The American Medical Association (AMA) appreciates the opportunity to respond to the Office of the National Coordinator for Health Information Technology's (ONC) request for information (RFI) on the Electronic Health Record (EHR) Reporting Program as established in Section 4002 of the 21st Century Cures Act (Cures).

Enabling physicians to be more informed consumers of certified health information technology (CEHRT) is critical to improve the selection, purchasing, and implementation of CEHRT. Physicians do not have sufficient information or data to accurately compare products, nor have they been instilled with equitable consumer power to shift or sway EHR market forces. Since utilization of CEHRT is required by many Centers for Medicare & Medicaid Services' (CMS) physician reporting programs, its use has proliferated. As such, the AMA supports ONC's efforts to better inform physicians and other consumers of CEHRT performance. Therefore, **the goal of the EHR Reporting Program should be focused on products becoming more effective at supporting patient treatment and care coordination rather than just addressing CMS program requirements.**

We are further encouraged by the opportunity to inform health information technology (health IT) development based on real-world use of products and services. The AMA continues to highlight that health IT development is bound too closely with federal reporting program and certification requirements rather than the needs of patients and physicians. Certification should be viewed as a floor, and more must be done to balance legislative and regulatory requirements with the consequences of regulating innovation out of technology development.

Through certification, health IT developers are required to submit reporting criteria on: security; interoperability; usability and user-centered design; conformance to certification testing; and other categories as appropriate to measure the performance of CEHRT. Coupling CEHRT performance reporting with condition and maintenance certification requirements builds on ONC's 2016 Enhanced Oversight and Accountability final rule. The AMA supports this framework as it enhances health IT vendors' accountability for product performance and adds "teeth" to their ongoing certification conformance, which is leveraged through ONC-initiated corrective action plans and certification suspension or termination.

Close the Product Development Loop

While enabling physicians and other providers to make better purchasing decisions is an important goal, we note that most hospitals and physicians have already purchased CEHRT.[1] In addition to informing purchasing decisions, the EHR Reporting Program should also be leveraged to provide vital user data, based on objective and subjective information, that enables 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. While we recognize Cures does not explicitly direct HHS to use collected information in this fashion, not leveraging this vital data would be a lost opportunity. **We ask that ONC: 1) work closely with end-users and the independent entity chosen to administer the EHR Reporting Program to disseminate program information in an easily accessible, digitally consumable, and consistent manner; 2) where appropriate, utilize program**

[1] https://dashboard.healthit.gov/apps/health-information-technology-data-summaries.php?state=National&cat9=all+data#summary-data

information to inform ONC's Certification Program and future rulemaking; and 3) strongly urge health IT developers to proactively improve their products' performance and functionality using information gathered in the program. It is vital that ONC openly encourage health IT developers to act on this information since the alternative would be further top-down regulation and prescriptive requirements on CEHRT design.

EHR Vendor-assisted Reporting

ONC is seeking input on how best to use CMS' EHR Reporting Program information. ONC should use this information to reduce physician burden. Studies have identified significant physician burden associated with Meaningful Use and Advancing Care Information measure reporting.[2,3] Rebranding these programs as the Promoting Interoperability (PI) Program does not ameliorate many of those issues. Public comments on CMS' 2019 Quality Payment Program proposed rule reflect concerns from physician and medical professional organizations. The AMA shares many of these concerns and believes HHS has an opportunity to shift reporting burden away from the clinical community by utilizing ONC's EHR Reporting Program as an alternative. Indeed, ONC suggests that PI reporting could contribute to the EHR Reporting Program; however, the program's launch is years away. **In the meantime, the AMA encourages ONC and CMS to leverage EHR vendor-generated information to reduce physician burden and to meet both agency's needs to collect data on EHR usage.** This change can be made immediately.

ONC should work with CMS to leverage EHR data generated as a byproduct of PI participation. EHR vendors already track and record many data points used for PI reporting, so there is no need to continue to use physicians as reporting intermediaries. For instance, CMS' "Support Electronic Referral Loops by Receiving and Incorporating Health Information" measure lumps summary of care records received and the reconciliation of clinical information into one process. Physicians are required to manage and report both the acceptance of summary documents and the reconciliation process. This tasks physicians with juggling the technical aspect of interoperability, i.e., digital document capture and incorporation, and the laborious process of reconciliation. In fact, in our conversations one physician described information reconciliation in an EHR as "overwhelming, with a lot of non-meaningful noise."

