

# What Comparative Information Is Needed for the EHR Reporting Program?

*Priorities Identified through the Stakeholder Engagement Process*

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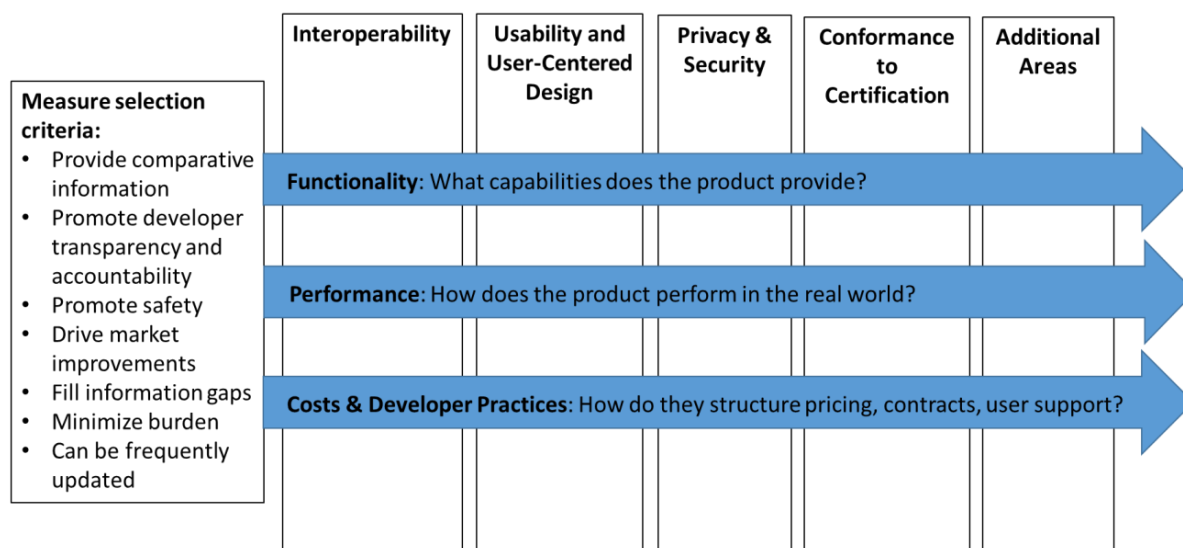
## Executive Summary

The 21st Century Cures Act of 2016 (Cures Act) created a new Electronic Health Record (EHR) Reporting Program to provide publicly available, comparative information about certified health IT to help stakeholders assess available products. The development of the new EHR Reporting Program is being informed by a robust stakeholder engagement process to collect feedback through a Request for Information (RFI) by the Office of the National Coordinator for Health Information Technology (ONC), public forums, listening sessions, and discussions with experts and key stakeholders, including health IT end users and developers. This report summarizes stakeholder input on the EHR Reporting Program between February 2019 and October 2019.

### Overall Priorities and Framework

Though most stakeholders believed the EHR Reporting Program would provide useful information to guide providers' certified health IT purchasing decisions, many suggested additional priorities for the program, such as promoting transparency and driving improvements in the health IT market. To that end, many stakeholders argued the program would be particularly valuable if it provided information about the real-world performance of certified health IT products. To guide selection of reporting criteria and development of measures for the EHR Reporting Program, we developed a framework that incorporates stakeholder input on overall program priorities and the five domains outlined in the Cures Act. For each of the framework domains, stakeholders identified specific information that is needed about certified health IT products in the areas of product functionality, real-world performance, and associated costs and developer practices (Figure ES.1).

**Figure ES.1. EHR Reporting Program Measurement Framework**



## Stakeholder Feedback

*Interoperability* rose to the top of stakeholder priorities, with many noting current limitations and frustrations with EHR interoperability, including insufficient capabilities to exchange data with other entities, unexpected and often high costs of interfaces, and “information blocking” by developers. Stakeholders emphasized the importance of developing measures to assess both the product’s ability and efficiency in accomplishing an interoperability-related task. In addition, many noted that greater transparency around costs and developer practices related to interoperability and data exchange could be achieved through the EHR Reporting Program (table ES.1).

**Table ES.1. High-Priority Measure Topics for Interoperability**

Topic for Measurement	Potential Data Sources	Cross-Cutting Area
Exchange with national networks (eHX, DirectTrust, Commonwell)	Developers, networks, PI	Performance
HIE/HIO interoperability	Developers, HIE/HIO, SHIEC, PI	Performance
Submit/edit/retrieve functionality with registries (state, federal, specialized)	Developers, users, registries	Performance
Create and submit standardized reports on timely basis without added fees	Developers, users, registries	Costs/Practices
PDMP integration and/or portal support by state	Developers, states	Performance
Standards and versions supported (e.g., USCDI, ISA)	Developers, ONC, HL-7, IHE	Functionality
API use cases supported	Developers, HL-7	Functionality
Interfaces (functionality, costs, maintenance, upgrades)	Developers, users	Costs/Practices
Interoperability with laboratories, imaging, and diagnostic tests	Developers, associations, users	Performance
Patient matching when exchanging data with nonaffiliates	Developers, users	Functionality
Functionality supported in consumer-facing applications	Developers, users	Costs/Practices
Interoperability with nonaffiliated entities (e.g., burden to extract/use data)	Developers, users	Costs/Practices

Note: PI=Promoting Interoperability, HIE=Health Information Exchange, HIO=Health Information Organization, USCDI=US Core Data for Interoperability, ISA=International Standards on Auditing, IHE=Integrating the Healthcare Enterprise

*Usability*—the extent to which users can efficiently and effectively use a certified health IT product—was another frequently discussed topic (table ES.2). Many stakeholders noted that measures of usability may be particularly challenging to define given the various types of end users (e.g., physicians, nurses, social workers, analysts, practice administrators) and their specific needs, which may vary greatly even among different provider types and specialties. Stakeholders also highlighted the challenge that the usability of the same product may vary across organizations due to the implementation design decisions they make. To assess usability in the real world, stakeholders suggested that the EHR Reporting Program collect

data through user ratings and objective measures of usability, such as clickstreams, time to task, and audit logs.

**Table ES.2. High-Priority Measure Topics for Usability**

Topic for Measurement	Potential Data Sources	Cross-Cutting Area
Target use case for the health IT product	Developers	Functionality
Target end users and/or care settings for the health IT product	Developers	Functionality
Ease of installation of health IT product	Developers, users	Performance
Standard available features and functionalities (list and/or maturity rating)	Developers	Functionality
Customized available features and functionalities (list and/or maturity rating)	Developers	Functionality
Subjective usability - overall usability (rating and/or open-ended comments)	Users	Performance
Objective usability - clickstream for use case	Developers, users	Performance
Objective usability - time to task for use case	Developers, users	Performance
Objective usability - audit log for use case	Developers, users	Performance
Objective usability - video demonstration for use case	Developers	Performance
Objective usability - product examples (reports, forms, screen shots)	Developers	Performance
Objective usability - documentation time for use case	Developers, users	Performance
Safety	Developers, ONC SAFER guides*, NQF*, Leapfrog*, Pew/Medstar*	Performance

Note: NQF=National Quality Forum, \*Potential measure source

*Privacy and security* was less frequently discussed but was a priority for rural providers and consistently focused on security product features and standards, privacy features, and security breaches and patches (Table ES.3). In particular, a greater transparency over whether a product is compliant with 42 CFR Part 2, in relation to the segmentation of substance use treatment records, was highlighted by many stakeholders.

**Table ES.3. High-Priority Measure Topics for Privacy and Security**

Topic for Measurement	Potential Data Sources	Cross-Cutting Area
Two-factor authentication	Developers	Functionality
Compliance with security standards	Developers	Functionality
Role-based access control	Developers	Functionality
42 CFR Part 2	Developers	Functionality
Number and type of security breaches and ransomware attacks	Developers	Performance
Disclosure of any regulatory actions	Developers	Performance
Number of security patches to address security vulnerabilities	Developers	Performance

*Conformance to certification standards* was commonly cited because of concerns that certified products were not functioning as well in the field as they were in the laboratory certification testing process. Suggestions in this domain included measures that are reported on ONC's Certified Health IT Product List (CHPL) around a health IT product's certification, surveillance activities, and nonconformities. In addition, stakeholders requested more transparency on the results of conformance testing. Many stakeholders urged ONC to monitor how products perform in the real world (Table ES.4).

**Table ES.4. High Priority Measure Topics for Conformance to Certification**

Topic for Measurement	Potential Data Sources	Cross-Cutting Area
Successful attestation to PI requirements	Repositories, developers, PI	Performance
Certification status (editions met, nonconformities, surveillance activity)	CHPL	Functionality
Nonconformance in the real world	Real-world testing, users	Performance
Additional costs for product to meet certification requirements	Developers, users	Costs/Practices
Length of time to implement changes in measures for PI	Developers, users	Costs/Practices

*Additional areas* of interest to stakeholders included patient portals and a number of developer practices related to cost and contracting, including the overall cost of owning health IT (Table ES.5).

**Table ES.5. High-Priority Measure Topics for Additional Areas**

Topic for Measurement	Potential Data Sources	Cross-Cutting Area
Total cost of health IT product ownership (over period of time)	Developers, users	Costs/Practices
Cost of staffing to support health IT product	Users	Costs/Practices
Itemized cost of features and functionalities for health IT product	Developers	Costs/Practices
Cost of customization for health IT product	Developers	Costs/Practices
Developer support (training, call center, on-site, etc.)	Developers, users	Costs/Practices
Contractual information - "out clauses"	Developers, users	Costs/Practices
Contractual information - "gag clauses"	Developers, users	Costs/Practices
Market share	Developers, PI attestations, IQVIA survey	Costs/Practices
Developer approaches to updates and upgrades (frequency, downtime)	Developers, users	Costs/Practices

Note: PI=Promoting Interoperability

## **Data Sources and Presentation**

Stakeholders suggested a number of existing sources that the EHR Reporting Program could draw from, including CHPL, KLAS, Black Book, and the Promoting Interoperability program. A few stakeholders mentioned various survey data collected by private sector groups (e.g., MGMA, IQVIA, and AHA) and the federal government. Several RFI commenters recommended consolidating existing health IT comparison resources into a free (or low-cost), user-friendly format and integrating existing data sources directly into a single website.

