33 W Monroe, Suite 1700
Chicago, IL 60603
swillis@ehra.org
Phone: 312-915-9518
Twitter: @EHRAssociation

October 17, 2018

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

Dear Dr. Rucker,

Thank you for the opportunity to comment on the EHR Reporting Program. On behalf of the 35 member companies in the Electronic Health Record Association (EHRA), it is our pleasure to submit detailed responses to ONC's recent request for information (RFI) regarding the 21st Century Cures Act Electronic Health Record Reporting Program, published in the Federal Register on August 24, 2018.

Established in 2004, EHRA brings together companies that develop, market, and support electronic health records (EHRs) to collaborate on issues that impact our businesses and our collective customers — hospitals and providers that represent the majority of EHR users in the U.S. We work together to speak with a unified voice on these topics in a non-competitive, collegial effort to understand, educate, and collaborate with all stakeholders engaged with EHRs and health information and technology.

Our detailed comments on the RFI follow.

We thank you for considering our perspective as you make updates to the EHR Reporting Program.

Sincerely,

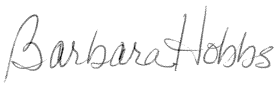
Cherie Holmes-Henry
Chair, EHR Association
NextGen Healthcare

Sasha TerMaat
Vice Chair, EHR Association
Epic

HIMSS EHR Association Executive Committee

Hans J. Buitendijk
Cerner Corporation

Nadeem Dhanani, MD, MPH
Modernizing Medicine



Barbara Hobbs
MEDITECH, Inc.

Rick Reeves, RPh
Evident

Courtney E. Tesvich, RN
Nextech

About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

Existing Data Sources

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.

EHRA is unaware of any new resources and believes the current resources to be active.

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?

EHRA believes that rural ambulatory and small practice settings would benefit most from low to no-cost comparison tools. We feel it would be best to promote sites that provide information related to practice size, specialty, etc. to ensure the needs of the majority of consumers can be met.

De-Duplication of Reported Data

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)?

The Health IT Dashboard provides a number of datasets, including the ability to see which providers have successfully attested and the CEHRT they claimed to use. This is an example of information that is publicly available, though few in the public healthcare consumer sector are aware of its existence. Also, EHRA believes it would be helpful for decision makers to know which optional measures are being successfully attested to.

What data reported to State agencies (e.g., Medicaid EHR Incentive Program data), if available nationally, would be useful for the EHR Reporting Program?

Should state agencies have this level of information, it could be another mechanism to help drive comparison data.

Data Reported by HIT Developers vs End-Users

What types of reporting criteria should developers of certified health IT report about their certified health IT products:

- ***That would be important to use in identifying trends, assessing interoperability and successful exchange of health care information, and supporting assessment of user experiences?***
- ***That would be valuable to those acquiring health IT in making health IT acquisition, upgrade, or customization decisions that best support end users' needs?***

Currently, the 2015 Edition Safety-Enhanced Design (SED) data, including Likert scale information which includes subjective user experience, is available via the CHPL. However, users must drill down into the site to find this information. Having the information more easily accessible would be helpful to users.

EHRA believes that compilation data on the number of client sites, electronic prescriptions, CCD exchanges, API calls, and apps in the developer's app store, could potentially be valuable to those acquiring CEHRT. However, this data must be tied to categories like specialty, practice size, etc. to ensure the data is kept in context.

What types of reporting criteria for health care providers, patients, and other users of certified health IT products would be most useful in making technology acquisition, upgrade, or customization decisions to best support end users' needs?

Existing information can be found in the transparency disclosures mandated by 2015 Edition certification. While this information is not populating the compare tool on CHPL, bringing more awareness to it by adding it to the CHPL compare tool could be assistive.

Additionally, the software that 2015 Edition CEHRT relied upon to achieve certification has recently been removed from the CHPL summary report, making this information more difficult for users to locate. EHRA believes that this information should be centralized on the Health IT Playbook website.

Also, there is attestation data reported by developers to their ACBs that is not publicly available, such as encryption and hashing algorithms used to comply with certification criteria.

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?

EHRA feels that the most-used public websites are KLAS, Blackbook, and Leapfrog. However, the majority of decision makers get their data through RFIs and reference site visits. Reference site visits and access to rank/file staff primarily drives transparency of feedback, with most of that feedback being anecdotal. The power of anecdotal feedback is invaluable to the process of selecting health IT.

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?

A variety of data is already available via the CHPL, including usability subjective task ratings, and other health IT comparison websites. This data could be even more useful to end users should additional

education and dissemination efforts be made to help consumers understand how to access and interpret the data.