Instead, more clarity is needed on whether the EHR was able to use the summary of care document without burdening the physician, whether the EHR was able to provide the physician with usable and actionable clinical information in a format that supports clinical decision making, and if the EHR enabled a closed-loop referral. This type and level of information is far more meaningful and valuable to physicians, CMS, and ONC, and should be supplied by the EHR developer. This information would expose the usefulness of the EHR, if the EHR could accommodate the needs of the physician, whether the EHR contributed to or detracted from patient care, and whether the EHR supported the goal of health information exchange. Second, it would provide measurable data on both the usability and

---

[2] G Talley Holman, Steven E Waldren, John W Beasley, Deborah J Cohen, Lawrence D Dardick, Chester H Fox, Jenna Marquard, Ryan Mullins, Charles Q North, Matt Rafalski, A Joy Rivera, Tosha B Wetterneck; Meaningful use's benefits and burdens for US family physicians, *Journal of the American Medical Informatics Association*, Volume 25, Issue 6, 1 June 2018, Pages 694–701, https://doi.org/10.1093/jamia/ocx158

[3] MGMA Regulatory Relief Survey, October 2018, Available at https://www.mgma.com/getattachment/0dcef899-fe2c-4225-ac94-5820df6475cf/MGMA-Regulatory-Relief-Survey-2018.pdf.aspx?lang=en-US&ext=.pd, Accessed October 2018.

interoperability of EHRs in real-world settings. Opportunely, because EHRs already capture what functionalities are used to perform tasks, EHR vendors should directly provide such information to CMS and ONC. This data capture mechanism also conveniently provides an audit trail for CMS.

ONC should work with CMS to implement a "record once, reuse multiple times" approach, leveraging EHR-captured data for both ONC's EHR Reporting Program and CMS' EHR Reporting Programs (e.g., PI). To be clear, the intent is to reduce the reporting requirements on physicians by using EHR-captured data—provided by the EHR vendor—as an alternative, supplement, or direct replacement for physician reporting in programs like PI. This data would contribute to EHR performance measurement needs of both agencies. Vendors could provide EHR user data by actual user, type of clinician, medical specialty, health facility type, geographic location, or any number of other valuable methods to provide useful real-world data while also reducing physician reporting burden. The AMA strongly suggests ONC work with CMS to identify a plan to operationalize this concept. We offer our assistance in further reducing physician burden through this and other novel approaches.

The AMA appreciates the opportunity to provide these recommendations and looks forward to working collaboratively with ONC to implement the EHR Reporting Program. We have attached additional recommendations, comments, and our response to specific RFI questions.