Stakeholders suggested several approaches to collecting new data from EHR developers, clinicians, patients, or others, agreeing that the EHR Reporting Program should be built from various data sources. Some stakeholders advised to carefully weigh costs and benefits of added reporting burden on developers. Stakeholders recommended that feedback from end users be gathered on a voluntary basis through surveys, user reviews, and star ratings that allow easy comparison (i.e., Yelp or Amazon-like reviews) and reacted positively to the crowdsourced example, InteropSelect. These approaches would require implementing strategies to encourage clinician participation (e.g., providing financial incentives, engaging professional association groups) and to ensure validity of collected data (e.g., verifying reviewers' identities and/or health IT product use).

## **Next Steps**

The next step will be to develop measures based on the recommended framework and the priority topics identified by stakeholders. These measures will constitute the draft reporting criteria, which will also be informed by our completed review of the available published literature and existing EHR comparison tools (Appendix A). The draft criteria will undergo cognitive and feasibility testing with a small sample of certified health IT developers and end users. After revisions based on this testing, proposed reporting criteria will be posted online for public comment in mid-2020.

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## Introduction

The 21st Century Cures Act of 2016 (Cures Act) directed the US Department of Health and Human Services to establish a new Electronic Health Record (EHR) Reporting Program to provide publicly available, comparative information about certified health information technology (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 opportunity for users of certified health IT to voluntarily report their experience using certified health IT products. The Cures Act requires reporting criteria to address the categories of security, usability, interoperability, conformance to certification testing, and other topics as appropriate.

The Cures Act required gathering input from various stakeholders to inform the development of the EHR Reporting Program. This report summarizes stakeholder input on the types of information needed regarding certified health IT, which will be used to inform the development of the new EHR Reporting Program.

### **Stakeholder Input**

Stakeholder input was obtained through

- a Request for Information (RFI) issued by the Office of the National Coordinator for Health Information Technology (ONC) in August 2018;
- public forums and office hours held in seven locations around the country;
- collection of feedback in the exhibit halls of four national professional association conferences: Healthcare Information and Management Systems Society (HIMSS), American Academy of Family Physicians (AAFP), American Association of Nurse Practitioners (AANP), and National Association of Community Health Centers (NACHC);
- nine virtual, small-group, open discussions that brought together experts and stakeholders to discuss specialized topics, including security and privacy, usability and user-centered design, payers, health information exchange and data-sharing networks, conformance to certification, patient advocates, trading partners, rural providers, and provider associations;
- nine one-on-one phone discussions with national experts;
- three market research calls with companies engaged in providing an EHR comparative tool; and
- a dedicated email inbox for public feedback.



Throughout the stakeholder input process, we obtained feedback from targeted groups of health IT end users (including front-line providers and other clinical end users, such as IT and administrative staff), health IT acquisition decision-makers, representatives from small ambulatory practices, urban and rural practices, and community health centers. We also sought input from health IT developers of diverse sizes and market shares.

Many stakeholders pointed to the lack of information regarding noncertified health IT products as a gap in the market (particularly information related to health IT products used by behavioral health and long-term and post-acute care [LTPAC] providers). However, the EHR Reporting Program only requires participation by developers of certified products. Expert and stakeholder input indicated there is presently no incentive or process for developers of behavioral health or LTPAC products to certify their products. Therefore, to inform our recommendations, feedback from these providers was collected from the perspective of information-trading partners of users of certified products. However, promoting publicly available information about non-certified health IT products could be a direction for future work.

For additional details on the stakeholder engagement process, see Appendix B.

### **Analysis and Next Steps**

RFI comments and notes from all stakeholder feedback activities were uploaded to NVivo qualitative analysis software for thematic content analysis by the categories listed in the Cures Act (interoperability, usability and user-centered design, privacy and security, conformance to certification testing, and other topics as appropriate) and stakeholder type.

We developed a framework based on stakeholder feedback to guide our development of recommended reporting criteria for the EHR Reporting Program. In the sections that follow, we present this framework and summarize what stakeholders suggested should be prioritized as topics to be covered within the program. We also summarize stakeholder input on potential data sources for the program and how the data should be presented.

The next step of this program will be to develop measures based on the recommended framework and the priority topics identified by stakeholders. These measures will constitute the draft reporting criteria, which will also be informed by our completed review of the available published literature and existing EHR comparison tools (Appendix A). The draft criteria will undergo cognitive and

feasibility testing with a small sample of certified health IT developers and end users. After revisions based on this testing, proposed reporting criteria will be posted online for public comment in mid-2020.

## Framework Based on Expert and Stakeholder Feedback

Overall, most stakeholders expressed support for the establishment of an EHR Reporting Program and believed it would provide important and useful information to inform certified health IT purchasing decisions, particularly for small and rural practices. Several stakeholders described how challenging and nearly impossible it can be for providers to switch from one EHR to another if they discover the original product does not meet their needs and noted that it would have been useful to have access to information like what will be included in the EHR Reporting Program when they made their purchasing decision. Stakeholders with certified health IT products noted that the program may be too late for them, because switching products is cost prohibitive, but that it would be helpful to include other types of certified health IT to inform future decisions about purchasing add-ons and other product types.

However, though some stakeholders saw value in a shopping tool, the general sentiment was that the EHR Reporting Program should go beyond other EHR comparison tools to create something that might drive market improvements. This sentiment is supported by literature on public reporting in health care that has shown that although well-designed reports can influence consumer behavior,<sup>1</sup> there is more evidence of its influence on provider behavior and its association with some improvements in outcomes<sup>2</sup> (but also at times with the unintended consequence of providers avoiding high-risk patients<sup>3</sup>). Some stakeholders thought existing EHR comparison tools could be compiled into a clearinghouse or could contribute existing data to a publicly available resource, but others felt there were limited useful existing tools for end users. However, one commenter representing a professional association where members have access to such comparative information reported that, though useful to inform some decisions, *“experience has shown that publishing this type of developer-specific usability*

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<sup>1</sup>Faber M, Bosch M, Wollersheim H, Leatherman S, Grol R. Public reporting in health care: How do consumers use quality-of-care information?: A systematic review. *Medical care*. 2009 Jan 1;47(1):1-8.

<sup>2</sup> Marshall MN, Shekelle PG, Leatherman S, Brook RH. The public release of performance data: what do we expect to gain? A review of the evidence. *Jama*. 2000 Apr 12;283(14):1866-74.

Werner RM, Bradlow ET. Public reporting on hospital process improvements is linked to better patient outcomes. *Health affairs*. 2010 Jul 1;29(7):1319-24.

<sup>3</sup> Narins CR, Dozier AM, Ling FS, Zareba W. The influence of public reporting of outcome data on medical decision making by physicians. *Archives of Internal Medicine*. 2005 Jan 10;165(1):83-7.

*information, even within a user-friendly, clear format, is not translating into better, more usable, safer, and interoperable products.”*

## **Overall Priorities**

Overall, stakeholders urged ONC to “*go beyond simply providing data that helps users make more informed decisions...[to provide] information to improve CEHRT interoperability, usability, safety, and security in the real world.*” As another commenter put it, “*The EHR Reporting Program could be most impactful by focusing on post-acquisition/post-implementation surveillance.*” Along those lines, stakeholders expressed the following priorities for the EHR Reporting Program:

- **Provide comparative information** on certified health IT products’ basic functionalities.
- **Promote transparency and accountability** among developers for their products’ performance, particularly related to
  - providers’ ability to meet reporting requirements (including those for incentive programs, federally qualified health centers [FQHCs] and Title X clinics);
  - interoperability, usability, and, to a lesser extent, privacy and security; and
  - differences between the product available “out of the box” and customized versions of the product.
- **Promote safety** and safe use of health IT.
- **Drive market improvements** in health IT by encouraging new solutions to fill gaps in functionality and potentially attracting new entrants or start-ups.
- **Fill information gaps** on
  - how certified health IT products perform in the real world; and
  - the cost of owning health IT products (pricing structure and total cost of ownership, including initial and ongoing, customization, and interface costs).
- **Minimize burden** on users and developers by a “record once, reuse multiple times” approach, leveraging existing data as much as possible and focusing on a parsimonious, targeted set of measures.
- **Provide frequent updates** so information is not outdated given how quickly the market evolves.

These priorities will be key considerations when selecting criteria and measures based on stakeholder feedback. Health IT developers expressed some concerns that, in practice, much of their products’ performance is driven by customization and the training of end users. However, a recurring theme was that EHR and other health IT developers should be held accountable for the performance of their

products given the real impact on patient outcomes and provider burden these products can have. Several stakeholder views echoed the commenter who suggested: *“Having developers report on how their systems function in real-world settings with real-world clinical variables at play will not only provide more useful information for the end user or ‘acquisition decision-maker’ but also provide a better mechanism for holding health IT developers accountable for developing truly usable products and drive market competition.”*

In addition, though the Cures Act emphasizes reporting comparative information at the product level, many of the suggested criteria would provide information at the developer level. Therefore, developers may be able to report such information one time if their approach is consistent across products. For example:

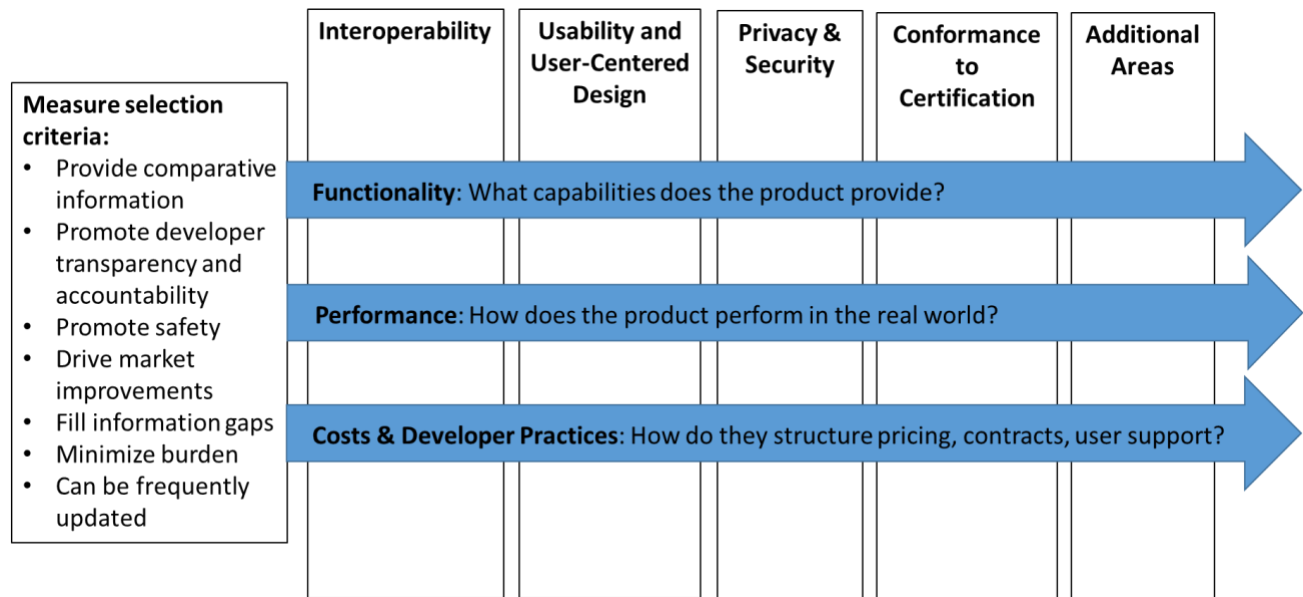
- available training and user support;
- frequency and cost of upgrades/maintenance requirements;
- adherence to privacy and security standards; and
- whether developers require contract clauses such as nondisclosure agreements or requirements that may be categorized as information blocking.

