Electronic Health Record (EHR)
Reporting Program Draft Voluntary
User-Reported Public Comments
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August 10, 2020

Urban Institute
Health Policy Center
RE: Electronic Health Record Reporting Program
mailto: EHRfeedback@urban.org

Dear Sir/Madam,

I am pleased to submit our comments to the Urban Institute regarding the Electronic Health Record Reporting Program, Draft Voluntary User-Reported Criteria survey. Allscripts, with a platform of clinical and business solutions for ambulatory, acute and post-acute settings, is relied upon by the largest network of providers – over 330,000 physicians in more than 70,000 different practice locations, 2,300 hospitals, and almost 10,000 post-acute care settings. It is through our three decades of experience partnering with and deploying software to this vast network of providers that we can submit informed comments today on this important topic.

**Which draft criteria would you prioritize for inclusion in the EHR Reporting Program, and why?**

The survey criteria should be prioritized based on feedback from the user community. With that said, as a health IT vendor who will be reading, interpreting, and analyzing the results, considering the demographics of the individual completing the survey are of the upmost importance. There are various end user roles who may complete the survey, and each role will have varying degrees of familiarity with the EHR system and use different functionality within it, and as such, their responses and perspectives will be vastly different. We recommend collecting this information in the beginning of the survey so those analyzing the results have more context when reviewing results. For instance, the following options to define their role should be included: Administrator, Prescribing Clinician, Other Clinician, IT Staff, and Other.

Additionally, we recommend omitting question 24 (“How would you rate your proficiency using [autofill primary product name based on Q1]” and rather ask the respondent what their cumulative number of years using health IT is. If they are a clinical provider, we also recommend asking for their cumulative number of years in practice when collecting the demographics. We have found in our own work to assess human factors and user experience within our products that asking for a user’s self-assessment on proficiency offers little insight into their usage patterns or ability to maximize the product.

We also recommend inserting questions directly after the demographics are collected to gauge the end user’s experience regarding implementation, the availability of end user system configuration choices, and ongoing system maintenance and education. Sample questions are below:

- What year did your organization implement the EHR system?
  - <insert year ranges>
- How many hours of initial training were you offered by your organization?
  - 1-5 hours
Last, we recommend questions provide more opportunity for the respondents to elaborate on their answers in an open-ended manner. There are many nuances and configuration choices that will likely emerge in the survey responses based on care setting and specialty; including an option for comments would be beneficial to those reading and interpreting the results.

**Which draft criteria should be rephrased, reworded, or removed?**

**Q1:** 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.

Allscripts recommends allowing for more specificity with this question. The survey is centered around their experience with the respondent’s certified product, therefore allowing for the CHPL listing to be included would be helpful. At the same time, the inclusion of the CHPL number should be optional, because many end users will not be aware of what specific version of a product they are using. For instance, it is likely the IT staff are aware but unlikely a clinician not working with the IT staff would not be familiar with this information. Further, some organizations use multiple certified products to meet government requirements. Therefore, we recommend only asking for the primary certified product. Many add-on products are integrated into the EHR as far as presentation to the end user, and in many cases, the end user is likely unaware they are using an “add-on” product. This is indicative of solid product integration and a quality EHR system. Please note that in some cases, organizations sometimes rebrand their EHR product internally, leaving the end user unaware of who the EHR vendor is at all.

**Q2:** What type of health IT user best describes you? Choose all that apply.

Allscripts recommends expanding this question to allow for respondents to indicate if they work in an ambulatory, inpatient, or integrated ambulatory and inpatient setting. If they are a clinician, they should be able to choose from a list of specialties, and the size of the organization as indicated by number of clinicians or number of hospital beds could also be useful.

**Q4:** How likely is it that you would recommend [autofill primary product name based on Q1] to a colleague with a practice similar to yours?

Allscripts supports the inclusion of the Net Promoter Score question, however we recommend changing the word “practice” to “care setting” because the word practice typically refers to an ambulatory care setting.
Q5.1-8: Interoperability

Allscripts recommends the sub questions be edited to provide more clarity. For example, this section references other systems in the first question (5.1); it is then unclear if the following two questions (5.2 and 5.3) are asking if information exchange is referring to clinicians who use the same system, a different system, or either.

Additionally, question 5.6 and 5.7 should be clearer, particularly for the clinical user; they should include the 2015 Edition Certification criterions §170.315(f)(1)-(7) transmission options.

Question 5.9 asks if the EHR produces all the reports that are required for an organization’s specialty; this is vague and implies a 1:1 relationship between organization and specialty. The reports an organization produces can be subjective and depend on their organizational policies and not be an accurate reflection of the EHR’s system capabilities.

Last, there are numerous 2015 Edition Certification items that are interoperability-related. We recommend this section be more specific to include references to them.

Q6: Usability

Allscripts recommends adding a question about System Usability Scale (SUS) testing and scoring. Allscripts uses SUS to evaluate its products before they are released, with products only released if they meet a defined threshold. System Usability Scores (SUS) give a better sense of how people evaluate a product since improving workflow, reducing clicks, etc., are necessary to improve a product’s SUS scores.

Q8.8: Optical character recognition (i.e., ability to encode scanned text and integrate into the product’s fields)

Allscripts’ interpretation of this question is that it combines optical character recognition and data parsing. We recommend breaking this into two questions - one for optical character recognition and one for data parsing.

Q1.13: User-configured interfaces (e.g., screen views, tabs, links, charts, reports, templates, alerts)

Allscripts recommends this question be updated to clarify if it is referring to user configuration options or organization-wide configuration options.

Q9: How would you rate your overall satisfaction with the implementation of [autofill primary product name based on Q1]? Please consider the explanation of the implementation process before it began, training and support for implementation, and whether the process met what was promised. If you were not involved in the implementation, mark “don’t know or not applicable.”

The answer to this question has everything to do with the level of effort the organization (and vendor) put into the initial implementation and the organization’s adaptability to change. It is important to recognize that training decisions in particular are made by the organization that is purchasing the system, and how strictly end users
are required to undergo focused and in-depth training varies significantly. Some organizations choose to offer less training to save money, and frequently frontline clinicians push back against time away from patients.

Decisions made during the implementation of an EHR system are variable, and as a result, the usability experience can vary extensively not only between implementations at various organizations but also within a single organization that has multiple specialties and/or departments with different needs and usage patterns of the EHR. We recommend adding an additional question or two that collect information regarding ongoing maintenance and support of the system to gauge the level of effort put forth by both the vendor and the healthcare organization itself.

**Q10.1: 24/7 help desk support**

Allscripts recommends this question differentiate between an organization’s internal help desk and the vendor help desk. Many times, only a few employees will have access to the vendor’s help desk and may not realize their vendor does provide a 24/7 help desk option. As such, we also recommend adding the option to answer, “don’t know”.

**Q12.3: Notification of upcoming upgrades or maintenance in advance of their implementation**

Allscripts recommends this question differentiate between an organization’s notification to its end users and the vendor’s notification to the customer. Within a healthcare organization of any size, this is frequently more likely to reflect on an organization’s internal support and operations than anything that is vendor-related.

**Q13: 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.)?**

Healthcare organizations are responsible for developing and managing their own privacy- and security-related policies and procedures. While the EHR product is the tool used for role-based access control, the roles and views are determined by and are the responsibility of the healthcare organization, not the vendor. Accordingly, we believe this question should be adjusted significantly or removed.

**Q14: What pricing model(s) does your [autofill primary product name based on Q1] operate on?**

Allscripts recommends a “don’t know” option be added to this question because most respondents will not know the pricing model their organization agreed to while contracting for the product. Additionally, there is a lot to pricing outside of the EHR licensing itself, including add-on costs for consulting, analysts, hardware (if self-hosted), organization size, hosted versus not-hosted, add-on training, managed services, in-house or outsourced IT department, etc. There are so many variables that may affect different pricing models that this question does not address. We recommend it be updated to reflect the pricing model of the EHR licensing only and ensure that Don’t Know is an option.

**Q18: In what setting do you primarily use [autofill primary product name based on Q1]? Select all that apply.**

Allscripts recommends this question be moved to the beginning of the survey where the other demographics-related questions are located. It is also important to note that some of the settings listed do not use certified
health IT unless they have a MIPS reporting provider; examples include long-term or post-acute care facilities, pharmacy, and school-based health center, and correctional facility. The survey is directed towards certified health IT users, so including end users that are unfamiliar with the purpose or use of certified health IT may skew answers or unintentionally misguide those analyzing results.

**Q20:** What best describes the types of services provided at the practice in which you use [autofill primary product name based on Q1]? Select all that apply.

Allscripts recommends this question be moved to the beginning of the survey where the other demographics-related questions are located. Also, we recommend changing the word “practice” to “care setting” because the word practice typically refers to an ambulatory care setting. Last, we recommend the list of services be expanded to include more services and their associated specialties.

**Q21:** In what state do you use [autofill primary product name based on Q1]? Select your primary location. [insert drop box].

Allscripts recommends respondents be able to choose more than one state, as some healthcare organizations span multiple states.

**Q22:** How would you describe the location of the practice in which you use [autofill primary product name based on Q1]?

Allscripts recommends changing the word “practice” to “care setting” because the word practice typically refers to an ambulatory care setting. Allscripts also recommends that rather than ask for the self-described location, the survey ask for one or more zip codes in which the care setting is located, which would allow the results to be translated to urban, suburban/small metropolitan, or rural based on the definitions used by the Department of Health and Human Services.

**Q23:** Approximately what percentage of patients at the practice in which you use [autofill primary product name based on Q1] are uninsured or covered by Medicaid?

Allscripts recommends changing the word “practice” to “care setting” because the word practice typically refers to an ambulatory care setting. Additionally, the setting in which the care is provided may have different numbers and therefore the question should have an option to provide the percentage of uninsured or Medicaid patients for both ambulatory and inpatient settings.

**Q24:** How would you rate your proficiency using [autofill primary product name based on Q1]?

As noted in the beginning of the comments, Allscripts recommends omitting question 24 and rather including asking the respondent what their cumulative number of years using health IT is. If the respondent is a clinician, we recommend asking for their cumulative number of years in practice when collecting other demographics.

*Should the voluntary user-reported criteria cover only the most recent version of a certified health IT product or all versions of the product?*
Allscripts recommends the survey promote transparency. The respondent should have the ability to report on the most recent version of the health IT product they are using. It is important to note that there are may be multiple versions of a product being used by various customers when the product is implemented using a self-hosted, on-premise model. The survey should provide the opportunity for the respondent to enter the version of the product they are using (as it currently does).

**What certified health IT users are most likely able to report on the criteria (e.g., clinicians, administrators, IT specialists)?**

Allscripts’ assumption is that IT department professionals and administrators are the most likely to respond to the survey, as they are the most familiar with the setup and maintenance of certified health IT. It would definitely be important to seek input from clinicians as much as is possible, given the impact of EHR use on their daily experience, but it will likely take special effort to secure time from those busy professionals.

**What could motivate end users to voluntarily report on certified health IT products?**

To encourage end users to voluntarily report on certified health IT products, we recommend the survey be easy and simple to fill out, and each question include an option of “skip” or “don’t know” so the respondent can complete it with ease. Further, we note that it frequently requires renumeration to get busy professional and especially clinicians to spend time on surveys.

Please note that we encourage that the survey results indicating end user experiences with certified health IT, positive or negative, should always be shared with the impacted parties (including the vendor). Allscripts has a strong desire to help our clients remedy any issue, and it would be very counterproductive for public reporting to replace existing mechanisms in place for learning of and managing challenges that come up. Further, we are concerned that such survey responses could be completed by providers in place of the formal feature/enhancement request process, which could negatively impact our ability to continually improve the safety and utility of our solutions.

**Conclusion**

Allscripts is appreciative of the opportunity to provide feedback on the Draft Voluntary User-Reported Criteria survey. We welcome the opportunity to speak further about any of our feedback and suggestions.

With Respect,

Leigh C. Burchell  
Vice President, Policy & Government Affairs  
Allscripts  
(919) 247-1144  
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July 10, 2020

Don Rucker, M.D.
National Coordinator
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

RE: Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program

Dear Dr. Rucker,

The American Academy of Neurology (AAN) is the world’s largest neurology specialty society representing more than 36,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer’s disease, Parkinson’s disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

The AAN appreciates the opportunity to comment on the “Draft Voluntary User-Reported Criteria for the Electronic Health Record (EHR) Reporting Program.” There is a significant need for publicly available comparative information on certified health information technology (IT) to inform the purchasing and implementation needs of certified health IT users. Upon review of the survey and draft criteria, the AAN is concerned that the average clinician may find this survey confusing and difficult to complete. The AAN recommends that this draft be modified so that it is better targeted to specific audiences in varying practice models and that a one-size fits all approach may not be appropriate. Additionally, we recommend that this survey be harmonized as much as possible with other similar surveys to reduce burden on clinicians. The AAN offers the following responses to the below requests for information.

**Which draft criteria would you prioritize for inclusion in the EHR Reporting Program, and why?**

We believe that criteria that has direct clinical impact should be prioritized. EHR functionality can greatly differ on issues related to usability, safety, and interoperability. The questions related to the electronic exchange of information with health information exchanges (HIEs) health information
organizations (HIOs), and prescription drug monitoring programs (PDMPs) are all clinically significant. Additionally, our organization notes that the questions related to patient safety and impact on the delivery of high-quality care are also of paramount importance. An EHR’s ease of exchanging of information with state and clinical registries also has significant implications for patient quality of care.

It is also of the utmost importance that comparative information is available related to administrative burdens. Key topics to prioritize include ease of attesting to the Merit-Based Incentive Payment System (MIPS), ease of exchange of information with clinicians from outside organizations and who use different EHR products, and ease of exchanging health information with payers. Ease of exchange of information with payers is especially important in reducing the burdens associated with prior authorization. The emergence and rapid development of telehealth capabilities have also been a significant development stemming from the ongoing Covid-19 public health emergency. The AAN believes that ease of use for telemedicine capabilities should be emphasized given the rapidly growing importance of telemedicine to care delivery. Telemedicine requires technological infrastructure and the lower the EHR can make this activation energy, the more impact telemedicine and neurologists can have on their patients.

**Which draft criteria should be rephrased, reworded, or removed?**

There are several questions that are unclear as to whether the question is requesting information related to services provided by the vendor itself or by the entity using an EHR product to the end user. The AAN recommends more precisely defining what is being referred to when discussing support, as types of IT support will be variable depending on practice type. At a large institution, much of one’s support may be the institution’s local IT staff, while in private practice, support may be primarily from an independent contractor or support from the EHR vendor. For the purpose of this survey, the we recommend asking specifically about support provided by the EHR vendor.

The AAN recommends splitting question 5.4 into two separate questions that separately asks about the ease of sending information to HIOs or HIEs and the ease of accepting and incorporating information from HIOs or HIEs into the EHR to be easily accessible. The difficulty of exchange of health information can place smaller practices at a disadvantage, while resulting in repeated diagnostics and potentially patient harm. Additionally, the AAN notes that some EHRs will import documents from fax or email, only as an image that is not searchable, some will import PDFs using optical character recognition, and some require that the document be printed and then scanned into the EHR.

The AAN notes that question 20 does not sufficiently cover the range of specialists and specialists other than behavioral health and obstetrics and gynecology are all grouped under the “other” category. Not capturing or delineating on the basis of specialty specific data could be a significant limitation on the utility of this survey. Question 8.11 should be modified to include both the creation and use of structured templates. This question may also not be needed for products in which there is sufficient integration with a voice recognition product. Question 17 could be clarified to specifically query regarding the ease of transition
to an alternate EHR, the cost for practice termination, as well as the transfer of responsibility for maintaining medical records and responding to records requests.

The AAN also recommends that the optical character and user-configured interfaces questions may be more appropriate in a separate category as these elements are not end-user tools and may require knowledge beyond that of the average clinician.

Additionally, the AAN believes that users could benefit from the additional inclusion of quantifiable information related to the number of required clicks and the average time required to complete a certain task. These may include navigating from the patient greeting to opening a templated clinical note, ordering a new non-narcotic medication, accessing a lab report from an outside provider, accessing images from an outside provider, reviewing and importing information from a patient’s family medical history, and reviewing and importing information from a patient’s social history. Users would also benefit from knowing the average time from receipt of outside medical record until it is integrated into the EHR and the typical number of annual system revisions and upgrades. It would also be beneficial for users to know whether a particular EHR updates to new Medicare and Medicaid requirements before the effective date of any changes.

**Should the voluntary user-reported criteria cover only the most recent version of a certified health IT product or all versions of the product?**

The AAN believes that user-reported criteria should cover as many versions as are in use at a given time. It is likely that some users will not be utilizing the most recent version or will not have taken up the most recent set of upgrades due to a lack of IT staff capacity or support. These users would therefore be left out of reporting on the version of the product that they are currently using. Additionally, it would be helpful for users to have reports on previous versions of products to show previously existing issues that were fixed in later product updates. To facilitate this, the AAN recommends that respondents be asked to specify the version of the EHR they use and the most recent upgrade date. Furthermore, some EHRs may not update in a timely manner, and users should have the opportunity to comment on the timeliness of upgrades.

**What certified health IT users are most likely able to report on the criteria (e.g., clinicians, administrators, IT specialists)?**

The AAN believes that input is needed from all categories of users but notes that administrators and IT specialists are likely to be in the best position to report on the criteria. Busy clinicians may not have the time, nor the inclination to voluntarily report on the user criteria. Although the current draft may be overly burdensome for some clinicians, the AAN notes that a targeted usability survey for clinicians may yield valuable data on priority topics, including interoperability.

**What could motivate end users to voluntarily report on certified health IT products?**

There are several ways to incentivize participation in this voluntary survey. Reimbursement or a discount from the EHR vendor for participating may be particularly effective and align
incentives between participating providers and vendors who benefit from robust participation. We request clarification on whether such an arrangement may be an impermissible inducement under the anti-kickback statute. Additional incentives may also include bonuses for participation in the survey through the MIPS program, recognition in other media, and clear indications of how survey feedback has impacted future product iterations, governmental rulemaking, and certification criteria. The AAN also recommends that voluntary respondents should be allowed access to compare their own responses with those from other users of the same product and from users of other EHRs, without disclosing deidentified data from individual clinicians or practices.

Conclusion

Addressing the administrative burdens related to the use of Health IT and EHRs is a top priority for the AAN. We appreciate ONC’s continued engagement and commitment on this issue. Through continued engagement with the provider community, meaningful feedback can be made available to ensure that clinicians and institutions have the information they need when making purchasing and implementation decisions. Our organization is committed to continued engagement with ONC as the health care system continues to make strides towards greater interoperability in health IT.

Thank you for the opportunity to provide comments on the draft “Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program.” Please contact Matt Kerschner, the AAN’s Government Relations Manager, at mkerschner@aan.com or Daniel Spirn, the AAN’s Senior Regulatory Counsel, at dspirn@aan.com with any questions or requests for additional information.

Sincerely,

James C. Stevens, MD

James C. Stevens, MD, FAAN
President, American Academy of Neurology
August 10, 2020

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

Submitted electronically: EHRfeedback@urban.org

SUBJECT: Request for Feedback on Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program

Dear Dr. Rucker:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing more than 4,000 neurosurgeons in the United States, we appreciate the opportunity to provide feedback on the draft voluntary user-reported criteria for the Electronic Health Record (EHR) Reporting Program. The 21st Century Cures Act, or Cures Act, directed the U.S. Department of Health and Human Services to establish a new EHR Reporting Program. The Office of the National Coordinator for Health IT (ONC) has contracted with the Urban Institute to develop the program, which aims to provide publicly available, comparative information on certified health IT products that will inform health IT users’ purchasing and implementation decisions. The AANS and CNS support the goals of this program. We believe it has potential to help clinicians make more informed decisions about EHR investments, but also to incentivize EHR vendors to be more receptive to the needs of clinicians.

Members of the AANS/CNS Neurosurgery Quality Council reviewed the draft potential new criteria to collect from certified health IT users for inclusion in the EHR Reporting Program. Overall, they thought it was a well thought out questionnaire. Listed below is more specific feedback from our members regarding the draft criteria and questionnaire:

- **Prioritizing Ease of Use.** We recommend prioritizing ease of use and interoperability since these are the areas that EHR users struggle with most.
  - If this program is intended to provide guidance for new purchasers, the question of how easy it will be to use the EHR “out of the box” is critical.
  - In addition to information about cost, prospective users might be interested in knowing how long the EHR took to implement, including installation, configuration and training.
  - It would also be helpful to know how long the user has been using the EHR, as the first year or so can be painful, but over time physicians often become more proficient with the system.

- **Ease of End-User Personalization.** The ability of end-users to personalize an EHR to their needs is a key part of end-user satisfaction, and the concept is not sufficiently captured by “ease of use.” For example, some systems allow a tremendous amount of personalization of
documentation (i.e., note templates) and order sets, which allow clinicians to make them useful to their practice. However, building, or making even the slightest change to, an electronic questionnaire (e.g., patient-reported outcomes measures (PROMs)), a discrete data form (e.g., review of systems, a screening or other clinician-rated instrument), or an analytic report takes months of painful emailing with a programmer.

- **Ease of image exchange.** We very much appreciate that image receipt and review were included in the usability draft criteria as it is a significant source of frustration for surgeons who want to see images and not just reports. We would also like to see the interoperability draft criteria specifically include the ease of exchange of imaging with clinicians outside the organization. This is really a separate category from other health data exchange that consistently falls short, but remains a major source of administrative waste and contributes to inefficient care.

- **Ease of integrating with PROMs.** We recommend adding a question(s) about the ease of integrating PROMs into the clinic workflow. PROMs are increasingly part of the standard of care but are a tremendous challenge to collect electronically if not integrated seamlessly into an EHR.

- **EHR-Registry interoperability.** The ability of EHRs to seamlessly communicate with registries has been a longstanding barrier to more efficient and higher quality care. While the landscape is slowing improving, it still has a long way to go. We appreciate that the questionnaire currently asks about these challenges, and we encourage ONC to maintain these critical questions.

- **Incentivizing feedback.** Completion of this questionnaire will require a dedication of time and resources from physicians, IT personnel and practice managers. ONC should work with professional societies to promote the value of contributing to this questionnaire. ONC should also work with CMS to consider potential ways to incentivize the use of the questionnaire through programs such as the Merit-Based Incentive Payment System (MIPS). For example, CMS could give credit under the Promoting Interoperability or Improvement Activities performance categories to clinicians who complete the questionnaire and take the time to share their experiences with other clinicians.

- **Control over EHR investment decisions.** Finally, we remind ONC that very few facility-based clinicians have the autonomy or authority to choose their own EHR system. The questionnaire should attempt to capture these arrangements and the extent to which clinicians have control over EHR selection and implementation.

The AANS and CNS appreciate the opportunity to contribute to the evolution of this program. Should you have any questions or wish to have a more in-depth discussion about our feedback, please contact Rachel Groman, VP Clinical Affairs and Quality, at rgroman@hhs.com or 202-618-3944.

Sincerely,

John A. Wilson, MD, President
American Association of Neurological Surgeons

Steven N. Kalkanis, MD, President
Congress of Neurological Surgeons
August 10, 2020

VIA ELECTRONIC SUBMISSION

Genevieve Kenney, PhD
Health Policy Center
Urban Institute
500 L’Enfant Plaza SW
Washington, D.C. 20024

Dear Dr. Kenney,

On behalf of the American College of Osteopathic Family Physicians (ACOFP), we appreciate the opportunity to comment on the draft Electronic Health Record (EHR) Reporting Program documents under development at the Urban Institute.

ACOFP is the professional organization representing more than 18,000 practicing osteopathic family physicians, residents, and students throughout the United States who are deeply committed to advancing our nation’s health care system by improving health care delivery and outcomes and ensuring that patients receive high-quality care.

As an organization of primary care physicians, we are acutely aware of the issues related to EHRs and medical documentation. Almost daily, family physicians interact with their EHRs and have a strong understanding of both the benefits and drawbacks of EHRs. While the draft documents are comprehensive, there are areas for improvement. We believe the documents should reflect issues related to patient satisfaction, efficiency, medical liability, and other physician concerns. Overall, we hope our feedback will help the Urban Institute develop a product that will drive innovation and efficiency in EHR technology.

Our full comments are detailed on the following pages. Thank you for the opportunity to share our feedback with you. Should you need any additional information or if you have any questions, please feel free to contact ACOFP at advocacy@acofp.org or (847) 952-5100.

Sincerely,

Robert C. DeLuca, DO, FACOFP dist.
ACOFP President
The growth of EHRs have been a double-edged sword for physicians. On one hand it has the potential to drive better patient health outcomes and improve efficiency in the health care system generally. In reality, however, EHRs have added countless hours of administrative work for physicians, leading to burnout and overall dissatisfaction with the profession. This has been particularly noticeable among primary care physicians as the bulk of EHR requirements are placed on them. We fear the excessive administrative workloads could push more medical students toward specialties and further exacerbate the primary care physician shortage across the country.

ACOFP surveyed osteopathic family physicians requesting their feedback on the draft documents. Our member physicians reviewed the Draft Voluntary User-Reported Criteria document and the Draft Voluntary User-Reported Criteria Summary Tables. In general, feedback was positive in that the documents were thorough and comprehensive. However, the documents do not adequately address physician-specific concerns related to patient satisfaction, efficiency, and other concerns. We summarize comments from our member physicians below.

**Patient Satisfaction**

EHRs often are used during an office visit or in conjunction with prescribing drugs for the patient. If a patient is waiting in the doctor's office while the physician has to operate a faulty EHR, the patient may blame the physician for any delays or disruptions in care. Both documents do not address this issue. Family physicians therefore support the addition of a question related to patient satisfaction as perceived by the physician. This would be helpful information for other EHR end-users to know if the product created any issues for the patient. We recommend including language in both documents that would capture this type of information.

Additionally, since entering data in an EHR often can take the physician's attention away from the patient during a visit, many physicians have hired scribes to capture in the EHR the interaction between the doctor and patient during an office visit. This is an expensive solution to a problem that instead could be addressed by making it more efficient to enter data into an EHR. The documents therefore should include a question that gauges whether a physician can efficiently input data into an EHR from a patient visit.

**Efficiency**

EHRs require considerable manipulation to achieve the desired results even for simple procedures or services. As an example, for a routine flu shot, some EHRs require physicians to click through page after page of documentation. EHRs should be streamlined in a way that allows physicians to quickly obtain a flu shot or perform a routine item. We recommend including questions that gauge an end-user's ability to quickly order items like flu shots through the EHR system. Additionally, EHRs should prompt basic information on providers, including which health care provider ordered an item or service and why that item or service was ordered. The documents therefore should include a question reflecting an EHR's ability to provide such basic information efficiently to other providers.

Furthermore, EHRs malfunction and occasionally require the physician or staff to troubleshoot the program or device. EHRs should be able to quickly troubleshoot and guide the provider back to the correct medical documentation. Since many personal computers or tablets are able to perform this function, so should EHRs. We recommend including questions related to the ability for the program or device to quickly resolve technical issues while also maintaining data the provider was reviewing or inputting when the issue occurred.
**Other Concerns**

Our surveyed members also mentioned a variety of general concerns related to EHR review. For example, there were no questions in the survey related to medical liability. Some physicians worry they will be exposed to litigation if an EHR malfunctions or provides inaccurate information. To the extent possible, the documents should include questions that gauge whether the EHR system had any safeguards to limit medical liability.

Additionally, EHRs could benefit from the ability to link to educational materials for the patient that supplement the provider’s medical advice. This information should also be available pictorially for illiterate patients as well as in multiple languages for non-English speaking individuals. We recommend including questions that gauge the ability of EHRs to provide these types of resources for physicians and patients.

Also, as reflected in the documents, interoperability among EHRs is critical in gauging a successful system. The questions should adequately reflect the ability to exchange information across platforms, in the same health system, and between specialists and primary care physicians or any care provider. We also encourage questions that capture the ease of merging EHRs and the fees associated with accessing records from prior EHR systems or from a physician no longer practicing. All these pieces of interoperability are usually overlooked, but critical for a successful EHR system.

Specifically, some physicians noted that question 20 in the Draft Voluntary User-Reported Criteria document did not include “inpatient” setting as an option. We recommend including that option. Additionally, questions 15 through 17 and 23 are not typically known to end-users in large health systems. Those questions may not be best suited for providers in large health systems.

Finally, the survey is thorough and comprehensive, but is time consuming for physicians. We recommend a survey for health care administrators and another shorter survey tailored to physicians.

**Conclusion**

The work of the Urban Institute is important to ensure that EHR end-users can provide candid feedback that will influence purchasing habits. We are hopeful this feedback will incentivize EHR developers to create user friendly, efficient, and clinically helpful products that can leverage critical health patient data while not impeding care delivery through inefficient program designs. Thank you for your consideration of our comments.
August 7, 2020

Don Rucker, M.D.
National Coordinator
Office of the National Coordinator for Health Information Technology
330 C Street, SW
Washington, DC 20201

Re: Request for Public Feedback on Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program

Dear National Coordinator Rucker,

On behalf of the American College of Physicians (ACP), I am pleased to share our feedback on the Office of the National Coordinator for Health Information Technology (ONC) and the Urban Institute’s Request for Public Feedback on Draft Voluntary User-Reported Criteria for the Electronic Health Record (EHR) Reporting Program. ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 163,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The College appreciates the effort of ONC and the Urban Institute in developing criteria and seeking stakeholder feedback throughout the process. We also appreciate the effort to make sure the end user reporting process and criteria are not too time-consuming and burdensome. However, ACP is concerned that the questions are too high-level to gather feedback on specific functionalities of health IT systems, and thus, will not yield information that is useful to end users. We encourage ONC and the Urban Institute to focus future work on gathering information that will improve both functionality and effectiveness of systems in real-world settings. To this end, ACP recommends improvements to collect information on and evaluate exact functionalities of health IT systems, such as examples we have provided below.
ACP encourages ONC and the Urban Institute to draw from our experiences with our past development and maintenance of AmericanEHR\(^1\) – a free web-based “consumer-reports” for EHRs. AmericanEHR collected user data through extensive annual surveys that, though time-consuming and labor extensive, found the support of clinicians who were willing to provide the information because they found value in the content. ACP recommends ONC and the Urban Institute organize the reporting process so that the users reporting data see value in the process and content of what they are reporting – leading to a greater degree of participation and collection of more meaningful information. This will require questions and feedback that benefit the end user reporters – similar to AmericanEHR.

An important part of this reorganizing should also include shifting focus from IT specialists to that of the actual clinical end users. The criteria are written with such technicality, or with an object to gather information that would be technical in nature, that the average end user would have to defer to an IT specialist – a burdensome and unnecessary task. Question one, which asks participants about the version of the certified health IT system they are using, is illustrative of this issue. Clinicians are not likely to know the version identifier of their system or what add-on products they use. In order to not be burdensome, the criteria should gather specific information that is useful to end users – and this includes targeting feedback from the actual end users themselves.

Should the aforementioned attempts to attain user participation fail, incentives could be provided. For example, the Centers for Medicare and Medicaid Services (CMS) could provide bonus points through the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category for those users that submit data to the EHR Reporting Program. ACP encourages the ONC and the Urban Institute to engage with end users of health IT to better understand how to obtain their meaningful participation in the EHR Reporting Program.

The following contains specific feedback on ONC’s EHR Reporting Program Criteria Categories:

**Interoperability:**

Most of the criteria’s interoperability focus is on measuring the actual movement of data from one place to another, which while important, does not really address whether interoperability promotes the sharing of meaningful and actionable information. Rather than just measuring the exchange of data, ACP recommends the interoperability measurement ask whether EHR systems help reduce unwarranted tests or diagnostic studies because that information was readily available or easy to access/exchange/incorporate into the system. We also believe the criteria could benefit from broadening “exchange” (as used in 5.1-5.7) to collect information on the ease of which users can send, receive, and integrate data into the patient record. By gathering more data on these specificities, ONC and the Urban Institute will have more telling information, aside from the ordinary existence or inexistence of an occurrence, such as the exchange.

In order to better promote and measure interoperability, ACP recommends ONC and the Urban Institute collect evidence of value as well as evidence of data movement. An example of this could be asking how EHR systems address mitigating inaccurate data. As ACP noted in its comments on ONC’s Interoperability Standards Advisory\(^2\), as much as it is important to gather evidence on the exchange of information, it is equally important to address the spread of incomplete or inaccurate health information – and the need for uniform implementation and management of provenance functionality within EHR systems. Presence of such functionality will also decrease the likelihood of bad data in EHRs causing care delivery errors.

**Usability:**

As ONC and the Urban Institute continue rethinking the criteria, ACP encourages the consideration of a more detailed analysis in improving the usability reporting criteria, such as the following:

- **Medication Management and e-Prescribing** – checking patient formulary information, managing drug alert interactions, recording non-prescription medications, receiving a refill request, generating and transmitting an electronic prescription, etc.
- **Capturing and Generating Patient Information** – documenting care plans, documenting a progress note, Evaluation and Management (E/M) coding support, recording family and social history, generating an electronic copy of patient’s medical record, generating a useful and readable summary of care reporting, generating a patient referral letter, etc.
- **Capturing Patient Narrative** – capturing the patient’s story, collecting patient-reported outcomes, integrating patient-generated data, etc.
- **Patient Safety** – addressing “near misses” or when the EHR could have caused patient harm but did not
- **Order Management and Tracking** – viewing lab results, viewing radiology images or studies, ordering a lab test, generating lists of patients who have overdue lab results and flagging overdue tests, etc.
- **Population Management and Public Health Reporting** – generating lists of patients with specific conditions or patients on specific drugs, generating reminders for preventative care, ability to send information or surveillance data to a specialized registry, etc.
- **Data Visualization and Decision Support** – providing context-sensitive clinical decision support in useful forms, creating automatic reminders, creating templates for specific clinical conditions, editing of reminder rules, supporting text macros, user control of alerts, etc.
- **Vendor Tech Support** – directly connecting to vendor IT support (e.g., tech support button within the EHR)

\(^2\) ACP’s Comments on ONC’s 2018 Interoperability Standards Advisory: https://www.acponline.org/acp_policy/letters/acp_comments_on_interoperability_standards_advisory_2018.pdf.
Privacy and Security:

Due to the sensitive nature of the information stored within EHRs, ACP recommends ONC and the Urban Institute include more than just one question on privacy and security. This area could benefit from a broader collection of information pertaining to health IT systems’ administrative controls and safeguards. ACP believes this information could be crucial in identifying and correcting errors of systems, as well as how to address and resolve the “near misses” discussed earlier.