Cross-Cutting Topics	ONC Questions	AMA Answers
Existing Data Sources	Please identify any sources of health IT comparison information that were not in the EHR Compare Report that would be helpful as potential reporting criteria are considered. In addition, please comment on whether any of the sources of health IT comparison information that were available at the time of the EHR Compare Report have changed notably or are no longer available.	The AMA suggests that ONC leverage data collected by ONC-Accredited Certification Bodies (ACBs). ONC regulations require ACBs to conduct reactive surveillance, which refers to the examination of systems when they become aware of areas that may not conform to certification criteria, including around safety-related functions. Similarly, ACBs must conduct random surveillance of Certified Electronic Health Record Technology (CEHRT). The findings from ACBs' reactive and random surveillance should be summarized and made available via the Reporting Program. Furthermore, ONC may conduct, as part of its oversight function, onsite reviews of CEHRT independent of or related to ACBs' surveillance. ONC already provides information when CEHRT vendors are undergoing corrective action plans or have their certification suspended or terminated. Information posted on the Certified Health Information Technology Product List (CHPL) should be incorporated in the Reporting Program. For example, the ONC CHPL contains those products that have been tested and certified by ONC. In addition, the CHPL contains a list of certified health IT products that have elements that do not conform with the agency's EHR certification criteria. The developers of these products must file a corrective action plan as to how they will resolve the discrepancy; as of early October 2018, more than 125 products have corrective action plans. This list of products with corrective action plans—especially if coupled with additional information—can inform clinicians of certification discrepancies with products they are using. Further, ONC has the authority—as codified in a 2016 final rule—to conduct direct oversight of EHRs. That direct oversight could reveal critical usability- and safety-related information that would be useful for health care facilities. ONC should also consider reviewing Reports to Congress, studies, or other publications generated by or in coordination with ONC, CMS, FDA, and other federal agencies or major industry stakeholders (e.g., reports on information blocking or studies on EHR usability). Finally, regardless of the source of information, Reporting Program information should be made easily accessible in both an online version (i.e., searchable/filterable web portal), and via an open application programing interface (API). Medical practices of different sizes and specialties have differing needs. ONC should seek routine feedback from users to improve the usability of this information and the Reporting Program. This should be a core requirement of the independent entity ONC chooses to administer the Reporting Program.
	Which, if any, of these sources are particularly relevant	The Reporting Program should place special emphasis on collecting information about ambulatory and small practice settings given the lack of market power and resources typically available to physicians in such

	or should be considered as they relate to certified health IT for ambulatory and small practice settings?	settings. The Reporting Program administrator should consider denoting any reporting information or conclusions derived from sources that pertain particularly to small practices in its reports or other deliverables.
	What, if any, types of information reported by providers as part of their participation in HHS programs would be useful for the EHR Reporting Program (e.g., to inform health IT acquisition, upgrade, or customization decisions)?	See comments on CMS' EHR Reporting Program in the attached cover letter.
Data Reported by Health IT Developers versus End-Users	What types of reporting criteria should developers of certified health IT report about their certified health IT products: • That would be important to use in identifying trends, assessing interoperability and successful exchange of health care information, and supporting assessment of user experiences? • That would be valuable to those acquiring health IT in making health IT acquisition, upgrade, or customization decisions that best	It would be useful for vendors to report on similar metrics to the AMA/MedStar Health EHR Usability study* (including clicks, error rates, types of errors, and time spent on tasks), to support assessment of user experiences. Our study shows there is significant variability in these metrics across vendors and within the same vendor product across implementation sites. These areas should be the initial focal point for reporting. *https://academic.oup.com/jamia/article-abstract/25/9/1197/5047907 Customization and upgrades: Understanding customizations and upgrades is crucial. It is important that providers have a good command of what is entailed when they are signing contracts, especially from a cost perspective. ONC may want to consider reviewing the relationship between being able to meet Promoting Interoperability (PI) requirements and vendor issues. We are aware of practices that were taken by surprise when they learned their EHR vendors were not going to upgrade to the next version of certified software. Reporting should include: a. What are the costs of customizations? b. What is the testing plan for customizations? c. How frequently are upgrades released? d. What is the upgrade schedule and is a physician required to accept upgrades? Health care organizations should also have access to the number of

	support end users' needs?	clicks and time spent on tasks. Typical time spent after hours (i.e., "pajama time"), should also be reported; this information could be gathered by collecting time stamps from when users log in and out of the EHR. The AMA also supports and provides the mini-z burnout assessment**, which specifically addresses EHRs. Looking at this data could be useful in understanding end-user experience with EHRs at the vendor level and help others make decisions related to products. **https://www.stepsforward.org/modules/physician-burnout-survey