### **Measurement Framework**

In light of these overall priorities reported through stakeholder engagement, we developed a framework to select reporting criteria and develop measures for the EHR Reporting Program. The framework incorporates stakeholder input on overall program priorities and the Cures Act domains of interoperability, usability and user-centered design, privacy and security, conformance to certification testing, and other topics as appropriate (Figure 1).

Given how experts and stakeholders described their priorities in these topics, the framework includes cross-cutting areas of functionality, performance, and cost and developer practices, which were discussed across domains.

**Figure 1. EHR Reporting Program Measurement Framework**



For each framework domain, stakeholders mentioned several specific capabilities and suggested the program report information on the following:

- **functionality:** whether a specific capability is available in the product
- **performance:** how well the capability performs in the real world
- **costs and developer practices:**
  - whether a capability requires additional costs
  - whether contracting limitations affect the use of a capability

In the next stage of this project, we will develop measures based on the priorities that experts and stakeholders identified in these categories, which will be informed by the program priorities outlined above. Because the current program is being developed for implementation in future years, and the health IT market evolves so rapidly, we will focus on measurement and documentation of functions and conformance to certification standards rather than the specific standards or technologies currently used. We will aim to select criteria and measures that are realistic to keep relatively up to date with limited reporting burden. In addition, efforts will be made to select measures that are meaningful to small, rural, and safety net providers and that do not disadvantage smaller and newer developers.

## Priority Topics Identified by Stakeholders

The following sections will summarize the priorities of stakeholders and experts by domain, describing which capabilities they most commonly identified and discussed and the information they thought would be useful regarding the functionality, performance, costs, and developer practices related to those capabilities.

### Interoperability and Data Exchange

Overwhelmingly, stakeholders emphasized interoperability as an important category for the reporting program that could drive improvements in the market. Stakeholders described current 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 “information blocking” by developers. Similar concerns were shared by end users of certified health IT products and their trading partners (such as those in behavioral health, LTPAC, and public health).

Central to the comments was a frustration with the interfaces required for exchange by certified health IT products relative to both cost and capabilities. As a commenter stated, *“When people first purchased their EHR and then discovered they had to purchase expensive interfaces in order to exchange with an HIE, that was very distressing for them—they thought that was provided and that their EHR included everything they needed.”*

In addition to issues with interfaces, stakeholders were particularly interested in specific information on products’ reporting capabilities, exchange with various entities including trading partners, standards versions, and application programming interfaces (APIs) supporting interoperability and interoperability measurement. These topics are presented within the framework categories below.

### Functionality

The measurement of the capability and performance of certified health IT products in supporting interoperability activities was identified as a high priority by stakeholders. They identified the importance of product functionality and often mentioned the program should prioritize providing information on a product’s capabilities related to exchange with various entities, reporting, and specific standards used in support of interoperability and data exchange.

#### *Exchange with Various Entities*

Commenters identified measuring the ability to exchange data with various entities and the ability to use the exchanged data as key criteria for the Reporting Program. These abilities can be categorized as exchange with (1) regional and national networks, (2) specific trading partners, (3) consumer-facing applications and services, and (4) intra-organizational connectivity. Specific suggestions include documentation of the product's capability to:

- exchange with regional and national networks, including
  - names and numbers of regional HIE connections,
  - support for direct messaging, including integration into workflow,
  - support and integration with national standards-based initiatives, such as the CommonWell network and the Carequality framework,
  - connection with eHealth Exchange, both point-to-point and hub-based, and
  - patient-matching performance based upon exchange through each type of network;
- exchange capability with specific trading partners, including
  - bidirectional exchanges with federal, state, and local governments (names and numbers),
  - access to and utilization of provider directories,
  - support for payer inquiries,
  - types of exchange supported with long-term post-acute care and behavioral health providers,
  - support of prescription drug monitoring program (PDMP) connectivity through both HIEs and portal access,
  - exchange capability with school nurse data systems,
  - support of telehealth consultations, and
  - registry exchange (detailed in the next section);
- 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; and
- perform intra-organizational exchanges, including
  - integrating with medical devices (e.g., ICD devices) within a healthcare system, and
  - integrating with practice management software.

Many of these suggested criteria are currently part of the certification process and self-reported in the Certified Health IT Product List (CHPL). Stakeholders recommended providing more detailed information than whether the system can accomplish the task and instead including some measures of performance as discussed in the performance section. Intra-organizational exchange has not been considered for measurement in the past and does not strictly fit into the interoperability and data exchange domain, but multiple stakeholders identified it as important criterion for consideration.

### *Reporting Capabilities*

The ability to submit, edit, and retrieve data from registries and other sources was one of the most frequently commented on topics. In particular, documenting health IT products' quality reporting capabilities, including specific lists of the quality reports a product can create and submit, was a top priority. Multiple commenters noted the need for the simple measurement of "how many registries the EHRs interface with," but others were interested in the specific registries supported.

Suggested interoperable reporting capability criteria fell into in three general categories: the types of registries and reports supported, functionality characteristics of the product, and technical characteristics. Specific suggestions for reporting criteria include a product's capabilities regarding the following:

- registries and reports supported:
  - bidirectional exchange with immunization registries (a consistently cited criterion),
  - names of specific state and federal programs supported (e.g., MIPS, CPC+, UDS, MDS, OPA, CDC, other state and federal programs, etc.),
  - submitting pediatric quality measures, including those for children with special health needs,
  - submitting to specialty registries (e.g., ophthalmology), and
  - distinguishing product support between registries that use standards-based exchange of data and registries that use nonstandard or proprietary exchange methods;
- technical characteristics:
  - providing information on the format and methods of how reports are submitted (e.g., HL7 V2, file transfer, C-CDA, FHIR, Direct),
  - FHIR resources available for specific reporting use cases, and



- distinguishing between a lack of customer requests for registry connectivity and the inability to connect to registries.

Suggested measures for reporting capabilities included registry interoperability and the ability to create, submit, and retrieve specific standardized reports. As with other domains, stakeholders felt reporting measures need to move beyond the binary ability to connect and instead evaluate the discrete functions of successful submission and retrieval. Another suggested measure was the ability to edit data resident in a registry. Given the large number of registries, commenters suggested the program present information on each certified product on the ability to edit data in commonly used federal, state, and specialty registries.

### *Standards, Versions, and APIs Supporting Interoperability*

In terms of interoperability, commenters suggested specific criteria concerning a product's technical characteristics. These fell into three categories: API functionality, standards supported, and technical implementation of those standards:

- API functionality characteristics included
  - list of use cases supported by APIs,
  - list of third-party API applications supported,
  - identification of FHIR resources supporting exchange with specific trading partners, including registries, and
  - ability to generate C-CDA documents using FHIR specifications;
- Standards supported included
  - standards and algorithms used in patient matching,
  - standards supported for sharing image files (e.g., scanned documents, ECGs, diagnostic imaging),
  - use of recognized updated best practice standards, as identified in the Interoperability Standards Advisory (ISA),
  - version of US Core Data for Interoperability (USCDI) supported, and
  - support of the future Trusted Exchange Framework & Common Agreement (TEFCA);
- Technical implementation of standards included
  - methods used to maintain and track data provenance,
  - electronic health case reporting using HL-7 standards for both the report and the reportability response, and

- data mapping measures for exchanged data (incongruent implementation of standards, misaligned standards, semantics, inconsistent implementation).

Suggested measurement for these criteria included the identification of the specific standards for version(s) supported by each product and the confirmation of the support for these standards. There may be opportunity to align measures on these topics with ONC's Interoperability Standards Measurement Framework and related efforts. Additional measures included (1) an actual count/report of the number of interfaces associated with a specific criterion to ensure that interfaces are deployed in real-world use and not just certified and (2) a message or traffic count. Specific recommendations for Direct messaging included the number of Direct messages sent per patient, number of messages received per patient, number of direct addresses maintained per provider, the number of messages received that result in the integration of discrete clinical data (e.g., problems, allergies, medications, immunizations, results).

## **Performance**

Stakeholders commented on the performance of the certified products as distinct from the functions supported. The standard criticism was that the measure of the ability to accomplish an interoperability-related task or support a use case is different from how well and efficiently that task is performed in the real world. Specific criteria were recommended related to exchange with various entities, reporting capabilities, and standards.

### *Exchange with Various Entities*

The most general performance comment was the absence or lack of interoperability because of technical issues, regardless of costs. Commenters' suggested direct measures of the performance of exchange with various entities were primarily descriptive and consisted of counts.

- The most common suggestion for the measurement of performance were numeric counts, including
  - the number of connections and/or the number of exchange transactions,
  - the identification of entities with which the developer has established interoperable connections, by stakeholder category, and
  - additional recommended approaches, such as customer surveys or customer attestations relative to interoperability performance;
- Numerous stakeholders commented on interface requirements and performance, including

- the need for new interfaces to support new exchange partners, and
- continual interface upgrades and their frequency and costs.

### *Reporting Capabilities*

Stakeholders indicated a significant frustration with the ability to connect with registries and databases associated with clinical measurement requirements. In addition, the ability to extract data and write reports in an exportable format often required consultants or the purchase of additional services from the developer. Recommended criteria for performance characteristics include

- customization requirements (i.e., are forms already available or do they need to be created?);
- users' ability to see baseline data used to create measures (rather than a black box reporting system);
- support for automatic reporting to registries;
- ability to create and export standards-based case reports;
- the need for a vendor's customers to hire consultants to extract data and create reports; and
- the timeline for when reports for new measures become available (e.g., within six weeks of announced changes to the MIPS program, or examples of historical turnaround time for new measures).