Cost and Implementation:

The draft reporting criteria fail to address the gap in information on base, subscription, and transaction costs associated with the purchase and implementation of EHRs. To address this, ACP recommends ONC and the Urban Institute distinguish between implementation, customization, and upgrade costs – as well as other add-ons that might be needed once the system is fully implemented. In some cases, these additional costs can come from sources outside of the EHR or health IT vendor, such as state-based regulations that require certain add-ons or functionality. Additional costs may also be paid to independent implementation consultants, or additional technical/product support. It is important for these costs to be accounted for and distinguished between so as to most accurately capture cost reporting that is useful to end users.

In order to be most reflective of the real-world settings in which EHRs are used, ACP recommends the implementation measurement assess how EHR systems perform once they are fully employed and running in a real product environment. Once implemented, it is incredibly difficult for practices to “shop around” for an entirely new system if it is not meeting their needs. This is due to the significant costs and the substantial amount of time it takes to implement EHR systems, as well as the time to roll out any system upgrades. ONC and the Urban Institute should gather specific information in this area that will be helpful to end users and make implementation a less burdensome and more transparent task. Future drafts should focus the implementation criteria to reflect this very real concern.

Conclusion:

We thank ONC and the Urban Institute for the opportunity to offer feedback on the draft user-reported criteria. As it relates to the improvement of health IT systems, the importance of the information gathered from the user-reported criteria cannot be overstated. We hope that you will find value in our response and continue to engage with our organization and the broader stakeholder community in future deliberations. Should you have any questions, please contact Dejah Johnson, Analyst for Health IT Policy and Regulatory Affairs, at djohnson@acponline.org.
Sincerely,

Zeshan A. Rajput, MD, MS
Chair, Medical Informatics Committee
American College of Physicians
August 10, 2020

Dr. Donald Rucker
National Coordinator
Office of the National Coordinator for Health Information Technology
330 C Street, SW
Floor 7, Switzer Building
Washington, DC 20024

Re: Electronic Health Record Reporting Program

Submitted electronically at: EHRfeedback@urban.org

Dear Dr. Rucker:

Thank you for the opportunity to provide feedback on the Electronic Health Record (EHR) Reporting Program.

AHIMA is a global nonprofit association of health information (HI) professionals. AHIMA represents professionals who work with health data for more than one billion patient visits each year. AHIMA’s mission of empowering people to impact health drives our members and credentialed HI professionals to ensure that health information is accurate, complete, and available to patients and clinicians. Our leaders work at the intersection of healthcare, technology, and business, and are found in data integrity and information privacy job functions worldwide.

We offer the following responses to questions posed by the Urban Institute.

**Which draft criteria would you prioritize for inclusion in the EHR Reporting Program, and why?**

AHIMA agrees with much of the criteria that has been proposed for the EHR Reporting Program. However, we would like to prioritize two key areas for inclusion in the program: documentation and data analytics.

Proper documentation can be facilitated through the effective use of structured EHR templates. Structured templates can support the capture of clinical content in a standardized and structured manner. Leveraging structured templates will not only improve clinical documentation, thereby leading to a higher quality of care, but can improve the design of clinically robust algorithms and better tracking of outcomes of care. Given the importance of structured EHR templates to enhancing proper documentation and improving quality of care, documenting the ease in which stakeholders use such structured templates is critical to understanding how such functionality may be improved within EHRs and health IT systems.

Data analytics is also a key priority for inclusion in the EHR Reporting program for AHIMA. As the volume, velocity and variety of health data continues to grow, making better use of it has huge potential
for lowering costs and improving quality in healthcare. Understanding the ease in which EHRs and health IT systems may be used for data analytics purposes is important to not only improve clinical and administrative operations but also for research, public health, and evidence-based medicine.¹

That said, two key criteria are missing from the EHR Reporting Program that we believe should be prioritized. First, we believe the inclusion of social determinants of health (SDoH) functionalities should be prioritized for inclusion in the program, including whether an EHR or health IT system supports SDoH-related data collection and the extent to which patients can be referred to community resources including social services. AHIMA recently conducted a survey of its membership and found 50 percent of respondents reported that lack of discrete EHR fields and/or functionality was a major challenge in collecting SDoH data.

Complete, accurate, and timely health data, including SDoH, can help identify opportunities “to create social and physical environments that promote good health for all.”² There are challenges in standardizing SDoH data in EHRs and for that reason AHIMA and our members are active participants in the Gravity Project. However, according to ONC, as of December 2019, 72 health IT developers had voluntarily certified 93 unique products to an SDoH-oriented certification criterion, and these 72 developers offer technology to nearly half of all office-based clinicians and nearly a third of hospitals.³ Indeed, in AHIMA’s recent SDoH membership survey, we found that approximately 56 percent of respondents’ organizations collect SDoH data. For that reason, we believe it is appropriate that SDoH functionalities be documented as part of the reporting program.

The second criteria that is missing from the EHR Reporting Program that should be prioritized is patient matching. This is particularly disappointing given that patient matching (when exchanging data with nonaffiliates) is listed as a “High Priority Measure Topic” that was identified by stakeholders in the report, What Comparative Information is Needed for the EHR Reporting Program: Priorities Identified through the Stakeholder Engagement Process.⁴ The ability to accurately match an individual to their health information is fundamental to achieving the promise of nationwide interoperability but more importantly it is necessary for patient safety. EHRs and health IT systems can vary in accuracy and sophistication in matching patients to their health information given the use of different standards and algorithms. Allowing users to document their EHR or health IT system’s patient matching performance would encourage transparency and allow stakeholders the ability to examine comparatively how different EHRs and health IT systems perform.

Which draft criteria should be rephrased, reworded, or removed?

Question 5.1: Ease of exchange with clinicians who have a different EHR/health IT product

AHIMA recommends question 5.1 be clarified to include both intra-organizational exchange and electronic exchange external to the organization. HI professionals continue to struggle with intra-organizational exchange given the use of downstream systems that may be a different EHR or health IT

² Available at: https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.
³ Available at: https://www.healthit.gov/buzz-blog/interoperability/advancing-interoperable-social-determinants-of-health-data#_ftn1.
⁴ Available at: https://www.urban.org/sites/default/files/publication/102087/what-comparative-information-is-needed-for-the-ehr-reporting-program_4.pdf.
product or version. While numerous larger health systems continue to move toward a single platform/vendor, many systems continue to utilize a host of different EHR vendors, products, and versions. Clarifying question 5.1 would enable a more meaningful survey response and allow stakeholders to more meaningfully consume the survey data.

**Question 5.5: Ease of exchange with payers**

“Electronically exchanging health information with payers” should be further clarified in Question 5.5. Today, exchanging clinical data with payers may involve sending the information via paper/fax, sending the information via mail on a CD, uploading the information to a payer’s portal, using an automated HIPAA transaction standard, or providing direct electronic access to a subset of records. In each of these instances, multiple formats may be used for a single patient stay or encounter and can involve multiple back-and-forth exchanges. Phone calls may also be needed to check status and address additional questions. We are concerned that question 5.5 as currently drafted oversimplifies the complexity involved in electronically exchanging data between providers and payers and could skew responses by attributing some of the challenges associated with exchanging clinical data for administrative purposes to an EHR or health IT system when such challenges may be beyond the scope of the product or system.

**Question 7.2: “Has an intuitive workflow”**

AHIMA recommends that ONC adopt the language in Table 2: Usability Draft Criteria, “aligns with practice workflow” versus “has an intuitive workflow” as currently drafted in question 7.2. We believe the language in Table 2 is clearer and easier to comprehend.

**Question 7.4: “Produces clinical benefits for the practice”**

AHIMA recommends that question 7.4 be revised to state “produces measurable clinical benefits for the practice.” This clarification would more accurately capture whether the EHR or health IT system did in fact produce clinical benefits for the practice (regardless of the size of the actual benefit.) Furthermore, from a stakeholder’s perspective of using the EHR Reporting Program, such a clarification would offer more meaningful information in assessing available products.

**Should the voluntary user-reported criteria cover only the most recent version of a certified health IT product or all versions of the product?**

To reduce confusion and to mitigate unnecessary burden on providers, the voluntary user-reported criteria should cover the edition of CEHRT in use by the Promoting Interoperability Programs and the Merit-based Incentive Payment System (MIPS). Should the PI programs or MIPS allow the use of more than one edition or a combination of both, the user-reported criteria should cover both.

**What certified health IT users are most likely able to report on the criteria (e.g.—clinicians, administrators, IT specialists)?**

HI professionals are strategically well-placed to report on the program’s criteria. HI professionals are active participants in the entire EHR lifecycle, leveraging their expertise in data governance, privacy and security, workflows and health information exchange to capture, maintain and produce accurate, timely and complete quality data. Furthermore, because HI professionals are primarily tasked within their institutions with understanding the flow of where and when health information needs to travel and the
integrity of that information, they have a clear understanding of the certified health IT products in use and the performance of these products as they relate to interoperability and usability. Because HIM departments work closely with IT departments on the implementation of certified health IT products, they also have a deep understanding of the implementation process itself, related product support, and upgrades and maintenance.

**What could motivate end users to voluntarily report on certified health IT products?**

To motivate end users to voluntarily report on certified health IT products, AHIMA suggests that ONC work closely with specialty societies and other professional organizations. Working closely with these organizations will not only encourage reporting under the program but help ensure that the data reported as part of the EHR Reporting Program are credible and verifiable.

AHIMA also recommends offering end users financial incentives to enhance survey responses. Such incentives could include offering bonus points under the Promoting Interoperability Programs and MIPS upon completion of the EHR Reporting Program survey. The extent to which the survey could be integrated into existing reporting requirements for these CMS programs would help to limit administrative burden for stakeholders and streamline such reporting requirements.

We appreciate the opportunity to submit comments on the Electronic Health Reporting Program. We hope that you will continue to engage extensively with stakeholders on the reporting program and we look forward to working with you to ensure its successful launch and implementation. Should you or your staff have any additional questions or comments, please contact Lauren Riplinger, Vice President, Policy & Government Affairs, at lauren.riplinger@ahima.org and (202) 839-1218.

Sincerely,

Dr. Wylecia Wiggs Harris, PhD, CAE
Chief Executive Officer
AHIMA
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 programing 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 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 verses 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 “addons” routinely cost tens of thousands of dollars. Worse still, physicians face challenges using interoperable addons 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 verse 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.
Electronic Health Record Reporting Program

Submitted August 10, 2020

Dr. Luann Whittenburg, PhD, RN, FNP, FHIMSS, FAAN
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Comments: Draft Voluntary User-Reported Criteria
Summary Tables

Note: Physicians are one of the many clinical providers using electronic health records. Each practice, clinical setting, facility, and enterprise must accommodate all clinicians including professional Nurses. As anticipated by ONC, these clinicians can achieve interoperable and integrated healthcare records and improve care outcomes and costs. Professional Nurses participate in ONC requests for comments and must be recognized and acknowledged as a full professional partners and key clinical contributors to patient healthcare outcomes. Clinical practice by professional Nurses is a distinct practice and should not be interchanged with physicians/provider services.

Comments and recommendations for the “Electronic Health Record Reporting Program”: Table 2 and the User-Reported Criteria are highlighted in bold, blue text below.
Comments A: on Usability Table 2

Table 2: Usability Draft Criteria

<table>
<thead>
<tr>
<th>Stakeholder Priority Topic</th>
<th>User Questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall usability</td>
<td>5 Satisfaction with overall usability</td>
</tr>
<tr>
<td>Provider burden</td>
<td>Satisfaction with product:</td>
</tr>
<tr>
<td>7.1</td>
<td>Allows users to be more productive</td>
</tr>
<tr>
<td>7.2</td>
<td>Aligns with practice workflow</td>
</tr>
<tr>
<td>7.3</td>
<td>Easily accesses and assimilates data from other products</td>
</tr>
<tr>
<td>7.4</td>
<td>Produces clinical benefits for the practice</td>
</tr>
<tr>
<td>7.5</td>
<td>Decreases time spent documenting patient care</td>
</tr>
<tr>
<td>Quality and safety</td>
<td>Satisfaction with product:</td>
</tr>
<tr>
<td>7.6</td>
<td>Enables delivery of high-quality care</td>
</tr>
<tr>
<td>7.7</td>
<td>Improves patient safety</td>
</tr>
<tr>
<td>7.8</td>
<td>Does not disrupt interaction with patients</td>
</tr>
<tr>
<td>7.9</td>
<td>Easily produces understandable clinical summaries</td>
</tr>
<tr>
<td>7.10</td>
<td>Helps prevent care delivery errors</td>
</tr>
<tr>
<td>7.11</td>
<td>Has advantages that outweigh the disadvantages overall</td>
</tr>
<tr>
<td>Analytics</td>
<td>8.1 Ease of use for data analytics</td>
</tr>
<tr>
<td>Orders</td>
<td>8.2 Ease of use for default values for common orders</td>
</tr>
<tr>
<td>Documentation</td>
<td>8.4 Ease of use for evidence-based order sets and charting templates</td>
</tr>
<tr>
<td>e-Prescribing controlled substances</td>
<td>8.3 Ease of e-prescribing of controlled substances</td>
</tr>
<tr>
<td>Receiving and reviewing images</td>
<td>8.5 Ease of image receipt and review</td>
</tr>
<tr>
<td>Chronic disease management tool</td>
<td>8.6 Ease of use for integrated chronic care management tool</td>
</tr>
</tbody>
</table>

Part of Table 2: Provider Burden – Include Nursing

7.2 Aligns with practice workflow
  7.2.1 Aligns with nursing workflow
  7.2.2 Aligns with other clinical workflows (physical therapy, respiratory therapy, others)

7.4 Produces clinical benefits for the practice
  7.4.1 Produces clinical benefits for the facility

7.5 Decreases time spent documenting patient care
  7.5.1 Increases time spent with patients

Analytics

8.1 Ease of use for data analytics
  8.1.1 Includes coded data for Nursing Services analytics
8.1.2 Coded Nursing Services in approved terminology of the American Nurses Association
8.1.3 Able to determine cost of Nursing Services (e.g. by Service, by population)
8.1.4 Able to determine cost of Nursing Services by Plan of Care

Orders
8.2 Ease of use for default values for common orders
8.2.3 Able to determine provider orders were completed by coded Nursing Service
8.4 Ease of use for evidence-based order sets and charting templates
   8.1.3 Able to develop Plans of Care (e.g. by patient population)
   * Reference terminology, such for SNOMED and LOINC, are not meaningful at the point of care. These lack Nursing Services definitions for consistent application of the Service (concept) between and among organizations.

Documentation
8.11 Ease of use for structured templates
   8.11.1 Able to develop Plans of Care (e.g. by patient population)
   8.11.2 Decreases nursing time documenting Nursing Services

Comments B on Draft Voluntary User-Reported Criteria

Question 2. What type of health IT user best describes you? Choose all that apply.

For all questions in this survey, please consider only [autofill primary product name based on Q1 response].

2. What type of health IT user best describes you? Choose all that apply:
   a. Practicing physician
   b. Practicing other clinician
   c. Pharmacist
   d. Health IT or administrative clinician
   e. Health IT staff (nonclinician)
   f. Other nonhealth IT administrator (nonclinician)
   g. Other [please specify]

Practicing Other Clinician may include nursing; the ambiguity of the role is also applicable to physical therapists, respiratory therapists, and others. The nurses’ role in the use of certified health IT products is unique. The role of the nurse has special significance in product evaluations. Nursing is a distinct practice. Add PROFESSIONAL REGISTERED NURSE
Part of Voluntary User-Reported Criteria: Usability

Question 7. The extent to which the certified health IT product 7.1 allows users to be more productive:

7. How would you rate your satisfaction with the following aspects of [autofill primary product name based on Q1]?
   a. Very satisfied
   b. Satisfied
   c. Neither satisfied nor dissatisfied
   d. Dissatisfied
   e. Very dissatisfied
   f. Don’t know or not applicable

The extent to which the certified health IT product

7.1 allows users to be more productive
7.2 has an intuitive workflow
7.3 easily accesses and assimilates data from other products
7.4 produces clinical benefits for the practice
7.5 decreases the time users spend documenting patient care
7.6 enables clinicians to deliver high-quality care
7.7 improves patient safety
7.8 does not disrupt clinician interaction with patients
7.9 easily produces understandable clinical summaries
7.10 provides system alerts that help prevent care delivery errors
7.11 has advantages that outweigh its disadvantages overall
7.12 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)

Include

7.12 Provides coded data for Nursing Services analytics
7.13 Provides coded Nursing Services in approved terminology of the American Nurses Association
7.14 Provides structured Plans of Care for Nurses

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

Response Options
a. Very easy
b. Easy
c. Neither easy nor difficult
d. Difficult
e. Very difficult
f. Don’t know or not applicable (e.g., do not use this function)
g. Product does not have this function

8.1 Data analytics
(e.g., produce feedback reports, identify high-risk patients, create data visualizations and graphics)

8.2 Default values for common orders
(e.g., medication order specifics, routine laboratory draw times)

8.3 E-prescribing of controlled substances
(e.g., using e-prescribing for Schedule II–V controlled substances)

8.4 Evidence-based order sets and charting templates
(e.g., prepopulated order sets and charts)

8.5 Image receipt and review
(e.g., x-rays, CTs, and MRIs)

8.6 Integrated chronic care management tool
(e.g., care plans, care transitions, coordination with home- and community-based services)

8.7 Mobile accessibility
(e.g., mobile-friendly web interfaces, ease of use on smartphone)

8.8 Optical character recognition
(i.e., ability to encode scanned text and integrate into the product’s data fields)

8.9 Patient reminders
(e.g., ability to send through patient portal, automated reminder calls)

8.10 Remote accessibility
(i.e., access from home computers and tablets)

8.11 Structured templates
(e.g., prepopulation of templates with patient information or with clinician name and information)

8.12 Telemedicine capabilities
(e.g., virtual visits, video, and/or data collection within health IT product)

8.13 User-configured interfaces
(e.g., screen views, tabs, links, charts, reports, templates, alerts)

8.14 Voice recognition/voice-to-text capabilities
(e.g., voice-activated recording, natural language processing)

8.15 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]

Include

8.15 Nursing Services
8.15.1 Includes coded data for Nursing Services analytics
8.15.2 Coded Nursing Services in approved terminology of the American Nurses Association
8.15.3 Able to determine cost of Nursing Services (e.g. by Service, by population)
8.15.4 Able to determine cost of Nursing Services by Plans of Care
8.15.5 Able to develop Plans of Care (e.g. by population)

Clinical practice by professional nurses is a distinct practice and should not be interchanged with physicians/provider services.
July 27, 2020
The Urban Institute
On Behalf of the Office of the National Coordinator (ONC) for Health Information Technology

Dear Sir or Madam,

Cerner Corporation, a leading supplier of electronic health record, clinical and revenue cycle information systems appreciate the opportunity to submit comments on the draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program documents posted by the Urban Institute on their web site in support of the development of the EHR Reporting program by ONC under directive of the 21st Century Cures Act (Cures Act).

Cerner Corporation hopes these comments will be of value to ONC and The Urban Institute in their development of the EHR Reporting Program. We are happy to help clarify any of the comments should either ONC or The Urban Institute wish to pursue any such conversations with us during the period of public comment review.

Sincerely,

John Travis
Vice President and Regulatory Strategy Executive
Cerner Corporation
General Comments
As drafted, the criteria and the survey seem to be unclear or incomplete on several points.

- First, the purpose and use of the data to be collected in unclear relative to other forms of data and feedback that may be collected from other sources. In its report developed by The Urban Institute that preceded the publication of the draft criteria, potential data sources were identified by topic for measurement. We recommend that a statement of context for how data collected through the draft criteria survey would be used relative to the other sources of data collection.

- Second, how is the data to be collected? It is not clear how the “users” are to be identified with any degree of accuracy and reliability or what if any role in identifying them health information technology developers will provide. What is to be the source of identifying “users” and will developers be able to have any input or ability to validate they are indeed “users” of any given product? How is the user population and sample to be drawn and by what method?

- Third, the survey seems to be inordinately focused on ambulatory EHR use. We mention where and how several times in our detailed comments, but the use of the term “practice” and the apparent focus on ambulatory use cases or purposes of use paired with a lack of mention of institutional settings in certain places in the draft criteria leads the reader to believe that the scope of focus of the criteria is incomplete.

- Fourth, the survey criteria are unclear as to whether or not the scope of the criteria are limited to certified health information technology or if questions are crossing into areas that are not part of either the capabilities that are directly tested in certification or necessary to support implementation of certified health information technology. Given the EHR Reporting Program is intended by our understanding for the comparison of certified health information technology, its scope should remain within that understanding.

- Fifth, the “user” role is unclear in this survey, and the workflows related to use of certified health information technology are also unclear as to what participation the user has in use the way it is represented in the criteria.

- Sixth, the focus on interoperability seems incomplete. It does not seem to contain much emphasis on the purpose of interoperability (e.g. what is health information exchange being used to accomplish) or in what form or by what standard it is occurring. There also is little information being sought on just what exchanges are supported by a given certified health information technology product or module, and little on the actual production experience of the use of health information technology is requested in substance.
Lastly, several perspectives are lacking in this survey that are a part of the scope of function of certified health information technology. Most notably, this includes anything representing the consumer, quality reporting or public health reporting.

Electronic Health Record Reporting Program: Draft User-Voluntary Reported Criteria Questions

Question 2: What type of health IT user best describes you?

The response options to this question seem limited when it comes to non-clinical roles. There are other user roles that seem over aggregated to be classified under “administrative” or “non-clinician”. Specifically, we recommend that roles for consumer engagement, quality and public health or infection control be added to appropriately represent the types of Certified Health Information Technology (CHIT) capabilities important to consumer, quality reporting and public health reporting types of uses. We also recommend removal of the role “pharmacist” which is not a role that uses CHIT at least in any direct way significant to the capabilities of CHIT.

Questions 3 and 4 – Formatting
The questions are written as if in the format of a standard Likert scale for responses but are enumerated “a-e” and not “1-5”.

Overall Satisfaction: Question 4: How likely is it that you would recommend (autofill primary product name based on Q1) to a colleague with a practice similar to yours?

The wording of this question seems inordinately focused on ambulatory CHIT. A lay reader would not understand this question to be applicable to hospitals, institutional post-acute care settings or other care settings. The term “practice” has a loaded meaning to connote a physician or clinician practice such as would be true for a participant in the MACRA QPP/MIPS program. ONC uses the term “settings” in its Cures Act rulemaking in reference to program requirements like Real World Testing that asks developers of CHIT to indicate what venues of care to which their products are marketed. We recommend that the same kind of representation of venue be used in the questionnaire used for collection of user-voluntary reported criteria instead of “practice”.

Interoperability: Question 5: Indicate the level of ease or difficulty completing each of the following tasks using (autofill primary product name based on Q1).

The question seems inappropriately vague on what is meant by identifying what is meant by task and the ease or difficulty of its completion. Is the manner of interoperability easy to use or is it
easy to configure and implement? We suggest separating out questions of implementation or configuration from use.

We also do not see that the purpose of exchange is reflected in this question aside from a few questions that ask about specific types of exchange such as for public health reporting or for connecting to Prescription Drug Monitoring Databases (PDMPs). We understand that ONC may not want to make this data collection overly burdensome but we think that when the question is generic to purpose (e.g. connection to HIOs or HIEs), the purpose or type of exchange should be included as the connections are most often purpose specific such as for electronic prescribing, clinical document based exchange or of transactional data for revenue cycle/administrative purposes.

We believe the sub questions incomplete for what they ask. We have several suggested additions.

- While there are questions on electronically exchanging health information through health information organizations (HIOs) or health information exchanges (HIEs), we believe there should be a question on which HIEs or HIOs the primary CHIT connects to. A provider might connect with numerous HIEs or HIOs but may have connectivity challenges with only one among many and yet respond to the current question negatively. The current question is too high level and should be restructured to allow for specificity of at least any representation of difficulty of connectivity specific to a given HIE or HIO versus general issues. We believe this significant to understand the scope or experience base of a given developer of CHIT.
  - For exchange with payers, which ones?
  - For public health submission, which registries or States?
  - For clinical registries, which ones?
  - For PDMPs, which States and through what mechanisms?
- Again, we believe the purpose(s) of exchange or of the interoperability at hand should be asked anytime the question is generic to the purpose such as for connection to HIEs or HIOs or for exchange with other clinicians inside or outside of the organization.

The structure of the question also mixes in reporting with interoperability on the last two sub-questions.

- Question 5.9, distinct from the submission of health information, asks about “producing all the reports that are required for my organization’s specialty”? This question seems to be worded more for physician or ambulatory practice needs such as are part of the practice requirements and HIT requirements for CMS’s CPC+ medical home model program where feedback reports for quality measurements for internal use for the practice are required. However, does that really belong in a question about interoperability? And is the wording broad enough to also capture hospital or institutional provider settings? We recommend again the wording be more of “venue” or “setting”.
- Similarly, question 5.10 asks about the ability of the CHIT to support attestation to Promoting Interoperability or to the MACRA QPP/MIPS program. We agree that this is an important evaluative point but recommend reporting be separated out as its own question.
Usability: Question 6: How would you rate the overall usability of (autofill primary product name based on Q1)?

This question seems quite general and while it may provide an opportunity for an overall evaluative statement about CHIT, a single overall usability question representing the entire EHR provides no meaningful value to the survey. “Usability” alone has 4-5 different concepts (e.g., effectiveness, efficiency, satisfaction, and learnability) essential to a fair evaluation and each of those constructs would have to be evaluated individually to derive any meaning from this question.

Usability: Question 7: How would you rate your satisfaction with the following aspects of (autofill primary product name based on Q1)?

This question does a good job at getting at certain aspects of usability but we do have some questions about certain of the sub-questions. In particular:

- 7.2 implies ‘intuitive’ means the same thing to everyone
- 7.5 & 7.1 are basically two different ways of asking about “efficiency”
- Only 2 sub-questions address the ‘effectiveness’ construct (7.3 & 7.10). We recommend they be combined into a new question #8.
- We are uncertain if question 7.4 is really a usability question. It seems to ask more as to the operational impact of the CHIT on the function of the provider. It may merit being its own question more in the implementation or support experience sections of the criteria. We also repeat our earlier observation on the use of the term “practice” versus use of terms such as “care setting” or “venue”.
- 7.8 should probably be part of a distinct ‘consumer engagement’ section as is mentioned below
- 7.9 represents the readability construct which may be outside the scope of this evaluation
- We do not see any sub-questions that focus on consumer engagement which is an important area of both usability and use of CHIT. We recommend that a distinct section of questions be developed to focus on the use of consumer facing CHIT capabilities.

Usability: Question 8: Indicate the ease of use for each of the following features and functionalities in (autofill primary product name based on Q1)

The sub-questions for question 8 include a number of functionalities or technologies that seem unrelated to the capabilities fair to include in a comparative evaluation of CHIT. We do understand that it is appropriate to include in a comparative evaluation of CHIT not just those capabilities that are outright tested capabilities of CHIT under ONC’s certification program but those significant to the function of CHIT. This includes such capabilities as mobile accessibility, user-configured interfaces and functionalities important to the use of CHIT. However, there are many sub-questions that ask about capabilities that are unrelated to anything that is a certification requirement or a function or feature that supports the use of certified capabilities. This should be an evaluation of CHIT for its abilities to be used in the real world for the purposes intended. This should not be an evaluation of CHIT for unrelated capabilities that are beyond the scope of the
functionalities of CHIT or those necessary to support the use of CHIT. This does not mean some of the listed capabilities referenced in the sub-questions are important for what they are but it does mean they are not functions and features we believe should be part of the basis of evaluation of CHIT. These include:

- Data analytics
- Integrated chronic care management tool
- Optical character recognition
- Patient reminders (which once were a certification item but are no longer)
- Telemedicine capabilities
- Voice recognition/voice to test capabilities

Further, the items asked about for sub-questions 8.1, 8.7, 8.10 and 8.13 would not typically be considered “features” from a user perspective but are more capabilities of the overall product.

We again note there are no sub-questions on consumer access or consumer engagement, and we believe this an omission in need of correction.

Implementation: Question 9: How would you rate your overall satisfaction with the implementation of (autofill primary product name based on Q1)?

This question is too broad and misses on asking about specific aspects of the implementation experience. While the italicized note asks the respondent to consider some aspects of implementation, we believe this question should have sub-questions focusing on each of the items mentioned along with:

- Configurability or customization
- Availability and quality of reference information or guidance
- Availability and quality of recommended practices
- Ability to be self-directed
- Requirements for vendor involvement or degree of reliance on vendor/developer

Upgrades: Question 12: How would you rate your satisfaction with the following aspects of upgrades or maintenance for (autofill primary product name based on Q1)?

The sub-questions as they are listed are good however we believe additional sub-questions on the following should be added:

- The upgrade approach itself
- The frequency of upgrades
- Requirements of the vendor to stay on a current release
Cost: Question 15: What was the approximate total cost of implementing (autofill primary product name based on Q1)?

The cost ranges seem too fine grained for smaller implementations and too gross cut for larger ones. Also, in terms of any presentation of findings of this study, we urge that they be presented in terms of qualifying the responses to this question correlated to the size of the provider setting, and by the type of provider setting. For a par level comparison, that information will need to be presented that way for a fair evaluation to result.

Cost: Question 16: What is the approximate annual cost to maintain your product (autofill primary product name) for all users in your organization?

We recommend that interface costs also be included by specific mention in the italicized text of the question.

General Questions on User Characteristics: Question 18: In what setting do you primarily use (autofill primary product name based on Q1)?

A number of the settings listed are not valid as venues where CHIT may be used as such for the program purposes of CMS for Promoting Interoperability, MACRA QPP/MIPS or for Advanced Alternative Payment Models of the CMS Innovation Center. This is again about an evaluative comparison of CHIT and not of HIT writ more broadly. For example, laboratories, pharmacies, public health agencies, school-based health centers and correctional facilities are not locations where CHIT is used as such for any required purpose. Similarly, ASCs and imaging centers would make at best very limited use of CHIT insufficient to qualify for CMS program purposes. We urge that this list be pared down to those settings relevant to sites of service that qualify users for participation in federal and state programs that require the use of CHIT. Other options seem of little value to the purpose of evaluation.

General Questions on User Characteristics: Question 19: About how many clinicians work in the practice or organization where you use (autofill primary product name based on Q1)?

The ranges are biased towards physician or clinician practices and over generalize the size of larger organizations such as hospitals and health systems to be “more than 100”. We urge the ranges to be restated as:

- “Solo or less than 5”
- 6-10
- 11-50
- 51-100
- 101-500
- 501-1000
- More than 1000
General Questions on User Characteristics: Question 20: What best describes the types of services provided at the practice in which you use (autofill primary product name based on Q1)?

As stated before, this question seems inordinately biased towards physician or clinician practices and does not really consider hospital based or institutional care settings. This list should be modified to include different kinds of those settings such as women’s health, medical/surgical hospital care, intensive/critical care, children’s care, orthopedics, emergency services, cancer and other common acute care service lines.

Electronic Health Record Reporting Program: Draft Voluntary User-Reported Criteria Summary Tables

Table 1: Interoperability Draft Criteria

As general comments on this table:

- We recommend that there be questions on what interoperability is used for or for what types of exchange it is used for when it comes to general topics such as the use of HIEs and HIOs and exchange with other providers.
- Similarly, we think it important to include questions on what means of interoperability is used or at a high level by what standards is the interoperability supported?
- We recommend that questions be included on the abilities of the CHIT being evaluated to support import or export of electronic personal health information (ePHI). Such questions might focus on specific types of ePHI or for particular purposes such as of quality measures data or for purposes of transition from one EHR to another.
- There are no questions about quality measure reporting, public health reporting or patient safety reporting.

As to specific comments on individual questions and criteria:

- For item 5.4, we suggest the criteria be expanded upon or added to ask what HIEs or HIOs are supported, and for what purposes of interoperability?
- For item 5.8, we suggest modifying the criteria or adding a new criteria to ask what state PDMPs are connected to or if some form (and what specifically) of integrator/intermediary is used for PDMP connections.
- For item 5.5, we question if connection to payers is a valid basis of comparative review of CHIT? There are no requirements of CHIT to support payer/provider interoperability. It is an important question but not one we believe appropriate for a comparative evaluation of CHIT.
- For item 5.9, we do not understand why reports and data belong in the interoperability section of the criteria. That may be better suited in another section.
For 5.10, we agree that Promoting Interoperability and MIPS are important programs to ask about as to ease of attestation but wonder at this being an interoperability question unless it is whether or not the CHIT supports an actual means of e-submission available for these programs. Also, there are no questions about submission of electronic clinical quality measures where there are actually means of electronic submission. This seems an omission.

Table 2: Usability Draft Criteria

As a general observation, there is nothing asked about consumer engagement in this table for usability of capabilities and features intended to be consumer facing.

We also reiterate the comment made in the questionnaire about item 7.4. It does not seem to quite fit the usability topic.

We also refer back to our comments that many of the functionalities included in this table are not capabilities that are certification requirements or that are necessary to implement and use certified capabilities. We recommend their removal.

Table 4: Other Draft Criteria

We recommend that criteria be added for Maintenance and Upgrades to ask about frequency of upgrades and any vendor requirements for providers and users to maintain currency on the release of CHIT they have implemented.

Conclusion

We support ONC’s efforts to develop an EHR Reporting Program under the directive of the Cures Act. We believe it a significant and beneficial resource to the industry not only for buyers of CHIT but for users of CHIT to have crucial information from CHIT vendors and developers. We recommend further work be done on this aspect of the EHR Reporting Program so as to improve and deepen the quality of the information that might be collected from users, and to focus that collection on what is a fair contextual evaluation of CHIT based on the scope of what it is and what it is used for.
Hi all. Below are comments regarding the User-Reported Criteria for the Electronic Health Record Reporting Program. I think you have done a great job, and this survey will be of great benefit. My comments are both in response the specific questions you called out as well as the survey itself. In general, my comments are minor suggestions for improvement or consideration as I think what you have is very well done, but hopefully this will spur other further ideas and improvements for the final version. Thank you.

