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January 11, 2016

Andrew Lyzenga
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National Quality Forum
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Dear Mr. Lyzenga:

On behalf of more than 30 member companies of the Electronic Health Record Association (EHRA), we submit the following comments on the *Draft Report: Identification and Prioritization of Health IT Patient Safety Measures* which was published in November 2015. Individuals who work on the EHRA's Patient Safety Workgroup represent EHR developer organizations that serve the majority of hospitals and ambulatory organizations across the US that are actively using EHRs to provide more effective and efficient care to their patients. Our collective experiences in working with these organizations are reflected in these comments as we attempt to provide practical advice on the complex topic of health IT and its potential impacts on patient safety. These comments follow the flow of the report so are not necessarily in priority order.

Please note that the comments submitted online are truncated due to space limitations. This letter has our full and detailed comments.

Generally speaking, EHRA reviewers found that while the draft report makes many valid points, there are some areas where the recommendations do not seem to reflect practical experience. Because of time constraints, the EHRA is unable to provide as detailed a level of comments as we would like and we would welcome the opportunity to provide more comprehensive feedback at a later date. Given the upcoming deadline for submission of comments, we are offering the following high-level input.

- The report references a "multi-stakeholder committee" that was convened to provide input and direction on the development of a conceptual framework for analyzing measures of safety in health IT and to identify priority measurement areas with the greatest potential for both improving the safety of HIT and using HIT to improve patient safety. Please clarify that this is the same committee

later referred to as "the HIT Safety Committee." If so, references to this committee should be the same throughout the document.

- In some places, the report uses the term "framework", and in other places the term "model" is used. Terminology should be consistent throughout, assuming these terms reference the same thing. It is also difficult to differentiate between when the framework/model is that adopted by the HIT Safety Committee and when framework/model refers to the content of the cited publications of Drs. Singh and Sittig. The report needs to more clearly differentiate these references.
- The report makes reference to "seamless interoperability" and patient records being "stored centrally" for easy access. We would point out that with truly seamless interoperability, the concept of central storage is not typically needed or desirable. In the same paragraph, there is an example of a patient in an emergency department where providers have "access to prior records through electronic health records (EHRs)". We suggest you broaden that to "electronic health records or other data sources."
- In the paragraph on page four that suggests that the use of computerized provider order entry (CPOE) can also to help to reduce prescription and other errors resulting from the illegible handwriting, we suggest adding generic e-prescribing (eRX) and bar code medication administration (BCMA) as other health IT capabilities that can reduce these errors.
- There are two fallacies in the discussion regarding the lack of interoperability. First, the report attributes this solely to "broad variation in how HIT has been implemented". Health IT implementation is only one of the barriers to achieving broad interoperability, as has been recognized by the Office of the National Coordinator for Health IT (ONC) in Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap version 1.0 (Roadmap) [PDF - 3.7 MB]. Second, it is not only user interfaces that lead to inadvertent mistakes, but as described elsewhere in the report, the complex gamut of people, processes, and culture combine to create an environment where errors can occur.
- The report acknowledges that studies of health IT's impact on patient safety are often narrowly focused. The EHRA agrees and reinforces that there are often multiple participants in an adverse event. Analyses must take a systems view, not focus on a single actor or component of the system.
- On page seven in the "HIT Design" sub-section, we suggest adding the word "may" to the first sentence regarding what is included in the design of health IT.
- In the following paragraph on the same page regarding health IT implementation, the EHRA compliments the NQF HIT Safety Committee report for recognizing the importance of adequate planning, workflow redesign, and staff education/training in the implementation process.
- We disagree that the three-phase framework for the development of EHR-specific patient safety goals on page nine are chronological phases. Implementers could be working in all three "phases" concurrently from the outset – i.e., using health IT to improve quality and safety is something that is expected from the first day of implementation.
- On page 10, in categorizing types of HIT-related safety concerns, the EHRA finds that there is still a narrow focus on system components and single actors, rather than on the broader "cultural" aspects of HIT safety, despite the earlier discussion in the "Role of Human Factors in HIT Safety" sub-section.
- Although we very much respect the work of Drs. Singh and Sittig, we point out that this categorization is still a conceptual model. In an evidence-based learning system, the model must be corroborated by other researchers and implementers and supported by empirical evidence. We do not oppose proceeding based on this as a conceptual model, but future work will need more specificity in defining issues and describing exactly what is being measured. Most of that work would need to happen later during development of the actual measures.
- We recognize that Table 1 on page eleven is taken largely from the cited works of Drs. Singh and Sittig, but since the report states that the NQF HIT Safety Committee "... determined that a variation of the model ..." is what they would work with, we point out that what Table 1 labels as "levels"