### *Standards, Versions, and APIs Supporting Interoperability*

Stakeholders were primarily interested in identifying standards, versions, and APIs used in particular versions of products. As discussed in the conformance to certification standards section of this report, there were various criteria and approaches recommended to measure "performance in the real world" by the developer using the specific standards.

### **Costs/Developer Practices**

Costs and developer practices were commonly identified as very important criteria for the program relative to interoperability and data exchange. As previously identified, the cost of interfaces was a commonly cited issue. Additional cost criteria included incremental charges for messaging, report creation, and data conversion. Stakeholders also identified issues with specific developer practices relative to cost transparency as it relates to interoperability that could be addressed through reporting criteria.

Stakeholders also suggested information be available on costs (in dollars, resources, and time) and suggested the following for the criteria related to interfaces and incremental costs:

- Interfaces
  - set-up costs for a common interface (e.g., lab and radiology interfaces),
  - component interface costs (e.g., required licenses, initial installation, and maintenance),
  - frequency of required interface upgrades and associated costs,
  - estimates of the cost of the interface versus the value of information received,
  - cost of point-to-point connections versus hub connections for eHealth Exchange, and
  - Cost for connection on a per registry basis;
- Incremental fees/costs
  - whether the developer charges a fee for each Direct Secure Message (DSM),
  - charges to create reports or update the measures in the report when a change is required,
  - cost of data conversion required to comply with reporting formats and standards, and
  - cost for data portability (e.g., bulk CCD extracts);
- Stakeholders also felt greater transparency is needed on the following developer practices:
  - whether a developer has proposed exceptions to information blocking as part of the proposed interoperability rule,
  - whether the developer provides training on how to use DSM, such as by providing screen shots on how to send a Direct message using their EHR,
  - users' ability to complete quality reporting without developer assistance (including access to roster files), and
  - whether the developer disables functions related to interoperability on an EHR.

In terms of identifying costs and developer practices, stakeholders cited the constraints of non-disclosure agreements (NDAs) in contracts as well as the protection of information as trade secrets and otherwise proprietary information. One commenter cited a potential transparency of the cost and limitations clause of contracts as a significant solution to the problem of costs and developer practices. Commenters also indicated that crowdsourcing solutions for sharing information between shareholders could potentially help address the need for product information while remaining within the constraints of contracts.

## Usability

Information on usability—the extent to which a product supports users to efficiently and effectively achieve their desired goals—was frequently discussed by RFI commenters and stakeholders. One stakeholder emphasized the critical role of usability and the goal of a user-centered tool, explaining, “The more we can get away from creating a tool for compliance purposes to more of a patient- and user-centered tool—that really needs to be in this thought process.” Commenters discussed the many aspects of health IT that make it easy or difficult to use, often reporting that information about these characteristics is not currently available for comparison purposes when considering purchasing or upgrading health IT. Measuring usability in a meaningful way was mentioned as a challenge by many stakeholders. These comments were reinforced by conflicting suggestions for how to best construct measures of usability.

Stakeholders also provided thoughtful comments on the questions of usability for whom, highlighting the various users of health IT products. They noted that functions or designs that make a product easy to use for providers may not necessarily make a product easy to use for data analysts or practice administrators. Even among providers, we heard different priorities for usability from individuals representing different provider types and specialties.

## Functionality

Broadly, stakeholders were interested in both understanding the target use cases for a given product and the environment it was intended for (e.g., large hospital system versus small clinic; primary care versus behavioral health or LTPAC; providers versus clinical support staff versus data analysts) as important context needed for information on usability to be meaningful. They were also interested in the full range of features and functionalities available for a given product, to assess not only whether it included the tools they need to achieve their goals but the ease of product use and the extent to which using a given health IT product might be burdensome for users, including providers.

Stakeholders expressed interest in documenting the presence or absence of the following functionalities:

- internal data integration and automated field population (e.g., automatic population of corresponding fields once data are entered anywhere in the product for a given measure, pre-population of templates with patient information, pre-population of templates with provider name and information, automated chart updates from notes);

- customizability (e.g., screen views, tabs, links, charts, reports, templates, alerts, supported languages for forms and patient portal);
- data analytics functionalities (e.g., ability to use the product for analytics, produce feedback reports, access roster files, identify high-risk patients, create data visualizations and graphics);
- population health functionalities (e.g., whether the product includes tools needed for population health analytics, population health–related measures collected, types of analysis supported);
- social determinants of health (SDoH) functionalities (e.g., whether the product supports SDoH-related data collection and to what extent, ability to refer patients to community resources including social services);
- clinical decision support (e.g., integrated clinical guidelines, screening tools, alerts for lab results, integration of data from remote devices);
- patient education support (e.g., integrated health education content suitable for distributing directly to patients, integration with MedlinePlus, provision of educational materials in multiple languages);
- integrated patient portal (rather than requiring a separate patient portal module or product);
- financial, administrative, and billing capabilities (e.g., revenue cycle management, insurance verification, immunization stock management, and a dashboard integrating clinical, operational, and financial data within a practice); and
- other miscellaneous functionalities (e.g., collect patient experience data, collect comprehensive vital statistics data, receive and review images, telemedicine capabilities, and ability to integrate with legacy health IT systems).

Stakeholders were also interested in documenting features that are not currently part of certification but are important for a health IT product to be user friendly, including

- single sign-on access;
- ability to send patient reminders (e.g., through the patient portal, automated reminder calls, Direct messages);
- voice-to-text capabilities (e.g., voice-activated recording, dictation);
- optical character recognition (i.e., ability to encode scanned text and integrate into the product’s data fields);

- remote and mobile accessibility (e.g., access from home computers and tablets, mobile-friendly web interfaces, app availability);
- computing type (software as a service [SaaS], cloud-based, thin client [e.g., Citrix]); and
- speed (e.g., loading time when opening new windows, speed of cloud or remote connections).

Commenters provided feedback on how best to measure the specific features and functionalities that are important to understanding the usability of a health IT product. Suggestions included developing a list of key features and functionalities and either indicating whether each product has that capability or providing a summary of the product's capabilities for each feature or functionality. An alternative suggestion was to create product maturity rating scales that summarize the total number of identified key features and functionalities included in a product (e.g., 1–4 functionalities = basic, 5–9 functionalities = intermediate, 10–14 functionalities = advanced, 15+ functionalities = very advanced).

Stakeholders were also interested in seeing and testing product examples to judge for themselves the usability of specific functionalities in a health IT product. For example, the ability to access an example report or other form or template in the system would allow potential users to assess whether the product would meet their needs and whether they consider the interface intuitive. Beyond making existing documents available, stakeholders also suggested creating consistent and comparable video demonstrations for all products. These videos could walk through a given use case or task, demonstrating the workflow (including the number of clicks, mouse movements, and screen changes) and again allowing potential users to judge the product for themselves. Stakeholders cautioned that it would be important to ensure that videos were purely factual and not marketing products, and some were concerned that the requirement of videos could put undue burden on new entrants to the market relative to longstanding developers and products. There were also some concerns from developers that videos would share proprietary information.

## **Performance**

Beyond documenting the presence or absence of key features and functionalities important for usability, as described above, stakeholders were consistently interested in ways to move beyond using binary yes or no measures such as those used in certification. Stakeholders also suggested the program collect information on usability in the real world through user ratings (e.g., overall assessments, star ratings, open-ended comments) and objective measures of usability (e.g., clickstreams, audit logs, time to task).

Stakeholders, particularly providers and other end users, were very receptive to user ratings as a way to measure usability of health IT products. Suggestions for this type of measurement were broad, consisting of requests to ask product users whether, based on their experience, they consider the product to be user friendly and helpful in achieving their goals. Stakeholders acknowledged that asking for user reviews may result in only gathering feedback from the tails of the user satisfaction distribution—users who like their product and would provide a very positive rating and those who do not like their product and would provide a very negative usability rating. But, many stakeholders were still interested in collecting information on users’ experience despite this limitation. Stakeholders consistently expressed the importance of documenting key characteristics of the users providing reviews (e.g., provider type, patient mix, practice type, years using product, specific product details, version) so that reviews could be interpreted in context and consumers could look for reviews by users like themselves.

Commenters discussed the importance of objective measures of usability, asking for “very specific data and how much time and effort it takes to get to certain things and being able to compare that across vendors.” We identified three primary ways to collect objective measures of usability, as discussed by stakeholders: clickstreams, time required to complete a task, and audit logs. However, a challenge with these types of measures may be capturing the measures in a uniform way across developers that allows for comparison across products.

Clickstreams. Stakeholders were interested in the potential for clickstreams to produce objective and consistent measurement of usability across products by documenting the number of clicks required to accomplish a given task or complete a specific workflow. Though this was an appealing measure to many commenters, some were concerned it might imply that a product requiring more clicks to complete a task is less user friendly. Commenters noted this is not necessarily the case, particularly if additional clicks allow for more complete care or higher-quality outcomes.

Time to task. Stakeholders were somewhat more interested in using time-to-task measures of objective usability than clickstreams, in part because the time required to use a health IT product is perceived as a significant burden on providers. Therefore, the amount of time a task takes, rather than the number of clicks a task takes, was a more intuitive measure for some commenters. But commenters also noted that there is more user-driven variation in time to task. For example, an experienced product user may be able to complete a task faster than a new user with the same product. To account for this variation,



commenters suggested measuring average time across a range of users or classifying times by levels of user expertise.

Audit logs. Finally, some users thought audit logs would be a useful way to collect objective usability data from real-world use. But there were concerns about the readability and interpretability of audit log data, whether developers had the ability to share audit logs (or whether audit log data was instead the property of the practice or system), and comparability of audit logs across developers. There was generally less excitement about audit logs than for time-to-task or clickstream measures.

### *Safety*

End users were particularly interested in documenting functionalities and features to better understand usability of health IT, but members of the developer community and health IT researchers more frequently discussed patient safety issues that may be associated with poor usability. Stakeholders from these groups suggested collecting information on the number and type of patient safety issues reported for a given product to understand its usability. They also suggested documenting the frequency of patient safety alert triggers and the rate at which alerts were overridden by administrators or users in the system. We did not generally hear similar comments about patient safety and alerts from providers or other end users.

To measure safety, commenters shared suggestions of using a Leapfrog test that assesses products' CPOE functions or developing safety-focused reporting criteria based on the ONC SAFER guides. The Pew Charitable Trust and MedStar Health's National Center for Human Factors in Healthcare have also worked to identify and recommend a set of safety-related usability criteria.