- As far as which type of health IT users can report on this, I think it depends on the section. For example, section 8 is primarily for providers and clinical staff, but I would think IT specialists would be important for section 5 with interoperability. The administrator users would know best for section 10 on product support. One idea you could consider is breaking this up into 3 sections called “Technical” / “Clinical” / “Administrative” and put the respective sections in each one. That could encourage provider to see the feedback within their organization from the people best suited to answer.
- I think all the sections are valuable, but I had to pick the criteria that should be prioritized I would go with Interoperability, Usability (specifically section 8 which is very good), and Cost. Implementation, Upgrades, Support are not as important IMO.
- As far as encouraging provider organizations to respond, the best way would be to get a MIPS/Promoting Interoperability bonus point associated with it, but that is probably not possible. Beyond that, working with organizations like AMA and AHA and others to get it promoted and encourage their users to complete it. Also, if you could turn the report into an app that allows providers groups to access and use that might encourage use (although making mobile apps is not easy and may not have return value we are seeking).
- If you had an app, you could also connect it with the products listed on the ONC CHPL to make it easier for them (hopefully) to identify the specific product they are using. Or do the same thing with a webpage form/connecting with CHPL.
- Regarding which version of health IT to use, I don’t know if average health IT user is aware of which version of the product they are using. They typically just know the name of the product. I think I would suggest just having the users report on their experience within the last say 12 months or so to keep it focused on most recent activities. Then over time we can see the changes from year-to-year.
- In survey Question 1 about health IT products used, it would be useful to collect how long the product has been used by the organization to gauge their experience with it. Newer, less experience users, may have different evaluation results indicating a different level of intuitive usability. Or maybe that goes into General Questions at the end.
- Regarding 5.1 question on exchanging with clinicians who have a different EHR/health IT product than the one used by my organization, very few users would be able to know what EHRs their other clinicians would be using. I don’t think this question would bring much value and probably be interpreted the same as 5.2 question. I think it could be removed.
- It would be good to have some question about how easy-difficult it is to communicate with patients using the EHR messaging service in the interoperability section.
- In the interoperability section, it would be useful to know the number of different HIEs or clinical/state registries they connect with. I know that does not quite go with the Very Easy – Very Difficult type scale, but it would useful to evaluate with this metric. For example, response of very difficult to exchange with HIEs from an organization who connects with 5+ HIEs compared to another response with very easy exchange but only exchanging with 1 HIE would be useful to compare high volume exchanges vs low volume.

Kyle Meadors, Chart Lux Consulting
August 10, 2020

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RE: Comment of the Connected Health Initiative on the Urban Institute’s Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program

ACT | The App Association’s Connected Health Initiative (CHI)\(^1\) appreciates the opportunity to provide input to the Urban Institute on its draft voluntary user-reported criteria for the Electronic Health Record Reporting Program.\(^2\)

CHI is the leading advocate for digital health policy and law advancements, representing a broad consensus of stakeholders across the healthcare and technology sectors. Our mission is to support the responsible and secure use of connected health innovations throughout the continuum of care to improve patients’ and consumers’ experience and health outcomes. CHI is a long-time active advocate for the increased use of innovative technology in the delivery of healthcare and engages with a broad and diverse cross-section of industry stakeholders focused on advancing clinically validated digital medicine solutions.

Data and clinical evidence from a variety of use cases continue to demonstrate how the connected health technologies available today—whether called “telehealth,” “mHealth,” “store and forward,” “remote patient monitoring,” or other similar terms—improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, particularly for the chronically ill.

\(^1\) [http://www.connectedhi.com/](http://www.connectedhi.com/)

\(^2\) [https://www.urban.org/policy-centers/health-policy-center/projects/electronic-health-record-reporting-program](https://www.urban.org/policy-centers/health-policy-center/projects/electronic-health-record-reporting-program)
Connected health tools, including wireless health products, mobile medical device data systems, telemonitoring-converged medical devices, and cloud-based patient portals, can fundamentally improve and transform American healthcare. By securely enabling the exchange of health information and incorporating patient-generated health data (PGHD) into the continuum of care, connected health tools can render meaningful and actionable change in the delivery of care. We urge ONC’s review of CHI’s aggregation of numerous studies that demonstrate the improved outcomes and reduced costs associated with greater use of connected health innovations.  

We appreciate the Urban Institute’s efforts to reflect developers’ and voluntary end users’ reporting of comparative information on certified health IT through this request for information. We offer the following specific input:

- Because 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), including a unique CHPL ID (connected with product edition, developer, product name, version, and certification date), CHI proposes that the survey include a field for the CHPL ID of the product they are reviewing (as well as a link to ONC’s CHPL site). Including this information will make the Electronic Health Record (EHR) Reporting Program’s more accurate accuracy and analysis of user-reported criteria.

- Under Question 5, CHI recommends that the survey reflect that “interoperability” includes access, exchange, and use of electronic health information (EHI), as access to information does not necessarily mean that the information is usable. Revisions to the survey should allow respondents to identify products with respect to both information access and use. Revisions of Questions 5.1-5.7 should include “electronically accessing, exchanging, and using” when discussing health information interoperability.

- CHI strongly encourages the Urban Institute to update its survey to reflect the need to capture social determinants of health (SDoH) information to improve population health management. HHS’ policy reflects the value of SDoH, and is, for example, holding a roundtable on the topic August 12-13, 2020. CHI strongly recommends adding “social determinants of health (SDoH) functionalities” as an additional listed feature. Further, because ONC’s health IT certification and information blocking final rule includes updated certification criteria supporting Substitutable Medical Applications, Reusable Technologies (SMART) application programing interfaces (APIs), we recommend that the Urban Institute capture an electronic health record’s (EHR’s) support for SMART APIs and apps by adding “Physician and patient-facing application (app) support (e.g., SMART APIs and smartphone apps)” as an additional listed feature.

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3 This CHI resource is publicly accessible at https://bit.ly/2MblRou.
Rather than a single question that addresses security and privacy features (Question 13), CHI recommends that the Urban Institute break out questions on these two distinct (but related) topics in multiple questions. While security is the protection of data from unauthorized access and manipulation, privacy is a process used to steward and manage data. The survey should ask one or more questions about how security is addressed (e.g., if multi-factor authentication is being used, compliance with security standards, etc.). Separately, the survey should ask one or more questions about privacy practices through requesting whether certified health IT captures a software app’s attestation to publicly sharing its privacy-related practices, that this privacy policy is shared with users before use and is written in plain and easily-understood language, and to meeting privacy best practices (and if so, specify what best practices). CHI notes that ONC’s final information blocking rules recommends this approach, specifically stating that it does not consider requesting and capturing app attestations to be “information blocking” in the case of interference with the access, exchange, or use of EHI if an “actor” (as defined by the final rule) engages in practices to educate patients about the privacy and security risks posed by the apps the patients choose to receive their EHI.

- CHI supports adding a question to the survey that collects information on the return on investment realized by the survey respondent as a result of their health IT adoption efforts. Such data will assist ONC in assessing burdens and benefits of the EHR reporting program.

- ONC’s final information blocking rules have also taken steps to prohibit the use of “gag clauses” by EHR vendors that would generally block the ability to share product information about a product’s characteristics (usability, security, interoperability, etc.). CHI requests that a question be added to the survey to request experiences with such gag clauses, which would assist ONC in advancing its goals in the information blocking rule.

- CHI supports revisions to the survey to add one or more questions that will address the experiences in managing risk to patient safety through use of EHRs. We advise that the questions asked by the survey address both low-risk functions and high-risk functions (such as electronic prescribing of controlled substances).
CHI thanks you in advance for your time and consideration of the input above.

Sincerely,

Brian Scarpelli
Senior Global Policy Counsel

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Washington, DC 20005
p: +1 517-507-1446
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The Connected Health Initiative (CHI), an initiative of ACT | The App Association, is the leading multistakeholder spanning the connected health ecosystem seeking to effect policy changes that encourage the responsible use of digital health innovations throughout the continuum of care, supporting an environment in which patients and consumers can see improvements in their health. CHI is driven by the its Steering Committee, which consists of the American Medical Association, Apple, Bose Corporation, Boston Children’s Hospital, Cambia Health Solutions, Dogtown Media, George Washington University Hospital, HIMSS, Intel Corporation, Kaia Health, Microsoft, Novo Nordisk, The Omega Concern, Otsuka Pharmaceutical, Podimetrics, Rimidi, Roche, United Health Group, the University of California-Davis, the University of Mississippi Medical Center (UMMC) Center for Telehealth, the University of New Orleans, and the University of Virginia Center for Telehealth.

For more information, see www.connectedhi.com.
August 10, 2020

The Urban Institute
500 L'Enfant Plaza SW
Washington, DC 20024

Re: Request for Public Feedback on Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program

Submitted electronically at EHRfeedback@urban.org

To Whom it May Concern:

ECRI Institute appreciates the opportunity to submit comments to the Urban Institute on the Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program. We recognize the importance of these criteria and the Electronic Health Record (EHR) Reporting Program to be administered by the Office of the National Coordinator for Health Information Technology (ONC). We also appreciate the opportunity for a 60-day public feedback period. Our comments focus on criteria related to patient safety.

ECRI is a 52-year-old independent, nonprofit, 501(c)(3) that improves the safety, quality, and cost effectiveness of patient care across all healthcare settings. ECRI’s work in patient safety, medical product testing and evaluation, evidence-based guidelines, accident investigation, and dissemination of alerts and recommendations aligns with the vision, mission, and goals of the Federal Health IT Strategic Plan. ECRI’s Patient Safety Organization (PSO) is certified by the U.S. Department of Health & Human Services and is now one of the largest in the U.S.; ECRI is a designated Evidence-based Practice Center (EPC)—ECRI-Penn Medicine Evidence-based Practice Center—by the U.S. Agency for Healthcare Research and Quality. We do not accept gifts or grants from the pharmaceutical or medical device industries and our publications and informational products carry no outside advertising.

Since 2014, ECRI has convened and operated the Partnership for Health IT Patient Safety (Partnership), a multi-stakeholder collaborative that identifies and examines health IT-related safety concerns, develops evidence-based safe practices, provides tools and resources for implementation, and widely disseminates learnings and strategies for use. The Partnership brings together clinicians, healthcare organizations, professional societies, EHR and content developers/vendors, insurers, regulators, patient safety organizations (PSOs), human factor experts, researchers, patient advocates, and thought leaders to identify, address, and mitigate safety issues through recommendations and implementations. Reports on focused topics, available at www.hitsafety.org, are relevant to the proposed user reporting criteria.
The 21st Century Cures Act requires the Department of Health and Human Services (HHS) to establish an Electronic Health Record Reporting Program. According to ONC, the EHR Reporting Program is intended to “provide publicly available, comparative information about certified health IT. This information will be collected as a requirement of certification and maintenance of certification for health IT developers. The program will also provide an opportunity for users of certified health IT to voluntarily report their experience using certified health IT products. Reporting criteria will be related to security, usability, interoperability, conformance to certification testing, and other topics as appropriate.”\(^1\) We presume that this information will complement that already included in the ONC Certified Health IT Product List (CHPL).\(^2\)

We are very supportive of this vision of an EHR Reporting Program to provide needed assistance for current and potential purchasers and users of EHRs and the emphasis on non-burdensome data collection. ECRI submitted comments in response to an ONC Request for Information (RFI) on the Reporting Program in 2018\(^3\).

ECRI’s vision is in alignment with ONC’s goals as we strive to advancing effective, evidence-based healthcare globally. Given our extensive work in patient safety, and in particular health IT patient safety, our comments focus on safety-related provisions of the draft strategic plan. With this focus, our detailed suggestions in response to the questions posed by the Urban Institute are in the attached Appendix.

**General Comments**

We agree strongly with the overall thrust and specific points made of comments in the April 2020 report (Report) to the ONC by the Urban Institute What Comparative Information Is Needed for the EHR Reporting Program? that the EHR Reporting Program should include priority criteria that address patient safety. At the same time, we believe that safety should not be primarily viewed as a sub-topic within usability; safety is truly its own domain and also cuts across multiple domains, including interoperability, usability, privacy, and security.

We agree with the proposed focus on three major dimensions: Functionality, Performance, and Costs and Developer Practices. With each of the workgroups conducted by our Partnership for Health IT Safety we learned about the critical and intertwined nature of both functionality and performance and the need to consider which users are expected to interact with specific features and the ease with which they do this.

We do suggest that, as the Urban Institute and ONC continue their work in this project, they identify and take into account pertinent environmental changes since the passage of Cures and the 2018 RFI, especially regarding the goals and expected benefits of the Reporting Program. We also applaud the recognition that data collection from users must take careful account of potential respondent burden and its impact on response rates and data quality as well as documentation of the role and applicable experience and expertise of survey respondents for the overall survey and specific questions as applicable.

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2. [https://chpl.healthit.gov/#/search](https://chpl.healthit.gov/#/search)
We also emphasize the need for the Urban Institute and ONC to consider the “shelf life” of survey responses, to address the need for regular data updates and issues of comparability across data collection periods, and to focus on responses that are likely to be the most durable over time and across products and developers. In this regard, it would be useful to assess changing views on a specific product over time, which suggests some value in having a defined “panel” of respondents whose views are assessed periodically.

We also suggest consideration of questions that address product maturity, which is a useful summary measure that is likely to be correlated with product safety. Such ratings may help compensate for the fact that measures of detailed elements are likely to be highly variable and subject to rapid change, for example as users become familiar with new functions and products are updated in response to user feedback.

In addition, we urge that the Urban Institute and ONC place a major emphasis on ensuring valid and reliable comparisons across EHR products and developers of certified health IT. For example, we note the discussion on these issues that accompanied your recent June 17, 2020 presentation to the ONC HIT Advisory Committee (HITAC). Based on our extensive experience in product evaluations, we believe strongly that as much attention needs to be paid to data collection methods, including administration of surveys, as on development of survey instruments. We also urge that the Reporting Program enable those who rely on the program to assess whether and how particular summarized responses are or are not applicable to their specific situation and use cases.

Conclusions

ECRI Institute looks forward to continued collaboration with the Urban Institute and ONC as they proceed with planning and implementation of the EHR Reporting Program. For questions, please do not hesitate to contact me at kschoelles@ecri.org. ECRI Institute welcomes further discussion on this topic. Our website is www.ecri.org.

Sincerely,

Karen Schoelles, MD, SM, FACP
Vice President, Clinical Excellence and Patient Safety

Attachment

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4 [https://www.healthit.gov/hitac/events/health-it-advisory-committee-26](https://www.healthit.gov/hitac/events/health-it-advisory-committee-26)
Appendix: Detailed ECRI Comments on the Request for Public Feedback on Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program

We address the specific questions asked by the Urban Institute, with a focus on patient safety.

Which draft criteria would you prioritize for inclusion in the EHR Reporting Program, and why?

- **Patient safety**, as documented in the April 2020 Report, should be prioritized, both as a distinct domain and as a rationale for criteria in other domains (e.g., usability, interoperability, privacy, and security). It was the third priority topic in the April 2020 Report and although developers and experts focused more explicitly on safety than end users, their shared focus on safety highlights the importance of gathering end user perspectives on this critical topic. In addition, safety is not primarily a subset of usability; usability is an important determinant of patient safety. Finally, it is important to assess the extent to which EHRs can safely advance healthy and safe practices through EHRs and other health IT, as exemplified by the Partnership’s work on patient identification, improving drug allergy communications and safer opioid prescribing.5

- **Behavioral health and substance use disorder support** are a very high priority, especially with the continuing national problem with opioid use and Substance Use Disorder (SUD) as well as the increased behavioral health risks associated with the COVID-19 pandemic and its aftereffects. These issues cut across several of the criteria domains, including interoperability, usability, and privacy and security. To this end, we suggest:
  - An emphasis on EHR support for connectivity and integration with prescription drug monitoring programs (PDMPs), recognizing that many of the limits on connectivity and integration come from state law and regulation and PDMP policies,
  - Addressing the usability and effectiveness of data segmentation to support 42 CFR Part 2 and for other purposes, and
  - Asking about EHR functions to enhance appropriate use of opioids (e.g., dosing tools, screening, clinical decision support (CDS), and risk estimation).6

- **Usability**, based on our extensive Partnership experience, remains a very high priority topic. Usability is a critical determinant of patient safety, including reducing levels of clinician/user burden that can compromise patient safety.
  - **Provider burden** is a very high priority within the usability domain and encompasses such issues as clinician burnout and after hours “pajama time” needed to complete documentation. This priority is reflected in Partnership work on drug allergies, alerts, opioids, copy and paste and the reuse of information, and patient identification and matching. It will be important to keep the criteria and questions simple and focused

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5https://assets.ecri.org/PDF/HIT-Partnership/ECRI-Implementation-Guide-Patient-Id.pdf
6https://www.ecri.org/hit/safer-opioid-prescribing
and these should emphasize burdens caused by the EHR and not primarily by external regulatory or clinical requirements.

- **Telemedicine** is a priority but not just with respect to ease of use but also to the presence of telemedicine support and the integration with clinical and billing functionality. For example, it would be useful to know how users verify the identity of the patient, how connectivity is documented, the ability to connect any number of devices such as otoscopes or EKGs to the EHR for use in telemedicine, and the availability of specialized templates that fulfill clinical and billing needs.

- We also suggest that you consider adding a question on opportunities and limits of **audit log data** for assessment of safety and usability (important for Developer data collection as well.). The widespread use of electronic health records (EHRs) may offer new opportunities to drive safety through the evaluation of systems data captured within EHRs. The *Partnership’s* most recent work looks at systems and audit log data to determine how to gather, aggregate, and learn from this information.⁷

- Other key usability dimensions include **actionable access to data, clear and concise patient information,** and **alerts that are meaningful.**

- **Interoperability**, including bidirectional connections with health information exchanges (HIEs) and other clinicians, pharmacies, payers and with patients, is a very high priority as documented in the April 2020 Report. It is also a key determinant of patient safety (e.g., for behavioral health, opioids, accurate patient identity, and elements of documentation). Based on our experience within the *Partnership,* we suggest a shift in emphasis to the use and usefulness of data received rather than the current emphasis on ease of use. We also urge that questions be designed to reflect what respondents would know about interoperability functionality and perhaps targeted at those with such knowledge. We suggest adding questions on:

  - **Patient matching**, which has been extensively addressed⁸ by the *Partnership* and which was a priority in the Report. Accurate patient matching is essential within as well as across health care organizations, providers and those support organizations that help to inform care (e.g., PDMPs and HIEs). Some specific areas to consider for questions would be:
    - Does the EHR allow you to see a patient’s photo on every screen and can they be printed out for labels?
    - What patient matching capabilities does the EHR support (e.g., does it include or enable use of an enterprise master patient index and if the former, what matching algorithms are used) and how accurate and usable are they?
    - What are additional costs associated with supported patient matching solutions?

  - **Data reconciliation**, which is critical for useful incorporation of received data into the EHR.

  - **Data access within a health care organization** (HCO), whether on the same or different EHR platforms, which is also essential to safety; this is not usually only an issue of exchange but also of access and would include role-based access. Accurate

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⁸ [https://assets.ecri.org/PDF/HIT-Partnership/ECRI-Implementation-Guide-Patient-Id.pdf](https://assets.ecri.org/PDF/HIT-Partnership/ECRI-Implementation-Guide-Patient-Id.pdf)
data access would include data mapping and consistent terminology use to ensure the fidelity of shared/exchanged information.

- **Exchange with patient-facing applications and services** by:
  - supporting both patient access to and patient-mediated exchange of data,
  - supporting the patient to download records in a computable format, and
  - integrating with remote patient-monitoring devices.

- **Security and Privacy** are very high priority topics for user reporting given the need for effective security and privacy assurance for the consistent and extensive use and exchange of electronic data needed to support patient safety. Focusing on end user priorities; security is a clear patient safety issue and it would be important for users to know what features are available and what must be added on to the EHR. We suggest:
  - Separating privacy and security as distinct questions or sub-topics, even if these are kept at a high level; they are two distinct domains and would be seen as such by appropriate user respondents.
  - Asking whether clinicians could record and access patient privacy preferences and consent and have that information readily visible and accessible.

- **Implementation, Support, and Upgrades** are each very important and worthy of specific questions. These are critical to usability, safety, and interoperability and a key focus of health care organizational health IT safety programs.⁹

- **Medication orders and use** are critical factors in patient safety.
  - We suggest asking users about general e-prescribing as well as separately asking about e-prescribing for controlled substances (EPCS).
  - We also suggest asking users about functions to enhance medication safety, including clinical decision support (CDS, such as drug-drug and drug-allergy checking¹⁰).

- **Testing and referrals** are important topics for an EHR user survey. These should address:
  - Ease of ordering.
  - Ease of referrals; and
  - Closing the loop on diagnostic evaluations¹¹.

- **Detailed cost data** should probably not be sought in this user survey. Costs are obviously important for EHR reporting but it is not clear that user-reported costs are the best approach. Certainly, it is unlikely that detailed user supplied cost data can be kept current. One option would be for users to use a system like: $, $$, $$$, $$$$ to indicate their view of the cost level of a product overall and perhaps for specific functions. It might also be possible to indicate what features (including connectivity, special features, training) have an additional cost and perhaps the potential range of that cost (e.g., low, medium, high). Transparency and predictability in costs can be a safety issues. For example, if a purchaser did not understand or anticipate additional costs and therefore decides not to incorporate or do something, there

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¹¹ [https://www.ecri.org/hit/implementation-approaches-closing-the-loop](https://www.ecri.org/hit/implementation-approaches-closing-the-loop)
could be safety consequences. This could happen when there are unanticipated costs for advanced user training or for a functionality or capability. Finally, the usefulness of Questions 15 and 16 is unclear as the questionnaire does not capture actual practice size and number of users but asks about broad ranges.

Which draft criteria should be rephrased, reworded, or removed?

Each of the comments below reflects the critical roles of these dimensions on patient safety.

Interoperability

- 5.3 Electronically exchanging health information with clinicians inside my organization
  - From a safety perspective, the issue is typically more of an issue of access than exchange (although both are important), including access to shared medical records and internal exchange via secure messaging and other tools.
- 5.8 Connecting with your local prescription drug monitoring program (PDMP) through your certified health IT product
  - This issue is not only connecting but use for intended purpose, we suggest rephrasing and recognizing that many of the limits on connectivity and integration come from state law and regulation and PDMP policies.
- 5.9 Producing all the reports that are required for my organization’s specialty
  - We suggest being very clear on the types and use of reports; it is also not clear why this topic is under Interoperability. In addition, the burden and usability of report generation and use should be addressed.
- We suggest adding at least one question on two-way communications with patients via such tools as portals, messaging, and apps.
- We suggest adding at least one question on accurate patient matching\(^\text{12}\); this capability is central to safe and effective interoperability.

Usability

- 7.3 easily accesses and assimilates data from other products
  - This question as worded is too vague; is this integration with other practice systems or bringing in and using data via interoperability tools and methods like, HIEs, C-CDA standard documents, and HL7® FHIR®-based application programming interfaces (APIs)? Both areas are critical to safety. It would also be useful to address how different products work together and the extent to which they are “plug and play.”
- 7.9 easily produces understandable clinical summaries
  - The question should not combine "ease" and “understandable” and we suggest focusing on the latter as understandability is the priority aim. We also suggest asking about the extent to which clinical summaries can be customized for the intended use and recipient (e.g., some specialties might best use one template and others another template and it would be useful to be able to contract or expand the information provided).
- 7.10 provides system alerts that help prevent care delivery errors
  - We assume that this question is about clinical decision support (CDS) and suggest using this specific term and broadening beyond alerts to other types of CDS that can

\(^{12}\) https://assets.ecri.org/PDF/HIT-Partnership/ECRI-Implementation-Guide-Patient-IId.pdf
prevent care errors. We suggest that you sharpen this question and call out specific areas like medication safety. Also, CDS is not just to prevent care errors but also to enhance quality. Finally, we suggest addressing the extent to which alerts can be customized by end users and whether reports can be generated to identify alerting patterns and potential refinements in alerting approaches.

- **8.1 Data analytics (e.g., produce feedback reports, identify high-risk patients, create data visualizations and graphics)**
  - Data analytics is a very important safety issue and the closer the reports are to real-time the better. We suggest that this question be sharpened to be less general and to be clear for whom “ease of use” (from instructions for section 8) is being evaluated.

- **8.2 Default values for common orders (e.g., medication order specifics, routine laboratory draw times)**
  - This is a very important issue for safety but as with several of these questions, it is not clear that ease of use is the most useful lens to evaluate such values.

- **8.3 E-prescribing of controlled substances (e.g., using e-prescribing for Schedule II–V controlled substances)**
  - We suggest that this question be split into two, one for general e-prescribing and one for EPCC and that it address associated CDS for both. Medication orders are a critical patient safety issue.

- **8.4 Evidence-based order sets and charting templates (e.g., prepopulated order sets and charts)**
  - We agree with the importance of this topic but are concerned that including the term "evidence-based" in a single question could confuse responses and respondents and narrow the order sets that are considered. In addition, because both order sets and templates are critical to patient safety and two very different areas of functionality, we suggest splitting this question into two and separately addressing whether the order sets are evidence based, which is very important for patient safety.

- **8.5 Image receipt, access [our addition] and review (e.g., x-rays, CTs, and MRIs)**
  - This issue is not only "receipt"; often images are accessed externally via links and we suggest adding “access” to this important question.

- **8.11 Structured templates (e.g., prepopulation of templates with patient information or with clinician name and information)**
  - We suggest that you address the ability to prevent “note bloat” and problematic copy and paste functionality, including effective and efficient reuse of information.¹³

- **8.12 Telemedicine capabilities**
  - The issue is not just ease of use but whether this functionality has been integrated in a manner that promotes safe and effective care (see our comments in the prior section). We suggest being less general or adding some parenthetical dimensions of focus for respondents’ consideration.

- **Quality and Safety [our addition]**
  - We suggest adding a question about the extent to which the product helps to avoid harm to patients, including identification of such product features.

Orders [our addition]

- We suggest adding a question on general user satisfaction with orders functionality, which is a critical safety-related function.
- We also suggest a question on the extent to which the product assists in “closing the loop” on orders.\(^{14}\)

Privacy and Security

- 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.)?
  - We suggest splitting out privacy and security
    - Ask whether clinicians can record and access patient privacy preferences and consent.
    - Focus on end user priorities.

Contractual Information

- Question 17: It might be useful to define and ask about “gag clauses”. Also, for the current Question 17, it would be appropriate to ask about the costs of changing EHRs, including transparency of such costs, the extent to which they are a barrier to changing, whether the costs are from the current or new EHR, and the costs and capabilities to export data to a new EHR.

Should the voluntary user-reported criteria cover only the most recent version of a certified health IT product or all versions of the product?

- We suggest that user surveys go back two versions (with the version being reported on clearly identified). Such a policy will enable the broadest and most relevant set of responses.

What certified health IT users are most likely able to report on the criteria (e.g., clinicians, administrators, IT specialists)?

- The answer will vary by the criteria. We suggest that the questionnaire identify the likely users for a given question and ask respondents for an organization to ensure that responses reflect the experiences of these end users.

What could motivate end users to voluntarily report on certified health IT products?

- In our experience, endorsement by professional and other pertinent associations could be very valuable.
- In addition, providing respondents value in terms of special reports based on survey responses could also be an important incentive to respond.

\(^{14}\) https://www.ecri.org/hit/implementation-approaches-closing-the-loop
Commented [GD1]:
Comments submitted by Gary Dickinson FHL7
• Executive Director, EHR Standards Consulting
• Co-Chair, HL7 EHR Work Group
• Co-Facilitator, HL7 Reducing Clinician Burden Project • Co-Facilitator, HL7 EHR Interoperability Work Group
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Submitted on 10 August 2020
Disclaimer: The source document (on the left side) is a close, but not perfect, rendition of the original. Such are the vicissitudes of modern translation algorithms, in this case .pdf to .docx, yet not dissimilar to frequent anomalies in translation (transformation, transmutation) of health data/record content to/from exchange artifacts in the course of transmission between source and receiving EHR/HIT systems. Anomalies include errors, alteration, omissions and disjunctions in content and related context.

Draft Voluntary User-Reported Criteria
Commented [GD2]:
Electronically exchanging information for early detection, monitoring, response and reporting of infectious disease outbreaks?
Commented [GD3]:
Items 5.1-5.8: These are quantitative assessments: can you connect or exchange with this or that organization or system? While this may be of interest, there is a more substantive need to understand/assess whether trusted exchange is the actual result of these connections. See next comment.

Commented [GD4]:
**Trusted Exchange (or not).** Clinicians are routinely confronted with externally-sourced data content that is not concise or relevant, not obviously trustworthy, not timely, not easily rendered in full context, and/or otherwise usable, useful, fit, applicable or action-able to effect immediate uptake in patient care, interventions and decision-making. Key questions absent from this survey – including some which tend to address, ease and remediate clinician burden...
In terms of externally-sourced data, are you able to...
• Establish confidence in its trustworthiness, accuracy and integrity?
• Determine its chronology and timeliness?
• Follow the chain of trust (data journey) from source to use? • Ensure fidelity to source (source of truth)?
• Ensure what the author saw is equivalent to what the end user (clinician...) sees?
• Ascertain authorship (including author’s role and credentials), accountability?
• Ensure immutable binding between authorship and content? • Ascertain provenance of discrete data elements?
• Ascertain data that has been attested or digitally signed?
• Ensure immutable binding between content and context, including clinical context?
• Track patient-sourced data content?
• Maintain vital linkages and relationships among data components (e.g., between medications, allergies, immunizations, problems, diagnoses, conditions, signs and symptoms, encounters, assessments, clinical decisions, diagnoses, orders, results, diagnostics, interventions, procedures, observations, therapies, care plans, status...)
• Ascertain that data (e.g., a data set) is complete versus known to be incomplete?
• Determine if data has been updated (i.e., corrected or supplemented) from its original content, with persistent record of updates (by whom & when)?
• Determine if data is sourced by an automated instrument or device and subsequently verified (by whom & when), or not • Establish confidence sufficient to allow data content to be fully integrated into the local health record or instead must it be kept segregated, managed and accessed separately?
• Ensure certainty of identity matching of patients and providers (organizational and individual)?
• Recognize data content that is composed by qualified humans versus algorithmically assembled by software (without human intervention, review or verification)?
• Reduce or eliminate data duplication – same data from multiple sources (often resulting in
information overload)?

- Restrict access based on principles of “minimum necessary” and “need to know”?

**Commented [GD5]:**
- Errors, alterations, omissions and disjunctions in data received (via exchange) can be readily reported and response assured
- Safety risks (related to data exchange) can be readily reported and response assured

**Commented [GD6]:**
And/or allows personalization or customization of work flows specific to an individual (clinician or user), department, service or specialty

**Commented [GD7]:**
See trusted exchange comments above.

**Commented [GD8]:**
Again serving a vital focus on burden reduction...
- Is fit for use, fit for purpose
- Allows efficient navigation and data entry which minimizes clicks and keystrokes, reduces redundancy, avoids deeply nested menus and unwieldy pull-down lists
- Allows tasks to be assigned or routed to others for completion
- Allows alerts and messages to be assigned or routed to others for follow up and resolution
- Is transparent with regard to source of truth
- Is transparent with regard to audit triggers and audit trails
- Is transparent with regard to how decision support, medical logic and artificial intelligence events are detected, triggered and presented, including rules, metrics, algorithms, units and methods of measure
- Is transparent with regard to how homogeneous and heterogeneous EHR/HIT systems and devices are integrated: e.g., showing how disparities in functionality, sequence and data are reconciled/resolved
- Is transparent with regard to how data is integrated between EHR/HIT systems (e.g., data mapping and transformation), showing any potential loss (or corruption) of content, context or meaning, incompatible units and methods of measure, variance in visual presentation
- Is transparent with regard to information copied forward from previous instances (e.g., in notes and observations)
- Has a consistent user interface across all functions, systems and modules, without distracting/interruptive transitions such as multiple sign-ons, disparate user interfaces and disjoint data entry schemes
- Allows software, data and system failures and evident safety risks to be readily reported with assured response
- Allows patient-related events to be presented in chronological sequence, i.e., in the order of actions taken: who did what when where and why
- Allows presentation of historical (past), current (present/now) and prospective (future) events
- Is certified for User Center Design yet still exhibits poor usability behaviors
Commented [GD9]:
Locally designed, user-configured and/or personalized: • Work flows, activity sequences
• Patient flows
• Information flows
• Alerts and reminders, alert/reminder over-rides
• Alert, notification and message routing, assignment
• Task assignment and routing
• Decision support rules and triggers
• Screen layout, presentation and sequence
• Data definition: content, context, names, descriptions, units of measure, purpose of capture
• Data grouping, dataset definition
• Order verification, routing, fulfillment
• Resource and deployment management: people, time, locations, equipment, supplies
• Referral management
• Infectious disease management, including early detection, monitoring, response and reporting

Commented [GD10]:
Again stressing clinical efficacy and burden reduction priorities:
• Confidence that software and system upgrades are rigorously tested before being installed in production
• Confidence that locally defined, customized and personalized software and system configurations and settings are preserved and not reset or over-written by upgrades
• Confidence that clinical priorities (including patient safety) priorities are primary and are not being superseded by external and non-clinical demands in provision of software and system upgrades
Dear Dr. Rucker,

The Electronic Health Record Association is grateful for this opportunity to provide feedback on the Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program.

The EHR Association’s 30 member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our core objectives focus on collaborative efforts to accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care through the use of these important technologies.

Before we provide feedback on specific questions proposed in the draft, we have some overall recommendations for this project.

Start at the End
Our Clinician Experience group had a difficult time understanding the use cases we anticipate this data being leveraged to solve. The mandated goal is supporting small practitioner and rural purchasing decisions, but the data being collected seems to lack key elements to allow for stratification by those groups. These clinical organizations will have a clear sense of how tech-savvy, paper-centric, or team based their approach to care is, but will not be able to stratify responses based on those crucial factors. We encourage a user-centered design process to explore the resulting uses of this data. We believe that the question of “is this the right vendor for me” should be an easy question for a variety of health IT stakeholders reviewing the data to answer.
Center the Survey around the User

As drafted, this survey is generalized to be answered by any respondent in the healthcare system, creating a mismatch between what various users can successfully give feedback on, the language and mental models of their toolset, and their ability to confidently answer the entire questionnaire.

We recommend the survey first establish the role of the answering participant and then ask questions specifically tuned to them. This will ensure that participants are answering questions as accurately as possible and likely increase the number of participants who complete the questionnaire.

For example, questions could be stratified depending on a participant’s role in the institution:

<table>
<thead>
<tr>
<th>Section</th>
<th>End User</th>
<th>IT Staff</th>
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</thead>
<tbody>
<tr>
<td>Overall</td>
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<td>✓</td>
</tr>
<tr>
<td>Interoperability</td>
<td>▲</td>
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<td>Usability</td>
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<td>Support</td>
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<td>Contracts</td>
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<td>General</td>
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</tbody>
</table>

Allow More Depth

Interoperability and usability are complex topics with significant room for different interpretations, yet the language in this survey is neither specific nor colloquial enough to limit misinterpretation by some participants. As long as the language remains as-is, data gathered in these critical areas will be difficult to interpret. Specific examples are provided in our detailed comments below.

In addition to improving the language used for each question in these areas, particularly the usability topic, shifting from a one-size-fits-all approach to a more tailored approach may improve the data gathered. For example, questions draw inconsistently on inpatient and outpatient examples, sometimes within the same question. Providing specific examples based on the user’s primary setting will produce more accurate feedback.