	What types of reporting criteria for health care providers, patients, and other users of certified health IT products would be most useful in making technology acquisition, upgrade, or customization decisions to best support end users' needs?	We have identified several pieces of information which could be included in the Reporting Program to make the purchase and review of vendors more comprehensive and valuable:
		• Product Information:
		  ○ Base install product cost (production system hardware, software, and services).
		  ○ Cost (hardware, software, and services) for redundant (or highly redundant) systems – including definitions of what they believe redundant is.
		  ○ Average number of upgrades provided yearly (and whether these upgrades include changes required by regulatory agencies). How quickly do changes required by regulatory agencies become available in the base product?
		  ○ Are upgrades included in base install product cost? If not, provide costs for upgrades. Are customers required to upgrade?
		  ○ Average time from security patch identification to update and implementation. Are there additional costs to implement security patches?
		  ○ Average time for customer optimization request to incorporation into the product (it would also be helpful if consumer if they understood how these optimizations were prioritized).
		• Implementation:
		  ○ Vendors need to be transparent about what type of implementation is needed to inform clinicians on how such efforts will impact billing, associated costs of support, and usability.
		• Costs:
		  ○ Implementation (service costs) for base installation.
		  ○ Training (service costs) for base installation.
		  ○ Customization costs (including licenses and service implementation costs).
		  ○ Costs for interfaces (licenses and service(s) costs) with other data exchanges.
		• Ongoing support:

		○ Costs of ongoing support maintenance fees. ○ Is a contract for ongoing support required at the time of EHR purchase? ○ Are upgrades included in the ongoing maintenance fees? ○ Are security patches included in ongoing maintenance fees? ○ Downtime procedures. • Upgrade and patch testing procedures: ○ How long is my system down when I upgrade? ○ Is service after hours an extra cost? ○ If applicable, how often are mandatory upgrades performed? • Standards: ○ Physicians still report frustration with data sharing across disparate EHRs. Without a defined set of standards defining structural data standards, interoperability challenges will persist. The ability to accurately and efficiently share discrete data among vendors requires detailed data standards and definitions, including naming conventions and taxonomies. Today, this does not exist, which creates confusion for providers.
	What types of reporting criteria would be useful to obtain from both developers and end users to inform health IT comparisons? What about these types of reporting criteria makes them particularly amenable to reporting from both the developer and end user perspective?	See comments on CMS' EHR Reporting Program in the attached cover letter.
User-Reported Criteria	How can data be collected without creating or increasing burden on providers?	Clinicians already express frustration in the degree to which they use EHRs in routine care; therefore, the Reporting Program should limit any additional reporting requirements on the clinical end users. Information on EHR use and safety is already collected—including via routine clinical care and testing that organizations may already employ. That information, though, may not be aggregated or combined from different data sources to provide insights on the usability and safety of different EHR systems. To the greatest degree possible, ONC should leverage the existing information being collected or that could be

		generated by EHRs. Data may exist from existing testing programs, artifacts on the development process created by EHR vendors, incorporated into automated EHR tools, and otherwise obtained by ONC and other organizations.
	Discuss the benefits and limitations of requiring users be verified before submitting reviews. What should be required for such verification?	User verification is critical to ensuring that reviews submitted under the EHR Reporting Program are valid and credible. However, the AMA questions whether ONC's current budget includes the resources necessary to implement a stand-alone verification process under the program. The AMA recommends ONC evaluate the process AmericanEHR utilizes to verify users: "*All rating data undergoes a rigorous analysis and each submitted rating is manually reviewed and validated before the data is published as EHR satisfaction ratings;* *Registered users who have submitted rating data for an EHR product are verified in conjunction with their professional organization as a clinician;* *All rating data is analyzed for suspicious rating practices on an ongoing basis. If any such practices are identified, AmericanEHR Partners will take all necessary action.*"* *http://www.americanehr.com/Home.aspx
	Which reporting criteria are applicable generally across all providers? What reporting criteria would require customization across different provider types and specialties, including small practices and those in underserved areas?	Physicians, nurses, and other clinicians interact regularly with EHRs and possess an intimate knowledge of their functionality. ONC should actively engage with these clinicians to discuss and extract specific usability-related safety information, such as input on high-risk functions or other priorities. In addition, ONC should obtain input from researchers and other experts that have industry-wide knowledge about usability and safety challenges.
	How helpful are qualitative user reviews (such as 'star ratings' or Likert scales) compared to objective reports (e.g., that a system works as expected with quantifiable	Clinician perceptions on technology usability can provide key insights to inform system design and necessary modifications. These data can be obtained from surveys and other systems to obtain input from end-users. However, measurable, quantitative data on how these systems are used—such as the time it takes to perform functions, the frequency with which orders are not able to be correctly placed, or reports of errors—are also critical to guide EHR-related decisions. Data could be gathered on similar processes and functions to support comparisons across products. Given variability in how systems are implemented and used, some reporting criteria may benefit from providing ranges on