### *Provider Burden*

Stakeholders, particularly providers, were concerned about the burden health IT can place on providers and were interested in capturing a range of measures related to burden, including

- documentation time (e.g., time required or spent entering notes, number of places the same data needed to be entered into a health IT product);
- hours required to train people to use a health IT product; and
- frequency of help desk calls or other requests for support.

### **Costs and Developer Practices**

Beyond specific features and functionalities of health IT, stakeholders were interested in understanding the cost of successfully using health IT. We received feedback on the following aspects of cost related to usability:

- cost of the individual functionalities – if not included in the base model, the cost of adding each individual functionality discussed above;
- cost of customization – if a product supports user customization, what are the costs associated with edits (e.g., changing the standard screen view, reorganizing tabs and links, designing their own reports)?
- cost of staffing – the number and type of staff needed to support a health IT product (e.g., the number, type, training, and full-time equivalent hours required for staff working to support a specific health IT product in a practice). Stakeholders reported that this would be especially important for smaller practices, which do not have the same capacity to hire dedicated health IT staff as large health care systems;
- total cost of use – i.e., the cost of using a product for a set time period with a set number of providers, including upgrades, annual fees, per provider costs, and additional fees for a set list of features and functionalities; and
- developer base model structure – stakeholders repeatedly stressed the importance of understanding what is included in the base model of a health IT product (i.e., out of the box) and what requires customization or the purchase of additional modules.

## Security and Privacy

Input from the RFI commenters and stakeholders on privacy and security measures was less common than input on interoperability and usability, but were of particular importance to representatives of rural providers given reports that smaller facilities had fewer resources to prevent security attacks. These comments were generally consistent and focused on security product features, assessments, standards, breaches, and privacy features. Stakeholder feedback in this domain was often related to a desire for greater transparency over whether a product is compliant with 42 CFR Part 2 in relation to the required segmentation of substance use treatment records, which providers have found to be particularly challenging. One RFI commenter gave the example of a rural provider who provides substance use treatment that *“discovered that the EHR they use states they allow the segregation of [substance use disorder] records required for 42 CFR Part 2 does not, in fact, provide the necessary segregation, leaving them to have paper records for their [medication-assisted treatment] while using their EHR for all other care.”* As another stakeholder noted, *“Security and 42 CFR Part 2 is always an industry challenge.”*

### Functionality

Stakeholders named several security and privacy functionalities they thought would be useful for the program to report on.

#### *Security Product Features and Standards Used*

RFI commenters and stakeholders requested identification of whether products have particular security features, including

- two-factor authentication to log on (e.g., a username and password *plus* a code sent to a clinician’s smart phone);
- use of biometric devices to sign on (e.g., fingerprint readers);
- the degree to which health IT products comply with various security standards, such as NIST Cybersecurity Framework, FISMA 800-53, HEALTH ITRUST Certification, Carequality Technical Trust Policy, Version 2.0, and the General Data Protection Regulation (GDPR, an international standard); and
- security standards used for APIs.

#### *Privacy Features*

Commenters and stakeholders were also interested in product privacy features designed to limit improper disclosures of patient records to individuals both *inside* and *outside* of a health care organization.

To manage *internal* access to patients' records within an organization, commenters and stakeholders wanted health IT developers to report if they offered role-based access control, which limits end users' access to only those records or portions thereof that they need to access, or whether the product ensures a given user can only log into one session at a time (to prevent unauthorized access). Some commenters wanted to know if a health IT product can generate audit logs showing which end users have accessed patient information and what operations they have performed (e.g., edit, view, print, download, email).

To manage disclosures of patients' information to individuals *external* to an organization, many commenters and stakeholders—particularly behavioral health providers—asked whether a health IT product can segment sensitive health information within a patient's records (e.g., records about substance use disorder treatment or a minor's sexual health) and how far down the record it can segment the data to shield portions of health records from disclosure, as allowed under federal (e.g., 42 CFR Part 2) and potentially stricter state laws. Unfortunately, though the recent interoperability NPRM has a section about simplifying compliance with 42 CFR Part 2, it is still challenging to measure compliance with this law across developers. Some information that would be useful for developers to disclose include the tools that are offered to comply with 42 CFR Part 2 and the limitations of the system with respect to 42 CFR Part 2.

Commenters also wanted to know if health IT products can electronically document and execute patients' privacy consent directives, which specify with whom patients' records can be shared. They also wanted to know if the health IT product can keep a log of to whom patients' records have been disclosed. Relatedly, knowing if the health IT product allows the patient to choose what part of their electronic health record could be shared and with whom is also important for securing and maintaining consumer trust in electronic health information and exchange.

## Performance

RFI commenters and stakeholders proposed several measures to provide greater transparency around security breaches and patches that occur after the product has been implemented, including:

- ability of the health IT product to provide contemporaneous notification of a security breach or other means of alerting clients;
- average amount of time a developer has taken historically from the point of identifying a security risk to (1) reporting the finding to customers and (2) distributing a security patch to and installing the patch for the end user (i.e., how quickly does the developer respond to security breaches?);
- number and types of security breaches and ransomware attacks involving a given health IT product (e.g., number of breaches in the past 12 months);
- causes of historical security breaches (e.g., external attack, human errors);
- number of currently open security breach cases at customer sites;
- disclosure of any regulatory actions; and
- number of patches required to address security vulnerabilities for each release and upgrade.

Commenters and stakeholders also suggested having independent experts assess products' security or report the results of penetration testing.

## Costs and Developer Practices

In addition, there were recommendations to promote greater transparency around costs and developer practices related to privacy and security, including the following:

- average costs and user downtime associated with security patches;
- cost related to providing specific levels of security;
- whether contracts with providers include "gag clauses," preventing providers from sharing details of security vulnerabilities with others;
- whether developers require providers to send them data (presumably de-identified), and if so, for what purposes they are using that data;
- whether EHR developers conduct or automate data backups; and
- subcontractors' (downstream developers) compliance with privacy and security standards such as HITRUST.

## Conformance to Certification

Stakeholders commonly suggested including criteria related to conformance to health IT certification standards in the Reporting Program. These suggestions were based on concerns that certified products were not functioning as well in the field as they were in the laboratory certification testing process performed by ONC-Authorized Testing Laboratories (ONC-ATLs). Providers suggested the cause of this performance gap may be deficiencies in the product, whereas developers suggested this may owe to providers not using the functionality properly or turning off functionality provided with the product.

Some stakeholders suggested a more stringent certification process and maintenance of certification requirements to protect providers from nonconforming products. Others recommended improvements in reporting post-certification issues back to ONC, such as by improving the current complaint process to collect more specific information and to clearly define follow-up steps. Most commonly, stakeholders strongly urged ONC to reinforce and broaden the scope of the surveillance system for identifying nonconformance in how products perform in the real world.

At a basic level, suggestions in this category included measures that are reported on the CHPL, such as each health IT product's certification status, including which certification edition requirements it had met, whether it had at any time become decertified, and whether the product is under surveillance by ONC because of customer complaints. Stakeholders were also interested in past non-conformities. Some experts and stakeholders saw utility in this type of information for current users of a given certified health IT product to alert them of an issue if the developer does not directly notify them. For example, as one expert said, *"You can have situations where an EHR is not following their certification and their clients aren't aware of it because it's buried deep in CHPL."*

## Functionality

Some experts and stakeholders desired more transparency on the results of conformance testing with more detail beyond the dichotomous outcome measures that are reported on the CHPL. One expert highlighted the utility of this information for making comparisons, saying, *"As a buyer, I'd be interested in which EHR meets the bare minimum and those that go above and beyond"* in terms of how certification criteria were met.

Examples of suggestions in this category include the following:

- which user-centered design test methodology was used in certification testing;

- number of interfaces associated with a specific product's certification criteria (to prevent the prior issue with EHR systems that completed ONC certification but did not implement/deploy their system with the interfaces required to implement the certified functionality);
- encryption and hashing algorithms used to comply with certification criteria;
- risk assessment methodologies (e.g., what vulnerability assessment protocol developers used) and results (e.g., what issues arose, how remediations are tested, and what continuous scanning penetration testing looks like);
- whether Disaster Recovery Plans (DRP) are part of the security risk assessment (there was also a suggestion that the DRPs be made public); and
- what auditable events the product can report on, such as time stamp initial entry, modification, or exchange of data, and identify the actor/principal taking the action as required by users' scope of practice, organizational policy, or jurisdiction law.

This type of information is reported by developers to their ONC-Authorized Certification Bodies (ONC-ACBs) as part of the certification process and could be made publicly available. Another suggestion was to have developers provide more information on how they've implemented different certification criteria, in addition to their attestation. However, there were concerns that developer self-assessments would not be verified.

An additional suggestion was to identify if the EHR has successfully completed other non-ONC conformance testing (e.g., The eHealth Exchange's Product Testing Program, and the Radiological Society of North America's Image Share Validation Testing Program).

## **Performance**

A more common priority was for the EHR Reporting Program to provide information, beyond details on certification testing, regarding whether products perform according to these standards in the real world, most commonly suggested through *"post-acquisition/post-implementation surveillance and improvement of certified technology."* In addition to being helpful to potential and current users of a product, it was suggested this information would *"enable health IT developers to improve on their products' performance. This closed-loop approach is necessary to ensure next-generation product improvements are based on real-world end-user feedback."* There were many ideas for how ongoing surveillance of performance in the real world could be achieved:

- create a developer scorecard using MIPS aggregated data that demonstrates end-user success rates in submitting data and average MIPS scores (or, rather than MIPS, any other national initiative that is a CMS or ONC priority);
- leverage real-world production data currently available through certified health IT. For example, one well-known developer has the capacity to report how frequently a summary-of-care record failed to send for an ordered care transition. In this example, users can see if the failure occurred in the ordering workflow (e.g., if there is no known Direct address), if the failure occurred in transit (e.g., a Health Information Service Provider's [HISP's] failure), and whether the transaction was received and acknowledged by the recipient system;
- connect-a-thons to bring groups together to check on conformance to a standard;
- random audits of certified health IT developers and/or audits of ONC-Authorized Certification Bodies (ONC-ACB), or a similar mechanism, to ensure ONC-ACBs conduct random in-field surveillance of certified EHRs (which ONC has proposed under the Cures Act that ONC-ACBs may conduct at their discretion); and
- reporting complaints, litigation, or class-action lawsuits pending with developers that are the result of an inability to meet reporting requirements, information blocking, or other issues with the software resulting in losses to client health care organizations.

