.
27. Describe other useful security and privacy features or functions that a certified health IT product may offer beyond those required by HIPAA and the ONC Health IT Certification Program, such as functions related to requirements under 42 CFR Part 2.	We urge ONC to leverage efforts underway (such as those undertaken by NIST and the Cyber Security Health Sector Coordinating Council) to identify key priority reporting criteria for security.
Usability and User-Centered Design	
28. How can the usability results currently available in the CHPL best be used to assist in comparisons between certified health IT products?	See comments in letter
29. Describe the availability and feasibility of common frameworks or standard scores from established usability assessment tools that would allow acquisition decision makers to compare usability of systems.	See comments in letter

30. Discuss the merits and risks of seeking a common set of measures for the purpose of real world testing that health IT developers could use to compare usability of systems. What specific types of data from current users would reflect how well the certified health IT product:	See comments in letter
31. Supports the cognitive work of clinical users (e.g., displays relevant information in useful formats at relevant points in workflow)?	See comments in letter
32. Reflects the ability of implementers to make customization and implementation decisions in a user-centered manner?	See comments in letter
33. What usability assessment data, if available, are less resource intensive than traditional measures (e.g., time motion studies)?	See comments in letter
34. Comment on the feasibility and applicability of usability measures created from audit log data. How would health IT acquisition decision makers use this information to improve their system acquisition, upgrade, and customization decisions to best support end users' needs?	See comments in letter
35. Who should report audit log data and by what mechanism?	Premier recommends that ONC require EHR vendors to report audit log data via the ONC certification, testing and surveillance programs.
Interoperability	
36. Please comment on the usefulness of product integration as a primary means of assessing interoperability (as proposed in the EHR Compare Report).	Premier recommends that ONC require EHR vendors to demonstrate interoperability (the sending and receiving of data to and from EHRs) via the ONC certification, testing and surveillance programs.
37. What other domains of interoperability (beyond those already identified and referenced above) would be	Premier recommends that ONC require EHR vendors to demonstrate interoperability (the sending and receiving of data to and from EHRs) via the ONC certification, testing and surveillance programs.

useful for comparative purposes?	
38. Of the data sources described in this RFI, which data sources would be useful for measuring the interoperability performance of certified health IT products?	Premier recommends that ONC require EHR vendors to demonstrate interoperability (the sending and receiving of data to and from EHRs) via the ONC certification, testing and surveillance programs.
39. Comment on whether State Medicaid agencies would be able to share detailed attestation-level data for the purpose of developing reports at a more detailed level, such as by health IT product. If so, how would this information be useful to compare performance on interoperability across health IT products?	At this time, we do not believe that State Medicaid agency attestation level data would be useful to compare performance on interoperability across health IT products.
40. How helpful would CMS program data (e.g., Quality Payment Program MIPS Promoting Interoperability Category, Inpatient Hospital Promoting Interoperability Program, and Medicaid Promoting Interoperability Programs) related to exchange and interoperability be for comparative purposes? What measures should be selected for this purpose? Given that some of these data may be reported across providers rather than at the individual clinical level, how would this affect reporting of performance by health IT product?	It is possible that data from CMS programs could be useful to provide descriptive and aggregated information about Quality Payment Program, and/or Promoting Interoperability measures. However, Premier does not believe that such data should serve as indicators of EHR data exchange or interoperability; nor should such data be used in lieu of vendors' providing EHR data directly.
41. What other data sources and measures could be used to compare performance on interoperability across certified health IT products?	Premier recommends that ONC require EHR vendors to demonstrate interoperability (the sending and receiving of data to and from EHRs) via the ONC certification, testing and surveillance programs.
Conformance to Certification Testing	
42. What additional information about certified health IT's conformance to the certification testing (beyond what is currently available on the	See comments in body of letter. As currently organized and presented, we do not believe that the CPHL adequately serves as a user friendly source of comparative data about certified EHRs.

CHPL) would be useful for comparison purposes?	
43. What mechanisms or approaches could be considered to obtain such data?	See comments in letter
44. What barriers might exist for developers and/or end users in reporting on such data?	ONC should minimize any additional provider (end users) reporting requirements outside of data already reported as part of Federal programs (such as Promoting Interoperability; QPP). We recommend that ONC rely on provider self-reported data from national surveys and federal reporting requirements. The national surveys include data from office-based physicians, hospitals, individuals and a subset of providers in long-term care settings. Other options for user (provider) data includes leveraging data already provided federal Promoting Interoperability reporting requirements.
Other Categories for Consideration	
45. How should the above categories be prioritized for inclusion/exclusion in the EHR Reporting Program, and why? What other criteria would be helpful for comparative purposes to best support end users' needs (e.g., to inform health IT acquisition, upgrade, and implementation decisions)?	ONC could consider asking EHR vendors to provide screen shots for certification criteria/functions; and copies of EHR vendor standard contract terms and conditions.
46. What data sources could be used to compare performance on these categories across certified health IT products?	See comments in letter
47. Please comment on different types of information, or measures, in this area that would be useful to acquisition, upgrade, and customization decisions in the ambulatory setting as opposed to inpatient settings?	See comments in letter
Other Questions	
48. Please comment on the usefulness and feasibility of including criteria on quality reporting and population health in the EHR Reporting Program. What criteria should be considered to assess health IT performance in generating quality measures, reporting quality measures, and the	See comments in letter

functions required for supporting population health analytics (e.g., bulk data export)?	
49. What data sources, if any, are available to assess certified health IT product capabilities and performance in collecting, generating, and reporting on quality measures, and the ability to export multiple records for population health analytics? Are these data sources publicly available?	See comments in letter
50. Please comment on other categories, if any, besides those listed in this RFI that should be considered to be included in the EHR Reporting Program. Why should these be included, and what data sources exist to report on performance for the suggested categories?	See comments in letter
Hospitals and Health Systems	
51. Please describe the types of comparative information about certified health IT hospitals and health systems currently use (e.g., to inform health IT acquisition, upgrade, and customization decisions). What are the sources of this information? What information would be useful but is currently unavailable?	See comments in letter
52. What types of comparative information about certified health IT, if any, are specifically useful to hospitals and health systems, as opposed to ambulatory or small practices? What types of information could be collected or reported that would be helpful to both hospitals and health systems and to ambulatory and smaller providers?	See comments in letter
53. Please comment on how an EHR Reporting Program could best reflect the information	We urge ONC to require a minimum set of common data (reporting criteria) to be reported by EHR vendors and to add setting-specific criteria as appropriate.

needed for hospitals and health systems, ambulatory and smaller provider settings, and overlapping information in developing summary reports or comparison tools.	

Conclusion

The Premier healthcare alliance appreciates the opportunity to submit comments regarding the 21st Century Cures Act Electronic Health Record Reporting Program Premier shares the vision of achieving nationwide interoperability to enable an interoperable, learning health 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 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 Inc.