Several areas list multiple questions that are followed by a single free-text field. Such an approach can be limiting. Instead, it would be useful to allow commentary on each element to allow for more nuanced analysis.
Concerns around Methodology
We are concerned at the lack of detail about how this survey will be distributed, who will receive it, and what methods will be used to “normalize” the dataset. Providing meaningful feedback without answers to these questions is difficult.

We specifically request clarity on what steps will be taken to validate that participants actually use the software product they are assessing and how recently they have used it. A related issue is validating that the respondent knows which health IT product does what at their organization. This could be done by presenting some of the common workflows that the product addresses and allowing the user to select what they specifically use the product for. Ironing out those wrinkles will be very helpful before this draft is finalized, and we would like the opportunity to comment on any updates.

Another area of interest is understanding the “floor” for the sample size: what will constitute enough data to be shown? Is one poor rating the equivalent of 600 positive ratings? Clearly, transparency with the data is useful, but providing a sense of scale is also likely to be helpful. Our recommendation is to establish a clear set of expectations around acceptable deviation from the norm, minimum n for inclusion, and clarity around the period and frequency of survey responses.

Our input on specific questions follows. Thank you for considering our feedback.

Sincerely,

Hans J. Buitendijk
Chair, EHR Association
Cerner Corporation

David J. Bucciferro
Vice Chair, EHR Association
Foothold Technology

HIMSS EHR Association Executive Committee

Barbara Hobbs
MEDITECH, Inc.

Cherie Holmes-Henry
NextGen Healthcare

Stephanie Jamison
Greenway Health

Rick Reeves, RPh
CPSI

More than Fifteen Years of Advocacy, Education, & Outreach
2004 – 2020

August 10, 2020
About the HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 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](http://www.ehra.org).
EHR Association Feedback
on the Draft Voluntary User-Reported Criteria
for the Electronic Health Record Reporting Program

HIGH-LEVEL QUESTIONS

Which draft criteria would you prioritize for inclusion in the EHR Reporting Program, and why?

We recommend a focus on criteria that contributes to better purchasing decisions, if that’s the intent of the program. It is important that reviewers are able to both find other organizations like them and assess their success with the product. Reviewers must be able to see the standard deviation of responses from across the organization and within user groups – this will help account for selection bias. Alongside identifying the data to be collected, it is important to concurrently design the way the data will be used (e.g., realistic scenarios, “jobs to be done” (JTBD) of purchasing users).

Which draft criteria should be rephrased, reworded, or removed?

Please see our comments on individual criteria.

Should the voluntary user-reported criteria cover only the most recent version of a certified health IT product or all versions of the product?

Because purchasers can only purchase the most recent version of the software, it makes sense to gather feedback from users of more recent versions. Given customer adoption timelines, the most recent version may not be feasible, so one-year-old versions would be appropriate.

We note that the process of loading system updates within a hospital system is typically an IT function. As drafted, the survey does not assure evaluation is occurring on an updated system. Since developers are given the option to provide specific or non-specific version information on the ONC CHPL, it is important the evaluation ask if the user is evaluating an updated system, and not one that may be far behind in handling the change management process.

What certified health IT users are most likely able to report on the criteria (e.g., clinicians, administrators, IT specialists)?

The answer to this will, reasonably, vary widely. End-users are best positioned to explain their own experience. Those working on the IT side (or responsible for administering the system) are best positioned to explain configurability, upgrades, maintenance, implementation, and so on. Those working in a clinical setting are best positioned to comment on issues such as usability. We recommend that the questionnaire reflect this reality, and allow the correct subset to speak to their knowledge base.

As we note several times in our evaluation of specific criteria, the one-size-fits-all approach to the survey seems inadequate to capture meaningful information.
What could motivate end users to voluntarily report on certified health IT products?

Extremely unsatisfied and extremely satisfied users are more likely to give feedback, with probably a tendency to skew unsatisfied. How can that be statistically controlled for? How will significant deviation be handled? See various studies: here, here.

The longer and more complex the questionnaire is, the more likely it is to lose users with more subtle and nuanced views of the products they use.

A potential motivator could be a clear outcome: yearly reports that review the current trends in this feedback, and even allow for forums to discuss issues and what vendors will/can/should do about them.

OTHER FEEDBACK

The survey as written is likely twice the length of the predicted (and reasonable) 10-15 minutes.

We recommend addition of an optional “additional comments” field for all ranking questions, rather than a single “any additional thoughts” field at the end of a complex section.

Each section should end with the overall score rather than start with it, allowing respondents to think through their use of the product prior to assigning a more accurate score.

We have several questions related to respondents:

- What is the recruiting process for potential respondents?
- How will it be determined if they are actually users of the product?
- What is the representative sample of users?
- Will respondents be categorized to help understand the results? e.g., rural clinics, critical care, ambulatory care, etc.

For hospital reporting regarding EHR satisfaction it is important to know the utilization of the EHR hospital-wide versus distinct departments, as well as specific locations within a healthcare system, in order to effectively inform others.

Hospital size should be considered to further guide the applicability of the answers to future reviewers.

The quality of the answers is of course key to the value of the data gathered. What is the minimum data set before reporting? Will there be a drop of high/low? Standard deviation should guide what data are included. Additionally, we encourage evaluation of each survey to ensure that appropriate questions were addressed; results will be skewed if information from incomplete surveys are included, which may have been submitted to discredit an EHR.
PRODUCT CHARACTERISTICS

1. What certified health IT products do you use?

The EHR Association has no recommendations for this question.

USER CHARACTERISTICS

2. What type of health IT user best describes you?

We recommend adding operational leadership options (e.g. clinic managers, quality managers). Including operational leadership will allow deeper insight into the day-to-day experience of change management, maintenance, and integration of clinician feedback into the system. If these roles are not included, it will be more difficult for operational leaders to use the Reporting Program to inform their purchasing decisions.

We also recommend adding other roles that relate to other uses and types of certified health IT, such as quality management, consumer/consumer engagement, or infection control/public health reporting.

We recommend removing “pharmacist” as an available user type, as pharmacists are not the target users of certified health IT.

In order to account for the ‘many hats’ nature of today’s clinicians, we further suggest the survey ask for both a primary role and other secondary roles. Broad categories of secondary roles will help for later data stratification.

We note that many of the questions that follow will only be answerable (accurately, at least) by one type of user. To reduce user burden, clinical end-users of the software should receive a different set of questions than IT staff responsible for supporting the software.

OVERALL SATISFACTION

4. How likely is it that you would recommend [autofill primary product name based on Q1] to a colleague with a practice similar to yours?

This question seems to be implicitly focused on an ambulatory setting – the term “practice” seems limiting. We recommend that the phrase, “in a setting similar to yours” be used instead, given that is the term ONC uses for real-world testing, to include both institutional and ambulatory settings.

INTEROPERABILITY

5. Indicate the level of ease or difficulty completing each of the following tasks using [autofill primary product name based on Q1].
The questions in this section are not “tasks” in the sense that end-users would think of. They are functions of the system that happen as part of a more specific clinical workflow. If interoperability is working at all, the individual functions will be lost on many users. Focusing the question on a specific workflow that exemplifies the functionality would be more effective.

5.1 **Electronically exchanging health information with clinicians who have a different EHR/health IT product than the one used by organization**

We recommend a user-centric study design, asking more specifically about the entities with which the clinical end-user can exchange data: e.g., clinicians outside the organization, clinicians inside the organization, payers, state registries/public health, clinical registries, etc. It is unlikely that a clinical end user will be aware of which developers develop EHRs their EHR exchanges data with; this question is more suited to someone on the IT team.

5.2 **Electronically exchanging health information with clinicians outside my organization**

We recommend clarifying this question. The draft language is ambiguous and likely will not match participants’ experience. What does this question actually mean? Does it refer to sending a patient chart to a specialist or another type of exchange? It is important that participants clearly understand what is being asked.

5.3 **Electronically exchanging health information with clinicians inside my organization**

We recommend clarifying this question. The draft language is ambiguous and likely will not match participants’ experience. What does this question actually mean? Does it refer to sending a patient chart to a specialist or another type of exchange? It is important that participants clearly understand what is being asked.

5.4 **Electronically exchanging health information with health information organizations (HIOs) or health information exchanges (HIEs)**

A clinical end user may not be able to distinguish between connections to HIEs/HIOs, and connections directly to another provider’s practice. This is a more appropriate question for IT staff.

5.5 **Electronically exchanging health information with payers (e.g., Medicare, Medicaid, private payers)**

This question may not be appropriate for all participants, as some payer info may be processed through practice management software and not the certified health IT. This type of configuration should be an option in the responses.
We also note that Medicaid may not be a useful example; because there is no standardized format for Medicaid, responses may differ from state to state. Exchanging health information with private payers may yield more useful responses.

5.8 Connecting with your local prescription drug monitoring program (PDMP) through your certified health IT product

We recommend removing this question.

Responses to this question will vary widely, not necessarily because the technology is not available within the EHR, but because in the absence of a federal, standards-based approach, states have created complex environments that are misaligned, confusing, and costly to healthcare providers and EHR developers. This wide variation in the implementation and use of PDMPs at the state level has created a barrier to the effective use of EHRs and other health information technology in the fight against the opioid epidemic, and adds to clinician burden by not allowing for efficient and routine workflows.

5.9 Producing all the reports that are required for my organization’s specialty

We believe that end-users will likely see reporting as being distinct from interoperability and we recommend this question be moved to section 8. If the intent of the question is specifically about the provider’s ability to produce specialty-specific aggregate quality measures for submission to an external benchmarking database, we recommend the question be reworded to more precisely capture that scenario.

5.10 Attesting to the Promoting Interoperability Program and the Merit-Based Incentive Payment System (MIPS)

This question will not apply to hospitalists or inpatient systems. We note there are no similar questions about eCQM submission or attestation for hospital based quality reporting or Promoting Interoperability.

5.11 Please share any comments related to your responses that you are willing to make publicly available.

USABILITY

6. How would you rate the overall usability of [autofill primary product name based on Q1]?

“Usability” is a concept that is experienced by clinical end-users, not something all end-users have the vocabulary to speak to. If another word is not considered, it will be important to define what is meant by the term when asking questions about usability.

However phrased, this question is appropriate for clinical end-users, and not for IT staff.
7. **How would you rate your satisfaction with the following aspects of [autofill primary product name based on Q1]?**

We note that many of the questions in Section 7 are phrased in a comparative way, but it's not clear what participants are supposed to be comparing to. Other EHRs? Paper charts? This becomes especially complicated when thinking of 'EHR-first' clinicians, who have had little or no experience with paper charts.

Reframing these questions to ask about a common scenario that represents the specific criterion would be more helpful. (e.g., “I can talk to patients while entering information,” “It is easy for me to see what information is required,” or “The system alerts me before an error occurs.”) Another option would be to shift the questions to the Nielsen Norman (or other) usability heuristics that may be familiar to users, or at least have agreed-upon definitions.

Additionally, we suggest changing the “satisfied/unsatisfied” scale to agree/disagree, which is a better fit for these questions.

Finally, the ambulatory bias comes through again with use of the term “practice” – again, we recommend “setting” as used by ONC in other contexts.

**7.1 allows users to be more productive**

“Productivity” is a vague concept that can be widely interpreted. We recommend tying this question more closely to clinical practice and measurement.

**7.2 has an intuitive workflow**

This question is likely to be interpreted in different ways by different participants, as it can apply to a variety of workflows. One solution could be to break it out into subsections that cover a wide range of common workflows.

**7.5 decreases the time users spend documenting patient care**

We support this question, which seems like a more useful way to address the productivity metric. We note again that “decrease” is a relative term that may not be answerable by all users.

**7.7 improves patient safety**

“Improves” is a vague term and open to interpretation. Improves compared to what? Does a low score equate to ‘they increase the risk of harm’? Patient safety is not limited to an organization's EHR; there are multiple layers and structures to safety and quality measures at organizations. Focusing this question on how well the EHR integrates into ensuring safety protocols and clinical processes for patient safety would be more effective to assist in purchasing decisions.
7.9 *easy produces understandable clinical summaries*

We find this question unclear. Is it asking about the quality of discharge summaries, the ability to present summarized clinical data, or something else? We suggest the question be reworded to better identify what is being asked.

We further note that developers are responsible for producing clinical summaries based upon associated standards such as CCDA. Developers are bound under certification to follow standards and do not have latitude to individually address usability concerns therein.

7.11 *has advantages that outweigh its disadvantages overall*

This question is very vague, and we predict answers will likely be biased by other factors (e.g., the respondent’s attitude toward technology). If this question is included it should include a free-text comment.

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

Focusing questions on specific workflows that exemplify each functionality would be more effective.

As drafted, these questions fall into a complex organizational space, as there is little guarantee that healthcare delivery organizations will allow each piece of functionality to be used, that the configuration is the same across different organizations, or that individual clinical end-users know a feature is available.

Additionally, there are areas of functionality or capability that have nothing to do with certified health IT such as data analytics, integrated chronic care management tool, patient reminders, voice recognition, optical character recognition and telemedicine. The focus should be on capabilities of certified health IT or on capabilities necessary to implement and maintain certified health IT.

8.1 *Data analytics (e.g., produce feedback reports, identify high-risk patients, create data visualizations and graphics)*

Based on the examples provided, this is half a clinical end-user question, and half an IT staff question. We suggest breaking it out into separate questions for each group.

8.2 *Default values for common orders (e.g., medication order specifics, routine laboratory draw times)*

Ideally, examples would be tuned to the clinical context of the user (e.g., routine lab draw times don’t mean much in the ambulatory space).
8.4 Evidence-based order sets and charting templates (e.g., prepopulated order sets and charts)

We recommend these be broken down into separate questions, as order sets and charting templates are different.

We note that while these items may be integrated into the EHR, they are not usually part of the EHR software. The order sets and charting templates provided are typically purchased or created at the discretion of the healthcare delivery organization, and the extent to which they are evidence-based are not a quality inherent to the EHR technology.

8.6 Integrated chronic care management tool (e.g., care plans, care transitions, coordination with home and community-based services)

Prior to asking this question, we suggest it will be important to clarify if multiple health IT systems are in place at an organization as transitions of care can often be paralleled by a transition of product. If we do not understand the variety of products at play these results will be misleading.

8.7 Mobile accessibility (e.g., mobile-friendly web interfaces, ease of use on smartphone)

We recommend rewording this question, as the term “accessibility” could be misleading to some participants.

8.8 Optical character recognition (i.e., ability to encode scanned text and integrate into the product’s data fields)

This question would benefit from additional clarification. Are participants being asked to consider the accuracy of OCR, or how easy it is to use this functionality within the product?

8.9 Patient reminders (e.g., ability to send through patient portal, automated reminder calls)

Clinical end-users may not be aware of automated reminders, as they do not need end-user intervention. We also note that this functionality would likely not apply in an inpatient setting.

8.10 Remote accessibility (i.e., access from home computers and tablets)

We recommend rewording this question, as the term 'accessibility' could be misleading to some participants.

8.12 Telemedicine capabilities (e.g., virtual visits, video, and/or data collection within health IT product)
This question would benefit from additional clarification. Is it asking about telemedicine capabilities (i.e. features available in the product), or the user experience of the telehealth system? We also recommend the question be reworded to distinguish between the provider and patient experience.

8.13 **User-configured interfaces (e.g., screen views, tabs, links, charts, reports, templates, alerts)**

Healthcare delivery organizations may choose to disable user-configuration to promote standardization of care and best practices. We recommend this question be removed or otherwise account for how an organization might choose to limit an EHR’s capabilities.

8.14 **Voice recognition/voice-to-text capabilities (e.g., voice-activated recording, natural language processing)**

This question would benefit from additional clarification. Are participants being asked to consider the accuracy of voice capabilities, or how easy it is to use this functionality within the product?

**IMPLEMENTATION**

9. **How would you rate your overall satisfaction with the implementation of [autofill primary product name based on Q1]? Please consider the explanation of the implementation process before it began, training and support for implementation, and whether the process met what was promised. If you were not involved in the implementation, mark “don’t know or not applicable.”**

This question is appropriate for IT staff, and not for clinical end-users.

This question is too broad and misses several specific aspects of the implementation experience. We recommend the question include sub-question response options, in place of the italicized note, asking about specific aspects of implementation such as configurability, customizability, availability/quality of reference information or guidance, availability and quality of recommended practices, ability to be self-directed in implementation, requirements for vendor involvement, and degree of reliance on vendor/developer performing specific tasks.

Finally, we note that some developers work directly with organizations to implement EHR software, some rely entirely on external firms, and some allow organizations to choose. We recommend the survey first capture who was responsible for the implementation and then support further stratification based on external implementation service firms.

**HEALTH IT PRODUCT SUPPORT**

10. **Indicate whether each of the following types of ongoing product support are available for [autofill primary product name based on Q1]. Do not consider support for implementation.**
This question is appropriate for IT staff, who should be asked if they are providing direct end-user support, or if their health IT provider is providing all or some of that support. For participants at larger organizations, their IT staff is likely the first level for product support. In those cases, responses by clinical end-users would likely refer to IT staff within their own organization.

**10.3 In-person support**

We note that the availability of in-person support from EHR developers is affected by COVID-19.

**10.4 Online user guides and/or video tutorials**

The EHR Association has no recommendations for this question.

**10.5 Live and/or recorded webinars**

The EHR Association has no recommendations for this question.

**11. How would you rate the available support for [autofill primary product name based on Q1]?**

This question is appropriate for IT staff, who should be asked if they are providing direct end-user support, or if their health IT provider is providing all or some of that support. For participants at larger organizations, their IT staff is likely the first level for product support. In those cases, responses by clinical end-users would likely refer to IT staff within their own organization.

**UPGRADES**

**12. How would you rate your satisfaction with the following aspects of upgrades and maintenance for [autofill primary product name based on Q1]?**

This section has little meaning to clinical end-users, so would be best limited to IT staff participants.

We note that some healthcare delivery organizations do not handle messaging/change management on their own.

Sub-questions would be useful, to include the upgrade approach used, the frequency of upgrades and requirements of the developer to have the provider remain on a current/supported release.

**PRIVACY AND SECURITY**

**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.)?**

This question is appropriate for IT staff, and not for clinical end-users.
COST

14. What pricing model(s) does your [autofill primary product name based on Q1] operate on?

This question is appropriate for IT staff, and not for clinical end-users.

15. What was the approximate total cost of implementing [autofill primary product name based on Q1]? Please consider all costs paid to the vendor for implementation, implementation training, travel for an on-site training, etc. Do not consider costs beyond those paid to the vendor (e.g., purchasing computers and tablets, staff hours, workflow redesign). Please provide your best estimate.

This question is appropriate for IT staff, and not for clinical end-users.

The cost ranges offered seem too fine-grained for smaller implementations, and too gross cut for larger ones.

16. What is the approximate annual cost to maintain your product, [autofill primary product name], for all users in your organization? Please consider all costs paid to the vendor, including for customization, features and functionalities, and reporting. Do not consider costs beyond those paid to the vendor (e.g., purchasing computers and tablets, staff hours, workflow redesign). Please provide your best estimate.

This question is appropriate for IT staff, and not for clinical end-users. The question should also include interface costs.

We note it will be difficult to obtain apples-to-apples comparisons, particularly for vendors that supply a variety of products. We question the utility of this question in helping others make informed purchasing decisions.

CONTRACTUAL INFORMATION

17. Does your contract for purchasing [autofill primary product name based on Q1] include a defined cost and/or procedure to leave the product (sometimes called an “out clause”)?

This question is appropriate for IT staff, and not for clinical end-users.

GENERAL QUESTIONS ON USER CHARACTERISTICS

18. In what setting do you primarily use [autofill primary product name based on Q1]?

We wonder why “independent” is an option? Is that a “size of practice” detail? Overall the response options include a number of settings that are not valid for the use of certified health IT. If this survey is
intended to compare certified health IT products, per the original Congressional mandate, inappropriate settings should be removed.

19. About how many clinicians work in the practice or organization where you use [autofill primary product name based on Q1]? Include all locations in your organization or health system.

The ranges offered seem to assume a focus on physician or clinician practices, and over-generalize the sizes of larger organizations. We suggest more meaningful ranges may be:

- Solo or less than 5
- 6-10
- 11-50
- 51-100
- 101-500
- 501-1000
- More than 1000

We also note that an end-user may have little awareness of the total number of clinicians who fall under the “organization’s” umbrella. Additionally, larger organizations deploy different EHRs across providers under their umbrella, further underscoring the variability in this data. We question the utility of this question.

20. What best describes the types of services provided at the practice in which you use [autofill primary product name based on Q1]? Select all that apply.

We note that the responses are extremely outpatient focused; we recommend those responses only be shown to those participants, and that separate options be made available for acute care participants.

23. Approximately what percentage of patients at the practice in which you use [autofill primary product name based on Q1] are uninsured or covered by Medicaid?

This question is not relevant to the EHR.

24. How would you rate your proficiency using [autofill primary product name based on Q1]?

We recommend adding a preceding question about the clinician’s technical proficiency in general. This will allow users reviewing data to more specifically hone in on the experiences of providers with a similar level of technical expertise and expectations to themselves.
August 10, 2020

Christal Ramos, Ph.D., MPH
Urban Institute Health Policy Center
500 L'Enfant Plaza SW
Washington, DC 20024

Re: EHR Reporting Program Draft Voluntary User-Reported Criteria Request for Feedback

Dear Ms. Ramos:

Thank you for the opportunity to provide feedback on the Urban Institute’s draft voluntary user-reported criteria for the EHR Reporting Program. Epic is a health IT developer based in Verona, Wisconsin. We have participated in ONC’s Health IT Certification Program since its inception and offer certified health IT products that are used by hundreds of thousands of clinicians in rural and urban settings across the country.

We support open and transparent communications between health IT developers and their customers regarding the capabilities of certified health IT products and users’ experiences with those products. To that end, we voluntarily participate in several private sector initiatives to measure and share the performance of our health IT products and services. Our knowledge of the initiatives and resources currently available to inform health IT purchasing decisions leaves us concerned that inclusion of the proposed user-reported criteria in a government-sponsored “consumer reports” for health IT will increase administrative burden while offering marginal additional benefit. We recommend that the Urban Institute work closely with ONC to evaluate how the EHR Reporting Program, and the user-reported criteria specifically, may be duplicative of existing measurement initiatives and transparency requirements finalized in recent regulations, and take efforts to minimize such duplication.

Our feedback below: (1) identifies areas where the draft EHR Reporting Program user-reported criteria overlap with existing resources that compare health IT solutions, and (2) offers suggestions on how the criteria could be modified to eliminate redundancy and improve the quality of users’ responses.

We are happy to be a resource as you develop the EHR Reporting Program and can make ourselves available to answer any questions you might have about our comments. Please feel free to contact us at info@epic.com.

Thank you for your consideration.

Sincerely,

Sasha TerMaat
Epic

cc: Don Rocker, M.D., National Coordinator for Health Information Technology
    Steve Posnack, MS, MHS, Deputy National Coordinator for Health Information Technology
    Elise Sweeney Anthony, J.D. Executive Director, Office of Policy
General Feedback

1. **Leverage existing user experience research channels**

We recognize that ONC and Urban Institute’s objective in creating a voluntary questionnaire is to minimize the administrative burden placed on healthcare providers and individual clinicians, which we support. However, relying on voluntary responses to the questionnaire could result in non-representative sets of responses, or a small number of responses, making it challenging to control for variations among types of users and creating risks that summarized responses are not appropriately representative of industry experience with certified products. A framework based on voluntary responses could also result in data integrity issues if the data collection process does not include steps to authenticate whether responses are from legitimate users of the certified product.

We are concerned that developing techniques to resolve these challenges will take significant time and investment and be duplicative of the efforts of existing private industry actors that research and compare health IT products. These actors, such as KLAS and Black Book, have honed their research methodologies over the course of years and produce widely respected and used reports comparing the capabilities of health IT products in a manner similar to that envisioned for the EHR Reporting Program. Duplicating those efforts would result in an increased burden on all industry actors, and distort the well-functioning market for those comparison services.

We recommend that the Urban Institute and ONC investigate the areas where their program overlaps with the reports already offered by actors like KLAS and Black Book, and create a program that incorporates their existing research efforts rather than duplicating it. Such an approach would minimize the burden on health IT developers and provider organizations while resulting in improved access to research that compares certified products for small and rural practices.

2. **Clarify intended respondents and promote transparency**

The breadth of topics and the blend of objective and subjective questions included in the questionnaire will also create challenges in its administration. It is unlikely that any individual respondent at a healthcare organization will be in a position to provide well-informed and accurate responses to questions across each of the five topics included in the draft questionnaire. Subjective user-experience and satisfaction related questions will be better targeted toward end-users of the product. In contrast, objective questions about the implementation, support, and maintenance services offered by the developer will be better answered at an organizational level or by the health IT developer itself. Clarifying the intended respondents to each survey question would reduce confusion as respondents complete the survey, and ultimately capture more accurate data.

Organizations using data points originating from user-reported criteria to make health IT procurement decisions will need to know the number of respondents to any user-reported criteria questionnaire, the number of healthcare organizations they represent, and the types of health IT users they represent. The EHR Reporting Program should include processes to provide transparency to the public about the breadth, volume, and quality of user responses used by the program to assess certified health IT. Purchasers should be clearly informed about the feedback sample size and user characteristics that impacted a health IT product’s performance on a given metric.
Detailed Feedback on Draft User-Reported Criteria

1. Interoperability Draft Criteria
   
a. Ease of exchange with health information organizations (HIOs) or health information exchanges (HIEs), clinicians who have a different EHR/health IT product, clinicians outside the organization, payers, state registries including public health, and clinical registries.

   We recommend clarifying whether these criteria intend to capture information about the usability of the workflows users follow to exchange data with the specified entity, or information about the amount of effort required to establish a connection with the specified entity.

   Other existing components of the ONC certification program, such as the Real World Testing requirement, may already offer similar insight about the performance and usability of interoperability functionality in certified health IT. If the intent of these questions is to capture information about the usability and ease with which exchange takes place, it will be important for it to ensure the data collected through the user-reported criteria is not duplicative with those other program requirements.

   The Urban Institute and ONC will also want to consider how the criteria will control for factors outside of the control of the developer of the certified product that often play a significant role in both the ease with which actors can establish an exchange connection and the ease with which users can exchange health information. Some examples of these factors include:

   - Whether the exchange partner uses commonly adopted interoperability standards.
   - The privacy, security, and data use policies of the exchange partner.
   - Testing requirements imposed by the exchange partner before going live.
   - Design and infrastructure decisions of the exchange partner.

   Finally, many health IT products facilitate exchange using behind-the-scenes automated processes that require no action on the part of users. The Urban Institute will want to assess how it will want to account for these automated exchange processes in its measurements of the ease of exchange. It could accomplish that would be by measuring the usability of “push” exchange workflows (e.g., Direct messaging) whether the product offers query based exchange workflows and/or automates exchange processes.

   b. Ease of connecting with local prescription drug monitoring programs

   The ways in which users of a particular certified product are able to connect with a PDMP will vary based on the jurisdiction of the PDMP and the entity administering it. Common factors outside of the control of developers of certified products that vary by jurisdiction and by PDMP that will impact the ease with which users are able to connect include:

   - The method(s) of connection/integration offered by the PDMP (e.g., via NCPDP standards, Single Sign On, embedded web portal within the EHR, custom interfaces, etc.).
   - State and local privacy and security laws and related data use regulations, whether imposed by government or by the developer of the PDMP.
   - Testing requirements imposed by the PDMP to complete connections.
   - State or local workflow and reporting requirements placed on prescribers.

   Because of these numerous differences across PDMPs, it may be difficult for purchasers to understand how a product’s performance on this criterion is likely to translate to their own experience. Instead, capturing information about the methods of PDMP integration offered by the product may provide more useful
information to purchasers, who could then couple it with information about their jurisdiction’s PDMP design and infrastructure to help inform their decision.

c. **Ease of access among clinicians within the same healthcare organization**

Integrated health IT products built on a single patient record eliminate the need for exchange of patient records within an organization. Instead, clinicians within the same organization would be able to directly access and use a unified patient record. We recommend providing additional context for this criterion that specifies that intra-organizational exchange needs might be met through shared access to an integrated patient chart.

d. **Ease of producing all the reports required for specialty**

The ability of health IT to generate reports for a specialty is not typically considered a measure of interoperability. Additionally, since organizations’ reporting needs will vary based on their care delivery model and the specialties they offer, purchasers reviewing a product’s performance on the criterion will instead want detailed information the reports the product can produce to support the specialties they offer. We recommend refocusing the criterion on the ability to generate specific reports identified as important for a set of high priority specialties.

e. **Ease of attesting to the Promoting Interoperability Program and the Merit-based Incentive Payment System (MIPS)**

Much of the experience of attesting to Promoting Interoperability or the Merit-based Incentive Payment System is based on CMS’s portals and capabilities, not health IT. For example, CMS remains unable to accept API-based submissions from EHRs.

If this question is included, it should be revised to focus on the usability of certified functionality that organizations or clinicians use to generate data for the Promoting Interoperability and MIPS programs, and not the experience entering or uploading that data to CMS.

2. **Usability Draft Criteria**

a. **Satisfaction with overall usability, provider burden, quality, and safety**

While we agree these criteria capture information useful to inform purchasing decisions, they collect information duplicative with existing industry resources, such as KLAS reports. In addition to offering aggregate scores on user satisfaction, however, those existing resources also conduct extensive research on how a variety of factors contribute to a product’s usability and its impact on provider burden, quality, and safety that are of interest to purchasers of health IT such as:

- Configurability and configuration decisions made by the organization implementing the product.
- Regulatory requirements that require adherence to particular documentation or workflow standards.
- The amount and quality of the training the user received.

Rather than duplicating those data collection and analysis efforts, we recommend the Urban Institute and ONC investigate how it can leverage those existing reports and incorporate them directly into the EHR Reporting Program. This will reduce the administrative burden on providers and health IT developers and eliminate the need for substantial investment in establishing a research and data collection framework for these criteria from scratch.
b. Ease of use for analytics, orders, documentation, e-Prescribing controlled substances, receiving and reviewing images, chronic disease management tools, mobile and remote access, optical character recognition, patient reminders, telemedicine, user-configured interfaces, and voice recognition

Existing industry resources to compare health IT already collect user-reported feedback to measure satisfaction and ease of use for these capabilities. We recommend examining how the EHR Reporting program can leverage and incorporate those existing resources to avoid increasing burden through duplicative efforts.

3. Privacy and Security Draft Criteria
42 CFR Part 2 and HIPAA are regulatory requirements and not examples of privacy and security functions or features. We recommend rephrasing those examples to say “features that support compliance with 42 CFR Part 2 and HIPAA.”

4. Other Draft Criteria
   a. Overall satisfaction

We agree that these questions will collect useful information for organizations making health IT procurement decisions. However, existing industry resources to compare health IT already collect user-reported feedback to measure overall satisfaction, as well as satisfaction with the implementation, maintenance, and support services offered by health IT developers. We recommend examining how the EHR Reporting program can leverage and incorporate those existing resources to avoid increasing burden through duplicative efforts.

   b. Pricing model, implementation cost, maintenance costs, and contractual information

It may require significant effort on the part of users to collect implementation and maintenance costs for the purpose of reporting to the EHR Reporting Program, and that variations in pricing based on their unique blend of software and service needs will limit the usefulness of the reported cost in informing other organizations’ purchasing decisions. Instead, health IT developers typically work closely with individual prospective clients to provide a pricing quote tailored to their particular needs.

   c. Implementation process, maintenance and upgrades, and support for standard use

Information about the scope and pricing of implementation, maintenance, and support services offered by a health IT developer will be better collected directly from the health IT developer rather than individual users.

5. Product and User Characteristics
   a. Certified health IT product(s) used (vendor/product/version selected from drop-down)

A menu of certified health IT products will include hundreds of options, and many organizations use several different products simultaneously. We recommend asking respondents to enter a CMS Cert ID generated from the Certified Health IT Products List based on the modules their organization uses, instead of selecting from a drop-down menu.

   b. User characteristics

Type of clinical or non-clinical user
Refer to our general feedback above regarding the intended respondents of the survey.
Setting, practice size, types of services provided at the practice, state, urban/suburban/rural, share of patients uninsured or covered by Medicaid, user proficiency with product

Some of these questions, including practice size, state, urban/suburban/rural, and share of patients uninsured or covered by Medicaid, would be better answered at an organizational level rather than by individual clinicians.
FEHRM (DOD and VA) Comments for EHR Reporting Program Draft Voluntary User-Reported Public Comments

- Table 1 – item 5.1: Ease of exchange with clinicians who have a different EHR/health IT product
  - Program Executive Office of General Counsel (PEO OGC) comment:
  - This and similar factors related to ease and efficiency of use for end users and patients should rank among the highest criteria.

- Table 1 - Other Providers and Payers
  - Program Executive Office of General Counsel (PEO OGC) comment:
  - What about a criterion relating to exchanging information and data from medical devices, which is distinct from 8.7 and 8.10 that appear to pertain solely to access.

- Table 1 - item 5.5: Electronically exchanging health information with payers (e.g., Medicare, Medicaid, private payers)
  - Program Executive Office of General Counsel (PEO OGC) comment:
  - Another criterion should be added (or an existing one revised) to address accessing and exchanging patient generated information. This functionality would ensure greater patient involvement in their own healthcare.

- Table 1 - item 5.9: Production of reports specific to organization / specialization
  - Program Executive Office of General Counsel (PEO OGC) comment:
  - Do any vendors incorporate within the data reports that are available any option for comparative analyses with other providers? or other providers for a particular specialty? If so, then you may want to include criteria for such forward-thinking vendors. In addition, you may want to include a criterion as to ways a user uses the technology for its own comparative quality analyses. This is distinct from 8.1.

- Table 1 - Reports and Data
  - Program Executive Office of General Counsel (PEO OGC) comment:
  - What about ease of producing a complete copy of a patient’s health information from the technology in a computable format.
- **Table 1 - item 5.10: Attesting to the Promoting Interoperability Program and the Merit-Based Incentive**
  - Program Executive Office of General Counsel (PEO OGC) comment:
  - In addition to “ease” of attesting, a criterion should include “accuracy” in attesting. If the product inappropriately or inaccurately provides attestations that are inaccurate, there may arise fraud and abuse allegations.

- **Table 2 - Provider Burden**
  - Program Executive Office of General Counsel (PEO OGC) comment:
  - Perhaps include a criterion eliciting how configurable the technology is for that user’s purposes.