Several measurement approaches were suggested to collect information on performance in the real world. The first consisted of user surveys 6 or 12 months after implementation, and the second consisted of field audits. It was suggested ONC should require public reporting of the outcomes of those audits, including identified deficiencies and corrective actions. Another suggestion was to get performance statistics from the developer based on production data.

An additional opportunity to collect information in this area may be through the new requirement for maintenance of certification that health IT developers successfully test the real-world use of their products for interoperability in the setting where the product will be marketed. A recent ONC Interoperability NPRM outlines what successful "real-world testing" means for this condition of certification.

### **Costs and Developer Practices**



Stakeholders suggested standardizing what the cost and limitations disclosure needs to look like and building that into the CHPL to *“provide that information with a couple of clicks instead of having to interpret some legal mumbo jumbo.”* Examples of limitations for disclosure include the following:

- whether there is an additional cost for data portability and the user needs to buy that functionality – if the user never attempts to use that data portability functionality, they may never know they don’t have it and are therefore technically not using a fully certified product; and
- whether in the user’s contract the product automatically upgrades to the next version with implementation costs and other limitations that were not originally disclosed to the user – the user may not be aware of the change and attest to using a certified EHR, when, in fact, they are not.

Stakeholders also requested information on how long it takes developers to implement capabilities to report on incentive program measures when a change in those measures occurs. There were reports that at times the EHR developers do not roll out the changes until late in the program year, when it may be too late for the providers to incorporate and meet the requirements of the incentive program for that year. Or, in many cases, the EHR developer reportedly charges the provider to add the necessary component and the provider cannot afford the extra cost.

## Additional Areas

The Cures Act includes “Other Topics as Appropriate” as a domain, which generated a number of stakeholder ideas. However, some RFI commenters cautioned that this domain was too broad and had the potential to create reporting burdens if not carefully curated. Some of the feedback we received from stakeholders in this domain aligned with specified domains. In those cases, we included the topics earlier in the report. For example, we received many comments about cost, which have been integrated as a cross-cutting area for each domain discussed. We also received comments about customization, which have been integrated into the usability section, and quality reporting capabilities, which have been integrated into the interoperability and data exchange section. Here, we present comments on patient portals, a frequently discussed topic outside the scope of the key domains. We also present additional comments we heard about the cross-cutting areas of cost and developer practices that were not specific to the key domains discussed earlier.

### Patient Portals

In addition to being discussed within the context of usability, health IT products’ support of patient portals arose during conversations about the other topics domain. One commenter noted they received *“a lot of complaints from our hospitals on patient portals. They’re really not satisfied with the patient portal that their EMR has.”* Another explained, *“I think this is the kind of thing that hasn’t kept up with the technology, and maybe [we should be] looking at something else to exchange that information with patients.”* Stakeholders discussed patient portals both as freestanding health IT products and as features of larger integrated health IT products, such as EHRs. Given the industry appears to be moving towards making information available to patients through APIs and consumer-facing applications, information relevant to these stakeholder’s concerns will be incorporated through criteria developed in the interoperability domain, as previously described under *“Exchange with Various Entities”* in that section).

### **Functionality**

Regardless of structure, stakeholders identified the following features as important to a high-quality patient portal:

- ability for patients to access their complete medical records (both electronically and as a printable version);
- mobile access (through a mobile-friendly website or an app);
- bidirectional information sharing between patients and providers;
- easy enrollment into the portal and account creation;

- capacity to send automated patient summaries;
- appointment scheduling, check in, and management;
- ability for patients to complete forms through patient portal rather than in person; and
- patient access in a variety of languages.

## **Performance**

Beyond measuring specific functionalities, stakeholders were interested in capturing overall patient portal quality. Suggested measures related to patient portals included the share of patients with access to a patient portal who used it and measures of repeated use. However, some stakeholders cautioned that this type of measurement may reflect the patient population (e.g., age, engagement, access to internet) rather than the quality of the patient portal itself.

## **Costs and Developer Practices**

As with other functionalities, stakeholders were interested to know whether the costs of a patient portal were included in the base price for health IT, whether the patient portal would be a single add-on cost, or whether each aspect of the patient portal would have specific costs (e.g., cost per patient, cost per message sent, cost per lab connection).

### Costs

As documented in each earlier section, cost was a frequently discussed topic by stakeholders. Nearly all stakeholders who provided feedback requested information about the overall cost of owning health IT. Cost was discussed both broadly (e.g., the total cost of owning a health IT product) and specifically (e.g., itemized costs of specific features or functionalities). We received feedback from stakeholders requesting information on the following cost-related areas, in addition to what has been reported within the other domains:

- total cost of usability (i.e., the cost of using a product for a set time period with a set number of providers, including upgrades, annual fees, per provider costs, and additional fees for a set list of features and functionalities);
- the cost of staff needed to support the successful use of a health IT product (i.e., the number and type of full-time employees dedicated to the product and their salaries);
- itemized costs of specific features and functionalities (e.g., included in the cost of the product or price to add, one-time versus monthly/annual fees, cost per report run); and

- costs of maintaining a health IT product after initial purchase (e.g., maintenance costs, per provider costs, hosting fees, security fees, developer support, ongoing fees for customized products).

Stakeholders emphasized the importance of transparency when measuring health IT costs, whether measured as a total cost or a la carte. For example, if cost is measured as the total product costs, stakeholders noted the importance of defining clear specifications (e.g., product version, number of providers, any customizations, included features and functionalities). If cost is measured for each feature or functionality, stakeholders reported the need to include all relevant costs for including that feature (e.g., cost to customize, ongoing maintenance costs, costs per report). Another key concern was comparability across products, as pricing structures vary across developers. One suggestion to address this concern was to develop a standard package for a product type with defined features and functionalities (or a specific use case) and require developers to provide a quote for that package. A final suggestion was to document historical costs for existing users and changes over time, rather than collecting new or speculative cost data.

#### Developer Practices

In addition to the developer practices discussed in the earlier sections, commenters also discussed developer support, contractual information, market share, and developer policies related to users switching health IT products.

#### *Developer Support*

Stakeholders suggested collecting data on developer support—the technical support and training provided by the developer to health IT product users. Suggested details to document include the following:

- level and type of installation support (e.g., onsite support, hands-on remote support, product demonstration, written documentation only);
- level and type of upgrade support (e.g., onsite support, hands-on remote support, product demonstration, written documentation only);
- average required time for training;
- available support during typical use (e.g., help desk, video tutorials, written documentation);
- access to dedicated support staff at the developer;
- timeliness of help desk ticket closures; and

- developer support costs (e.g., what is available for free, what is available for an additional cost, how much do additional services cost).

### *Contractual Information*

Stakeholders also wanted to know whether contracts for purchasing health IT included an “out clause”—a cost to getting out of the contract and leaving the product if a user is dissatisfied. End users were most frequently concerned about contract “gag clauses,” which preclude users from sharing information about their experience using a health IT product. Concerns were about documenting not only the use of gag clauses to inform consumer choices when purchasing health IT but also concerns about whether end users would even be able to provide feedback on the health IT they use for the EHR Reporting Program if their contract includes a gag clause. Beyond the EHR Reporting Program, some stakeholders reported that gag clauses had prevented them from discussing best practices and learning from the experiences of other health IT users.

Another issue raised was whether the contract states that the EHR automatically upgrades to the next version with implemented costs and other limitations that were not originally disclosed to the user. It was reported that at times, these automatic updates result in the EHR no longer complying with certification standards.

### *Market Share*

A less commonly discussed topic was market share. Some stakeholders were interested in the share of the market a given product or developer serves, including trends in market share over time. Market share was discussed by users as an important measure to help customers select an established developer or a developer less likely to go out of business. But this also raised concerns for new entrants to the health IT market. Other related measures discussed include the year a company was founded, the number of employees, history of mergers and acquisitions, and how frequently customers left a product for a competitor. Some interest in market share was spurred by wanting to know the target use case and practice type for a given product.

### *Developer Approach to Upgrades*

Stakeholders thought it would be useful to provide potential customers with information on how upgrade processes compare across health IT products. Key factors discussed include:

- timing of the upgrade schedule (e.g., how many upgrades per year, scheduled in advance, always on weekends);

- whether upgrades require practices to go fully offline;
- how long the upgrade process takes (e.g., a few hours, a full weekend); and
- notification processes for upgrades.

Generally, stakeholders were interested in historical information on how upgrades have been handled for a given health IT product in the past.

#### *Developer Policies for Switching Health IT Products*

Remaining stakeholder feedback asked for information about the ability to switch or change health IT products (e.g., costs associated with switching, process for data transfer to a new system, legacy hosting of data on an old system).

## Potential Data Sources and Data Presentation

RFI commenters and stakeholders sometimes suggested existing data sources to potentially draw on for the new EHR Reporting Program or offered thoughts on approaches to collecting new data from health IT developers, clinicians, patients, or others. In this section, we summarize the feedback on these potential data sources, including identified pros and cons, and discuss the potential reporting format for data collected through the EHR Reporting Program.

### Existing Data Sources

The most commonly discussed existing data source during the stakeholder engagement process was the ONC's Certified Health IT Product List (CHPL). CHPL includes a comprehensive listing of EHRs' product versions and health IT modules that have been tested and certified through the ONC Health IT Certification Program. CHPL primarily includes measures with dichotomous variables and does not include ratings from verified users of individual products or information on costs. Key information provided by the CHPL include:

- the name of and contact information for the developer of the certified health IT product;
- health IT product name and version;
- certification status;<sup>4</sup>
- results from ONC surveillance activities to assess whether certified health IT meets the requirements of certification in a controlled testing environment; and<sup>5</sup>
- 61 indicators as to whether the listing was certified to the specified certification criteria.<sup>6</sup>

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<sup>4</sup> Active; Suspended by ONC; Suspended by ONC-ACB; Withdrawn by Developer; Withdrawn by Developer Under Surveillance/Review; Withdrawn by ONC-ACB; Terminated by ONC; Retired

<sup>5</sup> Total surveillance activities (The total number of surveillance activities that were conducted for the corresponding listing, regardless of whether a nonconformity was found); total nonconformities; open conformities.

