

The American Medical Association (AMA) appreciates the opportunity to provide comment on the Electronic Health Record (EHR) Reporting Program Draft Voluntary User-Reported Criteria. The proposed survey offers an important opportunity for physicians, nurses, and other clinicians to provide their assessment of EHR technology. The capture, analysis, and communication of certified health information technology (IT) measures provided by health IT users will improve the overall transparency of products used real-world settings. The information gleaned from the survey will also aid physicians and other purchasers of certified health IT (e.g., EHRs) to become more empowered consumers, allowing for pro-competitive market practices to increase competition and innovation. The AMA has provided several survey recommendations to bolster these core objectives.

Question #1 *What certified health IT products do you use? Please select the vendor name, product name, and version used for each certified health IT product you use from the drop boxes below, including your primary EHR and any add-on products.*

AMA comment:

Many of the draft measures and questions will require several individuals (e.g., physicians, nurses, practice administrators, etc.) to assist in completing the responses. Compiling the information may take longer than the expected 10 to 15 minutes to complete. We recommend the survey include a suggestion for respondents to complete the survey when all necessary staff are available and to note the expected time to complete it may vary by health care facility.

Additionally, all certified health IT products are listed on the Office of the National Coordinator for Health IT's (ONC) Certified Health IT Product List (CHPL). Each product is coupled with a unique CHPL ID associated with the product edition, developer, product name, version, and certification date. Asking survey participants to include the CHPL ID of the product they are reviewing will improve the EHR Reporting Program's accuracy and analysis of user-reported criteria. In addition to the drop down boxes listed, we recommend capturing the CHPL ID and including a link to ONC's [CHPL site](#).

Question #5 *Indicate the level of ease or difficulty completing each of the following tasks using [autofill primary product name based on Q1].*

AMA comment:

The term *interoperability* comprises the concepts of *access*, *exchange* and *use* of electronic health information (EHI). Identifying products that perform well for both information access **and** use continues to be a significant challenge for our members. Simply having the ability to exchange information does not mean that information is easily accessible and useful in a physician's clinical workflow. Transparency of all aspects of interoperability is essential. We recommend rephrasing the responses 5.1 through 5.7 to include the following language "Electronically accessing, exchanging, and using health information from or with..."

For response 5.9 *Producing all the reports that are required for my organization's specialty*, we recommend rephrasing to include the following language "Producing and submitting all the reports that are required for my organization's specialty or practice type".

Question #8 *Indicate the ease of use for each of the following features and functionalities in [autofill primary product name based on Q1].*

AMA comment:

There is a growing need to capture social determinants of health (SDoH) information for individual care and population health. Tracking this functionality will help inform physicians which products meet this emerging need and will help monitor SDoH adoption over time. We recommend including “social determinants of health (SDoH) functionalities” as an additional listed feature.

ONC’s health IT certification and information blocking final rule includes updated certification criteria supporting Substitutable Medical Applications, Reusable Technologies (SMART) application programming interfaces (APIs). SMART APIs help both physicians and patients access, exchange, and use health information. Several EHR products already support SMART technology. However, with the introduction of ONC’s new API certification requirement, we expect many certified EHR vendors to adopt SMART within the next 24 months. Capturing an EHR’s support for SMART APIs and applications (apps) will provide health IT users information on which products offer this important feature. We recommend including “Physician and patient-facing application (app) support (e.g., SMART APIs and smartphone apps)” as an additional listed feature.

Question #13 *Overall, how would you rate the security and privacy features of [autofill primary product name based on Q1] (e.g., multifactor authentication, role-based access control, 42 CFR Part 2, HIPAA, etc.)?*

AMA comment:

Data privacy and security are related but two distinct issues. Security refers to the process of protecting data from unauthorized access and data corruption. Privacy describes practices that ensure that data shared by individuals are only used for an intended purpose. Physicians have a duty and obligation to secure an individual’s personal information and to maintain the privacy and confidentiality of that information. Compromising either data security or privacy jeopardizes the trust patients place in physicians and could ultimately cause patient harm. The AMA strongly recommends at least two separate questions to capture health IT users’ privacy and security considerations.

Security questions and responses could address the following topics:

- questions around multi-factor authentication;
- the use of biometric devices for sign on and medication prescribing;
- the degree to which health IT products comply with various security standards, such as NIST Cybersecurity Framework, FISMA 800-53, and HITRUST Certification; and
- security standards used for APIs.

ONC’s final rule clarified that it would not be considered “interference with” the access, exchange, or use of EHI (and thus not “information blocking”) if an “actor” (as defined by the final rule) engaged in practices to educate patients about the privacy and security risks posed by the apps the patients choose to receive their EHI. For example, actors may establish processes where they notify a patient, call to a patient’s attention, or display in advance (as part of the app authorization process with certified API technology) whether the third-party developer of the app that the patient is about to authorize to receive their EHI has attested in the positive or negative as to whether the third party’s privacy policy and practices (including security practices) meet certain “best practices” set by the market for privacy policies and practices. The collection of app attestations will be an important part of evaluating EHR vendor adoption of enhanced privacy and security practices allowable under ONC’s policy. Additionally, as APIs and consumer-facing app use increases, physicians and patients will need an authoritative listing of certified health IT products that can check for and collect app attestations to build trust and inform purchasing decisions. The AMA strongly recommends that a privacy question be included in the reporting

program with the following language reflecting the practices highlighted as permissible by ONC in its final rule:

“As part of an application’s (app) authorization or registration process, does [autofill primary product name based on Q1] support the functionality to check for and capture an app’s attestation to the following privacy policies and practices? Mark Yes, No, or Unknown.

