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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,

On behalf of the EHR Association, we are reaching out to express significant concerns with recent certification program oversight guidance issued by the Office of the National Coordinator for Health IT.

In particular, *ONC Health IT Certification Program: Program Policy Resource #18-01: Post-certification Assessment of Program Requirements* includes troubling guidance, and similar concerns can be found in Resource #18-02 and #18-03.[1] Regrettably, the guidance in these resources appears to have been developed without engaging health IT developers or their clients. We worry that it was created in a vacuum without important stakeholder input and feedback on real-world implications.

Members of the Association are especially troubled by a post-certification surveillance that will subject our products to "interpretations" and "judgement" rather than specified written certification criteria, standards, and test procedures.

Certification surveillance and determinations of conformity must be based solely on published written regulation (certification criteria or conditions of certification) and referenced standards and test procedures. If other materials--such as developer statements--are to be referenced also, then that expectation and the specifics of their content should be set in regulation clearly.

Inclusion of guidance in regulation is particularly important when such guidance has implications for development or for healthcare provider investments, so that the

[1] https://www.healthit.gov/sites/default/files/page/2018-10/PostcertAssessmentResource_1.pdf Accessed October 13, 2018. Last updated October 5, 2018.

industry impact of the regulation can be commented on and accurately estimated. As such, it is incumbent upon the agency setting the regulation--in this case ONC—to ensure that the published written regulation, referenced standards, test procedures, and any other materials incorporated properly address interpretative items to ensure clarity on content and scope.

In the guidance document, developers do not have a clear understanding of what is expected in a post-market surveillance activity or to what standard they and their products are being held. The current guidance places too much emphasis on the ONC-Authorized Certification Bodies' judgment having the potential to raise non-conformities in areas where there is no clear written expectation for developers.

To avoid introducing unnecessary confusion into the health IT industry, EHRA urges ONC to:

- Retract the current guidance documents 18-01, 18-02, and 18-03 until they can be revised
- Engage health IT developers and providers to help identify what are reasonable expected uses of health IT and allow for a public comment opportunity on revised guidance
- Develop examples of non-conformities that focus on failure to match written test procedures.
- Provide guidance to ONC-ACBs on how to interpret and apply "reasonable expected uses" to evaluating health IT, with a focus on the written test procedures

The EHR Association and its member companies have consistently asked ONC for more guidance and additional examples, in advance of certification testing, so that we may in turn develop products that clearly meet the expectations set forth in the normative regulatory text--without being subject to arbitrary interpretations. It is critical that ONC ensures clarity and completeness of all expectations within the normative regulatory text.

Developers commit significant resources toward working with ONC-ACBs in efforts to reasonably ensure certification testing meets the intended purposes and objectives of the normative certification criteria. Yet, phrasing within ONC guidance, such as "realize any and all uses" and "should have been anticipated" is concerning because it suggests open-ended capabilities, establishing an ambiguous scope.

EHRA asks that ONC clearly state grounds for non-conformity assessment in writing, for public comment. If guidance has developer or healthcare provider economic impact, it should be specified through proposed rulemaking to allow for accurate estimation, including considerations such as:

1. Restrictions around whether a service can be outsourced to a third party or the developer rather than being done by the provider or their staff
2. Expectations of support levels or timeliness of such services
3. Software performance levels for given volumes of data with given hardware constraints
4. Expectations for provision of documentation or assistance with features
5. Expectations that certain features be "recommended" or "not recommended" by a developer
6. Expectations around user education and training for access to new features

User education would be an example of a requirement a developer may institute prior to enabling certain EHR features. Training can be a critical part of safe health IT deployment. However, this ONC guidance document describes additional procedures or requirements (such as training) as potential "interference," which would be subject to non-conformity. The Association is alarmed that a reasonable practice, recognized for its role in patient safety and physician usability, and which was not previously indicated to be inappropriate, would potentially be considered non-conformant in this guidance.

There are many other examples in this document that point to either a possible misunderstanding of the complexities inherent in certification and implementation, or to guidance provided to ONC-ACBs that has resulted in conflicting and ambiguous meaning. To broadly illustrate EHRA's concerns with the guidance provided in 18-01, we will follow an example from that document, of post-certification assessment regarding generation of clinical quality measures, which we understand is meant to illustrate the general policy that certifiers would follow.

The guidance posits that in this example, failure to generate clinical quality measures within an unspecified time frame is not compliant with certification requirements. Although we will use the same example to illustrate the general reasons that this policy is problematic, this example should not be considered the full extent of our concerns.

First, ONC is proposing enforcement of a requirement of timeliness or on-demand use as a condition of conformity in the use of certified capabilities.[2] Yet, the only discussion of timing in the draft regulation was that users must be able to export quality measures "at any time the user chooses:"

> ***User Ability To Export CQM Data***
> *We have received stakeholder feedback that some systems certified to the 2014 Edition "CQM—capture and export" certification criterion do not provide users with the ability to export data "on demand" nor to export batches of multiple patients simultaneously. Rather, some users of certified health IT must request this functionality from the health IT developer. Our intent is that users should be able to export CQM data formatted to the QRDA standard at any time the user chooses for one or multiple patients and without additional assistance. Thus, as proposed, when a Health IT Module is presented for certification to this criterion, we would expect that testing of the Health IT Module would include demonstration of a user's ability to export CQM data without subsequent health IT developer assistance beyond normal orientation/training.*

ONC thus failed to solicit public comment on the development and provider hardware investment implications of certain performance thresholds that are being introduced in surveillance guidance.