should not be considered levels. For instance, "Use of HIT to Improve Patient Safety" is categorized as "Level 3" when it should absolutely be a Level 1 factor. We suggest changing the term "level" to "category", and thus recognizing that the items in each category are not necessarily dependent on achievement of previous categories.

- In the description of Level 2 in the same table, what is "correct HIT use"? Some health IT features and functions are user-configurable and some are not. "Correct" use may or may not be "as intended", given varying workflows and preferences among different end-users of the same product. Correctness may be impossible to define or measure.
- In the description of Level 3 in this table, what is "safe ... patient engagement"? This reference was not clear to the EHRA reviewers. We suggest "HIT enables effective patient engagement to enhance safety." Health IT is the enabler, not the driver; process and culture are the drivers. So, it is health IT in combination with patient engagement that enhances safety.
- On page 13, the report comments that many organizations often do not have the expertise needed to conduct investigation of health IT-related patient safety incidents (*e.g.*, informatics, human factors, ergonomics). We believe that this lack of expertise may not be the largest factor in failure to do proper investigation and analysis. We suggest culture may be at least an equally important factor. We suggest amended language: "However, many organizations have not developed the culture of safety which might be as important as having expertise."
- Although the nine key measurement areas discussed on pages 15 and 16 seem to be reasonable, we do not necessarily agree with the priority ranking. For example, we believe that high quality documentation should be much higher on the list. The narrative description of how the prioritizations were determined is also a bit perplexing. The report would benefit from a more transparent prioritization process, as well as from a better explanation of how "feasibility" was ascertained. Neither prioritization nor feasibility seems to be quantifiable, replicable, or evidence-based.
- We have several comments on the clinical decision support (CDS) measurement areas section. First, the CDS measure concepts as described will not be easy to measure. Second, the section seems to confuse CDS metrics with alert fatigue metrics, which are not at all the same. The section should be very specific about what is being measured, and the potential measure concepts amended accordingly. Third, while it would be possible to record clinical reaction to active alerts, it would not be possible to record reaction to passive alerts (e.g., flags, highlighted results, bold, underlined, colored text). Creating a way to monitor reactions to passive alerts would introduce major administrative burdens into the clinical workflow for end-users. Fourth, measuring the alert rate would tell us nothing about the importance of the alerts or the effectiveness of the alerts. A greater number of alerts could be either a good thing for safety or a bad thing. Lastly, appropriate alert levels may vary by user role, clinical setting, or other factors (e.g., ICU, radiology, office visit, home health visit).
- Similar to the CDS section comments, the System Interoperability measure concepts on page seventeen suffer from a lack of real focus and any real specificity about what is to be measured. Also similar to the CDS measures, it is not clear that the results of such measurements will provide actionable information. We are concerned that a lot of effort by health IT developers and end-users would be required with little demonstrable value for the effort. Alternative approaches could measure the volume of data exchanged, or the number of messages the system receives but fail to get delivered to the end-user. The potential measures fail to recognize that data errors may be the cause of non-delivery, not just system/interface errors. We also wonder whether these potential measures are really looking at HIT, or simply looking at a carryover of the paper system's inability to share information – i.e., is this an HIT problem or a culture/workflow problem? Ultimately, for these measure areas and all the others, this report is simply a conceptual framework. Clearly qualified measure developers would need to do the work to bring each of these concepts from the

theoretical stage to where they would be ready for proof-of-concept testing. We suggest that the report more clearly highlight the need for this further work.