- **Table 2 - item 7.2**
  - Program Executive Office of General Counsel (PEO OGC) comment:
  - Providers do not all maintain the same workflow in their practices. The more pertinent question would be whether the product’s practice workflow is intuitive. In many cases, the practice will likely be adjusting its workflow to follow the EHR, but only if the EHR workflow is logical and intuitive.

- **Table 2 - item 7.4**
  - Program Executive Office of General Counsel (PEO OGC) comment:
  - This should be one of the top priorities.

- **Table 3 - item 13**
  - Program Executive Office of General Counsel (PEO OGC) comment:
  - This criterion is quite broad. We suggest that privacy and security features be broken out for greater granularity of the users’ satisfaction with the technology’s features relating to privacy and separately to security. Additionally, some consideration should be given to eliciting the user’s knowledge of and satisfaction with the vendor’s stated privacy policies and practices.

- **Table 3 - Overall Privacy and Security**
  - Program Executive Office of General Counsel (PEO OGC) comment:
  - A criterion should include whether the product includes options for differing privacy levels, according to patients’ preferences.
• **Table 4 - Contractual Information**

  Program Executive Office of General Counsel (PEO OGC) comment:

  One of the initial “contractual” criteria should be whether the product performs as was advertised and/or marketed. This is critical.

• **Overall Satisfaction - item 3.1**

  Program Executive Office of General Counsel (PEO OGC) comment:

  You may want to ask for comments that will not be attributed to the survey responder, but that you can state come from a verified purchaser.

• **Interoperability - item 5**

  Program Executive Office of General Counsel (PEO OGC) comment:

  In addition to querying the “level of ease or difficulty” of completing these tasks, you may want to ask about the format and usefulness of the data received. Many of these tasks may be easy to perform, but the format in which the data is received may limit the use of the data (which is more granular than the subsequent section).

• **Usability - item 8.8**

  Program Executive Office of General Counsel (PEO OGC) comment:

  We would suggest also querying the accuracy of OCR (integrity of data); differing formats can create translational problems during character recognition.

• **Privacy and Security - item 13**

  Program Executive Office of General Counsel (PEO OGC) comment:

  We suggest breaking out “privacy” and “security.” We also recommend identifying and asking about specific core privacy and security features.

• **Privacy and Security - item 13**

  Program Executive Office of General Counsel (PEO OGC) comment:

  We suggest breaking out “privacy” and “security.” We also recommend identifying and asking about specific core privacy and security features.

• **Contractual Information - item 17**

  Program Executive Office of General Counsel (PEO OGC) comment:
- You may want to ask about other contractual provisions: guaranteed system availability; product consistency with marketing/sales materials; limitations on price increases (subscription pricing); etc.

- **Item 2**
- Program Executive Office Defense Healthcare Management Systems (PEO DHMS) comment:
- Based on review of the stakeholder input report, there may be an unintended bias towards data collection from only physicians. Recommend changing 2a-Practicing Physicians to 2a-Practicing Providers, which includes PAs, NPs, DNPs, Dentists, etc.

- **General Reference**
- Program Executive Office Defense Healthcare Management Systems (PEO DHMS) comment:
- There are many similarities in this proposed survey with a DoD-approved MHS GENESIS end user survey already approved IAW DoD Manual 8910.01 and DHA AI 8900.01, suggesting higher rate of survey fatigue.

- **Line 8 under Question 1**
- Defense Health Agency (DHA/J-5) Comment:
- After "+for additional add-on products, if applicable," add a colon (";") after the word "applicable."

- **Lines 1-11 under Question 1**
- Defense Health Agency (DHA/J-5) Comment:
- The question asks what "products" do you use. Then proceeds to ask about additional "add-on products". Given the remainder of the questions are auto filled based on the initial response, how would multiple products be handled? Possibly, this should be a singular response question dealing only with the primary tool, add additional questions to address multiple tools if desired. In addition, it is likely the providers who use the tool may not be totally aware of the primary vender and/or version. As such, it is possible to have multiple versions operating in the same institution.

- **Lines 1-8 under Question 2**
• Defense Health Agency (DHA/J-5) Comment:
• If the desire is to be able to determine differences in health IT products based on the roles if individuals using the products, this may be difficult if respondents are able to select multiple roles. It is recommended to make the list of responses broader to include all levels of potential users of the IT products and exclusive so that the differences between users based on their roles can be determined. Possibly have respondents select their "main" role only. In addition, it may be most accurate to describe the role rather than the individual. For example, instead ask: "What type of health IT user best describes your role?"

• **Lines 1-7 under Question 3**
• Defense Health Agency (DHA/J-5) Comment:
• It may help to add a quantitative scale to the anchors (e.g., -2 to 2) to reduce some of the variability associated with subjective ranking. This should be done throughout for consistency if implemented.

• **Lines 1-3 under Question 3**
• Defense Health Agency (DHA/J-5) Comment:
• In the previous question (Question 3) a 5 point scale starting with the most positive at the top (selection 1) and least at the bottom (selection 5). However, in question 4 the scale is 10 point scale with the least important starting with selection 1 and going to the most important up to selection 10. Generally, it is helpful when survey designs follow a consistent pattern. It is recommended selections should resemble the order and flow similar to other question numbers (e.g., question 3).

• **Line 9 under Question 7**
• Defense Health Agency (DHA/J-5) Comment:
• There are two selection options under response selection "f": "don't know" and "not applicable," which are two different things. As such, it is important to know which respondents report "don’t know" versus those where the question "don't apply." It is recommended this response item is separated out into two different response options. Also "not applicable" may be selected if the tool does not have the function. This applies to other questions with this selection item as well (e.g., see questions 8, 9, 11, and 12).

• **Lines 11 and 12 under Question 5**
• Defense Health Agency (DHA/J-5) Comment:
• In the phrase "Electronically exchanging health information with clinicians who have a different EHR/health IT product than the one used by organization" add 'my' prior to the word "organization"

• **Line 2 under Question 7**
• Defense Health Agency (DHA/J-5) Comment:
• Insert "Response Options" in a new line above "a."

• **Line 9 under Question 7**
• Defense Health Agency (DHA/J-5) Comment:
• In the phrase, "The extent to which the certified health IT product," add a colon (";") after the word "product."

• **Line 22 under Question 8**
• Defense Health Agency (DHA/J-5) Comment:
• It is suggested to change “tool” to “tools.”

• **Line 32 under Question 8**
• Defense Health Agency (DHA/J-5) Comment:
• In the term "(i.e., access from home computers and tablets)," it is suggested to update "i.e." to "e.g." as the items included could be more of "examples" rather than the "items listed".

• **Lines 1-10 under Question 9**
• Defense Health Agency (DHA/J-5) Comment:
• The stem of this question is really is multiple questions (e.g., 1. before it began, 2. training and support for implementation, and 3. process met what was promised). If the ability to analyze on these differences is desired, it is recommended question 9 becomes multiple questions to support all three items.

• **Line 2 under Question 12**
• Defense Health Agency (DHA/J-5) Comment:
• Insert "Response Options" in a new line above "a."

• **Lines 1-9 under Question 13**
• Defense Health Agency (DHA/J-5) Comment:
• This question is similar to other questions in that the question asks about security and privacy which are related but difference issues. IT professionals will rate these issues in a very different way than providers and other end users. Consider updating this question separating out the differing issues.

• **Lines 1-5 under Question 14**
  Defense Health Agency (DHA/J-5) Comment:
  The response options may not be mutually exclusive. It is suggested that another response option is added for "don't know" responses.

• **Lines 1-19 under Question 18**
  Defense Health Agency (DHA/J-5) Comment:
  For response "a," break out "solo" and "group ambulatory physician practice" as the IT products and tools are likely to be much different based on the size of the practice. In addition, it is suggested that selection options are alphabetized.

• **Lines 1-2 under Question 23**
  Defense Health Agency (DHA/J-5) Comment:
  Question 23 explores patients who are uninsured or covered by Medicaid. Being uninsured and being covered by Medicaid are two different things. As such, this question may be confusing as Medicaid is a form of insurance administered by the state for those who qualify for the program. Possibly separating out these two items into two separate questions would be helpful.

• **Overarching update suggestion**
  Defense Health Agency (DHA/J-5) Comment:
  There is a lack of consistency in grouping similar questions together within the survey, which is conveyed in the order numbering of questions. For example, questions linked to "orders" are not back to back within the survey such as questions 8.2 and 8.4 asks about items prioritized under “orders” in the document. In order to group this set of questions together, for example, it may be useful to update question 8.4 question 8.3 instead. This would need to be consistently checked and updated throughout both documents pending the implementation of this comment.

• **N/A - First sentence within the document**
  Defense Health Agency (DHA/J-5) Comment:
• The sentence starting with "Tables 1-4 below summarize draft voluntary user-reported criteria…, may be difficult for users to understand. It may be helpful to include a short intro sentence such as the following: “In accordance with mandates from the 21st Century Cures Act, stakeholders (spell out who?) have identified specific product and user characteristics as criteria for comparing products. Tables 1-4 summarize…”

• N/A - Second sentence within the document

• Defense Health Agency (DHA/J-5) Comment:
  • In the second sentence starting with "In addition, table 5…," it is suggested that "t" in "table 5" is capitalized.

• N/A - Second sentence within the document

• Defense Health Agency (DHA/J-5) Comment:
  • In the second sentence ending with "based on criteria," it may be helpful to provide additional information for the reader to understand what criteria is being referenced.

• Question 8.6 under Table 2. Usability Draft Criteria

• Defense Health Agency (DHA/J-5) Comment:
  • It is suggested to change “tool” to “tools.”

• Question 7.10 under Table 2. Usability Draft Criteria

• Defense Health Agency (DHA/J-5) Comment:
  • In this table, 7.10 currently state "7.10 helps prevent care delivery errors." However, the survey from TAB C indicates “provides system alerts help prevent care delivery errors.” It would be helpful to clarify if the "system alerts” qualifier is accurate for all options?

• Question 23 under Table 5. Product and User Characteristics

• Defense Health Agency (DHA/J-5) Comment:
  • Question 23 explores patients who are uninsured or covered by Medicaid. Being uninsured and being covered by Medicaid are two different things. As such, this question may be confusing as Medicaid is a form of insurance administered by the state for those who qualify for the program. Possibly separating out these two items into two separate questions would be helpful.

• N/A - Overarching update suggestion

• Defense Health Agency (DHA/J-5) Comment:
• The following free text questions were not included in TAB A, which is inconsistent with information provided in TAB C: 3.1, 5.11, 6.1, 7.12, 8.15, 9.1, 11.1, 12.5, 13.1, 15.1, 16.1, and 17.1. It may be helpful to include these questions within the charts in TAB A as well as a statement that any information provided for these questions will be publicly available.

• **N/A - Overarching update suggestion**

Defense Health Agency (DHA/J-5) Comment:

• The questions within the tables that include sub questions are not consistently formatted. For example, in certain questions (5, 8, etc.), the main overarching question is missing (e.g., 5. ease or difficulty completing,” 8. “ease of use for”) while other questions (7, 10, 12, etc.) does have the overarching question listed (e.g., 7. “satisfaction with how product,” 10. “10. Availability of support and whether additional fee is required,” 12. “Satisfaction rating for”). It would be helpful for questions with sub questions to be consistent throughout the tables.

• **N/A - Overarching update suggestion**

Defense Health Agency (DHA/J-5) Comment:

• There is a lack of consistency in grouping similar questions together within the survey, which is conveyed in the order numbering of questions. Specifically, under “Table 2. Usability Draft Criteria” and the “Stakeholder Priority Topic” column, questions listed under “Orders." For example, questions 8.2 and 8.4 asks about items prioritized under “Orders” in both documents. In order to group this set of questions together, for example, it may be useful to update question 8.4 question 8.3 instead in the survey which will be also updated in the current table. This would need to be consistently checked and updated throughout both documents pending the implementation of this comment.

• **N/A - Overarching update suggestion**

Defense Health Agency (DHA/J-5) Comment:

• Throughout all tables, the alignment between text in the first column and second column is off. It is suggested that the table column alignment is updated throughout.

• **N/A - Overarching update suggestion**

Defense Health Agency (DHA/J-5) Comment:

• Throughout all tables, add a color gradient to clearly separate headers.
- **N/A - Overarching update suggestion**
- Defense Health Agency (DHA/J-5) Comment:
  - To clarify the second column header, it may be helpful to update the header title to "User Questionnaire Item?"

**Question 1**
- Defense Health Agency (DHA/J-5) Comment:
  - It is recommended to update question 1 to the following: "1) Which list criteria would you prioritize for inclusion in the EHR Reporting Program, and why?"

  **Response:** Certified health IT users would be most interested in providing information in the following areas to improve products and processes: Overall Satisfaction, Interoperability, Usability, and Cost. In addition, the prioritization depends on the role of the health IT professional or staff member using the product and since they are broken out now in Tab A by stakeholder priority, that may be most appropriate as well.

**Question 2**
- Defense Health Agency (DHA/J-5) Comment:
  - It is suggested that examples for rephrasing and re-wording are provided as well as the rationale for removing.

  **Response:** Please see the suggested updates denoted above under TABS A and C.

**Question 3**
- Defense Health Agency (DHA/J-5) Comment:
  - It may be helpful to include a supplemental question of "Why" because it could prove beneficial to hear the reasoning behind including older models, what information would be missed without including them.

  **Response:** The most recent version of a certified health IT product would be the most consistent as reporters may have various levels of knowledge regarding previous versions. In addition, the survey asks about upgrades, which may provide some information about versions. However, there could be multiple versions operating at the same time in some places.
• **Question 4**
  - Defense Health Agency (DHA/J-5) Comment:
  - It would be helpful to clarify if suitability the same across criteria. Perhaps a table to list who would be most appropriate for each criteria category.

  **Response:** This would vary depending on the role of the certified health IT user. For example, IT specialist may have knowledge regarding the implementation, upgrades, etc.; clinicians may provide more practical information regarding usability and satisfaction with the product; and administrators may provide relevant information regarding interoperability. All of these potential users would have interest in responding to the survey if they believe it could lead to improved processes and products; however, the bandwidth to complete the survey may differ for clinicians, administration, and IT specialists.

• **Question 5**
  - Defense Health Agency (DHA/J-5) Comment:
  - **Response:** Keeping the survey as short as possible; an explanation up front to outline how this information will be used (e.g., how will it help the certified health IT user in their role); the drop-down menus will help to ensure the survey can be completed quickly; develop a follow-up schedule for those surveys that have not yet been returned. In addition, a modest incentive helps as well.

• **Table 2 - Quality and Safety 7.11**
  - Federal Electronic Health Record Modernization (FEHRM) Comment:
  - Remove the word "overall"

• **Table 4 - Implementation 9**
  - Federal Electronic Health Record Modernization (FEHRM) Comment:
  - Include the words "satisfaction with the implementation process _of the EHR Vendor_." The goal is to provide a quantitative value of the subjective and objective user experience. Ensure that the user is evaluating the EHRs vendors implementation support and not an organizations poor culture or lack of engagement.
Federal Electronic Health Record Modernization (FEHRM) Comment:

Include the words "process met what was promised by the EHR vendor."

**Question 1**

Federal Electronic Health Record Modernization (FEHRM) Comment:

Ensure there is not a "hard stop" if the user does not know the version of the product.

**Question 2**

Federal Electronic Health Record Modernization (FEHRM) Comment:

Recommend changing ambiguous user role terminology. Could lead to confusion and mismatch of data related to user role assignments.

1

Federal Electronic Health Record Modernization (FEHRM) Comment:

The number one draft criteria would be the usability section of the EHR Reporting Program. Providers and end-users frustration with current health care practice can be derived from electronic health records. According to Tajirian et al. (2020) physician burnout symptoms are attributed to the EHR usability and clinician satisfaction 74% of the time. Being an end user myself, the intuitive nature of an EHR is ultimately key to my faith in the system in regards to safety and security. EHR vendors currently make it challenging to view hands-on demos of features and usability standards, thus having a reporting mechanism in place would be very beneficial for future buyers and healthcare organizations.


2

Federal Electronic Health Record Modernization (FEHRM) Comment:

N/A

3

Federal Electronic Health Record Modernization (FEHRM) Comment:
• From a patient safety perspective, all versions of the product should be evaluated. Multiple vendors charge fees to update systems or add packages, thus their entire product line (old to new) should be included.

• Federal Electronic Health Record Modernization (FEHRM) Comment:
  • Health IT specialist or Administration. Those with a more in-depth knowledge of the systems and functions. This is not optimal, as end-user experience and feedback would be more beneficial to establish a general consumer baselines and benchmark.

• Federal Electronic Health Record Modernization (FEHRM) Comment:
  • A thought-out and thorough communication campaign. Ensuring that the end-users have situational awareness of the impact and importance of voluntary reporting on certified health IT EHRs. This is a feedback loop opportunity to improve EHR accountability and functionality through consumer feedback and response.

• Overall Survey
  • Veterans Health Information Veterans Health Information Clinical Informatics and Data Management (VHA/10A7) Comment:
    • As discussed with ONC Leads on email and as many HITAC members commented: There are many fundamental problems with this survey that betray lack of expertise on the design team and lack of familiarity with standardized, validated measures of related concepts. I do think that the contractor needs help. Let us know, if we can be of more effective assistance.

• Interoperability Section 5 Page 2
  • Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
    • Response options - suggest separating "Don't know or not applicable (e.g. do not use this function)". There is a difference between not knowing if the product offers the functionality/if it has been implemented by the organization and if it is not applicable - where the end users knows it is a capability, but they do not use.
• **Interoperability Page 1 bottom**
  
  Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  
  Suggest adding "ease of connecting to other health products (e.g., medical devices) to inject and use data"

• **Interoperability Section 5**
  
  Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  
  Suggest adding a question about awareness/use of Direct Secure Messaging

• **Interoperability Section 5.6**
  
  Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  
  May want to give an example for "public health" - e.g. state Immunization Information Systems

• **Interoperability Section 5.7**
  
  Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  
  May want to provide an example to help the user distinguish between 5.6 and 5.7

• **Interoperability Section 5.8**
  
  Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  
  All prior responses refer to exchanging information - this option is refers to connecting. For consistency, consider - "Electronically exchanging information with a PDMP...." In addition, suggest removing reference to "local" and using only PDMP

• **Interoperability Section 5.9**
  
  Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  
  Suggest adding more specificity to interoperability for this item, currently is reads very broadly. It is also not clear to me how the organization's specialty fits.

• **Interoperability Section 5.10**
- Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  - Suggest adding "Medicare" prior to "Promoting Interoperability Program".

**Usability Section 7**

- Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  - Suggest adding a question to gauge satisfaction with the extent to which the product enables clinical decision support

**Usability Section 8**

- Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  - Suggest adding a question to gauge satisfaction with ease of use for managing patient consents and authorizations

**Health IT Product Support Section 11**

- Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  - Suggest adding a question concerning satisfaction with responsiveness for defect resolution

**Health IT Product Support Section 11**

- Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  - Suggest adding a question to measure Vendor interest/openness in satisfying end users requests for new product capabilities and functionalities

**Health IT Product Support Section 11**

- Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  - Suggest adding a question to measure Vendor interest/openness in satisfying end users requests for new product capabilities and functionalities

**Document**
• Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  • Should there be questions related to the EHR ability to support patient engagement/patient access to health data?

• Document
  • Veterans Health Information Veterans Health Information Exchange Program (VHA/10A7) Comment:
  • I believe the typical end-user Clinician will have difficulty answering some of the questions. Suggest branching logic to minimize survey burden.

• Page 1 Bottom
  • Veterans Health Administration Knowledge Based Systems (VHA/10A7)
  • Consider that response D and E are similar and E and F are similar. These should not be ambiguous. Please add Registered Nurse. Consider adding Clinical informatician

• All
  • Veterans Health Administration Human Factors Engineering (VHA/10A7)
  • The organization of the survey should follow survey design principles which include appropriate Likert scale layout and options (e.g., from response indicating the least amount of the construct to most amount of the construct, horizontal display of Likert scales if possible with minimal imposed inefficiency, layout of multiple rating criteria in a grid for quick and easy selection), consistency in term usage and phrasing/response options, ensuring response options have no overlap/ambiguity.

• All
  • Veterans Health Administration Human Factors Engineering (VHA/10A7)
  • The survey indicates it will take 10 to 15 minutes to complete. With the length and content of the survey, we are not confident that it could be completed in that amount of time, especially if the respondent provides comments on their ratings and responses. Suggest piloting (if not done already) to determine accurate time and uncover any potential comprehension or interaction problems.
• **Question 1: 1 to 9**

Veterans Health Administration Human Factors Engineering (VHA/10A7)

The stakeholder(s) being surveyed is not indicated. Many questions are geared towards clinicians. A clinician is unlikely to know the information needed to respond to this question about specific vendor product. Is it possible to map the healthcare facility to the product using CMS reimbursement data? Additionally, our review is limited since we cannot interact with the survey instrument. How will the Selection lists work? These could have lengthy lists to choose from. Will there be auto fill/search to filter the options to shorter lists?

• **Question 2: 1 to 4**

Veterans Health Administration Human Factors Engineering (VHA/10A7)

Stakeholders have different definitions for "clinician." This should be clarified.

• **Question 6: 1**

Veterans Health Administration Human Factors Engineering (VHA/10A7)

"Usability" should be defined for the stakeholder completing the survey. People have different understandings of usability. Recommend using the NIST definition which includes efficiency, effectiveness, and satisfaction. Given the robust literature on usability and safety, we recommend adding safety as well.

• **Questions 7 and 8 All**

Section 7 asks about satisfaction (one component of usability) and section 8 asks about ease of use. We recommend listing several features, like in section 8, and asking about all components of usability to include efficiency, effectiveness, satisfaction, and safety. We also recommend including features of patient identification, order entry, test results (reporting and follow-up), and clinician communication.

• **Question 7: 9**

Veterans Health Administration Human Factors Engineering (VHA/10A7)

Suggest adding additional elements for users to rate the display of information such as: "displays information in a way that is not cluttered," "displays relevant information on the same screen," and "presents only relevant options when placing orders."
• Questions 7 and 8 All
  Veterans Health Administration Human Factors Engineering (VHA/10A7)
  The criteria being rated in these sections do not solicit enough information about the usability and safety of certified health IT products. There should be additional criteria about usability issues that also impact safety such as default values, clinical decision support, entering wrong weight/height, selecting the wrong patient, ordering medications that are clearly out of therapeutic range, etc.

• Question 8 All
  Veterans Health Administration Human Factors Engineering (VHA/10A7)
  Response options of “not applicable” and “product does not have this function” may be confusing for respondents. This should be clarified so that there is no remaining ambiguity in which response option to choose.
  Should consider asking about patient safety risks during implementation. Was there appropriate training? Enough super users available for support? Appropriate IT support?

• Question 12 All
  Veterans Health Administration Human Factors Engineering (VHA/10A7)
  Should consider asking about safety in the context of upgrades such as are users of the product made aware of changes to the product? Is the product safety tested after an upgrade?

• Question 1
  Veterans Health Administration Human Factors Engineering (VHA/10A7)
  1) Which draft criteria would you prioritize for inclusion in the EHR Reporting Program, and why?
     • Usability first and then Interoperability. Usability, because that is a key component of clinician use and adoption and will impact patient care. Interoperability second, because that is what will ultimately help to improve healthcare delivery at a more global level.
     • Privacy and Security. User reported criteria could provide useful insight not only in how well a product meets criteria but also user experience in implementing and using the product.

• Question 2
  Veterans Health Administration Human Factors Engineering (VHA/10A7)
2) Which draft criteria should be rephrased, reworded, or removed?
   • Overall satisfaction is too broad. All the draft criteria can instead have their own individual satisfaction rating element.
   • Recommend adding independent criteria to assess training methodology and quality, which has a direct correlation with usability and adoption.
   • Privacy and Security should be related to specific federal requirements and should include features that respondents would like to see (i.e., perceived gaps).
   • Would recommend adding the below criteria to the Privacy and Security section as amendment functionality in EHRs is often lacking.

13.2 Does [autofill primary product name based on Q1] allow for amendment of electronic health information and linkage to a State of Disagreement as required by the HIPAA Privacy Rule?
   a. Yes
   b. No

• Question 3

• Veterans Health Administration Human Factors Engineering (VHA/10A7)

3) Should the voluntary user-reported criteria cover only the most recent version of a certified health IT product or all versions of the product?
   • All. That might help to trend how IT product development is impacted by user satisfaction ratings. A better criterion would be to include product versions that are currently vendor supported and still available for purchase and implementation. In other words, some upgrades may not be suitable, depending on the characteristics of the health care delivery organization.
   • It could cover all versions, thus showing the relative adoption of the product.

• Question 4

• Veterans Health Administration Human Factors Engineering (VHA/10A7)

4) What certified health IT users are most likely able to report on the criteria (e.g., clinicians, administrators, IT specialists)?
   • Administrators and IT specialists are more likely to report on the criteria, based upon resource availability. There should be recommended roles identified for completing the various survey components, e.g., clinicians evaluate usability, administrators evaluate
cost, etc.
• Will require a collaborative effort on the part of the health IT user as no one individual will have all of the information on user experience.
• IT Specialists who know the product in relation to purpose, other competing products and knowledge of clinician and administrator concerns.

• **Question 5**
  • Veterans Health Administration Human Factors Engineering (VHA/10A7)
  • 5) What could motivate end users to voluntarily report on certified health IT products?
    • If they receive some type of product back, i.e., receive some type of report, such as ECRI, KLAS, etc., that they can use for evaluating future product acquisitions.
    • Potentially the belief that their responses will assist in creation of EHR certification criteria in the future or assist the industry in resolving some existing deficiencies in EHRs.
    • Public publication of the results of the EHR Reporting Programs surveys by end user organization

• **Pg. 2 Table 1**
  • Veterans Affairs VA - OEHRM TIO
  • Table 1 - Recommend expanding these areas to better understand what "ease of use" may comprise of

• **Pg. 2 Table 1: HIE, HIOs**
  • Veterans Affairs VA - OEHRM TIO
  • - Are there more qualitative questions to assess a user's experience, such as "ability to exchange data with HIOs/HIEs in a timely manner?"
    - Add an additional quantitative question for how many providers/partners are in their HIE
    - Add an additional question for participation in a national network (CommonWell, eHealth Exchange)
    - Add an additional question about use of secure messaging

• **Pg. 2 Table 1: PDMPs**
  • Veterans Affairs VA - OEHRM TIO
• This only considers one local PDMP program, rather than the VA’s scale of implementation across multiple states. Recommend expanding question for greater depth.

• **Pg. 2 Table 1**
  Veterans Affairs VA - OEHRM TIO
  Recommend adding row about standards (i.e., use of APIs and FHIR resources)

• **Pg. 3 Table 2: Provider Burden - 7.3**
  Veterans Affairs VA - OEHRM TIO
  Expand on 7.3: Easily access and assimilates data from other products. Could this be quantified by adding how often data is synched with minimal lag time, ability of EHR to ensure data integrity and avoid data duplication

• **Pg. 2 Table 2: Analytics - 8.1**
  Veterans Affairs VA - OEHRM TIO
  Recommend adding question regarding use/ability for Clinical Decision Support

• **Pg. 4 Table 3: Privacy and Security Draft Criteria**
  Veterans Affairs VA - OEHRM TIO
  Recommend adding question about external/internal user authentication and user provisioning process and feasibility

• **Pg. 4 Table 4: Other Draft Criteria**
  Veterans Affairs VA - OEHRM TIO
  Recommend adding metrics for response time or system log in time to assess usability of EHR for providers and EHR efficiency. This metric would differ depending on the user role.

• **Pg. 2 Table 1: PDMPs**
  Veterans Affairs VA - OEHRM TIO
  Recommend change "connecting" to "exchanging" since it implies both reporting and querying functions.

• **Pg. 3 Table 1**
  Veterans Affairs VA - OEHRM TIO
  "Ease of use" could be affected by many human engineering factors such as screen structure, data display, data entry, screens navigation, system response time, … etc.) A
An application can be well designed from the human-factors engineering perspective but the system/application response time is lagging that causes "unease of use"!
Recommend be more specific to measure the targeted theme(s).

- **Pg. 6 Table 5: User characteristics**
- Veterans Affairs VA - OEHRM TIO
- Recommend adding Federal Facility (e.g., VA, DOD, IHS, etc.)

- **Overall**
  - Veterans Affairs OIT/OTI
  - There are over 70 questions which would take a over 15-20 minutes to answer. Not sure how 10 - 15 minutes was determined.

- **Overall**
  - Veterans Affairs OIT/OTI
  - It is unclear how the results of this survey will be used to inform policy.
August 10, 2020

Donald Rucker, MD
National Coordinator for Health Information Technology
US Department of Health and Human Services
Washington, DC  20201

Dear Dr. Rucker:

On behalf of the Healthcare Information and Management Systems Society (HIMSS), we are pleased to provide written comments on the Request for Public Feedback on Draft Voluntary User-Reported Criteria for the Electronic Health Record (EHR) Reporting Program. HIMSS appreciates the opportunity to leverage our members’ expertise in offering feedback on this program and describe our perspective on providing publicly available, comparative information on certified health IT products that will inform health IT users’ purchasing and implementation decisions.

HIMSS is a global advisor and thought leader supporting the transformation of the health ecosystem through information and technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research and analytics to advise global leaders, stakeholders and influencers on best practices in health information and technology. Through our innovation engine, HIMSS delivers key insights, education and engaging events to healthcare providers, governments and market suppliers, ensuring they have the right information at the point of decision. Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, the United Kingdom, the Middle East, and Asia Pacific. Our members include more than 80,000 individuals, 480 provider organizations and 650 health services organizations.

We are supportive of the work completed thus far on the EHR Reporting Program, and the effort of the Urban Institute and HealthTech Solutions to build this tool. The idea of providing free comparative information to help better inform potential EHR and certified health IT purchases as well as implementation decisions are worthwhile goals. How this program contributes to driving market improvements and filling information gaps are also important priorities.

However, before the criteria are finalized, HIMSS recommends that ONC share more details about how the survey will be distributed and what steps will be taken to validate that participants actually use the software product they are assessing, as well as how recently they have used it. ONC should also encourage respondents to put forward the employees that are best informed about all the roles of various health IT products in their organization, given that there are many systems that closely interact with certified products in an institutional setting, and the focus of this program is on reporting related only to certified health IT products.
HIMSS concurs that interoperability, usability, and privacy and security are essential criteria areas to include in this Reporting Program. We offer the following general observations:

- **Interoperability**: The questions are correct and cover the necessary angles for all participants.
- **Usability**: Includes specific questions related to patient safety as well as ease of use, and provides open-ended questions that allow respondents to incorporate more information or specific details if they are inclined. The patient safety question should focus on how well an EHR integrates into ensuring safety protocols and clinical processes for patient safety, rather than asking how an EHR improves patient safety.
- **Privacy and Security**: Include a question that focuses on the efficacy of privacy and security controls, to get more specific information beyond a user’s satisfaction with a particular EHR’s privacy and security controls.

In addition, we ask that the program include as much information as possible about all the available versions of a particular certified health IT product, rather than focus solely on the most recent version of a product. Potential purchasers of certified health IT would value more time trend information about a product as it evolves on the market rather than less, and the ability to see how users evaluated previous versions of a product would be helpful data points to consider when reviewing the totality of a vendor’s suite of certified products.

With these factors in mind, HIMSS offers the following thoughts on additional changes that we would like to see in the draft voluntary user-reported criteria to enhance the program:

### Ensure Program Alignment with ONC’s Terminology and Other Work Streams

HIMSS asks that ONC use the same terminology in the EHR Reporting Program that it uses in other programs and regulatory vehicles. For example, the draft criteria use the term “health information organization,” and [ONC’s Interoperability and Information Blocking Final Regulation](https://www.hhs.gov/health IT/regulations-and-guidance/index.html) focuses on the terms “health information exchange” and “health information network,” when describing the same kinds of entities. Using consistent terminology across all of ONC’s work would provide greater clarity and eliminate any confusion on behalf of the survey respondents or the users of the comparative information.

In addition, the draft criteria draw on information on specific certified health IT products from existing data sources, such as [ONC’s Certified Health IT Product List (CHPL)](https://chpl.hhs.gov/), as well as new data collection efforts from certified health IT users. We encourage ONC to fully integrate this program with CHPL, and endeavor to cross-reference information between both programs to enhance the value of information from each source and reinforce the data included.

Moreover, building on ONC’s broader efforts to minimize clinician regulatory and reporting burden, ONC should explore other data sources or previously-reported information that it could leverage to include in this program, rather than require new
information collection strictly for certified health IT product reporting. ONC should look to other data points that are collected from other government programs, such as the Centers for Medicare & Medicaid Services, Quality Payment Program, or other programs across the Department of Health and Human Services, which could be integrated into this work and would require less effort on the part of respondents, without losing any value to users.

Overall, we envision that respondents would only complete survey questions on the version of the product that they are currently using, and the Reporting Program will keep the historical information from prior responses in the survey data, as well as look at opportunities to leverage data from other government programs to minimize reporting burden.

Add Questions to the Program Questionnaire that Focus on the Functionalities of EHRs and Other Certified Products

As the role of EHRs and other certified products continue to be critical to any broader transformation efforts across the healthcare ecosystem, the Program should incorporate questions that allow end users to provide feedback on how they are using these products to functionally support the most pressing issues facing our healthcare system as it seeks to transform. As ONC has included questions in the draft criteria that focus on interoperability, usability, as well as privacy and security, we ask ONC to also integrate questions focused on additional functionalities, such as how EHRs and other certified products help enable value-based care, address social determinants of health (SDOH), facilitate patient engagement, incorporate patient-generated health data (PGHD), and undertake precision medicine. We are cognizant of making the user questionnaire too lengthy, but believe that brief questions on these additional topics will help inform the purchasing and implementation decisions of certified health IT users.

When discussing these functionalities, it is also important to emphasize that HIMSS is focused on the ecosystem of health IT products and the role certification and a Reporting Program can play in addressing these topics as well as further advance interoperability across the healthcare ecosystem. In many settings, an EHR will be very specific in scope, but other settings, distinct certified products and/or unique product modules will interact with an EHR to perform these functions. The EHR is just one—albeit a critical—component of the broader health interoperability ecosystem that influences the design, development, and interactions of other health IT products and also impacts the curation, collection, and transmission of health data.

For example, how a practitioner or organization utilizes an EHR or other certified product in the push toward value-based care would be a significant piece of any user’s health transformation efforts. As the magnitude of SDOH data continues to increase in addressing health system inequities, including a question on that topic would be of interest to many purchasers. How an EHR or certified product helps facilitate greater patient engagement is also important information for a potential purchaser to have available. In addition, how PGHD can be incorporated into certified products and added to clinicians’ workflow are also data points that would be of interest. Moreover, as precision medicine and integration of a patient’s genetic information becomes
more prominent, the idea of including that information in the questionnaire should be considered.