Currently, no data exists on the CHPL that is specific to specialties or other small practices. EHRA recommends exploring what these questions may be and what may be helpful per specialty. After collection of the data, it could then be published on the Health IT Playbook site.

User-Submitted Information

How can data be collected without creating or increasing burden on providers?

EHRA strongly encourages the continued use of data already reported for the various federal programs. We believe that this data should be centralized and made available via the Health IT Playbook. Within that site, a webpage could be created with links to the various comparison tools.

What recommendations do stakeholders have to improve the timeliness of the data so there are not significant lags between its collection and publication?

Centralizing the data to ensure de-duplication of efforts would relieve provider reporting burden and should reduce publication lags. Additionally, the certification program already requires quarterly reporting by developers on transparency disclosures, limitations, and cost. CHPL data is submitted regularly by ACBs with very little time delay.

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.

EHRA strongly encourages using existing data sources, educating the healthcare industry about the availability of the data, and helping them understand how to interpret it. New data sources should be driven holistically by market need.

Discuss the benefits and limitations of requiring users be verified before submitting reviews. What should be required for such verification?

There is a pervasive concern throughout all industries of users providing reviews that are patently false or by users who have been paid for the review. While it may be difficult to ensure, EHRA recommends first verifying that the individual is a confirmed end-user of the CEHRT before submitting a review. There is legitimate concern that allowing unconfirmed reviews would place a great deal of burden on the developer to evaluate each review and rebut, when necessary. We feel that a similar method is already in place for the complaint review process.

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?

The existing CHPL data is useful for all providers, especially the accessibility-centered design (ACD) and SED data. Some of this data (e.g. eRx) could be more/less beneficial depending on practice specialty. EHRA believes there is additional attestation data that developers submit to ACBs, which is not currently available on the CHPL, and some of that data could be beneficial to providers across different specialties.

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.

The existing data is useful to all practice sizes, but it must be recognized that practice needs may vary greatly for each care setting or specialty. Comparable data is useful to those participating in the various federal programs as well. We suggest the ability to filter on program(s) that the site is participating in. EHRA firmly believes that the more a practice can filter on the data that pertains to them, the better able they are to get good information for comparison.

Additionally, specific hospital departments (e.g. Cardiac, NICU, ED, etc.) have high degree of customization in the products available to serve their needs. Developers could report on which services their product supports to better help with data filtering.

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?

Qualitative reviews can be very helpful, though there is always the high possibility of fake reviews. Also, the context of a review is important; based on the subjective nature of each response, the review may alter depending on the user's perspective. For example, a review from a specialist might be highly different from a generalist. Because of the variability, we have concerns whether the qualitative reviews would have enough metadata to discern this. It is vital to the healthcare industry that the view of a product/review is not distorted.

EHRA finds a star rating system to be least effective, as it encourages those with complaints to be the most likely to post. Providers do not support this type of rating for themselves and may be unsatisfied with this type of rating system for a CEHRT. If a rating system is utilized, EHRA would endorse one that has some type of algorithm/method behind the creation of the scale. The most expeditious pathway would be to find a scale that already exists rather than creating a new one. For example, the Likert scale, based on subjective user experience, is already available via the SED data on the CHPL.

How could HHS encourage clinicians, patients, and other users to share their experiences with certified health IT?

EHRA defers to those groups representing this demographic. However, we believe that this feedback should be shared with developers to ensure useful data is not obscured from them. Developers have a

strong desire to help their clients and remedy any issues. If the feedback received is lacking sufficient detail, it would be difficult to act upon. We envision that the proper hierarchy would be for the client to first report the issue to the developer and then escalate as needed. This system works well in the existing complaint process through the ONC Health IT Certification Program.

Finally, we would like to again remind that user data is already reported via the SED data on the CHPL.

Which particular reporting mechanisms, if any, should be avoided?

EHRA recommends avoiding star ratings, anonymous reporting, and duplication of existing and already reported data.

HIT Developer-Reported Information

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.

Already, there exists a large amount of information that may not be easily digestible by sites with limited technical knowledge or resources.

Most sites have not heard of the CHPL or the compare feature, though they do care about the certification status. Even then, they typically rely upon the developer to tell them whether they're certified rather than checking for themselves. Anecdotal feedback from reference sites appears to be the most frequently used in informing acquisition, upgrade, or customization decisions.

EHRA has found that the transparency disclosures are not part of the CHPL Compare report, and we recommend adding each product's transparency disclosure URL to this function. Additionally, relied upon software is not easily accessible either and would benefit from being part of the compare function.

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?

There is already a wealth of information available on the CHPL, including the criteria to which each product has been certified. Before being able to respond to the effectiveness of creating a common set of criteria beyond what is already reported, EHRA would need more clarification on what these criteria would be.