<sup>6</sup>These measures include: Computerized Provider Order Entry (CPOE) – Medications, CPOE – Laboratory, CPOE – Diagnostic Imaging, Drug-Drug, Drug-Allergy Interaction Checks for CPOE, Demographics, Problem List, Medication List, Medication Allergy List, Clinical Decision Support, Drug-Formulary and Preferred Drug List Checks, Smoking Status, Family Health History, Patient-Specific Education Resources, Implantable Device List, Social, Psychological, and Behavioral Determinants Data, Transitions of Care, Clinical Information Reconciliation and Incorporation, Electronic Prescribing, Common Clinical Data Set Summary Record – Create, Common Clinical Data Set Summary Record – Receive, Data Export, Data Segmentation for Privacy – Send, Data Segmentation for Privacy – Receive, Care Plan, Clinical Quality Measures - Record and Export, Clinical Quality Measures - Import and Calculate, Clinical Quality Measures - Report, Clinical Quality Measures – Filter, Authentication, Access Control, Authorization, Auditable Events and Tamper-Resistance, Audit Report(s), Amendments, Automatic Access Time-out, Emergency Access, End-User Device Encryption, Integrity, Trusted Connection, Auditing Actions on Health Information, Accounting of Disclosures, View, Download, and Transmit to 3rd Party, Secure Messaging, Patient

CHPL is viewed as a high-quality resource in terms of impartiality and reliability, and existing information from this website could be linked to Promoting Interoperability (PI) Program data and incorporated into the EHR Reporting Program. However, to do so, many stakeholders thought that the information in the CHPL would need to be reformatted and expanded to make the tool more robust and user friendly. For example, the CHPL, or a new tool created by the EHR Reporting Program, could be used to gather and present more in-depth, timely, and side-by-side comparison information on areas such as detailed product capabilities, software or other implementation dependencies, and user input and reviews. Some RFI commenters and stakeholders also felt that some of the information on the CHPL site was too technical to be understood by purchasers without an IT background.

Several stakeholders also recommended using existing data from market research organizations such as KLAS, Leading Age, and Gartner. For example, the KLAS Arch Collaborative is a set of common end-user surveys of approximately 200 organizations (100,000 clinician respondents) that focuses on EHR, training, and governance to improve the EHR experience through measurement data.<sup>7</sup> Though these data can provide valuable information on individual measures related to the EHR experience,<sup>8</sup> KLAS does not report out responses by EHR developer. Additional pros and cons of these sources are included in Appendix A.

Some stakeholders also recommended using data collected from clinicians by Medicare and state Medicaid agencies through what were formerly known as the EHR Incentive Programs (now MIPS, Promoting Interoperability). But, many commenters recommended against using these data, because they felt these data do not reflect a health IT product's capability, nor whether a health IT product helps a provider accomplish a given task. Some commenters and stakeholders disagreed about whether to use health IT system log files that capture which buttons users clicked and when. Some suggested looking into this type of data, and others recommended against it because this type of data is not comparable

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Health Information Capture, Transmission to Immunization Registries, Transmission to Public Health Agencies - Syndromic Surveillance, Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results, Transmission to Cancer Registries, Transmission to Public Health Agencies - Electronic Case Reporting, Transmission to Public Health Agencies - Antimicrobial Use and Resistance Reporting, Transmission to Public Health Agencies - Health Care Surveys, Automated Numerator Recording, Automated Measure Calculation, Safety-Enhanced Design, Quality Management System, Accessibility-Centered Design, Consolidated CDA Creation, Application Access - Patient Selection, Application Access - Data Category Request, Application Access - All Data Request, Direct Project, Direct Project, Edge Protocol, and XDR/XDM.

<sup>7</sup> <https://klasresearch.com/arch-collaborative>

<sup>8</sup> The EHR Experience survey instrument can be found here: <https://klasresearch.com/files/assets/pages/usability-studies/base-emr-experience-survey.pdf>



across health IT developer systems and would not provide useful information for clinicians deciding between different products.

Finally, a few commenters and stakeholders mentioned various survey data collected by private-sector groups (e.g., MGMA, IQVIA, and AHA) and the federal government. However, these surveys typically lack information on the health IT developer's product used in a given setting and, even if they include this information, the data are not nuanced enough (e.g., version, implementation specifics) to include in the EHR Reporting Program. Additional research is needed to understand the cost and availability and the number and comparability of specialty- or care setting-specific surveys.

Several RFI commenters recommended consolidating existing health IT comparison resources into a free (or low-cost), user-friendly format. Integrating existing data sources directly into a single website, rather than directing users to external links, would more effectively present comparison data and require less user effort to navigate. For example, a single website (e.g., the CHPL, ONC's Health IT Playbook, or a new EHR Reporting Program website) could consolidate the following information from existing market research organizations (as discussed in Appendix B) and CHPL:

- quantitative metrics (e.g., star ratings) and free-text user reviews;
- certified health IT products' characteristics;
- reviews on key domains (e.g., usability) filterable by provider type, care setting, medical specialty, and practice demographics (e.g., size, rural versus urban) so users can find information from similar providers; and
- transparency about scoring methodologies and processes used to compile information from multiple sources.

Conversely, several RFI commenters cautioned against aggregating existing comparison tools and felt that compiling comparative data from existing resources alone would be insufficient to provide the information needed for the EHR Reporting Program. Existing comparison tools suffer from various limitations (as previously described), and ONC may not know how these other data were collected and therefore be unable to verify it.

## **New Data Sources**

Stakeholders and commenters responding to ONC's RFI offered several potential approaches to collecting new data from EHR developers, clinicians, patients, or others. These approaches include required reporting from EHR developers, voluntary surveys of providers, voluntary crowdsourcing of information from providers or patients, and other approaches. The consensus among stakeholders is that the EHR Reporting Program should not rely exclusively on one of these sources or methods, but should rather include a mix of data and approaches. Details of these approaches and their pros and cons are further discussed below.

### *Data from EHR Developers*

As part of the Cures Act EHR Reporting Program, certified health IT developers are expected to be required to report information on all of their certified technology as a condition of maintaining certification. As previously described, many RFI commenters and stakeholders recommended collecting measures from health IT developers that span the five areas of focus in the Cures Act. Some stakeholders mentioned that some entity would need to continuously verify the accuracy of information submitted by health IT developers and keep the information up to date.

Several stakeholders also recommended collecting data from health IT developers through surprise audits. These audits could require specific reporting or capabilities, without advance notice, to see how well health IT products perform in the field and if developers are accurately reporting information to the EHR Reporting Program. However, some stakeholders were concerned about the potential for surprise audits to burden providers and practices.

Some stakeholders also thought it would be useful for ONC to provide market analysis data of health IT developers that represent all products currently available for purchase. ONC could potentially collect new information through these existing organizations (e.g., KLAS, Leading Age, etc.) and/or conduct some additional interviews through health IT developer focus groups. This approach, however, could be cost prohibitive and difficult to maintain.

One major concern with collecting additional data from health IT developers is that some required measures could be overly burdensome to collect. Any new mandated data collection effort is going to add some burden to developers. The key is to determine if the value from the data being collected is worth this added burden and the costs to the government to collect this information.

## *Surveys of Providers*

Organizations and individuals who commented on collecting new data from health care providers uniformly opposed requiring providers to report any new data but often recommended asking providers to voluntarily submit feedback on their EHRs. Many stakeholders recommended collecting information from clinicians about their health IT products through surveys. These surveys could be used to collect information on topics ranging from broad concepts like satisfaction with health IT (overall and across domains such as usability) to targeted topic areas (e.g., surveys focused exclusively on APIs or EHR conformance to standard). In any survey, questions would need to be developed and tested to ensure respondents are not overwhelmed with too much information. To provide timely information, surveys would also need to be fielded frequently (e.g., biannually or annually). Otherwise the EHR Reporting Program tool would quickly become dated in an ever-changing environment. There were some suggestions that developers could be required to field satisfaction surveys six months after implementation of a new product to measure performance in the real world.

There are several trade-offs associated with clinician surveys to consider. On the one hand, surveys provide an opportunity to collect nationally representative information from providers overall and by various characteristics. On the other hand, stakeholders raised concerns regarding the burden of surveys to providers and the potential for low response rates that could ultimately undermine the quality and utility of the data collected. In addition, some thought simple and short surveys (e.g., five to eight minutes long) would maximize response rates but provide less useful and concrete information relative to longer surveys. Though some stakeholders previously fielded successful clinician surveys, others cited failed attempts because of low response rates. Finally, there are concerns that providers who choose to participate in a survey, even if sampled randomly, may not represent all providers. In the case of satisfaction, in particular, some stakeholders were concerned that only extremely satisfied or extremely dissatisfied providers would choose to complete the survey. There is also the problem with being able to verify that respondents are actual users of the health IT product they reviewed. However, both selection bias and ability to verify users are even larger concerns for crowdsourcing, as further discussed below.

Stakeholders suggested several ways to improve clinician survey response rates. These include providing financial incentives, engaging professional association groups (such as the AMA, nurse practitioner groups, the CIGNA provider group and other insurers, and HIMSS), administering an EHR

survey through CMS as part of the Consumer Assessment of Healthcare Providers & Systems (CAHPS) family of surveys, pushing the survey instrument to both the physician and office manager, and carefully wording the description of the government's EHR Reporting Program and describing how these survey data would benefit end users.

In addition, several stakeholders and RFI commenters suggested giving clinical end users a bonus or credit to help them meet requirements under Medicare's Promoting Interoperability program for hospitals and its MIPS program for clinicians. A few individuals also suggested incorporating data collected from clinicians for the EHR Reporting Program into these existing Medicare programs' reporting requirements to streamline provider requests. Some stakeholders also recommended pushing an immediate online survey to providers when they attest as part of an incentive program, such as MIPS. This survey—along with any other potential clinician survey—could be voluntarily submitted by users of certified health IT, as dictated by the Cures Act. But, some stakeholders did recommend that these surveys should be mandatory.

#### *Crowdsourcing Data from Providers*

Another commonly cited new data source would be reviews submitted by verified users of health IT submitted to the EHR Reporting Program through crowdsourcing (e.g., using Yelp or Amazon-like user reviews and star ratings). The major advantage of this approach is that the information would be easier to gather relative to surveys, the method is less burdensome than surveys, and the findings can be continuously updated as new and existing users submit reviews. The major challenge with crowdsourcing is that responses are likely to be biased—perhaps more so than survey responses; they likely come from those at the tail ends of the distribution—boosters (i.e., developers' references who are enthralled with the EHR system) and those with poor experiences—whereas the greatest number of users (i.e., those in the middle) typically do not submit online reviews. To encourage more individuals to submit unbiased reviews, many stakeholders and RFI commenters recommended offering end users some sort of incentive similar to those that could be used for surveys.

Many RFI commenters and stakeholders acknowledged the risk of fake reviews but felt appropriate policing methods could be established to verify reviewers' identities and/or health IT product use, such as by asking reviewers to confidentially disclose their National Provider Identifier to verify that they are clinicians or registered users of a health IT product (according to existing reporting programs or health IT developers' customer lists). Reviewers could also confidentially identify their

employer, job title, and contact information so that the EHR Reporting Program could contact the user to verify their identity.