- Overall, the EHRA is concerned that the imposition of many of the measurements envisioned by the report will significantly increase the administrative burden on the clinician, leading to frustration, non-participation, and deteriorating usability. We recommend focusing on what data can be captured without imposing data entry by clinicians that is not related to patient care.
- Also in this section, the magnitude of the issues implied by "many EHRs" and "problems often emerge" is not borne out by any of the cited research, and is therefore speculative and misleading. It also fails to differentiate between EHR/HIT-specific issues and system infrastructure, both within an enterprise and across enterprises.
- The EHRA finds the Patient Identification section and associated potential measures fairly well done. The measure concepts are focused and seem to offer actionable information.
- Given the general industry requirements for user-centered design under the ONC meaningful use (MU) certification program, this section (page 20) does not seem to be proposing anything new that would move the usability conversation forward. The potential measure concepts appear to be mostly checklists rather than measurable items.
- The "burdensome data entry requirements" described in the report are frequently the result of compliance requirements, which is not something that user-centered design can mitigate. Those data entry requirements that adversely impact usability stem from many external requirements (e.g., Medicare and Medicaid program rules, MU attestation requirements, ONC certification/audit requirements, state-mandated forms, certification organization documentation requirements). EHRA reviewers struggled with this section in that is does not appear to address any sort of health IT "measurement." The listed potential measurement concepts simply seem to list the process requirements already codified by ONC, and the standards and related guidance from NIST, ISO, and elsewhere.
- The EHRA finds the System Downtime section on page 23 and associated potential measures fairly well done. The measure concepts are focused and seem to offer actionable information.
- Regarding the Feedback and Information Sharing section on page 25, the EHRA and the developer community place a high value on continuing to enhance our products and averting patient safety problems. The EHR Developer Code of Conduct recognizes the importance of communications of patient safety issues by developers.
- On page 25 and 26, we do have concerns with some of the discussion in the Feedback and Information Sharing section:
    - "Committee members raised concern that some vendor contracts contain broad non-disclosure and confidentiality provisions as well as other intellectual property (IP) protections which prevent certain EHR software information, including screenshots and comparative user experiences, to be publicly shared." We believe that often this issue Is not so much about specific provisions and their terms than how these are applied in practice and especially, the process used by providers and journals to accept product-specific materials. Fundamentally, technology developers have an obligation and need to protect IP and must have processes, including industry-standard contract provisions, to do so.
    - "The Committee believed that such contract terms should not be broader than reasonably necessary to protect the vendor's legitimate intellectual property interests when balanced against patient safety concerns." This is a reasonable approach.
    - "The Committee further believed that such provisions are in direct conflict with the goal of sharing patient safety knowledge for quality improvement purposes across settings." This statement is far too broad in our view.
    - On p. 26 some of the Measure Concepts seem likely to be challenging to measure. In particular, "Software license and hardware purchase agreements permit shared learning of

comparative user experiences, timely vendor response to provider requests for information, and use of vendor product information in research studies for peer reviewed journals (e.g. screen shots) and promote shared accountability for HIT safety." - We do not believe that NQF standards for contract provisions are desirable and feasible and question how such provisions would be evaluated as such a measure was applied and who would evaluate them?