One recommendation is to conduct primary market research to determine the top priority needs of the target market. If additional criteria are to be created, we caution that they should be optional in nature in order to best cater to specialties, target demographics, etc.

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?

Again, we would like to point out that many criteria are already reported on the CHPL. We question the benefits of how this would add value rather than simply adding requirements to already burdened developers. In general, EHRA members have experienced that the more questions/criteria required, the less meaningful the information becomes, and the more overwhelming it is for consumers to digest and interpret the data.

Which criteria topics might be especially burdensome or difficult for a small or new developer to report on?

EHRA believes this affects not only small developers, but established developers with a new product also. Unfortunately, in these situations there is no way to report common user experience until the product is live at a client site and, many times, a client will not allow the product to be implemented until it is certified.

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?

Any data that requires a significant time commitment to collect favors a larger company. Established products have an easier time in obtaining user experience data. If you create the same requirements for vastly different products, this might skew the advantage.

In what ways can different health IT deployment architectures be accommodated? 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?

EHRA believes this is less about architecture and more about the data governance agreements - who owns the data, what access permissions does the other party have, etc. It appears that some of the data CMS wants to report would be owned by the hospital/site, and it is not the developer's right to share that data on their behalf.

Categories for the EHR Reporting Program

- ***Security, usability and user-centered design, interoperability, conformance to certification testing, and other categories, as appropriate to measure the performance of CEHRT***

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.

EHRA defers to end users on this question.

Security

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?

The 2015 Edition security criteria would provide information on meaningful differences between products in meeting specific security and privacy needs. Additionally, Web Content Accessibility Guidelines (WCAG) conformance is a part of the 170.315(e)(1) View, Download, and Transmit criterion, though this may not be scalable.

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.

EHRA finds that the following would be useful security and privacy features or functions that a CEHRT may offer beyond those required by HIPAA and the ONC Health IT Certification Program:

- 2-factor authentication;
- Biometrics (do they integrate with devices that use biometric authentication);
- Encrypted database features;
- Extensive password protection (complexity + reset frequency) - (Follow the NIST recommendations);
- Store, display, and print patient consent opt-in agreements;
- Custom privacy policy and terms of conditions for portals; and
- PCI compliance for credit card transactions.

What information about a certified health IT product's security and privacy capabilities and performance have acquisition decision makers used to inform decisions about acquisitions, upgrades, or use to best support end users' needs? How has that information helped inform decision-making?

EHRA defers to end users on this question. An RFP typically has extensive questions about security features, the answers to which are not easily reflected on a website.

What other information would be useful in comparing certified health IT products on security and privacy (e.g., compatibility with newer security technologies such as biometrics)?

Please see our comments above, in addition to supporting LDAP/Active Directory integration.

Usability and User-Centered Design

How can the usability results currently available in the CHPL best be used to assist in comparisons between certified health IT products?

EHRA has rarely heard of purchasers using SED data to make decisions. Even if they were educated to do so, it would be a trying task using the CHPL.

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.

Historically, there have been inherent problems with attempting to develop more test cases, as their success often depends as much on local configuration as on EHR feature sets. Instead, we strongly encourage the publication of best practice scenarios that developers and purchasers can consider. This approach leaves room for local innovation and openly recognizes that there is almost always more than one right way to accomplish the same task. We would like to avoid creating a misconception that products can be easily compared based on usability.

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:

- ***Supports the cognitive work of clinical users (e.g., displays relevant information in useful formats at relevant points in workflow)?***
- ***Reflects the ability of implementers to make customization and implementation decisions in a user-centered manner?***

The ONC Health IT Certification Program tests vastly different products and allows for a reasonable interpretation of how to comply with certification requirements so as not to inhibit innovation. It is generally recognized that the more detailed the workflow, the more difficult it is to standardize. For this to work, the requirements would need to be sufficiently flexible that it would work with many different types of systems/workflows, which then invalidates it for comparison purposes. An inherent risk is that additional data is collected, but it is not useful to purchasers.

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?

- ***Who should report audit log data and by what mechanism?***

It is incredibly difficult to create comparable information across such a large variety of products, settings, and implementation settings using audit log data. Although there is some standardization per certification requirements, there is still a lot of variability. Providers and hospitals can choose to review their own internal audit log data without government regulation.

How feasible would it be to implement usage monitoring tools (e.g., for time spent on specific tasks)?

EHRA finds this to be a case of usability versus utility. Distractions, complexity of activity, etc. all impact usage. There are simply too many variables to provide meaningful information at a global level. Usage

monitoring can be helpful based on the scenario and need, but this does not need to be mandated by the government nor collected for all CEHRT.

Interoperability

Please comment on the usefulness of product integration as a primary means of assessing interoperability (as proposed in the EHR Compare Report).