We advocate for insertion of the following questions to ensure that these topics are addressed in the user-reported criteria:

- How would you rate the overall ability of [autofill primary product name based on Q1] to support your shift to value-based care delivery or outcomes-based care?
  - a. Very satisfied
  - b. Satisfied
  - c. Neither satisfied nor dissatisfied
  - d. Dissatisfied
  - e. Very dissatisfied

- How would you rate the overall ability of [autofill primary product name based on Q1] to support you in collecting, integrating, and using social determinants of health data?
  - a. Very satisfied
  - b. Satisfied
  - c. Neither satisfied nor dissatisfied
  - d. Dissatisfied
  - e. Very dissatisfied

- How would you rate the overall ability of [autofill primary product name based on Q1] to support your work to facilitate broader patient engagement?
  - a. Very satisfied
  - b. Satisfied
  - c. Neither satisfied nor dissatisfied
  - d. Dissatisfied
  - e. Very dissatisfied

- How would you rate the overall ability of [autofill primary product name based on Q1] to support the incorporation of patient-generated health data and patient-reported outcomes?
  - a. Very satisfied
  - b. Satisfied
  - c. Neither satisfied nor dissatisfied
  - d. Dissatisfied
  - e. Very dissatisfied

- How would you rate the overall ability of [autofill primary product name based on Q1] to leverage precision medicine and a patient’s genetic information?
  - a. Very satisfied
  - b. Satisfied
  - c. Neither satisfied nor dissatisfied
  - d. Dissatisfied
  - e. Very dissatisfied
We recommend that each of these questions include the opportunity for respondents to provide more detailed information about how they are using their EHR or other certified product to address these topics:

- Please share any comments related to your rating of the overall ability of [autofill primary product name based on Q1] to perform value-based care/address social determinants of health data/etc., that you are willing to make publicly available.

[add box to collect optional free text/unstructured responses that can also be left blank]

Overall, the inclusion of these questions will make the information reported through this program more valuable and better position providers to transform healthcare.

**Highlight Other Publicly Available Resources Across the Market to Better Inform Potential Purchasers or Implementers**

HIMSS emphasizes the importance of highlighting other certified product comparison tools or data sources that could be used to complement or amplify the information available through this program. ONC should investigate other private sector efforts that could be leveraged to eliminate some of the challenges that purchasers or implementers face when reviewing new products. ONC has an opportunity to provide the resources of this program to support the market, but can also point to other tools that will help add additional perspectives or feedback that users have to share on products to ensure that potential purchasers or implementers are better informed before investing in a certified product.

For example, we collect data that could also contribute valuable information to this reporting effort. In 2006, HIMSS released the Electronic Medical Record Adoption Model (EMRAM) to incorporate methodology and algorithms to automatically score healthcare providers around the world relative to their electronic medical record (EMR) capabilities. Our eight-stage (0-7) model measures the adoption and utilization of EMR functions. As organizations move closer to achieving a near paperless environment that harnesses technology to support optimized patient care, they move to higher stages. HIMSS has many resources and data that may be helpful to complement this Reporting Program. Moreover, other organizations also have compelling information that could be valuable to health IT acquisition decision makers.

Overall, HIMSS supports the approach that ONC is taking to implement this program and equip potential purchasers and implementers with more information about their options from across the market. We do ask that before the criteria are finalized, more details are shared about how the survey will be distributed and what steps will be taken to encourage participants that use the software products they are assessing to complete the survey tool. We also recommend broader alignment across ONC’s terminology and work streams. In addition, HIMSS would like to add questions to the survey that focus on the functionalities of EHRs and other certified products, as this information will be front-of-mind for many users. Finally, we ask ONC to highlight other
publicly available resources to supplement the information that is available through this program.

We look forward to the opportunity to discuss these issues in more depth. Please feel free to contact Jeff Coughlin, HIMSS Senior Director of Government Relations, at jcoughlin@himss.org, with questions or for more information.

Thank you for your consideration.

Sincerely,

[signature]

Harold F. Wolf III, FHIMSS
President & CEO
As a member of [health care organization]. I support my access to my health records. I appreciate their ability to help me stay on track with my medication, tests, doctor’s messages.

Yet, I want them to be even better. I come to you as a patient and my experiences with my medical records.

I’ve asked a provider to change a record that I viewed as inaccurate, after six months of asking for this change, or adding my comments to my health record, [health care organization] Administration never allow any access or modify my medical record. I saw another provider in the clinic, and I clearly understood that the individual was treating me different due to the records complaint of his co-worker. Right to request a modification or addition did not exist for me in [health care organization].

I’ve contacted [health care organization] data processing several times about the lack of indexing and searching of my medical records. In the latest patient portal, the newly changed software has used this practice to buried information. It has and is more difficult to access my medical records. I need to search thru page after page to find the information of a past visit. There is limited indexing or searching ability. They have combined and crossed over the privacy line for patient by putting in administrative notices with my messages to my provider, making my manual record search even longer with the additional insurance notices that was added in the most recent software upgrade. I’m concerned about my complaints to administrative are seen by the medical staff and hurts my care.

Not all the clinic staff use the notes and share this information with their patient. When I go into the download of my medical records. What I find in my medical records is again a bloat practice of repeating of lab records and no notes. The exclusive medical records by the provider is alive and well, and not available to the patient.. It all depends on the provider that believes that the patient should have access to their medical records. I recently was prescribed nightly oxygen, and asked to talk with the provided that approved it, all I received was a short note that she agreed. I needed to ask for the test reports that was the basis for starting nightly oxygen.

An Endocrinologist fired me as a patient over accessing patient records, due to his nurse being upset over my requesting help with my medical records on the patient portal. Staff in [health care organization] are often not trained on the patient’s portal. In returning to the primary clinic, due to my requesting information, I was again asked to leave the practice of the provider because I would take too much time. This is a clinic that communication only goes one way, and the patient is not allowed to questions. I know that my [health care organization] clinic is busy, but good notes, access to my tests and the patient portal saves them time. I use the patient portal for many of my questions.

Please ensure the development of accessible medical records for the consumer.
The current pandemic creates unique demands for prompt, accurate data to support:
- Alerting and providing sound medical advice to clinic patients most at risk.
- Identifying patients who are unable to carry out preventative guidelines because of poverty or other social factors.
- Reporting test results to public health authorities.
- Identifying community hot spots for targeted testing and other interventions.
- Reporting on treatment outcomes.

It is likely that we will face other such scenarios in the future. Let’s learn from the current situation and apply lessons learned to this effort.
Individual Commenter C - EHR Reporting Program Draft Voluntary User-Reported
Public Comments

Response to: Request for Public Feedback on Draft Voluntary User-Reported Criteria for the
Electronic Health Record Reporting Program

Overall Concerns and Comments
1. How long will it take to complete the “voluntary questionnaire”? Suspect >20 min if
include comments. Suggest 2-tiered approach: 5 min questionnaire (including #6, 7, and
8 only) and then a question—“would you be willing to spend 15 min more on detailed
responses?”
2. Ask if vendor contract forbids criticism or public complaints about the product.
Responder may need to exit survey if prohibited from public complaints. Obviously, if
such a clause is present in a contract, results and response about this vendor will be
skewed.
3. Ask if responder has worked with more than 1 EHR in last 5 years. If so......name of
previous EHR(s), and 5-point scale comparison (much better than, somewhat better than,
about the same, somewhat worse than, a lot worse than) of current vs. previous EHR use.

Additional Questions:
1. How long in total for physician documentation of a 15 minute OV including data entry,
diagnosis, prescribing, answering alerts, etc (do not include time spent by other office
personnel, such as for printing, making appointments, etc)? How long to document a 30
min OV?
2. Does the EHR allow for correction of errors, and a way to prevent autopropagation of
incorrect historical information? Does the EHR allow for patient annotations appended
to the physician’s record?
3. Please rate your satisfaction with the user interface for reviewing information—such as
previous notes in this EHR, new laboratory/imaging/consultation notes, and older historic
information
4. How easily does the EHR allow external digital data (e.g., LOINC-coded laboratory
information, patient information such as allergies/ICD 10 problem lists and diagnoses) to
be imported into a note? Into the permanent record? If imported, is the imported data
“metatagged” with its source and date in a visible way?
5. In the last 1 year, have vendor upgrades reduced your administrative burden in
completing records? (a lot, somewhat, no change, made it somewhat worse, made it a lot
worse)

Answers to questions posed by Urban Institute

We welcome any public feedback and ask that reviewers consider the following:

- Which draft criteria would you prioritize for inclusion in the EHR Reporting Program,
and why? Q 6, 7, and 8; relate most strongly to user experience
• Which draft criteria should be rephrased, reworded, or removed? 8.2 – default values. Not clear if the ask is whether the user is happy with the default values, OR, how easy it is to change from default to customized values

• Should the voluntary user-reported criteria cover only the most recent version of a certified health IT product or all versions of the product? Most recent and 1 prior version (some vendors require additional payment for new versions, and new version roll-out for server-based installations may take some time to occur)

• What certified health IT users are most likely able to report on the criteria (e.g., clinicians, administrators, IT specialists)? Usability criteria should focus on the end-user: the clinician. Administrators, IT staff, etc, all support the clinician’s effort but are not primary to the effort

• What could motivate end users to voluntarily report on certified health IT products? Provide a gift card after completion of the survey to pay for their time spent. Otherwise, it is “yet another” salary reduction (that is, the clinician must do more data entry work that others used to do, but is not paid for the extra time spent doing so).
August 10, 2020

Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW
Floor 7
Washington, DC 20201

[Re: Request for Public Feedback on Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program; submitted electronically to EHRfeedback@urban.org]

Dear Dr. Rucker:

The Joint Commission appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology (ONC) Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program.

Founded in 1951, The Joint Commission seeks to continuously improve health care for the public in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value. An independent, not-for-profit organization, The Joint Commission accredits and/or certifies more than 22,000 health care organizations and programs in the United States. The Joint Commission evaluates health care organizations across the continuum of care, including most of the nation’s hospitals. In addition, Joint Commission programs encompass clinical laboratories, ambulatory care and office-based surgery facilities, behavioral health care, home care, hospice, and long-term care organizations. Joint Commission accreditation and certification are recognized nationwide as symbols of quality that reflect an organization’s commitment to meeting state-of-the-art performance standards. Although accreditation is voluntary, a variety of federal and state government regulatory bodies, including the Centers for Medicare and Medicaid Services, recognize and rely upon The Joint Commission’s decisions and findings for Medicare or licensure purposes.

**General Feedback**

The Joint Commission offers the following feedback in response to questions posed in the request for feedback.

*Should the voluntary user-reported criteria cover only the most recent version of a certified health IT product or all versions of the product?*

Users should be allowed to provide information about the version of a health IT product that they are using. Health IT upgrades and conversions occur over time, and all organizations should not be expected to use the same version of a given health IT product.
Request for Public Feedback on Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program

What could motivate end users to voluntarily report on certified health IT products?

The Joint Commission recommends that ONC market the survey in light of the need to coordinate care between different health entities and to ensure the usability of the EHR in an era when there is a need to quickly evolve health care strategies to maintain safe, effective, and quality care.

User Questionnaire

The Joint Commission offers the following comments on the user questionnaire for collecting information for draft voluntary user-reported criteria.

Question 2: What type of health IT user best describes you?

The Joint Commission recommends that ONC add a selection for “Practicing nurse” to the answer selections for this question. There are many types of clinicians that fall into the category of “practicing other clinician,” and nurses comprise the largest component of the health care workforce. The survey evaluation would benefit if the answers could be statistically analyzed with the ability to split nurse answers out separately.

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

The Joint Commission recommends modifying the wording of 5.1 by adding the word “my”:

- 5.1 Electronically exchanging health information with clinicians who have a different EHR/health IT product than the one used by my organization

The Joint Commission recommends modifying the wording of 5.2 and 5.3 by adding “or hospitals” to both tasks:

- 5.2 Electronically exchanging health information with clinicians or hospitals outside my organization
- 5.3 Electronically exchanging health information with clinicians or hospitals inside my organization

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

The Joint Commission recommends adding the following functionality:

- Lab results receipt and review (e.g., blood or urine lab tests)

Question 14: What pricing model(s) does your [autofill primary product name based on Q1] operate on? Select all that apply.
The Joint Commission recommends adding an option for “Don’t know.” The individual completing the survey may be unaware of the pricing model for the software purchased by his or her organization.

**Question 18:** In what setting do you primarily use [autofill primary product name based on Q1]? Select all that apply.

The Joint Commission recommends modifying “Mental health center” to “Mental health or addiction treatment center.” The Joint Commission also recommends adding selections for the following settings: “Orthopedic or other rehabilitation center,” “Birthing center,” “Dentist office,” “Dialysis center,” “Hospice,” “Nursing care center,” and “Telehealth.” The Joint Commission notes that “Dental” is included in the Question 20 types of services provided. While the survey contains an “other” category, fill-in-the-blank survey questions are difficult to use for statistical analysis because of differences in wording and spelling. These additions will reduce human error and ensure the best statistical analysis can occur.

**Question 20:** What best describes the types of services provided at the practice in which you use [autofill primary product name based on Q1]? Select all that apply.

The Joint Commission recommends adding “Oncology” to the answer selections. While the current question selections include an “other” category, The Joint Commission again recommends adding answer options to minimize the use of fill-in-the-blank survey question answers, which are difficult to use for statistical analysis because of differences in wording and spelling. Based upon the settings added to Question 18, The Joint Commission recommends adding appropriate types of services to Question 20.

**Question 22:** How would you describe the location of the practice in which you use [autofill primary product name based on Q1]?

The Joint Commission recommends adding “Metropolitan” as an answer selection.

**Recommended Additional General Question on User Characteristics**

The Joint Commission recommends that ONC add the following question concerning the survey responder’s role with the EHR product:

What is your role with the EHR at the practice in which you use [autofill primary product name based on Q1]? Select all that apply.

- a. User
- b. Administrator
- c. Informaticist (i.e., clinical or IT)
- d. Subject Matter Expert
- e. Implementor
- f. C-Suite (e.g., CMO, CNO, CIO)
Request for Public Feedback on Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program

The Joint Commission is pleased to answer any questions you may have regarding our comments. If you have any questions, please do not hesitate to contact me or my staff: Rachel Fleischer at 202-783-6655 or rfleischer@jointcommission.org.

Sincerely,

Kathryn E. Spates, JD
Executive Director, Federal Relations
August 4, 2020

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

Dear Dr. Rucker,

On behalf of Medical Information Technology, Inc. (MEDITECH), I am pleased to offer comments on the Electronic Health Record Reporting Program - Request for Public Feedback on Draft Voluntary User-Reported Criteria. Before we provide feedback on the specific questions, we would like to strongly echo the EHRA’s comment with some overall recommendations for the program.

Center the Survey Around the User
As drafted, this survey is generalized for any respondent in the healthcare system. This creates a mismatch between what various users can successfully give feedback on, based on the mental models of their toolbox, and their ability to answer the entire questionnaire confidently.

We recommend the survey first establish the role of the answering participant, and then tune specific questions to them. This will ensure that participants answer questions as accurately as possible, and likely increase the number of participants who complete the questionnaire.

For example:

<table>
<thead>
<tr>
<th>Section</th>
<th>End-User</th>
<th>IT Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Interoperability</td>
<td>△</td>
<td>✓</td>
</tr>
<tr>
<td>Usability</td>
<td>✓</td>
<td>△</td>
</tr>
<tr>
<td>Implementation</td>
<td>●</td>
<td>✓</td>
</tr>
<tr>
<td>Support</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Upgrades</td>
<td>●</td>
<td>✓</td>
</tr>
<tr>
<td>Security</td>
<td>●</td>
<td>✓</td>
</tr>
<tr>
<td>Cost</td>
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<td>✓</td>
</tr>
<tr>
<td>Contracts</td>
<td>●</td>
<td>✓</td>
</tr>
<tr>
<td>General</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

*Questions for IT staff could be further stratified depending on their role in the institution*
**Allow More Depth**

Interoperability and usability are complex topics with significant room for different interpretations, yet the language in this survey is neither specific nor colloquial enough to limit misinterpretation by some participants. As long as the language remains as-is, data gathered in these critical areas will be challenging to interpret.

In addition to improving the language used for each question in these areas, particularly the usability topic, shifting from a 'one-size-fits-all' approach to a more tailored approach may enhance the data gathered. For example, questions draw inconsistently on inpatient and outpatient examples, sometimes within the same question. Providing specific examples based on the user’s primary setting will produce more accurate feedback.

Several areas list multiple questions that are followed by a single free-text field. Such an approach can be limiting. Instead, it would be useful to allow commentary on each element to allow for more nuanced analysis.

**Concerns Around Methodology**

There is a concern at the lack of detail about how this survey will be distributed, who will receive it, and what methods will be used to ‘normalize’ the dataset. Providing meaningful feedback without answers to these questions is difficult.

We specifically request clarity on what steps will be taken to validate that participants actually use the software they are assessing and how recently they have used it. A related issue is verifying that the respondent knows which health IT product does what at their organization. This could be done by presenting some of the common workflows that the product addresses and allowing the user to select what they specifically use the product for. Ironing out those wrinkles will be very helpful before this draft is finalized, and we would like the opportunity to comment on any updates.

Another area of interest is understanding the ‘floor’ for the sample size: what will constitute enough data to be shown? Is one poor rating the equivalent of 600 positive ratings? Transparency with the data is useful, but providing a sense of scale is also helpful. Our recommendation is to establish a clear set of expectations around acceptable deviation from the norm, minimum n for inclusion, and clarity around the period and frequency of survey responses.

**URBAN Institute’s posed questions:**

*Which draft criteria would you prioritize for inclusion in the EHR Reporting Program, and why?*

We would recommend that Table 5. *Product and User Characteristics* be at the top of the survey. As stated above, if this criterion is first, then the survey could compile the correct grouping of questions, which would relate to how the participant interacts with the software. Also, at the top, there should be a section describing the software being rated. This would allow the participant evidence they are reviewing the correct product. The software statement would also provide the survey taker an understanding of what the software product is designed to do.

For each criterion, we recommend there be an “overall satisfaction” question at the top of each section. Then the remainder of the criterion questions can be asked, which will allow the participant to go into additional detail.
Which draft criteria should be rephrased, reworded, or removed?
We recommend that the criteria surveyed be based on certification requirements. As EHR Reporting is part of Conditions of Certification, all the questions and criteria should also be built on certification criteria. We recommend the following be removed as they are not part of Certification.
- Pricing Model
- Cost
- Implementation process
- Maintenance and upgrades
- Support for standard use
- Contractual information

- Table 4. Other Draft Criteria (criteria that are listed above)
  - If these criteria are not removed, we recommend that they are directed to someone in the healthcare organization who deals with day-to-day operations. This should not go out to end-users. Please see the chart above.
  - Again, if these questions are not removed, we recommend asking targeted questions regarding cost and pricing model. They should not be about how much the actual software costs. Examples are:
    - Are there fees associated with patient access to data? Are they appropriate or reasonable?
    - What are the costs of using APIs within the software?

- Criteria 13. Overall satisfaction rating for security and privacy features
  - We recommend a Y/N answer to this question to keep this section simple.

Should the voluntary user-reported criteria cover only the most recent version of a certified health IT product or all versions of the product?
We recommend that the user-reported criteria should only cover the most recent version of the EHR. Only the software that an EHR vendor is currently selling should be surveyable.

What certified health IT users are most likely able to report on the criteria (e.g., clinicians, administrators, IT specialists)?
As the questions are very diverse, our recommendation is to provide specific questions to the appropriate people. Please see the Center the Survey Around the User section above.

What could motivate end users to voluntarily report on certified health IT products?
We recommend that the survey be as minimally invasive as possible.

Additional comments and clarity needed:
- We request clarity on if these surveys are filled out anonymously. We, as an EHR vendor, would like to have the ability to reconcile with the people filling out the surveys. This would assist our customers with a better experience with our software if we are able to address the concerns they reference in the surveys. Perhaps before submitting the survey the user is asked whether the vendor was contacted in regards to the issue/concern/question.
• We recommend that only questions that are not currently addressed by looking at the CHPL be added and asked via the survey.

Thank you for your time and consideration. We look forward to your responses in the final rule.
The Medical Group Management Association (MGMA) is pleased to submit the following comments on the Urban Institute’s draft survey supporting the Office of the National Coordinator for Health Information Technology (ONC) Electronic Health Record (EHR) Reporting Program, required under the 2016 Cures Act. While the survey contains a number of very helpful questions, in this comment letter we suggest a number of modifications to existing questions and offer recommendations on additional issues that should be included in the survey that we believe will improve the Reporting Program.

MGMA is the premier association for professionals who lead medical practices. Since 1926, through data, people, insights, and advocacy, MGMA empowers medical group practices to innovate and create meaningful change in healthcare. With a membership of more than 58,000 medical practice administrators, executives, and leaders, MGMA represents more than 12,500 organizations of all sizes, types, structures, and specialties that deliver almost half of the healthcare in the United States.

An increasing number of physician practices are acquiring certified health IT. The development of effective tools that assist in identifying the most appropriate products that best meets a practice’s clinical and administrative needs will simplify this complex purchasing decision. Making the best decision for the practice will also lessen the chance that the practice will be forced to undergo a costly and burdensome “rip and replace” process should their current product not meet the needs of the organization.

EHRs have transformed the medical profession, providing better data to guide care, supporting enhanced patient safety through new automated tools, and creating more efficient processes by connecting different health systems. At the same time, variations in EHR design, customization, and use can also lead to inefficiencies or workflow challenges and can fail to prevent—or even contribute to—patient harm.

Safety hazards can be associated with EHR usability, based on the design and use of the technology and how clinicians interact with it. Usability challenges can frustrate clinicians because they make simple tasks take longer, lead to workarounds, or even contribute to patient safety concerns. These challenges can stem not only from the EHR design, but also from how the technology is implemented and operated in health care facilities; how clinicians are trained to use it; and how the EHR is maintained, updated, and customized. Each stage of EHR development and use—the software life cycle from development through implementation and use in a health care environment—can affect the usability and safety of the technology.

For practices, choosing the right EHR typically requires a certain level of technical expertise, an understanding of the functionalities necessary for quality improvement and value-based payment, and familiarity with legal and regulatory compliance requirements at both the state and federal levels. There are, however, few tools that currently provide practices comparative information on certified health IT. If implemented effectively, a resource that offers practices the ability to compare and contrast EHRs on the basis of usability, interoperability, patient safety, security, cost and other criteria would not only be helpful to the practice as they shop between
vendors, but could also incentivize software developers to compete for market share on these newly-measurable factors.

Summary of Key Recommendations

- MGMA strongly supports the ONC EHR Reporting Program and believes the public dissemination of practice and EHR vendor survey results will assist medical practices make more informed purchasing decisions.

- Accurate capture of the costs associated with EHR implementation and ongoing maintenance must be included in the survey. We also recommend augmenting the current questions to include costs related to version upgrades, interoperability connections, deployment of online patient portals, and support of APIs.

- The survey should be expanded to include additional questions related to patient safety and HIPAA Privacy and Security requirements. The safety of patients, related to the deployment and use of EHRs, has been a persistent problem for many years. Similarly, protecting the privacy and security of patient information is a top priority for medical practices. The Reporting Program should comprehensively account for the ability of the software to identify and address patient safety and privacy and security issues.

General Comments on the Draft Survey

- MGMA is very supportive of the EHR Reporting Program. It has the potential of providing important information to practices on the performance of EHR software that will assist them during their purchasing phase. However, the Cures Act requiring this program was passed nearly four years ago and we encourage the Institute and ONC to expedite development and deployment of this survey instrument and public release of the results.

- Throughout the survey, the term “Please share any comments related to your rating of overall satisfaction with implementation that you are willing to make publicly available” is used. The survey language should make it clear to respondents that the comment will be public, but NOT be attributed to the individual or their organization. We are very concerned that if the respondent and their practice were publicly named, this would serve as a significant deterrent to survey participation. While it is appropriate for ONC to know the identity of the respondent to verify authenticity, the individual and their organization completing the survey should not be publicly released.

- The introduction to the survey states: “We expect that this survey will take approximately 10 to 15 minutes to complete.” With the number of questions and sub-questions, the complexity of many of these questions, and the fact that multiple individuals within the organization may be required to answer the questions, we believe this is not an accurate estimation of the time required to complete the questionnaire. Once the final version of the instrument is complete, we recommend testing the survey with multiple end-users and recording the time required to complete the questionnaire prior to including a time estimate in the survey introduction.
• One persistent issue reported by our members has been the cost their organization incurs moving from one version of their EHR software to an upgraded version. This is particularly important when the new version is introduced to support a federal mandate (i.e., an updated diagnostic code set). We would recommend including a question asking respondents their level of satisfaction related to how efficiently a vendor moves from one version of their software to another and any charges associated with that upgrade.

• Practices are increasingly adopting online patient portals as an effective method of communicating with their patients and securely sharing health information. We would recommend incorporating a question into the survey that seeks feedback on the respondent’s level of satisfaction with their online patient portal, implementation costs, and ongoing maintenance fees.

• While ONC has focused its attention of the clinical use of HIT, it is important to recognize that practices leverage practice management system software for patient scheduling, billing, insurance eligibility verification, and many other administrative tasks. Optimally, the EHR and practice management systems will be integrated to provide the practice with a seamless workflow that can extract and utilize clinical data for administrative purposes. However, in many instances, the two do not integrate effectively (or inexpensively), causing significant challenges for practices. We urge ONC to consider incorporating into the survey questions that focus on the respondent’s satisfaction level of this integration, and costs associated with it.

• The Cures Act requires the ONC Health IT Certification Program support the privacy and security of electronic health information by establishing a detailed set of requirements that health IT developers must meet for their products to be certified as meeting the privacy and security criteria. The lack of a focus on these issues in the survey is concerning and we would encourage ONC and the Institute to include additional questions on these issues.

• Practices in 2022 will be expected to support application programming interface (API) standards and we anticipate that some will begin to leverage APIs in 2021. APIs will impact practice workflow as well as the privacy and security of patient information. We would encourage ONC and the Institute to include questions focused on the level of API support by the EHR software vendor, the costs incurred by the practice to offer this capability, and the associated privacy and security features.

MGMA Response to the Specific Draft Survey Questions

Comment on question 2

What type of health IT user best describes you? Choose all that apply. a. Practicing physician b. Practicing other clinician c. Pharmacist d. Health IT or administrative clinician e. Health IT staff (nonclinician) f. Other nonhealth IT administrator (nonclinician) g. Other [please specify]

MGMA response

Due to the complexity of the survey and the fact that the questions focus on both administrative and clinical issues, we anticipate that the practice may be required to identify multiple staff
members to complete the questionnaire. The potential of multiple respondents should be reflected in question 2. We note as well that question 2 should be harmonized with question 24 on the respondent’s level of software expertise. We also recommend that an additional category of respondent be included to reflect those non-clinicians (i.e., “g. non-clinician administrative staff”) who may be answering some or all of the survey questions.

**Comment on question 5.9/5.10**

*Producing all the reports that are required for my organization’s specialty*

5.10 *Attesting to the Promoting Interoperability Program and the Merit-Based Incentive Payment System (MIPS)*

**MGMA response**

We would recommend the Institute revise these questions as their current wording is misleading and inaccurate. Typically, those medical specialty societies that offer data registries do so on a voluntary basis. Therefore, the question should be worded: *Producing and submitting reports for medical specialty and other private sector data registries.* For question 5.10, as Promoting Interoperability is currently one of the four components of MIPS and practices may have clinicians participating in multiple reporting programs we recommend the wording of the question be revised to be: *Attesting to the Medicaid Promoting Interoperability Program and/or the requirements of the CMS Quality Payment Program, including the Promoting Interoperability component of the Merit-Based Incentive Payment System (MIPS).*

**Comment on Question 7.**

*How would you rate your satisfaction with the following aspects of [autofill primary product name based on Q1]? a. Very satisfied b. Satisfied c. Neither satisfied nor dissatisfied d. Dissatisfied e. Very dissatisfied f. Don’t know or not applicable*

The extent to which the certified health IT product 7.1 allows users to be more productive 7.2 has an intuitive workflow 7.3 easily accesses and assimilates data from other products 7.4 produces clinical benefits for the practice 7.5 decreases the time users spend documenting patient care 7.6 enables clinicians to deliver high-quality care 7.7 improves patient safety 7.8 does not disrupt clinician interaction with patients 7.9 easily produces understandable clinical summaries 7.10 provides system alerts that help prevent care delivery errors 7.11 has advantages that outweigh its disadvantages overall 7.12 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]

**MGMA response**

We appreciate the Institute’s inclusion of several usability factors in Question 7. The public release of these responses will drive purchasing decisions and may force software developers to improve their products. At the same time, we believe the surveying of patient safety is critical and warrants a separate question apart from usability issues.

We urge the Institute to include a stricter focus on the intersection of usability and safety to provide health information technology vendors more specific feedback for the improvement of their EHRs. 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. The survey should
include the following criteria for responses:

- Enables simple and intuitive entry of patient information;
- Provides uncluttered pick lists for placing medication orders; and
- Provides intuitive visual displays that enhance safety.

The Institute should also consider distinguishing between low- and high-risk functions. For low-risk functions, for example, focusing on their ease of use would help provide information to reduce clinician burden. We recommend the Institute update the survey 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 this question: “How likely is it for this functionality to risk patient harm?” Examples of high-risk functions for this category include:

- Default values for common orders;
- Evidenced based order sets and charting templates;
- E-prescribing of controlled substances;
- Data entry; and
- Patient reminders/alerts.

Finally, the survey should include an additional open-ended question to seek more in-depth information on 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?”

**Comment on question 10**

*Indicate whether each of the following types of ongoing product support are available for [autofill primary product name based on Q1]. Do not consider support for implementation. Response Options a. Available at no additional cost b. Available for additional cost c. Not available d. Don't know*

10.1 24/7 help desk support 10.2 Dedicated client support (e.g., same staff for every contact) 10.3 In-person support 10.4 Online user guides and/or video tutorials 10.5 Live and/or recorded webinars

**MGMA response**

Practice contracts with software developers often includes product support activities such as help desk access, client support, in-person support, online user guides, and webinars. Our members report, however, that in some contracts these support activities are only available for a limited time, with ongoing access to these activities requiring additional payment. This issue might be more effective broken into two questions—the first asking about the services available in the initial contract and the second focused on services available after any contractual obligations have ceased. If the survey continues with just one question, we recommend that it be revised to reflect the availability of these services and their associated costs after any contractual support for these services has ended.

**Comment on 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.)?  a. Very satisfied  b. Satisfied  c. Neither satisfied nor dissatisfied  d. Dissatisfied  e. Very dissatisfied  f. Don’t know or not applicable

MGMA response

We are concerned that this broad question is the only one focused on the privacy and security features of the EHR software and the capabilities are all lumped together in one question. Further, the examples provided in the question may be confusing. Stating simply “42 CFR Part 2” does not explain to the respondent what aspect of substance abuse records the question is seeking a response. Listing “HIPAA” as an “example” is similarly confusing as “HIPAA” relates to hundreds of compliance requirements—many not related to EHR software.

We contend that it will be important to differentiate between important privacy and security features. The question should be list of critical privacy and security features, whether the vendor supports these features, and the respondent’s level of satisfaction. Features to be considered include:

- Multifactor authentication,
- Role-based access control
- Supporting password and lock out security with password recovery tools
- Supporting user logged off from software after a user defined period of inactivity
- Providing documentation that vendor has a recognized Privacy and Security certification(s) (i.e. EHNAC, HITRUST, SAAS, SOC)
- Having and applying appropriate protocols for workforce members who violate policies and procedures
- Ability to record and examine access and other user activity in information systems that contain or use e-PHI
- Ability to support client use of encryption (i.e., encrypted database features mobile technology)
- Ability to offer the client audit trails and reports configuration
- Ability to permit the client to segment a patient’s record to ensure compliance with the self-pay privacy provision

Comment on question 15/16

What was the approximate total cost of implementing [autofill primary product name based on Q1]? Please consider all costs paid to the vendor for implementation, implementation training, travel for an on-site training, etc. Do not consider costs beyond those paid to the vendor (e.g., purchasing computers and tablets, staff hours, workflow redesign). Please provide your best estimate. a. $0–$4,999  b. $5,000–$9,999  c. $10,000–$24,999  d. $25,000–$49,999  e. $50,000–$74,999  f. $75,000–$99,999  g. $100,000–$499,999  h. $500,000–$999,999  i. $1,000,000+  j. Don’t know

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

16. What is the approximate annual cost to maintain your product,[autofill primary product name], for all users in your organization? Please consider all costs paid to the vendor, including for customization, features and functionalities, and reporting. Do not consider costs beyond those paid to the vendor (e.g., purchasing computers and tablets, staff hours, workflow redesign). Please provide your best estimate. a. $0–$999  b. $1,000–$2,499  c. $2,500–$4,999  d. $5,000–$7,499  e. $7,500–$9,999  f. $10,000–$14,999  g. $15,000–$19,999  h. $20,000–$24,999  i. $25,000–$49,999  j. $50,000–$74,999  k. $75,000–$99,999  l. $100,000+  m. Don’t know
16.1 Please share any comments related to your response for annual cost that you are willing to make publicly available. [add box to collect optional free text/unstructured responses that can also be left blank]

MGMA response

We appreciate the Institute including questions on cost as these results will offer information critical to the practice purchasing decision. We support asking respondents to report all implementation-related and ongoing maintenance costs. However, the information collected on the survey must be consistent and usable to the end user. As such, we urge that the existing survey question be revised to reflect the incurred by the practice per full-time equivalent (FTE) physicians. The current wording would capture total cost by practice with larger organizations naturally reporting higher costs. Capturing costs per FTE will facilitate a more accurate reporting of software implementation costs. Note that ALL questions in the survey asking about time and cost should reflect per FTE estimations.

We also recommend asking a question comparing the final implementation and maintenance costs related to the actual costs. This could be very illuminating in terms of the business practices employed by the software vendor and would aid the purchasing decision. We would recommend the following: “Regarding software implementation costs, describe your final costs compared to the vendor-supplied estimate (Much lower, lower, same, higher, much higher)” and “Regarding ongoing software maintenance costs, describe your final costs compared to the vendor-supplied estimate (Much lower, lower, same, higher, much higher).”

We also urge the Institute to include a question related to any interoperability “connection” fees incurred by the practice. A consistent barrier to interoperability has been the fees charged to practices for connections to hospitals, health information exchange entities, and other fees imposed on them by vendors. Transparency of fees charged by software vendors for these connections will be an important feature of the Reporting Program.