Though few suggested that reviewers' identities be revealed publicly, many stakeholders requested that contextual information (e.g., practice size, urban/rural location, specialty type, and years of product use) about users accompany their reviews. Displaying this information would allow those seeking information about a health IT product to assess or filter user reviews by reviewers' characteristics. For example, an ophthalmologist may wish to filter health IT product reviews to only see those submitted by other ophthalmologists, and a primary care provider in a rural area may give more weight to reviews submitted by primary care providers also practicing in rural areas. Those shopping for a new EHR could also be interested in filtering reviews by various characteristics (e.g., geographic region, similar system, specialty, size) and would value the ability to connect with providers or practices similar to themselves.

#### *Other New Sources*

Some less frequently mentioned new data sources include the following:

- asking patients for feedback, such as by adding questions to existing surveys fielded by the federal government or private research firms or electronically inviting patients to complete a survey immediately after logging out of a patient portal. These surveys could capture various data, including patient reported outcomes and experience with EHRs and patient portals;
- asking states to do environmental scans to collect information. However, this can be time consuming, expensive, burdensome, and difficult to sustain;
- additional usability testing (e.g., pre- and posttesting) beyond the lab testing conducted through the CHPL. Posttesting outside a lab could verify the quality and veracity of the information provided by health IT developers and potentially gauge errors (and corrections) within the system. While some thought additional usability test would be helpful, others were concerned about the costs and whether the information from these tests would help purchasers of certified health IT products because of a lack of comparability and appropriateness of measures; and
- specific use case information, which could potentially be provided by health IT developers or providers (e.g., ask users what their top use cases are).

## Reporting Format

As part of the stakeholder engagement process, we collected feedback on an example of an online tool where users can voluntarily self-report, search, and compare data and reviews on a product's performance.<sup>9</sup>

Stakeholders had very positive reactions to the example reporting format. The identified pros and cons of the example tool are consistent with the information discussed in the crowdsourcing section above. Based on stakeholder feedback, the most important features and recommendations for future design of the EHR Reporting Program tool include the following:

- overall star ratings, consistent with purchasing decisions in other industries, as well as more detailed information and reviews by subcategories;
- the ability to have apples-to-apples comparisons of various health IT products. This would be challenging as it requires making sure the categories are reliable, consistent, and objective to ensure comparability across various certified EHR products and versions. In many cases, comparison is difficult because purchased products are not specifically part of the certification bundle and are individually tailored;
- the ability to slice data by various provider characteristics (e.g., practice specialty, size, geography, user type contributing the information) and health IT product characteristics (e.g., product type, version, key functionalities) and sort the data in various ways (e.g., alphabetical order, number of user reviewers, average rating);
- knowing who transitions between different EHR products;
- the ability to connect with or see reviews from similar practitioners and access health IT-focused communities outside of EHR developers;
- usability and user-friendliness of the tool (e.g., create a simplified dashboard that is less technical);
- determining whether the tool should be limited to certified health IT products only;
- ensuring the tool includes the right information and asks the right type and amount of questions by doing the following:

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<sup>9</sup> The example shared for stakeholder feedback was InteropSelect, a separate project that was established through a cooperative agreement funded by ONC and developed by researchers at the University of California, San Francisco. InteropSelect uses crowdsourcing to obtain user reviews on purchasing health care connectivity solutions with the goal of increasing transparency.

- not making the reporting too broad, too complex, or too fast. Create a tool and get the industry to respond to it, then engage the users to react to it, and then update accordingly, and
- ensuring parsimonious prioritization of the data to be collected and determining the optimal number of criteria reported based on value and usefulness to the users. Some thought simple measures (e.g., overall satisfaction) would not be useful and that more specific questions would provide more valuable feedback, but others thought a more simplified approach with fewer questions/ratings would be better for both clinicians (i.e., fewer cognitive and usability burdens) and EHR developers (i.e., fewer reporting burdens);
- making the tool sustainable and frequently update it in a rapidly changing environment;
- combining the user-submitted reviews with other resources, such as CHPL and survey information; and
- figuring out how to include small and new developers.

## Conclusion

To summarize, stakeholders expressed that the EHR Reporting Program will **provide comparative information** on certified health IT products' basic functionalities; **promote transparency and accountability** among developers for their products' performance, particularly related to interoperability, usability, privacy and security, and provider's ability to meet reporting requirements; **promote safety** and safe health IT use; **drive market improvements** in health IT by encouraging new solutions to fill gaps in functionality and potentially attracting new entrants or start-ups; **fill information gaps** on costs and how certified health IT products perform in the real world; and **minimize burden** on users and developers, leveraging existing data as much as possible and focusing on a parsimonious, targeted set of measures. Stakeholders also emphasized that information collected as part of the EHR Reporting program needs to be **frequently updated** so information is not outdated, given how quickly the market evolves.

Overall, this report summarized nearly 200 stakeholder topics for potential measurement, across the Cures Act domains of interoperability, usability and user-centered design, privacy and security, conformance to certification testing, and other topics as appropriate. As a first step to narrow down these topics, Table 1 below lists high-priority topic areas identified by stakeholders, based on the project team's qualitative assessment notes from all feedback activities. Most of these topics are concentrated in the interoperability and usability domains and span cross-cutting areas of functionality, performance, and cost and developer practices. The potential data sources that can be used to develop measures in these areas also vary but are concentrated among certified health IT developers and users (for whom data collection will be voluntary).

Upon receiving feedback from ONC and the HITAC, the next step for this project is to further refine the high-priority topics and develop a firmer assessment of the methodological approach to collect data on these measures. This step will consider the following factors:

- developing a set of draft reporting criteria (i.e., precise measures) based on these high-priority topics, drawing upon measurement experts at Urban and HTS;
- determining to what extent existing data sources (such as CHPL) could be used to create these measures or if new data collection efforts would be needed (e.g., additional vendor reporting requirements and/or voluntary user-submitted reviews or survey responses);



- when necessary, assessing the burden (e.g., low, medium, or high) associated with new reporting requirements for vendors and new data collection efforts among users (e.g., surveys versus crowdsourcing); and
- considering trade-offs between the usefulness and burden of each measure and selecting measures with high value.

After this set of measures is developed, each criterion will undergo cognitive and feasibility testing with a small sample of certified health IT developers and end users. For this task, we will draw upon respondents to the RFI comments, existing contacts from the stakeholder engagement process, and cognitive/feasibility testing experts at Urban and HTS. Next, we plan on posting the proposed reporting criteria online for public comment in mid-2020, after we revise the measures based on the cognitive and feasibility testing. We would then finalize our data collection tools and methods based on public comment, begin data collection in early 2022, release comparison information to the public in late 2022, and collect feedback from stakeholders in 2023 to inform the future of the EHR Reporting Program.

**Table 1. High-Priority Measure Topics Identified by Stakeholders, by Domain Area**

Topic for Measurement	Potential Data Sources	Cross-Cutting Area
<i>Interoperability and Data Exchange</i>		
Exchange with national networks (eHX, DirectTrust, Commonwell)	Developers, networks, PI	Performance
HIE/HIO interoperability	Developers, HIE/HIO, SHIEC, PI	Performance
Submit/edit/retrieve functionality with registries (state, federal, specialized)	Developers, users, registries	Performance
Create and submit standardized report on timely basis without added fees	Developers, users, registries	Costs/practices
PDMP integration and/or portal support by state	Developers, states	Performance
Standards and versions supported (e.g., ISA)	Developers, ONC, HL-7, IHE	Functionality
API use cases supported	Developers, HL-7	Functionality
Interfaces (functionality, costs, maintenance, upgrades)	Developers, users	Costs/practices
Interoperability with laboratories, imaging, and diagnostic tests	Developers, associations, users	Performance
Patient matching when exchanging data with nonaffiliates	Developers, users	Functionality
Functionality supported in consumer-facing applications	Developers, users	Costs/practices
Interoperability with nonaffiliated entities (e.g., burden to extract/use data)	Developers, users	Costs/practices
<i>Usability</i>		
Target use case for the health IT product	Developers	Functionality
Target end users and/or care settings for the health IT product	Developers	Functionality
Ease of installation of health IT product	Developers, users	Performance
Standard available features and functionalities (list and/or maturity rating)	Developers	Functionality
Customized available features and functionalities (list and/or maturity rating)	Developers	Functionality
Subjective usability - overall usability (rating and/or open-ended comments)	Users	Performance
Objective usability - clickstream for use case	Developers, users	Performance
Objective usability - time to task for use case	Developers, users	Performance
Objective usability - audit log for use case	Developers, users	Performance
Objective usability - video demonstration for use case	Developers	Performance
Objective usability - product examples (reports, forms, screen shots)	Developers	Performance
Objective usability - documentation time for use case	Developers, users	Performance
Safety	Developers, SAFER*, NQF*, Leapfrog*, Pew/MedStar*	Performance

Topic for Measurement	Potential Data Sources	Cross-Cutting Area
<i>Security and Privacy</i>		
Two-factor authentication	Developers	Functionality
Compliance with security standards	Developers	Functionality
Role-based access control	Developers	Functionality
42 CFR Part 2	Developers	Functionality
Number and type of security breaches and ransomware attacks	Developers	Performance
Disclosure of any regulatory actions	Developers	Performance
Number of security patches required to address security vulnerabilities		
<i>Conformance to Certification</i>		
Successful attestation to PI requirements	Repositories, developers	Performance
Certification status (editions met, nonconformities, surveillance activity)	CHPL	Functionality
Nonconformance in the real world	Real world testing, users	Performance
Additional costs for product to meet certification requirements	Developer, users	Costs/practices
Length of time to implement changes in measures for PI	Developer, users	Costs/practices
<i>Additional Areas</i>		
Total cost of health IT product ownership (over period of time)	Developers, users	Costs/practices
Cost of staffing to support health IT product	Users	Costs/practices
Itemized cost of features and functionalities for health IT product	Developers	Costs/practices
Cost of customization for health IT product	Developers	Costs/practices
Developer support (training, call center, on-site, etc.)	Developers, users	Costs/practices
Contractual information - "out clauses"	Developers, users	Costs/practices
Contractual information - "gag clauses"	Developers, users	Costs/practices
Market share	Developers, PI attestations, IQVIA survey	Costs/practices
Developer approaches to updates and upgrades (frequency, downtime)	Developers, users	Costs/practices

\*Potential measures sources