While there is value in a product that has lots of integration, we cannot necessarily make a statement about its usefulness against another product without discounting many other factors. Some factors include third party products relied upon to perform certain functions, a variety of additional costs and limitations, and the many different levels of integration - fully embedded in workflow, data provided as an adjunct to workflow, etc.

What other domains of interoperability (beyond those already identified and referenced above) would be useful for comparative purposes?

Other domains would include the complexity of the product to integrate with others and the product's connectivity to networks such as CommonWell or Carequality.

Of the data sources described in this RFI, which data sources would be useful for measuring the interoperability performance of certified health IT products?

- ***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?***
- ***How helpful would CMS program data (e.g., Quality Payment Program MIPS Promoting Interoperability Category, Inpatient Hospital Promoting Interoperability Program, 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?***

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

As far as State Medicaid agencies go, it is generally known that raw data can be overwhelming and confusing. Before commenting on the usefulness of this data, EHRA would need more information on the type of data they would want to share, so we can better determine how helpful it would be. If the program function is similar to other federal programs, it seems likely that there would not be an

advantage to looking at one program over another (federal vs state) since they are collecting similar data.

What other data sources and measures could be used to compare performance on interoperability across certified health IT products?

EHRA recommends that you review programs such as CPC+ and ACOs to see what they require to determine whether there might be additional data that could be used to compare performance of interoperability across CEHRT.

Conformance to Certification Testing

What additional information about certified health IT's conformance to the certification testing (beyond what is currently available on the CHPL) would be useful for comparison purposes? What mechanisms or approaches could be considered to obtain such data? What barriers might exist for developers and/or end users in reporting on such data?

EHRA feels that this would be too complex to be valuable. We would also like to point out that corrective action plans and certified status is information that is already publicly available.

Other Categories for Consideration

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)?

The categories should be prioritized based on feedback from the user community. Overall, EHRA feels that the chosen categories seem to be fairly inclusive of criteria needed to support decision makers' needs.

What data sources could be used to compare performance on these categories across certified health IT products?

EHRA recommends that all data collected should be centralized on the Health IT Playbook website.

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?

We strongly encourage the ability to filter based on care setting, product niche, and other important metadata as this will be critical in making acquisition, upgrade, and customization decisions. Being able to obtain information at the specialty level or the individual client site level is better for evaluation purposes rather than trying to make this generalized for all.

Cost Transparency, Quality Metrics, and Population Health

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 functions required for supporting population health analytics (e.g., bulk data export)?

This question seems to conflate population health data with quality measures; we find these to be two distinct, separate issues. Perhaps it would be helpful to define population health analytics for the purpose of this RFI. EHRA strongly feels that the release or inclusion of population health data should be commented on by the providers using that data.

Currently, population health analytics are not part of certification, though the bulk export of data is included. For example, many developers offer population health analytics as a service, but it does not require bulk data export. If, however, an EHR customer wanted to use their EHR data in another platform (e.g. a population health analytics platform that is not associated with the EHR), providers could use the functionalities already part of 2015 Edition criterion 170.315(b)(6) Data Export.

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?

The criteria and associated criteria we find most helpful is as follows. Additionally, data related to all of these criteria are already publicly available via the CHPL.

- 170.315(b)(6) Data export;
- 170.315(c)(1) CQMs - record and export;
- 170.315(c)(2) CQMs - import and calculate;
- 170.315(c)(3) CQMs - report;
- 170.315(c)(4) CQMs - filter; and
- 170.315(g)(2) Automated measure calculation

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?

Overall, EHRA feels that the chosen categories seem to be fairly inclusive of criteria needed to support decision makers' needs.

Hospitals and Health Systems

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?

The most frequently utilized sources of comparative information can be found at Blackbook, KLAS, and the CHPL, in addition to those sites identified in the EHR Compare Report. The Health IT Dashboard site includes a number of reports, including the ability to determine the number of CMS attestations per developer.

Existing information can be found in the transparency disclosures mandated by 2015 Edition certification. While this information is not populating the compare tool on CHPL, bringing more awareness to it by adding it to the CHPL compare tool could be assistive.
Additionally, the software that 2015 Edition CEHRT relied upon to achieve certification, has recently been removed from the CHPL summary report, making this information more difficult for users to locate.

Also, there is attestation data reported by developers to their ACBs that is not publicly available such as encryption and hashing algorithms used to comply with certification criteria. This comparative information could be helpful and would not be overly burdensome to procure since it is already collected.

Please comment on how an EHR Reporting Program could best reflect the information needed for hospitals and health systems, ambulatory and smaller provider settings, and overlapping information in developing summary reports or comparison tools.

The most effective course would be to provide education on the resources currently available.