- The privacy policy is made publicly accessible at all times, including updated versions.
- The privacy policy is shared with all individuals that use the technology prior to the technology’s receipt of EHI from an actor.
- The privacy policy is written in plain language and in a manner calculated to inform the individual who uses the technology.
- The privacy policy includes a statement of whether and how the individual’s EHI may be accessed, exchanged, or used by any other person or other entity, including whether the individual’s EHI may be sold at any time (including in the future).
- The privacy policy includes a requirement for express consent from the individual before the individual’s EHI is accessed, exchanged, or used, including receiving the individual’s express consent before the individual’s EHI is sold (other than disclosures required by law or disclosures necessary in connection with the sale of the application or a similar transaction).

Please share any comments related to your responses that you are willing to make publicly available. [add box to collect optional free text/unstructured responses that can also be left blank]”

Cost

The AMA appreciates the inclusion of the cost category. Costs for health IT adoption, implementation, and use are frequently cited by our members as a major drain on medical practice resources. Physicians are often alarmed by the differences between EHR vendor-quoted costs versus the actual costs charged to physicians to maintain, upgrade, customize, and add needed functionality. Additionally, we are aware of many instances where physicians are required to purchase additional modules, features, or software packages to provide basic interoperability. These “add-ons” routinely cost tens of thousands of dollars. Worse still, physicians face challenges using interoperable add-ons since many of these features do not improve the access or use of the medical information and instead contribute to burden. We therefore recommended an additional question that captures health IT users’ perceived return on investment (ROI). Collecting ROI will help provide physicians with a sense of how their colleagues view the overall price versus performance of certified health IT products. Furthermore, ONC is tasked by the Department of Health and Human Services (HHS) to reduce the burden associated with using health IT; tracking ROI metrics can help evaluate the impact of ONC’s policy and efforts to address burden.

Contractual Information

ONC requires certified health IT developers to meet Conditions and Maintenance of Certification related to visual communications by health IT users. EHR vendors are now prohibited from restricting users from sharing product screenshots except in limited circumstances. EHR vendors are also not permitted to prohibit or restrict, or purport to prohibit or restrict, communications that would be a “fair use” of any copyright work comprised in the developer’s health IT. Visual communications are critical in addressing patient safety, usability, security, and interoperability issues related to health IT. ONC’s policy is a

response to physicians being blocked by EHR vendors through the use of “gag clauses” commonly found in customer contracts. We recommend including a question to capture users’ experience with EHR vendors blocking, limiting, or otherwise restricting the sharing of visual communications related to patient safety, usability, security, and interoperability. Capturing and tracking this information will improve contract transparency and monitor vendor compliance with ONC policy.

Patient Safety

While the survey includes EHR usability measures, the AMA recommends including a separate section devoted to patient safety. Providing greater detail on usability and safety is necessary to reduce risk, will support the overall assessment of high-risk functions, and help reduce patient harm. Our specific recommendations are listed below.

Providing greater detail on usability and safety to reduce risk

- To provide a more detailed focus on safety, the survey should also collect data on areas known to introduce simultaneous usability challenges and safety risks. For example, the survey should ask users whether their health IT:
 - Enables simple and intuitive entry of patient information;
 - Provides uncluttered pick lists for placing medication orders; and
 - Provides intuitive visual displays that enhance safety.
- To obtain more in-depth information on usability concerns and perceived safety risks, the survey should also include an additional open-ended question related to safety. For example, the survey could request open-ended data on the following: “What safety risks do you feel exist within your EHR?”

Assessing high-risk functions to reduce patient harm

- The survey should distinguish between low- and high-risk functions.
- For low-risk functions, focusing on their ease of use will help provide information to reduce physician burden.
- The survey should be modified to request information on whether high-risk functions contribute to safety issues—not just ease of use. For these high-risk functions, the survey should include a 5-point scale from “Very likely” to “Not very likely” in response to the question: “How likely is it for this functionality to risk patient harm?” The high-risk functions for this category should include:
 - *Default values for common orders and evidenced based order sets and charting templates.* Research indicates that 38% of usability-related errors that reached the patient and caused harm occurred because of challenges with order placement, of which a subset involved the use of default values.
 - *E-prescribing of controlled substances.* Medication errors can occur because of the suboptimal usability of health IT. Research indicates a 37% harm rate with medication errors. Issues with e-prescribing contribute to medication errors.
 - *Data entry.* Research has shown that patient harm occurs in 27% of EHR usability events involving data entry.
 - *Patient reminders/alerts.* Of EHR usability events involving alerts, research has shown that 22% of those events contributed to harm.
- The survey should include an additional open-ended question to seek more in-depth information on usability concerns and perceived safety risks to strengthen the EHR reporting program’s

comparative information. Specifically, the survey should request information on: “What EHR functions include prominent usability issues that contribute to burden or patient safety errors?”

Finally, while Urban is not yet collecting input on vendor reporting, it is vital to consider the importance of safety data from developers. Vendor reporting should include robust data on usability and safety to improve data available, address clinician burden, and reduce medical errors. The AMA, Pew Charitable Trusts, and MedStar Health developed [test cases](#) to focus on areas of known usability and safety issues. These test cases meet rigorous criteria to ensure they are representative, contain concrete goals, test risks, and focus on the intended audience. ONC and Urban should consider requiring the use of these test case scenarios—or those similar in rigor—and collect more data on the Safety Enhanced Design requirements. Such an approach would provide meaningful data on the general usability processes and safety.

We look forward to continuing our work with Urban and ONC on the implementation of the EHR Reporting Program. Please feel free to contact Matt Reid, Sr. Health IT Consultant, Federal Affairs, at matt.reid@ama-assn.org or 202-789-7419 with any questions.