Finally, we recommend including a question on whether the EHR software has real-time benefit transaction (RTBT) capability and, if so, what are the associated costs. RTBT software embedded in the EHR permits the clinician to automatically check benefits information, quickly process prior authorizations, establish patient out-of-pocket costs, and identify therapeutic alternatives at the point of care to drive down administrative costs and improve patient care. While vendors such as Surescripts offer this functionality to EHR vendors at no cost, many EHR vendors charge practices for this capability.

Comment on question 19

About how many clinicians work in the practice or organization where you use [autofill primary product name based on Q1]? Include all locations in your organization or health system.  a.  1  b. 2–3  c. 4–10  d. 11–50  e. 51–100  f. More than 100

MGMA response

MGMA has been conducting surveys of medical practices for many years. We recommend the following FTE clinician count for this survey:

- 4 or Fewer
- 5 to 10
- 11 to 25
- 26 to 50
Comment on question 20

What best describes the types of services provided at the practice in which you use [autofill primary product name based on Q1]? Select all that apply. a. Primary care, pediatrics b. Primary care, other (e.g., family medicine, internal medicine) c. Behavioral health d. Long-term or postacute care e. Obstetrics and gynecology f. Dental g. Ambulatory surgery h. Other [please specify]

MGMA response

It is unclear why the survey offers such a short list of potential services/specialties. We recommend having a drop-down menu that includes a complete list of services and medical specialties.

Comment on question 23

Approximately what percentage of patients at the practice in which you use [autofill primary product name based on Q1] are uninsured or covered by Medicaid? a. Less than 5% b. 5% to less than 25% c. 25% to less than 50% d. 50% to less than 75% e. More than 75%

MGMA response

It is not clear why this question on the percentage of uninsured/Medicaid patients is included in the survey. Nor is it clear why uninsured patients would be included with Medicaid patients. We would recommend removing this question. If it is deemed imperative to identify the patient base by insurance product, the question should be revised to include patients with commercial insurance coverage, Medicare patients, and self-pay patients (with insurance), along with uninsured and Medicaid patients.

Comment on question 24

How would you rate your proficiency using [autofill primary product name based on Q1]? a. Expert or super user b. Advanced user c. Intermediate user d. Novice user e. Struggling user

MGMA response

Due to the complexity of the survey and the fact that the questions focus on both administrative and clinical issues, we anticipate that the practice may identify multiple staff members to complete the questionnaire. The potential of multiple respondents should be reflected in question 24 or alternatively this question could be moved to the section on usability.

Conclusion

We are hopeful that, if implemented appropriately, the EHR Reporting Program will serve as an important resource to assist physician practices during their technology acquisition process. As the same time, the transparency associated with this new tool could spur market-driven software innovations that lead directly to improvements in health IT usability, interoperability, patient safety, and security. With the transition towards assessing and tracking health care quality, there is an increasing need for practices to select EHR software that meets their unique clinical and administrative needs. By leveraging the results from an effective survey instrument,
we are hopeful the Reporting Program will help to guide practices during the critical software review stage.

We appreciate the opportunity to share our comments regarding the development of the EHR Reporting Program and specifically on the draft provider survey instrument. Should you have any questions, please contact Robert Tennant at rtennant@mgma.org or 202-293-3450.

Sincerely,

/s/

Anders Gilberg, MGA
Senior Vice President, Government Affairs
Question 1 Comment:
Worth asking about how long they have had their primary product implemented? Could be useful to understand ratings - for new user vs those with more experience with the vendor/product.

Question 2 Comment:
Categories are confusing (for example, some consider pharmacists as clinicians...)

Seems like you want to know:
(1) are they a practicing clinician or not (and perhaps the type of clinician)?
(2) do they have an administrative role or not?

Would just ask those two questions.

Question 4 Comment:
Perhaps change "practice" to "clinical practice setting" to make more generalizable?

Question 4 Comment:
Did you consider a traditional net promoter score scale?

Question 5 Comment:
I really worry about the ability of a "typical" frontline clinician to answer these. They may have no idea what an HIO or HIE is. If you think most respondents will be IT savvy then probably fine to keep these distinctions, but if you are trying to capture a typical provider, I think you need to ask about more general HIE functions:
- how easy is it to electronically receive a copy of the patient record when they have been seen outside your organization?
- how easy is it to access lab results electronically when they have been generated outside your organization
- etc.

- I'd also suggest differentiating between electronic *exchange* and integration of outside information into EHR workflow. They are distinct and both very important.
Question 7 Letter Criteria Comment:
Ask also about # of clicks and # of screens to accomplish tasks... more than necessary?

Question 7.3 Comment:
don't understand this one. what counts as "other products"?

Question 7.4 Comment:
what is a "clinical benefit"?

Question 7.5 Comment:
decreases relative to what? paper records?

Question 7.6 Comment:
how is this different than 7.4? and 7.7, 7.8, etc -- perhaps use IOM framework quality domains?

Question 7.9 Comment:
understandable for patients (e.g., AVSs) or for clinicians (e.g., SCRs)?

Question 7.10 Comment:
would ask about both sensitivity and specificity of alerts

Question 9 Comment:
Do you want to capture the vendor side of this or the provider organization side, or both?

Question 10 Comment:
again - I think you will get answers that conflate what the vendor offers vs. what the organization is offering... try to clarify/specify.

Question 11 Comment:
not clear what "available support" refers to.

Question 16 Comment:
change to "maintain and upgrade"?
General:
The idea of a survey of real users is important and could add real value. It should allow users to comment on any version of a product and also to make comments on the integration of multiple products and their usability and suitability to support clinical workflows. A similar idea might be even more valuable put to PHRs and I would suggest the consideration of that type of feedback as well.

The problem with survey data is that it is very difficult to get a significant and representative sample of users to take the time to respond substantively. There is no clear incentive for participating in such a survey that I can see except catharsis for unhappy users, which may be an issue. Also voluntary data can never be used statistically because the sample isn’t representative—a fact which is often not considered or understood by laypeople, press and even healthcare decision-makers (this author, as a statistician/epidemiologist can speak to that from ample personal experience including with clinicians). More concerning, it also could be highly vulnerable to gaming by vendors who could compensate or do outreach to try to raise their survey results through targeted survey responses. The lack of an objective set of metrics here gives one pause—it could have much more impact to have “secret shoppers” who systematically test and use deployed systems than subjective nonrandom survey data.

For several years, ONC has been presented with the option to require EHR vendors to make real-time feedback to the vendor available anywhere within the EHR and to require that data to be reported along with the type of feedback and resolution/timing but has declined. This would most likely have a much greater impact on understanding the usability, safety and interoperability issues because these could be reported instantaneously. We strongly recommend this option to ONC to obtain greater volumes of data directly from EHR users.

It should also be noted that many of the priority areas in the report are targeted to developers and we would argue that developers are not the primary customer of the EHR and should play a limited role in evaluation (particularly given their history of being responsive to user needs).

Finally, many of the qualities asked about here may be the combination of good or bad work on the part of the implementing institution so that should be provided with several grains of salt.

Questionnaire:
1. Many users could struggle to know what product they use – at least which version, what the official name is (as opposed to Epic eg) and what accessory systems they have. Consider alternative ways for the user to identify where they are and what the system is
2. Allied health professionals are probably not included here but nurses (not generally referred to as clinicians), administra.ve staff, therapists, and assistants/scribes are also EHR users and probably have useful opinions here -- many physicians don’t have insight into many parts of the system and aren’t used to looking at all the data views and functionalities.
3. Agree with liberal ability to provide free text comments—would augment that where possible
   5—would include definitions of some of these—many average users will have little insight into this or may see some info but not the useful data and have a hard .me answering. For example, I get med lists from outside systems but they are often out of date or I get encounter
dates but no diagnoses or notes which I would need to actually inform decision making. Would consider creating different wording and responses depending on whether the person is a typical end user or an HIT expert/backend.

7—would add:
- presents data in a way that is easy to visualize, process or review
- allows me to send and receive actionable messages to other team members or clinicians about the patient in a timely fashion
- rarely provides me with interruptions that are low or no value
- gives me feedback—explaining what a field is used for or what it should contain, offers helpful suggestions about how to use the product
- is easy to customize or has many useful shortcuts for documentation, ordering etc.

8—would add more general accessibility—able to be used with poor vision, foreign accent, etc.

9—many users won’t be able to speak to this so consider again skipping sections or modifying questions: “were you employed at or involved with the .me of the implementation or introduction of X?”

10—would add real-.me, online support to the list even though not many offer it

12—knowing what shift someone works probably really important here (coming from nocturnist experience)

13—would provide more introduction to what is meant here than even the parentheses

14—again this will be hidden to regular users and probably lower IT staff

15—might want another over a million category—“cost of implementing” here actually omits all the real costs of implementing—the staff time? The consultants? The product? The training? This will be much more expensive than what the vendor charges

16—same as above the staff of the departments to support the tool will be many times the maintenance cost

17—specific to administration

18—24—no comments

Table 1:
- concept of exchange is tricky—there are several components all of which are important—the timing of exchange, the content (does it contain meaningful clinical summaries?), the ability for bidirectional exchange, the ability to request electronic info—lots of exchange is not actionable or usable for clinical decision-making which makes it somewhat irrelevant.
- Also “ease of” is for who? The user? It’s very easy if there’s no info available or if it comes up only in some cases—

Table 2:
- Would really want to see more about data extraction/analytics—NACHC is working with many different vendors and the experiences of their teams getting data out is horrific
- Should have a question about mapping—who does it and how much effort or cost is it?
- Documentation is not about structured templates—can include that but really want also NLP and real-time dictation services to be added
August 10, 2020

Donald Rucker, MD, National Coordinator
Office of the National Coordinator for Health IT (ONC)
330 C St. SW
Washington, DC 20201

RE: 21st Century Cares Act Electronic Health Record (EHR) Reporting Program

Dear Dr. Rucker:

The New York eHealth Collaborative (NYeC) is pleased to provide these comments in response to the proposed EHR Reporting Program.

NYeC is a 501(c)(3) and New York’s State Designated Entity (SDE) charged with the governance, coordination, and administration of the Statewide Health Information Network for New York (SHIN-NY). In this capacity, NYeC works in a public/private partnership with the New York State Department of Health (NYS DOH) on the development of policies and procedures that govern health information exchange through the SHIN-NY. The SHIN-NY is a “network of networks” consisting of Qualified Entities (QEs) also known as Regional Health Information Organizations (RHIOs) and a statewide connector that facilitates secure sharing of clinical data from participating providers’ electronic health records (EHRs). The SHIN-NY connects all hospitals in the state, is used by over 100,000 healthcare professionals, and serves millions of people who live in or receive care in New York. NYeC also served as a Regional Extension Center and leads a variety of programs designed to help providers select, implement, and leverage EHRs and HIE to transform healthcare.

NYeC appreciates the opportunity to provide comments and input on the EHR Reporting Program. In general, we urge ONC to take a focused and prioritized approach to this program. We support the voluntary nature of the User-Reported criteria and recommend that the survey process be as flexible and succinct as possible to minimize the time users are away from the critical work they perform, which we believe will increase responses. We have recommended some additional survey questions below but suggest that ONC add these on an optional basis. Highlights of our comment letter are as follows:

- ONC should prioritize the Interoperability criterion for inclusion in the Reporting Program, including information about associated usability and costs.
- NYeC recommends additional, optional detail on questions relating to usability, cost, interoperability, and privacy and security. Specifically, ONC should collect information on the specific features of a health IT product that directly contribute to providers’ ability to meet requirements for value-based payment and/or quality improvement programs; ease of connecting to patient portals and consumer-based apps; implementing, migrating, or
upgrading health IT products; privacy and security training; and limitations in a product's ability to support interoperability and exchange standards.

- NYeC recommends that the survey emphasize reporting on the most recent version of health IT available, but still allow users to report on previous versions of health IT if they choose.

- ONC should utilize a web-based tool that saves progress and is interactive, easy to search, customizable, and allows users within the same organization to send each other sections of the survey to complete as well as view which parts have already been completed.

**Questions:**

**Which draft criteria would you prioritize for inclusion in the EHR Reporting Program, and why?**

NYeC believes that interoperability is a principal priority for inclusion in the Reporting Program. Specifically, end-users must understand usability and cost information related to interoperability when purchasing a health IT product. As a Health Information Exchange (HIE), one of our primary goals is facilitating the ease of use for providers to connect across multiple electronic health records and health IT systems. However, many stakeholders describe limitations and frustrations with health IT interoperability, including absent or insufficient capabilities to exchange data with other systems (e.g., data registries, practice management systems, payer systems, or transition to a different EHR), high (and often unknown) costs for connecting to HIEs, and instances of perceived information blocking by developers.

Given the large variability in how health IT developers incorporate the capability to connect to different systems and HIEs, it is critical for providers to understand up front where there may be unanticipated gaps, or where they may need to pay extra for additional interoperability features. This is particularly important as additional integration of the HIE into health IT products would reduce provider burden, improve access to patient records, and ultimately improve care.

**Which draft criteria should be rephrased, reworded, or removed?**

**Usability**—Clinician perceptions on technology usability can provide key insights to other users when making health IT purchasing decisions. In addition to the topics included under Question #7, it would be useful if ONC were to collect information from providers on the specific features that directly contribute to providers’ ability to meet requirements for value-based payment and/or quality improvement programs through the Centers for Medicare & Medicaid Services (CMS) (e.g., MIPS Quality Payment Program and the Hospital Inpatient Quality Reporting Program).

Additionally, under Question #8, we suggest adding a question around ease of connecting to a patient portal or consumer-facing app if the product offers one. The question currently asks about patient reminders, but as federal regulations and the industry as a whole move in the direction of patient access, it is important to look beyond patient reminders and receive feedback on patient portals, as well as other consumer-facing services.
**Implementation and Upgrades**— One of the challenges faced by providers in our network is the total time and effort it takes to implement and upgrade a health IT product. Often the implementation process is longer than expected and includes unanticipated delays and obstacles. Instead of simply asking about overall satisfaction of implementation, as in Question #9, it would be helpful to add more specific questions asking how long the process took, costs associated with the implementation (including hidden fees), and whether the process met what was promised. Similarly, for the questions related to upgrades, it would be helpful to add questions regarding the length of the upgrade process and the associated costs.

Additionally, while the survey mentions implementations and upgrades, it does not address migrations to new EHRs or mergers with other systems. We receive feedback that the challenges associated with migrating to a new product, including costs, time, and inability to transfer data from system to system, can be prohibitive and cause providers to continue using a system that is not effective. Furthermore, mergers and acquisitions amongst health IT developers often force clients to migrate off legacy systems to newer products. Those who have experienced a migration could provide valuable data for other end-users embarking on such a transition.

**Privacy and Security**— The survey could expand on the Privacy and Security questions by adding questions related to the depth of training and understanding users have on the product’s privacy and security protocols. It would be helpful to know whether end-users are being trained on privacy and security features, and if so, who receives the trainings, how often, and their effectiveness.

**Interoperability**— We recommend modifying Question #5.4 regarding exchange with other health information exchanges to differentiate between private, state, and national health information network/exchanges. Additionally, it would be valuable for those purchasing health IT to know whether there are any limitations in the product’s ability to support interoperability and exchange standards currently in production, including but not limited to support of all data elements in the U.S Core Data for Interoperability (USCDI), compliance with federal rules (e.g. information blocking and CMS patient access rule), support of any FHIR resources, the system’s ability to parse data, and the ability to receive and integrate data from external sources.

*Should the voluntary user-reported criteria cover only the most recent version of a certified health IT product or all versions of the product?*

We recommend that ONC leave the survey open for users to report on any version of the health IT product they wish, with the caveat that the survey recommend that users report on the most recent version. While we believe it would be most beneficial to receive feedback on the most recent version of the product, we recognize that this survey is voluntary and should provide the user with as much flexibility as possible when completing.

*What certified health IT users are most likely able to report on the criteria (e.g., clinicians, administrators, IT specialists)?*

Based on our experience, the types of professionals most engaged or knowledgeable on topics
included in this survey vary from practice to practice. At larger practices, administrators or IT specialists may be more aware of pricing, technical support and training, or privacy and security questions, while clinicians can provide more valuable feedback on usability. However, at smaller practices, the same one or two individuals may be responsible for clinical, administrative, and IT tasks related to their practice. Given this variability and the need to maintain flexibility for end users, we suggest breaking the survey into sections by criterion and posting it in such a way to allow multiple users from a single practice to select individual sections for completion. This way, a clinician could respond to the usability section, while an IT specialist could respond to product support questions. It would be ideal if the interface were designed in such a way to allow users within the same organization to send each other sections of the survey to complete as well as view which parts have already been completed. We believe this flexibility would reduce the burden of completing the survey and incentivize more voluntary completion.

What could motivate end users to voluntarily report on certified health IT products?

NYeC strongly urges ONC to be mindful of the burdens completing such a survey could put on end users and to take necessary steps to maximize flexibility in the survey process. Absent any financial or regulatory incentives, we suggest performing a specific and focused outreach strategy that targets the right populations and highlights specifically how the information collected will help others in acquiring and updating health IT. Overall, the ease and flexibility of completing the survey will most likely determine the volume of responses received. As previously mentioned, ONC should use an electronic, web-based tool that saves progress and is interactive, easy to search, customizable, and allows flexibility for users to select and share questions that are most relevant to their area of expertise.

In summary, NYeC appreciates the opportunity to provide these comments and looks forward to continuing to work with ONC to improve the usability and availability of certified health IT.

Sincerely,

Valerie Grey
Chief Executive Officer
August 10, 2020

Frederic Blavin  
Principal Research Associate  
Christal Ramos  
Senior Research Associate  
The Urban Institute  
500 L’Enfant Plaza, SW  
Washington, DC 20024

RE: Electronic Health Record Reporting Program: Request for Public Feedback on Draft Voluntary User-Reported Criteria for the EHR Reporting Program

Dear Mr. Blavin and Ms. Ramos:

Thank you for providing the opportunity to submit comments on the voluntary user survey portion of the congressionally required electronic health record (EHR) reporting program. Established as part of the 21st Century Cures Act (Cures), the program will involve data collection on the capabilities of EHRs and has the potential to give health care providers, health information technology developers, and researchers better data to address barriers in the effective, efficient, and safe use of digital systems, and improve them accordingly. While the reporting program as a whole will involve critical data submission requirements from EHR developers, the proposed survey component offers an important opportunity for doctors, nurses, and other clinicians to provide their assessment of the technology, and should include a greater focus on aspects that can influence patient safety.

These comments are informed by a collaboration between The Pew Charitable Trusts and MedStar Health’s National Center for Human Factors in Healthcare. In March 2020, Pew and MedStar released recommendations for how the Office of the National Coordinator for Health Information Technology (ONC) could embed safety into the usability criteria of the EHR reporting program. The recommendations were designed based on a review of EHR safety and usability literature and expert interviews. These recommendations were provided to Urban during the 2019 stakeholder engagement process and are appended to this comment letter.

Pew is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of patient care, facilitating the development of new medical products, and enhancing the coordination of care. Pew’s health information technology initiative focuses on advancing the interoperable exchange of health data and improving the safe use of EHRs.

MedStar Health is a not-for-profit ten hospital healthcare system, the largest in the mid-Atlantic region of the United States. The MedStar Health National Center for Human Factors in
Healthcare is an internationally recognized applied research group with extensive expertise in health information technology usability and safety focused on improving frontline clinical practice as well as federal policy.

ONC contracted with the Urban Institute, a nonprofit research organization, to develop one of the last remaining health information technology provisions of Cures: the EHR reporting program. Specifically, Cures required ONC to develop the EHR reporting program to collect information from technology developers and publicly disclose the data to provide transparency on their functions. ONC will then publish those findings on its website to illuminate the gaps and deficiencies of EHR systems, while also providing trends across the industry and giving users comparative information to assist with their health information technology purchasing decisions.

This draft survey, which is only proposed as a portion of the EHR reporting program, will serve to gain insights across the health information technology lifecycle, including after the system’s deployment in facilities. A forthcoming proposal on data collection from vendors will also serve as an opportunity to gain data on functions, performance, and developer practices. In these comments, we provide feedback on the draft survey and offer preliminary input on the content that should be included in the forthcoming data collection effort from EHR developers related to usability and safety.

**EHR usability can affect patient safety**

Congress required that the EHR reporting program address usability, which refers to whether clinicians can efficiently, effectively, and satisfactorily interact with the technology. Usability challenges can result from the initial design of systems, how they are customized by facilities, unique workflows, user training, and other factors.\(^1\) Usability-related safety problems can emerge from confusing interfaces and cause clinicians to place orders for medications, labs, or diagnostic images or complete other important tasks to deliver inefficient care.\(^2\) These types of inefficiencies precipitate the need to develop workarounds, create an overabundance of unnecessary alerts, and can lead to many other issues given the central role that EHRs increasingly have in helping clinicians review health information, obtain decision support, and order procedures.\(^3\)

For example, research published in 2018 showed that EHR usability contributed to approximately a third of 9000 health information technology-related medication errors examined across three health care organizations that care for children; 609 of these usability related events reached the patients.\(^4\) In one case involving the birth of newborn twins, clinicians could not create a record for one of the infants, which delayed a necessary blood transfusion. Ordering a transfusion for the sibling provided a life-saving workaround that added time and opportunity for error.\(^5\) In another case, a clinician entered a child’s weight in pounds when the EHR was configured in kilograms, doubling the child’s weight and resulting in the patient receiving twice the appropriate medication dose.\(^6\)

Another recent study examined the safety of different EHR systems implemented in facilities.\(^7\) Using the Leapfrog Computerized Physician Order Entry (CPOE) tool, which assesses the EHR’s ability to alert clinicians to medication-related safety issues, researchers studied data on
safety from 8657 hospitals over a 10-year period (2009-2018). The researchers found that, despite progress, EHRs failed to detect safety issues up to a third of the time. Notably, even when examining the same system implemented differently in separate facilities, the researchers identified trends across those systems—meaning that aggregate data from EHRs used in distinct sites can still provide product-specific insights. This finding is notable for the EHR reporting program survey, wherein data on implemented systems would be combined to shed light on the overall functionality of EHRs.

These issues can detrimentally affect care, add to physician burden, and increase costs due to complications associated with medical errors.

**Recommendations for proposed survey data to improve EHR usability and add transparency on safety**

The draft voluntary survey of end users—which includes physicians, nurses, and other clinicians—focuses on the aspects of EHR functionality specified by Cures: interoperability; conformance to certification testing; privacy and security; usability and user-centered design; and other factors. The draft survey solicits input on two primary components: providing greater detail on the general usability; and safety of the system and assessing particular functions, such as the EHR’s ability to alert clinicians to medication errors.

1) **Providing a more detailed focus on usability and safety to reduce risk**

In Section 7 of the proposal, the survey would collect rating information from users on their overall satisfaction with EHRs, such as whether the system enables the clinician to provide high-quality care, if it improves patient safety, and whether alerts appropriately prevent errors. Users would rate their EHR using a 5-point scale from “Very satisfied” to “Very dissatisfied” or “Don’t know/Not applicable.”

This section appropriately requests user input on aspects of EHR design known to introduce frustration on clinicians and those elements tied to safety. For example, the survey would collect data on whether the EHR has generally intuitive workflows—which can both affect the time needed by clinicians when using the system and contribute to errors.

The survey can include an even greater focus on safety by collecting data on areas known to introduce simultaneous usability challenges and safety risks. For example, the survey should include the following criteria for responses:

- Enables simple and intuitive entry of patient information
- Provides uncluttered pick lists for placing medication orders
- Provides intuitive visual displays that enhance safety

Finally, 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?”
2) Assessing high-risk functions to reduce patient harm

In Section 8, Urban asks end users to rate various features and functionalities based on their ease of use—from “Very easy” to “Very difficult.” For some of these functions, which are low risk, focusing on their ease of use would help provide information to reduce clinician burden.

Based on existing research, the following functions proposed in the survey do not represent significant risks and would be appropriate to rate on their ease of use:

- Data analytics;
- Image receipt and review;
- Structured templates;
- Telemedicine capabilities;
- Integrated chronic care management tool;
- Mobile accessibility;
- Remote accessibility;
- Voice recognition/Voice-to-text capabilities;
- Optical character recognition;
- User-configured interfaces;
- Documentation; and
- Workflow support.

However, other functions present higher risk, and understanding their likelihood to introduce errors would more appropriately capture their effect on care quality and clinician experience. For example, research indicates that 38% of usability-related errors that reached the patient and caused harm occurred because of challenges with order placement, which can occur due to default values, order sets, and other reasons.8 Similarly, research shows that patient harm occurred in 27% of EHR usability events involving data entry.9 Finally, research reveals that 22% of EHR usability-related safety events involving alerts contributed to harm.10

Therefore, Urban should update the survey for these high-risk functions by instead including a 5-point scale from “Very likely” to “Not very likely” in response to this question: “How likely is it for this functionality to present a risk to patient safety?” Of the functions listed in the draft survey, the following categories are high-risk and should be rated based on safety and not ease of use:

- Default values for common orders;
- Evidenced-based order sets and charting templates;
- E-prescribing of controlled substances;
- Data entry; and
- Patient reminders/alerts.11

Finally, 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?”
Collecting robust vendor data on usability and safety will improve medical errors

While the proposed survey promises to share important feedback from end users, the data that health information technology vendors provide on their development practices will also serve as a foundation to an effective reporting program. Therefore, as Urban develops recommendations for vendor reporting, we encourage you to consider safety- and usability-related efforts as integral to data collection from EHR developers.

ONC’s certification program’s safety enhanced design (SED) requirements already capture some data that could be useful as part of the usability components of the EHR reporting program. Still, SED lacks certain data, such as number of clicks it takes to perform certain tasks or videos of different functions.

However, many of the approaches taken by EHR developers for SED differ; for example, technology vendors may not use the same test scenarios, which are designed to reflect realistic patient conditions and how health care providers treat individuals. However, there are no clear criteria for what constitutes a rigorous test scenario. Similarly, some of the scenarios for certification, while testing that certain functions work, may not effectively evaluate the EHR for usability or safety. Current certification test cases can be too specific, lack relevant details, or may not test aspects of the EHR that are recognized as posing safety risks. Because test cases in use often do not overlap with high-prevalence safety hazards, some important EHR features may not be sufficiently evaluated.

In 2018, Pew, MedStar Health, and the American Medical Association published a report summarizing findings from a meeting with EHR developers, health care providers, usability experts, and other stakeholders to define rigor for test case scenarios and create 14 such assessments.\textsuperscript{12} The Pew, MedStar Health, and AMA developed test cases focus on areas of known usability and safety issues, and meet the identified rigorous criteria to ensure that they are representative, contain concrete goals, test risks, and focus on the intended audience. ONC should consider requiring use of these test case scenarios—or those similar in rigor—and collect more data on the SED requirements for them. Such an approach would provide meaningful data on the general usability processes and safety.

Examples of how to include data from EHR developers in the reporting program are also included in the appended report.

Conclusion

EHRs affect and can improve nearly every aspect of patient care, yet when problems occur, they can be devastating—even deadly. The proposed survey represents the first step in leveraging the EHR reporting program to collect data to improve usability, and ultimately safety. Urban should further build out the survey to provide a more detailed focus on safety and usability and to assess high-risk functions for potential harm. Urban should also consider the importance of collecting data on safety when developing criteria for vendor reporting.
Thank you for the opportunity to comment on these proposed criteria. Should you have any questions or if Pew or MedStar can be of assistance, please contact Ben Moscovitch at (202)540-6333 or bmoscovitch@pewtrusts.org or Raj Ratwani at (202)244-9815 or Raj.M.Ratwani@medstar.net.

Sincerely,

Ben Moscovitch       Raj M. Ratwani
Project Director, Health Information Technology    Director
The Pew Charitable Trusts                           MedStar Health National Center for
                                                     Human Factors in Healthcare

5 Ibid.
6 Ibid.
9 Ibid.
10 Ibid.
11 Ibid.
Effective Reporting Could Improve Safe Use of Electronic Health Records

New government effort can collect data to help reduce patient harm

Overview

Despite the near ubiquitous adoption of electronic health record (EHR) systems to replace paper files in hospitals and doctors’ offices across the country, minimal data exist on the capabilities of different technologies, including the safety of these products. That omission inhibits the ability of EHR developers, health care providers, and government to address deficiencies in technology that contribute to patient harm. Greater information on the functions of EHRs could help provide solutions to existing gaps prevalent across many products, encourage technology developers to address deficiencies, and provide comparative data for hospitals and clinician offices that purchase electronic medical record systems.

To foster this type of transparency, Congress—through the 21st Century Cures Act—created a program to collect information from technology developers and clinicians that can be used to assess EHR performance. The federal agency that oversees EHRs, the Office of the National Coordinator for Health Information Technology (ONC), will administer the program by collecting data on the design of products, security, information exchange among
systems, and other capabilities of different technologies. The agency will then publish findings on its website to illuminate the strengths and weaknesses of EHR systems, and trends across the industry.

ONC collected public input on factors to prioritize in the EHR reporting program in 2018. In response, health information technology experts, clinicians, and key medical organizations emphasized that the program should address patient safety challenges born out of poor EHR usability—how doctors, nurses, and other staff interact with systems. Usability-related safety problems can result in patients obtaining the wrong drug dose, delays in care, and myriad other potentially deadly events. These usability challenges can occur as a result of EHR design, customizations by facilities, and varying workflows within sites of care. For example, recent data gathered from three hospital systems indicate that approximately a third of the health information technology-related medication safety events occurred in part because of EHR usability.

Given the broad interest in using the EHR reporting program to reduce harm, The Pew Charitable Trusts and the MedStar Health National Center for Human Factors in Healthcare investigated how ONC could incorporate patient safety into the usability aspects of the initiative. To identify and assess the safety-related data to include in the reporting program, Pew and MedStar Health conducted a literature search and interviewed usability experts, EHR vendors, policymakers, and health care providers. That analysis led to the identification of 15 examples of data to collect through the EHR reporting program that could shed light on usability-related safety issues.

By adopting some of these recommendations as criteria in the EHR reporting program, ONC can fill a critical gap in the information available on how medical record systems function—including their contributions to medical errors. Greater transparency on system functions can ensure that better information exists to identify industry-wide gaps, encourage an enhanced focus on safety by product developers, and give clinicians greater insight on the functions of the digital systems that they use. These measures could help make certain that patients entering the hospital are less likely to face harm associated with the computer systems that physicians and nurses use.

**Usability and patient safety are intertwined**

Opportunities exist throughout the EHR life cycle to remedy usability challenges with electronic systems. During design, technology developers can adopt best practices to identify and address usability deficiencies, such as by testing new functions. The implementers of EHRs—including executives at hospitals and doctors’ offices—can also apply strategies to detect and resolve poor usability. Given the contribution of site-specific factors such as unique workflows or customizations, health care providers can also unearth problems by monitoring usability and safety issues.

When unaddressed during development or implementation, EHR usability challenges can contribute to two key safety problems. First, the usability of systems can directly contribute to medical errors. For example, researchers evaluated 9,000 health information technology-related medication safety events across three pediatric health care facilities. The researchers found that subpar EHR usability contributed to 3,243 of those events, often related to patients obtaining or at risk of receiving an inappropriate drug dose. In one case, inadequate usability contributed to delays in a necessary blood transfusion for a newborn. In another case, a transplant patient missed several days of an organ rejection medication. Second, deficient usability can lead to clinician burnout when using EHRs. In turn, clinicians who experience higher rates of burden are more susceptible to making medical errors.

**EHR reporting program offers opportunity to address usability, safety**

Recognizing the importance of usability to the effective implementation of EHRs, Congress included this topic as a central aspect of the EHR reporting program, alongside security, interoperability (e.g., the exchange of health
Better data through the EHR reporting program would have three main benefits:

1. **Identifying industry-wide gaps and opportunities.** The aggregation of data on EHR functionality in a single location can help illuminate gaps across multiple products. For example, findings that few technology developers involve a breadth of different user types—such as physicians and nurses with different specialties—in the testing of systems can signal that EHRs on the market may not effectively consider the diverse group of end users. Similarly, data indicating an emerging approach by some vendors for quality improvement—such as aggregating and analyzing data to identify care gaps—may spur more EHR developers to add in that capability.

2. **Encouraging developers to address challenges.** Transparency on the functions of EHRs may also highlight those technology developers that adopt best practices to improve system performance, and those vendors that may lag. Highlighting that discrepancy can encourage developers with less favorable public data to address their deficiencies and prioritize improvements, particularly those related to safety.

3. **Offering purchasing support to providers.** The reporting program can also give the purchasers of systems—such as hospital administrators or clinicians who operate their medical practice—the data they need to compare the capabilities of different systems. The information can also help shed light on the strengths of different products in certain settings—such as for a specific medical subspecialty—so that purchasers can select the EHR system most appropriate for their practice. These data may be particularly meaningful for smaller practices or hospitals in underserved communities that may lack resources or expertise to conduct robust comparisons across products they intend to purchase.

In the 21st Century Cures Act, Congress did not specify the type of data that ONC should collect. Instead, Congress instructed ONC to determine the data to obtain from the developers of EHRs. Technology developers that fail to supply data could lose certification for their products. EHR developers seek product certification so that health care providers can use these systems to participate in certain federal payment programs, such as those administered through Medicare.

ONC may also obtain information from other sources such as health care providers or the accrediting bodies that certify EHRs to ONC criteria. Similarly, ONC may already have some information, including data submitted to the agency for the Certified Health IT Product List (CHPL), a database that contains some information on systems though is not intended for comparison across technologies.

Although Congress did not explicitly reference safety, the usability-related criteria developed in the EHR reporting program could focus on ways to reduce medical errors given the clear association between system design and medical errors. Therefore, ONC should embed safety into the usability-related criteria developed in the program.

### Proposed criteria for the EHR reporting program

Pew and MedStar Health collaborated to develop examples of how ONC could embed safety into the usability criteria of the EHR reporting program. The example criteria were designed based on a review of EHR safety and usability journal articles and other literature. In addition, MedStar Health interviewed 18 experts from academia, government, health technology development, and other organizations, including from outside health care, to provide ideas from other industries.

The example criteria fall into four categories:
1. General processes used to ensure usability and safety.
2. Effectiveness of alerts to potential safety concerns.
3. Data entry capabilities, such as entering medications.
4. Visual display of information, which refers to the ability to retrieve information documented in systems.

The first category reflects criteria that would address various EHR functions. Meanwhile, research has shown that the latter three categories—alerts, data entry, and visual display—are commonly associated with safety and usability problems. Prior research examined a database with more than 1.7 million patient safety reports and identified those three EHR usability-related functions as the ones most commonly associated with errors. More than half of all the EHR usability and safety issues reported were related to these categories. Consequently, focusing reporting criteria on these issues would address known patient safety-related usability challenges.