To enable on-demand access to generate and export CQM, it is typical of many products that the data must initially be made available in a dedicated database of the quality measures of the provider's choice, separate from the clinical production electronic health record. This is done to ensure operational

[2] https://www.federalregister.gov/d/2015-06612/p-630. Accessed October 13, 2018.

performance service levels. If the data is not moved, CQM report generation for export could have a negative impact on clinical production EHR performance, and thus user experience, depending on the volume of data to be analyzed.

For example, if a single doctor sees 20 patients per day, 210 days per year, this results in 4,200 annual encounters to be analyzed for an initial patient population, generating tens of thousands of orders, diagnoses, and results--each of which have important corresponding metadata. Because some quality measures have multi-year look-back periods for evaluation (past cancer screening, for example), those results will be an even larger data set.

Often, prerequisite steps are required in order to select and extract the relevant QRDA data to this separate database from which reports can be generated without impacting production performance. Only once the data is available for export in the separate database is on-demand access and reporting against this database available.

In our experience the main use cases for data export are not for internal performance improvement, but to support submission to CMS at the conclusion of the year, to use third party data submission products, or to support data extraction for registry reporting. The idea that export of QRDA files is the primary tool for quality improvement is not consistent with the use cases we've seen among our clients. In fact, users would find QRDA XML files very unfriendly for this purpose. Correspondingly, and in response to user needs, most health IT uses other tools (clinical decision support, dashboards, other analytics) for quality improvement purposes, making that use case irrelevant. Updated guidance could offer more realistic use cases by which to judge "export."

Additionally, while the statement "at any time" seems to reasonably allow for a variety of practices, such as scheduling a process to summarize quality data and/or generate files, the later "real-time" language is contradictory.

Instead of proposing a requirement for expected stakeholder evaluation and comment, there is an interpretative leap in ONC 2015 Edition Final Rule preamble guidance that requiring a user to be able to export CQM data "at any time" would "allow a provider or health system to view and verify their CQM results for quality improvement on a near real-time basis" in addition to being able to generate files for submission to payers.[3]

Pre-processing the quality data may be required in order to populate data files or tables that are optimized for export. Depending on the deployment model of the implementation, many of these processes may be outsourced to the developer to perform, with the developer acting as "user" or at least providing application management services. Lead time notification from the provider may be necessary for the developer to perform these services.

[3] https://www.federalregister.gov/d/2015-25597/p-692. Accessed October 13, 2018.

If timeliness of report output was judged a factor critical enough to justify a non-conformity, it should have been specified by ONC in the draft regulation with the corresponding reasoning for public input. This would have allowed for the correction of ONC's understanding about the use of QRDA XML for quality improvement and for an accurate estimate of the industry economic impact of the timeliness specified and the clarification of the role of transparency disclosure statements where a developer has taken on certain operational responsibilities.

Once such a timeliness expectation is established, delayed notification of need by the provider should not be judged as non-conformance by the developer. Provider failure to follow available reference guidelines on use in terms of implementation should similarly not be taken as non-conformance by the developer if it leads to delays due to support needed to rectify errors of implementation.

The lack of inclusion or recognition of expectations such as timelines without being prescriptive on specific processes in the proposed normative regulation text means that the impact of such a requirement or expectation was not estimated (by ONC or by stakeholders providing feedback) in the "Estimated average developmental hours," which were given by ONC as 200 (low) to 500 (high) for all quality measures.[4] EHRA's experience is that these estimates tend to be more accurate for a single quality measure.

Health IT developers have identified many ways to provide effective analytics to healthcare organizations while balancing other needs, such as maintaining system performance of the production EHR without interruption and avoiding overly expensive hardware investments. Current techniques for large scale analytics include, though are not limited to:

1. Differentiating system processes needed in real time (such as clinical decision support) from data needed for less urgent purposes (such as batch export of XML for submission to a payer) for the purpose of prioritization
2. Indexing and processes for incremental updates
3. Scheduling analytics processing during non-peak system usage hours (such as overnight or weekends)
4. Offloading analytics from the production database to reporting databases able to use other analytics tools and separate hardware, often via a periodic extract, transform and load (ETL) process
5. Load balancing functions--manual or automated--that allow administrators to prioritize activities happening within their system and maintain user response times
6. Hardware sizing recommendations that permit system administrators to determine their prioritization of system processing times within their budget for additional computing power

As health IT developers, we take seriously the need to provide data to users for the purposes of quality improvement, payment, and regulatory reporting. It is important to recognize that the mechanisms to do so are sophisticated and might involve different tools. Disappointingly, ONC's guidance oversimplifies and ignores this complexity.

[4] https://www.federalregister.gov/d/2015-06612/p-2318. Appendix A. Accessed October 13, 2018.

In summary, EHRA has significant concerns with a surveillance process that is based on subjective factors, rather than a process strongly rooted in reasonable expected use that accounts for variance in deployment. We have highlighted in this letter just one disturbing example, due to its focus in a recent document updated by ONC. Our unease, however, extends beyond that single example to the general trends of ONC guidance for certifiers and the program as well as the many other types of functionality examples that could be extrapolated.

EHRA strongly urges ONC to retract the current version of these three guidance documents (Health IT Certification Program: Program Policy Resources #18-01, #18-02, and #18-03) in favor of re-issuing them for official public comment before finalizing them.

Thank you for your consideration of our concerns. We look forward to resolving these concerns, and to continuing our cooperative participation with ONC on issues we are mutually passionate about, including improving interoperability, usability, and safety of health IT throughout the industry.

Sincerely,

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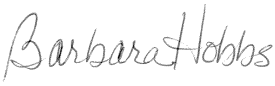

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## About the EHR Association

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.