- We recognize that the reports call-out that "meaningful feedback and information sharing" among developers and users is important. However, we believe the term "meaningful" is important, and that the general recommendations in this section of the report ignore that importance. A safety issue that is the result of a particular configuration or interface is not meaningful to any other client without that specific configuration or interface. Hence, the suggestion in the report to make all reported issues publicly available both fails the criterion of "meaningful" and also contributes to additional "alert fatigue" that the CDS section attempts to reduce. We believe, as stated in this report's Overarching Issue #8, that these frank discussions need to take place in what the recent RTI HIT Safety Report described as a "trusted space" for all. For the most part, that "trusted space" is the Patient Safety Organization (PSO) network of the Agency for Health Research and Quality (AHRQ). The PSO reporting system is evolving, and we agree with this report that the better means of dealing with this type of communication is to further enhance the PSO structure rather than build a duplicative, parallel, and stand-alone structure.
- Sub-section seven, Use of HIT to Facilitate Timely and High-Quality Documentation on page 26, seems to be more about how a clinician practices than about health IT. The EHR supports the clinician documenting the clinical encounter. What data that documentation requires is determined not by the HIT, but by the clinical workflow, requirements of the organization, requirements of state and federal government, and requirements of the various third party payers. The potential measurement areas here are only vaguely focused on HIT safety, carrying over from issues in the paper chart, and more about data exchange then documentation. As previously noted, this is perhaps an area that is best addressed by other existing health information exchange initiatives rather than NQF creating a duplicative, parallel process.
- With regard to the Patient Engagement section on page 28, the EHRA supports efforts of clinicians to engage patients in managing their healthcare. But, patients interacting directly with their clinicians' EHRs is not yet a widespread model. Most patient review of EHR data content is via portals, using CCDs or other documents generated by the EHR/HIT. To the extent that patients can point out when something is incorrect, we agree that such patient engagement is a valuable patient safety tool. However, the potential measure concepts here seem be more about influencing patient engagement rather than measuring any safety impact on health IT. For instance, the suggested 48-hour response time is arbitrary: 48 hours may be too long for something critical and not at all important for something the clinician and patient deem insignificant (e.g., the scheduling of a 6-month test.) Similarly, we are unclear what is envisioned by 48-hour telemedicine communications. There is no evidence that some minimum number of patient actions improve safety of care. We suggest that evidence needs to be established before constructing such potential measures.
- We note that sub-section nine is mostly targeted at providers, not vendors. Nonetheless, we offer a few comments. The EHRA believes the priority for risk management should be higher. We would like to see some incorporation of references to ISO 90001 or similar quality standards. Any health IT risk management system should be integrated into the organization's overall clinical risk management system, not stand-alone.
- On page 31, the EHRA concurs with these nine overarching issues. They are important concepts and considerations for how the HIT system works. We point out that while the opening section and the closing section of this report present these issues effectively, they do not appear to be applied to much of the work throughout the body of the report. In much of the report, these overarching

issues are set aside, the authors having opted to focus on overly narrow and out-of-context measures.

- The EHRA questions the terminology that calls HIT a "medical device." Health IT shares some aspects in common with a device but, as the report reiterates frequently, HIT is a combination of hardware, software, process, and culture, i.e., a socio-technical construct and not simply a device.
- As discussed on page 32, the EHRA concurs with the importance that burden on the end-user of HIT is an important factor in usability and, by extension, safety. We note that the measures discussed in this report must also be held to this same metric: if the end-user burden in increased in order to include a measure, then there must be definitive evidence that the value of that measure outweighs the increase in end-user burden and the incremental concern with patient safety.
- The EHRA is concerned with the statement that HIT-related measures may not necessarily meet NQF requirements for importance, scientific acceptability, usability and feasibility (page 33). We stress that any measurement developed must be well-defined, actually what is intended to be measured, and that the measurement provide meaningful knowledge to the healthcare learning system.

EHRA commends NQF on its effort to compile this report. We hope it will move the discussion further toward a ubiquitous culture of safety within a national learning system. While there is much good thought in the report, we believe it would benefit from significant editing to ensure that all of the sections of the report take into consideration the nine overarching Issues. We believe that many of the potential measure areas have strayed well outside of the stated intent of the report, namely to identify and prioritize health IT patient safety measures. In our opinion, many of the potential measurement areas seek to address policy issues rather than health IT safety metrics. We point out that many of the potential measure areas imply additional data entry burden for providers, which would exacerbate what the report acknowledges as already too much of a burden on clinicians. This must be reconciled.

Finally, we note that the potential measurement areas are conceptual. It will require considerable work by qualified measure developers to undertake the task of bringing them from concept to the bit-and-byte level. This will need to include precise definitions and clear evidence that the effort to develop and implement the measures will produce the value to make that investment worthwhile.

The EHRA and its Patient Safety Workgroup appreciates the opportunity to comment on the draft report. We also extend an open invitation to provide additional feedback to NQF, engaging other stakeholders as appropriate.

Sincerely,

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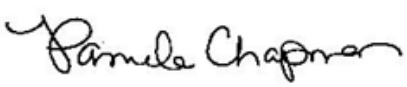

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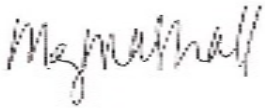

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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 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.ehrassociation.org.