Each category includes an assessment of example criteria with the following information:

- **General criteria.** Describes the criterion topic.
- **Rationale.** Explains background and justification for why ONC should consider each example criterion.
- **Usability assessment method.** Includes which one of four common ways to assess usability would be employed to evaluate each recommended criterion. The four common usability assessment methods are:
  - **User-centered design (UCD) processes.** UCD involves understanding the needs of the intended user population through observations, development of personas (which refer to fictional characters used to depict common roles in testing systems), designing prototypes, and refining technology based on user feedback.
  - **Objective usability testing.** This often involves using test scenarios to objectively evaluate whether clinicians can effectively interact with technology, and should resemble the actual EHR systems that clinicians would use.
  - **Subjective assessments of usability.** These assessments capture information on perceptions of usability, as opposed to measures of actual usability, through the use of surveys, focus groups, or interviews. Developers of EHRs or organizations that test EHRs for conformance to federal criteria could embed these types of subjective evaluations into product development or reviews of different systems, respectively.
  - **EHR data on user behaviors.** This approach uses data collected within the EHR, such as audit log information, to understand how clinicians actually use systems. These data indicate what happens within an EHR—for example, the buttons pressed or the precise time that clinicians enter orders—and can be used to identify challenges in system design.
- **Data sources.** Outlines whether the data already exist or whether new data will need to be created for analysis.
- **Specific criteria.** Describes in depth the specific criteria that ONC could embed in the EHR reporting program and how to measure or assess the data received.

**Criteria can build on safety-enhanced design**

Many of the data that could be used for the EHR reporting program are already developed and captured as part of the safety-enhanced design (SED) requirements in ONC’s health technology certification program. SED requirements include reporting on the types of participants used to evaluate systems, the test results of different tasks, narrative assessments of the system, and many other factors that can provide data on the usability and safety of technology.
Though important, SED may lack certain data such as the number of clicks it takes to perform certain tasks or videos of different functions. Through the EHR reporting program, enhancements to SED could generate meaningful comparative data across products.

Standard reporting of existing and expanded SED requirements to a range of safety-focused criteria would meet the goals of the EHR reporting program. However, many of the approaches taken by EHR developers for SED differ; for example, technology vendors may not use the same test scenarios. Therefore, the program should ensure that at least some of the test case scenarios are the same across products to ensure accurate comparisons across vendors through the EHR reporting program.

Pew, MedStar Health, and the American Medical Association convened EHR developers, health care providers, usability experts, and other stakeholders to define rigor for test case scenarios and created 14 such assessments. The developed test cases focus on areas of known usability and safety issues. ONC should consider requiring use of these test case scenarios and expanding SED requirements to them. Such an approach would provide meaningful data on both the general usability processes and the three known risk areas—alerts, data entry, and visual display—previously mentioned.

**General user-centered design process and usability testing criteria**

Criteria on general UCD process and usability testing are not related to specific functionalities but rather focus on processes that can improve the overall safety of systems. These criteria provide insight into the rigor of the UCD process and testing being used, particularly by system developers. Overall, these criteria mostly rely on data that already exist, though often are not reported or publicly released.
Table 1
Proposed Criteria: General User-Centered Design (UCD) Process and Usability Testing

<table>
<thead>
<tr>
<th>General criteria</th>
<th>Rationale</th>
<th>Usability assessment method</th>
<th>Data sources</th>
<th>Specific criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigor of the UCD process</td>
<td>Using a rigorous UCD process that includes observations in clinical environments, personas of intended users, and iterative testing of prototypes promotes a more usable product. Demonstrated benefits of this approach include reductions in time to complete tasks, fewer errors, and increased satisfaction.</td>
<td><strong>UCD process</strong>: EHR vendors are required by ONC’s 2015 edition certification to use a UCD process. The byproducts of this process, such as personas and test results, can serve as evidence of using a rigorous testing approach.</td>
<td>Data already exist, but not all data are reported as part of certification.</td>
<td><strong>Measured by</strong>: Attest to creating and using personas [yes/no]; provide and publish personas or the criteria used to create personas as evidence. Attest to conducting observations [yes/no]; if yes, provide general field notes as evidence; if no explain why no observations were needed.</td>
</tr>
<tr>
<td>Number of usability test participants</td>
<td>Final usability testing should include at least 10 participants because testing with this number of participants generally identifies 80 percent of usability issues. Testing with 15 participants generally captures 90 percent of issues.</td>
<td><strong>Objective testing</strong>: The number of participants in the usability testing conducted by the EHR vendor is reported in the safety-enhanced design report to ONC’s accrediting bodies and published in the Certified Health IT Product List (CHPL) database.</td>
<td>Data already exist in certification reports.</td>
<td><strong>Measured by</strong>: Number of participants used to test each capability (e.g., computerized provider order entry): [numeric value as submitted by the vendor]</td>
</tr>
<tr>
<td>Representation of usability test participants</td>
<td>Test participants should represent the end-user population that is intended to utilize the product. Otherwise, the individuals evaluating the system will not have the necessary knowledge to identify challenges. For example, for EHR functions that are intended for physicians, they should be tested with practicing physicians.</td>
<td><strong>Objective testing</strong>: The background of test participants in usability testing conducted by the EHR vendor is reported in the safety-enhanced design report to ONC’s accrediting bodies and published in the CHPL.</td>
<td>Data already exist in certification reports.</td>
<td><strong>Measured by</strong>: Number of participants who have the appropriate experience and clinical background for the capability being tested: [numeric value as submitted by the vendor] For example, medication ordering through computer-physician order entry systems should include doctors and nurses.</td>
</tr>
<tr>
<td>Rigor of test case scenarios</td>
<td>Test cases should represent actual clinical scenarios and be complex enough that they will serve to identify usability and safety challenges. Unrealistic test cases and cases that are too simple will not serve to test functionality of the EHR as used in the live clinical environment.</td>
<td><strong>UCD process</strong>: The test case scenarios employed in usability testing conducted by the EHR vendor are reported in the safety-enhanced design report to ONC’s accrediting bodies and published in the CHPL.</td>
<td>Some data already exist in certification reports; use of new, rigorous test case scenarios.</td>
<td><strong>Measured by</strong>: Attestation to the use of rigorous test case scenarios (such as ones developed jointly by Pew, MedStar Health, and the American Medical Association), and the submission of the safety-enhanced design (SED) data for them. <strong>Measured by</strong>: A subjective rating by the accrediting body of low, medium, or high for the test cases used by each vendor to assess the usability of their product.</td>
</tr>
</tbody>
</table>
Alerting-based criteria

EHR alerts can give clinicians critical information to avert medical errors, such as prescribing drugs to which an individual is allergic. However, alerts that are not accurate, trigger at the wrong time, or are ambiguous can have negative patient safety implications. Clinicians may dismiss—or reflexively ignore—alerts, resulting in health care providers missing critical information. Alerts that do not trigger at the right time may not guide the clinician appropriately, and may occur too early or too late to be effective. In one case examined in prior research, a patient had an allergy to gelatin that was documented in the EHR, yet an alert did not trigger to the clinician when a medication order was submitted that could cause harm. Clinicians may ignore alerts for a range of reasons, including that they were not designed properly or if the health care facility policies required alerts at inopportune times.

Reporting criteria focused on alerts can provide data on whether they are evidence-based and triggered in high-risk situations in a manner most useful to the end users. Alerts should present information to the user clearly, concisely, and accurately, and should not be interruptive unless the situation warrants it.

The use of test case scenarios—with SED requirements—can provide meaningful data on alert practices. Additional data on the utility of alerts, including for both the designed and implemented product, can provide information on whether institutional practices or the base technology affect the utility of alerts.
<table>
<thead>
<tr>
<th>General criteria</th>
<th>Rationale</th>
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<th>Data sources</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Alert override rates</strong></td>
<td>High alert override rates may indicate poorly designed alerts or ones triggered at an inopportune time. This may result in clinicians missing critical information.(^{22})</td>
<td><em>Audit log or usage data:</em> These data can be used to identify how many alerts are triggered and overridden. Data can be assessed as part of the vendor’s testing under ONC’s safety-enhanced design 2015 certification requirement or can be conducted on the implemented EHR product.</td>
<td>Some but not all data exist.</td>
<td><em>Measured by:</em> Number of alerts overridden relative to the number of alerts triggered: [(#\text{ overridden}/#\text{ triggered})]. The focus could be on a limited number of alerts that are recognized as being critical to safety (e.g., drug-allergy contraindications). The Leapfrog Group, a nonprofit organization led by large employers focused on improving patient safety, has developed a testing tool that includes many high-risk medication alerts and could be used as a model for how to structure a reporting program.</td>
</tr>
<tr>
<td><strong>Alert design and interpretability</strong></td>
<td>Alerts should be designed to provide information to the provider in a way that is easily interpretable. Alerts should not be confusing or require significant clinician time to respond.(^{23})</td>
<td><em>Audit log or usage data:</em> These data can be used to identify the time it takes to take an action—such as dismiss an alert or change a prescription—after an alert is triggered. Vendors could collect these data under ONC’s safety-enhanced design certification requirements or directly from the implemented EHR product. <em>Usability testing:</em> EHR vendors could modify existing testing scenarios to evaluate how long it takes to interpret alerts and whether appropriate actions are taken following the alert. In addition, EHR vendors could solicit user feedback specifically about the alert. EHR accrediting and testing bodies could help collect the necessary data. <em>Surveys/interviews:</em> Clinical users can be surveyed or interviewed about the design and interpretability of the alerts they receive. EHR vendors or accrediting bodies could perform these analyses.</td>
<td>Some but not all data exist.</td>
<td><em>Measured by:</em> Time to interpret the alert measured in seconds from time the alert triggers to time the clinician acknowledges the alert: [(\text{seconds to interpret alert})] <em>Measured by:</em> Time to interpret the alert measured in seconds from time the alert triggers to time the clinician acknowledges the alert: [(\text{seconds to interpret alert})] <em>Measured by:</em> Appropriate adherence to the alert given the clinical scenario [yes/no] assessed by study moderators. <em>Measured by:</em> Post-test question asking whether the alert was presented at the right time and whether it was clearly presented [yes/no] <em>Measured by:</em> A series of questions developed. Example: Considering the alerts you receive when prescribing penicillin to a patient who has a documented allergy to this medication, please rate the usability of the alert (is the alert timely and does it provide a clear message)? [1-5 Likert scale, 1 strongly disagree, 5 strongly agree]</td>
</tr>
</tbody>
</table>
Data entry-based criteria

EHR developers should ensure that clinicians can enter data intuitively, with users inputting the correct information into the appropriate fields on the interface. Difficult data entry can result in clinicians entering information in the wrong place within the EHR or omitting data because the user cannot determine where to record it. In one case identified in prior research, a physician attempted to place an order for an X-ray of the left elbow, wrist, and forearm, but because of a confusing display, ordered the images for the right arm, exposing the patient to unnecessary radiation.14

Table 3
Proposed Criteria: Data Entry

<table>
<thead>
<tr>
<th>General criteria</th>
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<th>Data sources</th>
<th>Specific criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Error prone EHR data entry interfaces</strong></td>
<td>The design of data entry displays may promote certain types of errors, such as entering the wrong medication dose or route.24</td>
<td><strong>Audit log or usage data:</strong> These data can be used to identify when EHR order details are entered and then modified or canceled within a specified duration of time. This should be conducted on the implemented EHR product. For example, methods already exist to use this information to determine if clinicians ordered—and then canceled—prescriptions entered on the wrong patient.25</td>
<td>Some but not all data exist.</td>
<td>Measured by: Number of orders that are modified or canceled for select medications relative to the total number of medication orders placed [modified or canceled orders/total orders placed]</td>
</tr>
<tr>
<td><strong>Data entry display design</strong></td>
<td>Data entry fields that are inconsistent across screens, poorly arranged, or poorly labeled can lead to time delays and errors that affect patient care.26</td>
<td><strong>Usability testing:</strong> New or existing clinical scenarios could be modified for clinicians to enter complex medication, lab, or diagnostic orders. Time and number of clicks to complete these orders and number of errors can be documented.</td>
<td>Some but not all data exist.</td>
<td>Measured by: Time and number of clicks to complete the clinical scenario relative to the optimal time and clicks, as indicated by the EHR vendor [actual time/optimal time and click]. Measured by: Number of errors when completing each scenario [number of accurately completed scenarios/total number of scenarios]</td>
</tr>
</tbody>
</table>

Survey: Users can be surveyed by an independent stakeholder, such as ONC’s accrediting bodies, to identify the intuitiveness of the data entry displays. This should be done on the implemented EHR product. New data need to be generated. Measured by: A series of questions developed. Example: Considering the data entry displays in your EHR for entering medication orders, rate the intuitiveness of the display [1-5 Likert scale, 1 not at all intuitive, 5 very intuitive]
Visual display of information

The EHR visual display should not be confusing, cluttered, or present inaccurate information to the user. Confusing visual displays can lead to the wrong medication, lab, or diagnostic image order. These displays can also precipitate the wrong medication prescribed or medications administered at the incorrect time. As an example of this challenge identified in previous research, a physician attempted to order 500 mg of a pain medication to be provided orally, but because of a confusing visual display that listed more than 70 different types of the drug, the clinician selected the wrong product.15

Table 4
Proposed Criteria: Visual Display

<table>
<thead>
<tr>
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</table>
| Cluttered pick lists, which are lists of orders from which clinicians can choose | Pick lists for placing medication and other types of orders should not be cluttered and should contain only relevant information.27 | **Usability testing:** New or existing clinical scenarios could be modified for clinicians to enter orders for medications that would be selected from a pick list. Time and number of clicks to complete these orders and number of errors can be documented. EHR developers or testing bodies could administer these assessments. | Some but not all data exist. | **Measured by:** Time and number of clicks to complete the clinical scenario relative to the optimal time and clicks, as indicated by the EHR vendor [actual time/ optimal time and clicks]  
**Measured by:** Number of errors when completing each scenario [number of accurately completed scenarios/total number of scenarios]  
**Measured by:** A series of questions developed. Example: Considering the pick lists when ordering [insert medication name], how cluttered is the list with irrelevant options? [1-5 Likert scale, 1 not cluttered, 5 not at all cluttered] |
| Intuitive visual displays for medication administration     | Interfaces displaying information on medications to be administered should be intuitive and contain the necessary information to complete the task. Information should be truncated only in low-risk situations and when necessary. Generally, the number of clicks should be minimized.28 | **Usability testing:** Clinical scenarios could be created for clinicians to view a list of medications that should be administered to a patient. The clinician can be asked to write down what should be administered, and error rates can be determined. EHR developers or testing bodies could administer these assessments. | Some but not all data exist. | **Measured by:** Number of errors when completing each scenario [number of accurately completed scenarios/total number of scenarios]  
**Measured by:** A series of questions developed. Example: Considering the medication administration interfaces you typically use, how easy to use are they? [1-5 Likert scale, 1 not easy to use, 5 very easy to use] |
Emerging themes offer guidance for the EHR reporting program

The analysis and development of these example criteria for the EHR reporting program illustrated four key themes to consider as part of data collection.

1. **Incorporate safety-enhanced design and standard safety tests.** ONC should include safety—as outlined in the tables above—in the usability measures of the EHR reporting program. Many subject matter experts interviewed underscored that the program offers a critical opportunity to enhance patient safety, as also reflected in written feedback many organizations provided ONC in 2018.

   SED criteria from ONC’s existing certification program could provide meaningful data. However, ONC should expand SED requirements to areas of known safety risk and standardize the test case scenarios used so that the assessments are comparable across technologies. Similarly, ONC should build on the SED requirements, including by expanding the data submissions (for example, to incorporate the number of clicks it takes to complete tasks and to include video images).

2. **Leverage data collected.** ONC should ensure that the program not only inform potential purchasers of systems, but also serve as a tool for policymakers and EHR developers to identify nationwide gaps and product-specific flaws. Several experts interviewed indicated that the EHR reporting program represents a promising opportunity to identify common usability and safety challenges that persist across many systems so that researchers, technology developers, and policymakers can identify solutions. In addition, the identification of industry-wide challenges can signal to health care providers the areas on which to focus during implementation and what to monitor once systems are in use. In parallel, EHR developers can use the collected data as a guide on how their products and processes compare to other vendors. Where they lag, developers can make adjustments to adopt best practices and further enhance the safety of their systems.

3. **Collect data on implementation.** ONC should ensure that measures in the EHR reporting program reflect both the designed products (e.g., pre-implementation) and those systems in use to identify customization and implementation challenges. Testing prior to implementation can identify usability and safety issues during EHR development so that the vendors can make necessary adjustments. However, many experts said that assessments of implemented products can provide even greater value, though this would likely require more dedicated resources. In addition, technology developers expressed some concern that variations in product implementation inaccurately reflects the designed product—a factor typically outside their control. However, some technologies may be more susceptible to usability and safety errors once customized than other systems. Data from the EHR reporting program can shed light on whether health care providers should take extra precautions when deciding on whether and how to customize certain systems. As a result, data collection from both phases of development and implementation would collect the most meaningful information.

To obtain data on implemented products, ONC should allow health care providers to submit information. As currently designed, data submission to the EHR reporting program on implemented products would be voluntary from providers. Health care facilities could choose to respond to surveys or submit their own test results given that many organizations already evaluate their products, as evidenced by the thousands of sites that have used a medication-ordering test developed by the Leapfrog Group. Additionally, health care providers could submit data from their audit logs, which likely reflect the best opportunity to obtain real-world data on the performance of implemented systems. ONC should work with physicians and vendors to develop standard approaches to audit logs so that the information can be uniformly and easily submitted to the EHR reporting program and measured.
In the future, vendors could submit data on implemented products such as via the collection of log file data on their systems. In addition, data on implemented products collected by EHR testing and accreditation bodies could also inform the program.

4. Enhance the program over time. Once ONC launches the EHR reporting program, the agency should build on the initial design of the initiative in the future. For example, ONC could focus the first iteration of the program on SED criteria and other recommendations from the tables where data already exist or could be more readily obtained. Future versions of this program should expand on those initial criteria by, for example, collecting log file data and incorporating the recommendations in the tables that ONC elects not to include in the initial iteration of the initiative.

Conclusion

EHRs affect and can improve nearly every aspect of patient care, yet when problems occur, they can be devastating—even deadly. However, little data exist on the performance of EHRs and critical functions, including the contribution of these systems to medical errors, such as individuals obtaining the wrong dose of a medication.

Congress recognized the gap in data on EHR functions and created a reporting program, which can equip product developers with new information to understand deficiencies in technology, and give health care providers more information when purchasing or implementing new systems.

ONC now has an opportunity to leverage this program to collect better data to improve the usability—and, consequently, safety—of care. The first iteration of the EHR reporting program should incorporate some of these safety-focused usability criteria to begin informing EHR developers and health care providers on opportunities to reduce medical errors. ONC could begin with those criteria that either already have data available or would provide the greatest insights. As the initiative evolves, ONC should build on these criteria to collect even more robust data on the usability of systems.

Through the reporting program, ONC has an opportunity to collect data on how EHRs function to equip clinicians and technology developers with more information that can improve system usability and reduce patient harm.

Endnotes


3 Howe et al., “Electronic Health Record Usability Issues.”


17 Kushniruk, Patel, and Cimino, “Usability Testing in Medical Informatics: Cognitive Approaches to Evaluation of Information Systems and User Interfaces.”


20 Topaz et al., “Rising Drug Allergy Alert.”


24 Adelman et al., “Understanding and Preventing Wrong-Patient Electronic Orders: A Randomized Controlled Trial.”


26 Ratwani et al., “A Usability and Safety Analysis of Electronic Health Records: A Multi-Center Study.”


For further information, please visit:
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Project website: medicalhumanfactors.net

National Center for Human Factors in Healthcare, MedStar Health. We are dedicated to improving the quality, safety, and efficiency of healthcare through innovative application of the science of human factors and system safety.
August 10, 2020

Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator (ONC)
U.S. Department of Health & Human Services

Submitted electronically at: EHRfeedback@urban.org

Re: Request for Public Feedback on Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program

Dear Dr. Rucker:

On behalf of the 4,000 U.S. hospitals and more than 175,000 other providers and organizations in the Premier healthcare alliance, we are pleased to submit these comments in response to the Office of the National Coordinator’s (ONC) Request for Public Feedback on Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program.

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 2016, Section 4002(c) of the 21st Century Cures Act (Cures) required an EHR Reporting Program (Program). The Program was intended to make comparative information on certified health information technology (IT) publicly available, and to require data from EHR vendors and voluntary input from end users of certified health IT to help inform the purchasing and implementation decisions of certified health IT users. ONC’s contractor, the Urban Institute, has developed and published draft voluntary user-reported criteria for public feedback.

In the comments below, we summarize Premier’s longstanding support for interoperability across the healthcare continuum, provide general comments about the proposed approach and offer feedback about the DRAFT voluntary user-reported criteria and questionnaire.

Ongoing Need for Interoperability

Premier supports efforts to transform healthcare through the power of data and health 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. Providers need robust, scalable, and interoperable health IT systems and electronic health records (EHRs) to improve clinical decision making and deliver improved outcomes.

Without connectivity and interoperability across the care continuum, EHRs do 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 the ability to access and aggregate information from different EHRs and health IT applications across multiple facilities and care settings.

General Comments about the Proposed EHR Reporting Program Approach

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. 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.

Cures required the development of an EHR Reporting Program and explicitly requires vendor reporting about health IT usability, interoperability, and security. The EHR Reporting Program was intended to help users make more informed decisions about EHR acquisition, upgrade, enhancement and/or replacements. We urge ONC to accelerate the implementation of the EHR Reporting Program to collect and curate comparative information to help improve CEHRT functionality, interoperability, usability, patient safety, and security in the real world. ONC should develop and publish draft EHR vendor reporting criteria for review and comment as soon as possible. EHR vendor compliance with reporting criteria is essential to an open, and competitive health IT marketplace.

ONC should consider recent (ONC and CMS) health IT, interoperability and data access regulations as it develops and implements the EHR Report Program. ONC recently finalized major changes to its EHR Certification program, information blocking, and to the Conditions and Maintenance of Certification\(^1\). CMS recently published its Inpatient Prospective Payment System\(^2\) and Physician Fee Schedule\(^3\) proposed rules which include potential implications for EHR functionality. The EHR Reporting program should comprehensively incorporate these (annual) changes and updates and assess EHR vendor timely compliance with current requirements. Furthermore, ONC should clearly depict how the data submitted to the EHR Reporting Program will be collected, validated, analyzed, and disseminated.

Existing policy levers and incentives continue to unfairly target and penalize providers (i.e., hospitals, health systems and clinicians). EHR vendors should be held accountable for demonstrating and assuring interoperability and compliance with CEHRT requirements. EHR vendors should be required to report data about their products and services. 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 continue to 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.\(^4\)\(^5\)

Provider (user) Burdens

As we have previously indicated in comments to ONC, Premier does not support any new or additional provider reporting or data collection requirements as part of the EHR Reporting

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1. [https://www.healthit.gov/curesrule/overview/major-changes-proposed-rule-final-rule](https://www.healthit.gov/curesrule/overview/major-changes-proposed-rule-final-rule)
3. [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched)
4. [https://jamanetwork.com/journals/jama/fullarticle/2707668](https://jamanetwork.com/journals/jama/fullarticle/2707668)
5. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4556429/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4556429/)
Additionally, ONC should focus attention on EHR vendor reporting and require EHR vendors to demonstrate interoperability, usability, security, and their platforms’ conformance to standards.

### EHR Reporting Program Implementation

Cures required that the EHR Reporting Program include product features and capabilities. Implementation of this Cures requirement is long overdue. **ONC's projected 2022 implementation timeline for the EHR Reporting Program is non-responsive to providers’ immediate needs and is inconsistent with Cures’ intentions.** Providers need timely, reliable, robust, and transparent information about certified EHRs. 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.

**ONC should accelerate its timeline to implement the EHR Reporting Program** and should conduct pilot testing (across various provider settings and users) prior to launch. ONC should ensure broad information dissemination as the Program is developed and implemented and ONC should conduct ongoing stakeholder awareness and education about the EHR Reporting Program.

### Draft EHR Vendor Criteria

Premier is disappointed that ONC has not yet focused 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 urge **ONC to establish reporting criteria for certified products that meet the “base” EHR definition.** ONC should require a common set of 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.

### Adoption and Use of Standards

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. **ONC should advance policies (i.e., certification and EHR Reporting criteria) that include specific interoperability standards (transport, syntax, and semantic) 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), for the information to be understandable and usable, thereby enabling interoperability.

**ONC should encourage EHR vendors’ consistent standards implementation, reduce implementation variability, and improve modularity in health data standards for terminology and...**

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vocabulary, coding, data content and format, transport, and security. Lacking such improvements to the standards, providers will not have EHRs that offer true coordinated, high-quality, cost-effective healthcare. Providers and clinicians remain 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.

We offer the following specific comments about the Draft Voluntary User-Reported Criteria:

- Additional Instructions about the “survey” and directions for its completion and submission are needed as is the voluntary nature of the reporting. It is unclear how often the survey responses are requested.
- It appears that there is a lack of consistency between the table summarizing draft criteria for end users by topic and data source and the user questionnaire for collecting information for draft voluntary user-reported criteria. A cross walk is needed to indicate the relationship between the two resources.
- We question the validity of the statement that the “survey will take approximately 10 to 15 minutes to complete” - we believe that it will require additional time.
- We urge ONC to conduct pilot(s) before finalizing the next version of user criteria.
- It seems unlikely that one individual can respond to all questions given the diverse questions and topics (security; costs; functionality) and the materials lack directions about how multiple respondents may be able to contribute.
- The terms “practice” and “organization” are not defined and used inconsistently in several questions.
- Question 1 - “additional add-on products” needs explanation and it is unclear why that information is requested, since the survey then states that respondent should only consider “the primary product.
- Question 12- suggest separating system upgrades and system maintenance.

5 https://www.nist.gov/programs-projects/health-it-usability
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_Useability.pdf
12 https://academic.oup.com/jamia/article/20/e1/e2/692244
14 https://www.phe.gov/preparedness/planning/CyberTF/Pages/default.aspx
• Question 13- combines privacy and security- they should be separate; specific attributes need to be overtly addressed (multifactor authentication, role-based access control, 42 CFR Part 2, HIPAA).
• Question 17-additional aspects of the EHR vendor contract should be included (i.e., gag clauses’ upgrade process/timeline; downtime).
• Question 19- Wording is unclear: “About how many clinicians work in the practice or organization”- does this mean how many employed clinicians are on staff?
• Question 23 seems out of place.
• Questions are needed about:
  o Costs for ongoing product maintenance; costs for product or version upgrades to comply with new regulations (such as CEHRT; USCDI); and costs for user training
  o Implementation of standards (open APIs; CDS hooks; bulk data on FHIR; bi-directional data flow into and out of EHRs)
  o Availability of product technical documentation and vendor business policies and practices
  o The ease of connecting and using third-party applications of the users’ choosing
  o Timeliness of product compliance with new public policies or regulations and functionality (such as data and interoperability standards; CEHRT or USCDI; Promoting Interoperability reporting)
  o Vendor responsiveness to service requests
  o Need for users’ development and implementation of work arounds due to product limitations
  o Length of time product has been used
    ▪ by the practice/organization
    ▪ by the user/respondent

Conclusion
The Premier healthcare alliance appreciates the opportunity to submit comments regarding Draft Voluntary User-Reported Criteria for the 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.

Sincerely,

Blair Childs
Senior Vice President, Public Affairs
Premier Inc.
As it relates to the draft criteria, healthcare professionals should be asked about the availability of U.S.-based help desk support as a subset to question 10 to better inform decision-makers seeking to purchase healthcare IT. This is a key factor for many decision-makers when selecting healthcare IT.
To Whom it May Concern:

The Sequoia Project is pleased to submit these comments on the Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program. We recognize the importance of these criteria and the proposed EHR Reporting Program to be administered by the Office of the National Coordinator for Health IT (ONC) and appreciate the provision of a 60-day public feedback period. Our comments focus on criteria related to interoperability and health information exchange.

The Sequoia Project is a non-profit, 501(c)(3) public-private collaborative that advances the interoperability of electronic health information for the public good. The Sequoia Project previously served as a corporate home for several independently governed health IT interoperability initiatives, including the eHealth Exchange health information network and the Carequality interoperability framework. The eHealth Exchange and Carequality now operate under their own non-profit organizations. The Sequoia Project currently supports the RSNA Image Share Validation Program, the Patient Unified Lookup System for Emergencies (PULSE), and the Interoperability Matters cooperative. Lastly, we are honored to have been selected by ONC to be the Recognized Coordinating Entity (RCE) for the Trusted Exchange Framework and Common Agreement (TEFCA).

These comments reflect our experience supporting large-scale, nationwide health information sharing, including active work with several federal government agencies. Through these efforts, we serve as an experienced, transparent, and neutral convener of public and private sector stakeholders to address and resolve practical challenges to interoperability. Our deep experience implementing nationwide health IT interoperability, including our track record of supporting and operationalizing federal government and private sector interoperability initiatives, provide a unique perspective on these draft criteria as they relate to interoperability and health information exchange.
Overall Perspectives

Our detailed comments are in the attached appendix. We also offer the following overall perspectives.

First, we agree strongly with the comments in the April 2020 report (Report) to the ONC by the Urban Institute “What Comparative Information Is Needed for the EHR Reporting Program?” (Report) that the EHR Reporting Program should prioritize criteria that measure the ability to exchange data with other entities and the ability to use exchanged data as key criteria for the Reporting Program. We further agree with the specific comments that reporting criteria should include documentation of a product’s capability to exchange with state-wide, regional, and national networks.

We also agree with comments summarized in the Report on the importance of reporting on security features and standards used and the recognition of the importance and value of the Carequality Technical Trust Policy, Version 2.0.

Finally, we urge Urban Institute and its partners to place a high priority on ensuring that comparisons across products and developers of certified health IT are valid and reliable. In this regard, we point you to the discussion that accompanied your recent presentation to the HITAC on June 17, 2020. We believe that as much attention needs to be paid to the methodology for data collection and fielding of surveys as on development of the criteria and survey instruments.

Conclusions

We appreciate the opportunity to provide you our comments on the Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program. The Sequoia Project stands ready to assist you in any way that we can.

Most respectfully,

Mariann Yeager
CEO, The Sequoia Project

Attachment
Appendix: Selected Detailed Feedback from The Sequoia Project on Draft Voluntary User-Reported Criteria for the Electronic Health Record Reporting Program

Which draft criteria would you prioritize for inclusion in the EHR Reporting Program, and why?

- Interoperability is a very high priority as documented in the April 2020 Report:
  - Support for connectivity with health information networks (HINs) is a very high priority given the need for effective data exchange among clinicians and healthcare organization and for patients’ access to their data, especially with an increased regulatory focus on information blocking.
  - Usable connectivity to PDMPs is a priority given the continuing national problem with opioid use and Substance Use Disorder (SUD).
  - Interoperability with other providers and payers is a very high priority as these are widely identified critical use cases; we suggest a much greater focus on use and usefulness of received data vs. ease of use.

- Usability is a very high priority topic as is widely recognized by policy makers, developers and especially the provider community.

- Behavioral health and substance use disorder support are a very high priority and, although related to privacy and security, cut across the other domains as well. We suggest:
  - A focus on product-side support for integration with PDMPs; and
  - Addressing the effectiveness of data segmentation to support 42 CFR Part 2 and for other purposes.

- Security and Privacy are very high priority topics, especially given recent breaches and the need for effective security and privacy assurance for use and exchange of electronic data. We suggest:
  - Splitting out privacy and security, even if these are kept at a high level; they are two distinct domains and would be seen as such by appropriate user respondents.

Which draft criteria should be rephrased, reworded, or removed?

Interoperability

- Question 5: Indicate the level of ease or difficulty completing each of the following tasks using [autofill primary product name based on Q1].
  - Overall, we suggest that these questions should focus less on ease of use and more on the ability to exchange and the usefulness of the received data within the product, including the ability of the product to integrate and display and make use of received data. Focusing only on ease of use would be a major missed opportunity.
  - We suggest adding a question about access to data and the ability to send data beyond the local area or state.
  - We suggest adding a question on product support for accurate patient matching, which was a priority in the Report.
We suggest adding a question on data reconciliation, which is critical to data use.

Consistent with comments in the Report, we also suggest adding a question on the ability of the product to usefully connect to national health information networks/and frameworks in addition to the focus in Question 5.4 on “exchanging health information with health information organizations (HIOs) or health information exchanges (HIEs)”.

- 5.5 Electronically exchanging health information with payers (e.g., Medicare, Medicaid, private payers)
  - We suggest splitting out sending data to payers and accessing and using data from payers.

- 5.8 Connecting with your local prescription drug monitoring program (PDMP) through your certified health IT product
  - We suggest rephrasing the question to focus less on connecting and more on use for the intended purpose.
  - We suggest that you ask a question about integration with PDMPs and the ability to link PDMP data to other relevant EHR functionality.
  - As noted above, it is important to recognize that much about EHR connectivity and integration with PDMPs depends on state laws and the policies and technical approaches of specific PDMPs.

Usability

- 7.3 easily accesses and assimilates data from other products
  - We believe that this question is too vague. Is this integration with other practice systems or bringing in data view HIE/interop tools like C-CDA and FHIR APIs?

- 7.9 easily produces understandable clinical summaries
  - The question whether "ease" and “understandable” should be combined. We suggesting focusing on the latter.

- 8.5 Image receipt, access and review (e.g., x-rays, CTs, and MRIs)
  - We suggest adding “access” to the question and not just focusing on "receipt, often images are accessed externally via links.

Privacy and Security

- 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.)?
  - We suggest splitting out privacy and security and asking if clinicians can record and access patient privacy preferences and consent.
  - We suggest a focus on end user priorities.
While I like the measure concepts, I don't like the subjective user assessments as being the only measures reported. I think there should be more objective measures for items such as interoperability: For example for, 5.4 Ease of exchange with health information organizations (HIOs) or health information exchanges (HIEs) PDMPs. I think you should ask, have they tried to connect to an HIO or HIE? How many active connections do they have? How many documents/artifacts do they exchange on a monthly basis? How many document errors, ie, failed to send or receive do you get each month?

5.8 Ease of connecting with local Prescription Drug Monitoring Program (PDMP) Similar to the HIE above. Have you tried to connect? How many are you using? How many times/month did your practice check the PDMP? How many time/month do you NOT find any patient information in the PDMP? How many times/month did you get an error?

For usability, I would like to see some objective measures such as:
1. mean screen load time per day
2. max screen load time per day
3. mean number of system crashes (requiring a system reboot, or religion) / user/day

I would like to see a similar analysis for all the proposed measures. when possible, the data should be automatically collected and reported from the EHR.'