	measures)? Which specific types of information are better reflected in one of these formats or another?	which data were received. For example, on quantitative criteria, ONC could list the minimums or maximums observed in addition to the mean.
	How could HHS encourage clinicians, patients, and other users to share their experiences with certified health IT?	HHS should provide additional education about the removing the prohibition of "gag clauses" in EHR contracts that prohibit providers from openly discussing problems with their systems. HHS should also ask providers how likely they would be to recommend their EHR to someone else. CMS could include an Improvement Activity in the Quality Payment Program that would provide credit to physicians who submit EHR experience data to ONC.
Health IT Developer-Reported Criteria	If you have used the certified health IT product data available on the ONC Certified Health IT Products List (CHPL) to compare products (e.g., to inform acquisition, upgrade, or customization decisions), what information was most helpful and what was missing? If providing a brief list of the information, please prioritize the information from most helpful to least helpful also considering their grouping into categories in Section IV.	The usability of EHRs can change significantly once implemented within healthcare facilities. Initial system design, unique workflows within facilities, interactions with other technologies used within each site, and individual clinician preferences all affect system usability. EHR developers differ in how they incorporate usability- and safety-related practices during system development, and the degree to which products can be customized differs among technologies. Therefore, ONC should ensure that the EHR reporting program incorporates information from all these stages in the EHR lifecycle—from product design through implementation. A variety of data is already available via the CHPL, including usability subjective task ratings, and other health IT comparison websites. Efforts should be made to help consumers understand how to access and interpret this data. Currently, no data exists on the CHPL that are specific to specialties or other small practices. The AMA recommends exploring what questions may be helpful per specialty and for all practice sizes. After collection of the data, those questions and answers could be published on the Health IT Playbook site.
	Would a common set of criteria reported on by all developers of certified health IT, or a mixed approach blending common and optional sets of criteria, be more	The AMA recommends starting with a common set of criteria to be most helpful to clinicians across practice settings.

	effective as we implement the EHR Reporting Program?	
	What developer-reported criteria are particularly relevant, or not relevant, to health IT users and acquisition decision makers in the ambulatory and small practice settings?	System or log files are the digital record of what happens within an electronic system, such as the buttons that were pressed or the time an entry was completed. These data can provide interesting information to help understand how systems are used, and the usability challenges encountered by clinicians. As part of the initial or future iterations of the Reporting Program, ONC should examine how to use system or log files to identify usability challenges and safety risks. Additionally, as identified in recent usability research papers, vendors report on their User Center Design (UCD) processes; however, these processes are not always adhered to post-certification.* After customizations are made at the organization level, the product may no longer function as tested during the certification process. ONC should identify a method for capturing UCD process performance pre and post-implementation to better understand the impact of implementation on EHR usability. This may require ONC to identify a post-implantation surveillance framework, similar to that used by the Food and Drug Administration (FDA). *https://academic.oup.com/jamia/article-abstract/25/9/1197/5047907?redirectedFrom=fulltext *https://www.pewtrusts.org/en/research-and-analysis/reports/2018/08/28/ways-to-improve-electronic-health-record-safety
Categories for the EHR Reporting Program	**ONC Questions**	**AMA Answers**
General Question	What categories of reporting criteria are end users most interested in (e.g., security, usability and user centered design, interoperability, conformance to certification testing)? Please list by priority.	1. Interoperability 2. User-centered design/Usability 3. Security 4. Conformance to certification testing
Security	What reporting criteria could provide information on	The following items would be helpful in better informing a purchaser of a vendor's security posture:

	meaningful differences between products in the ease and effectiveness that they enable end users to meet their security and privacy needs?	• A complete security risk assessment should be made available to EHR purchasers. This is especially true for cloud-based vendors since there is very little transparency around these vendors' cyber postures and procedures. Vendors should create and maintain supportive documentation of such assessments like that created by the Office for Civil Rights (OCR) and ONC's risk assessment tool. • Vendors should be required, as a condition of certification, to have annual security and penetration testing performed. The results should be made upon request. • Multi-factor authentication: is it used, what options are available to physicians, and what are the associated costs? • Information about encryption on the server, client, data base, and other EHR applications. • Information about role-based access control and if these roles are set or able to be configured. • What are the password protection standards (e.g., NIST)? • How the vendor handles audit trails and reports. • Availability of custom privacy policy, terms of conditions, and costs to enable patient portals. • Evidence of Payment Card Industry Data Security Standard compliance for credit card transactions. • Whether the vendor requires any gag clauses in contracts that would prevent a provider from sharing information around a cyber vulnerability. Medical device manufacturers are governed by the FDA's guidance and they are instructed to report uncontrolled risks (those which pose a risk to patient safety) to their customers within 30 days and to the FDA if they are not addressed within 60 days. Conceivably, EHR vendors could be held to comparable standards. At the very least, vendors should have a publicly stated process for how they handle vulnerabilities; more oversight to ensure vendors are adhering to this is needed. Separately, we believe it would be helpful to have a process to evaluate vendors' claims as being "HIPAA compliant". This claim is often made to customers but is not a recognized term by OCR. Claiming that a given product is "HIPAA compliant" provides a false and inaccurate promise of security to physicians.
	Describe other useful security and privacy features or functions that a certified health IT product may offer beyond those	Automated features associated with patient privacy would be very helpful and desirable to physicians. Physicians should have knowledge of an EHR's ability to track access rights, automate and track fulfilment of requests such as when a patient has requested an amendment to their record, automate patient preferences and state law around restrictions associated with sharing records (e.g., substance use disorder

	required by HIPAA and the ONC Health IT Certification Program, such as functions related to requirements under 42 CFR Part 2.	records, HIV-status data, information characterized as sensitive under state law, such as minors' sexual health, etc.), and accounting for disclosures. Managing these types of requests is a time-consuming and administrative challenge for physician offices of any size.
Usability and User-Centered Design	Describe the availability and feasibility of common frameworks or standard scores from established usability assessment tools that would allow acquisition decision makers to compare usability of systems.	The AMA, Pew, and MedStar recently released a report titled "Ways to Improve Electronic Health Record Safety," which provides a framework for considering the EHR life cycle. This can be used by both health IT developers and health care providers (*see table #1). The report also includes a set of rigorous test cases designed to test product safety pre- and post-implementation (and account for customizations that may have been done after the product has already been certified). *https://www.pewtrusts.org/en/research-and-analysis/reports/2018/08/28/ways-to-improve-electronic-health-record-safety
	Discuss the merits and risks of seeking a common set of measures for the purpose of real world testing that health IT developers could use to compare usability of systems. What specific types of data from current users would reflect how well the certified health IT product: • Supports the cognitive work of clinical users (e.g., displays relevant information in useful formats at relevant points in workflow)?	The EHR Usability Comparison study the AMA completed with MedStar examined clicks, error rates, types of errors, and time spent on tasks.* The use case scenarios focused on tasks that should be relatively simple for physicians to perform but posed a challenge for many. Examples include: dosing/medication titration (mental math required) and searching for drug names (no spelling forgiveness). *https://doi.org/10.1093/jamia/ocy088

	• Reflects the ability of implementers to make customization and implementation decisions in a user-centered manner?	
	How feasible would it be to implement usage monitoring tools (e.g., for time spent on specific tasks)?	This information is readily available in many of the larger EHRs today. They are able to track clicks, time spent on tasks, after-hours time (i.e., "pajama time"), etc.
Interoperability	Please comment on the usefulness of product integration as a primary means of assessing interoperability (as proposed in the EHR Compare Report).	Accessing product integration is not enough to assess the interoperability of a product. Furthermore, product integration can mean various things. For example, a physician clicking a hyperlink in their EHR to launch a webpage in a separate browser window could be considered "basic" integration. Alternatively, using an API to enable bi-directional information exchange with that same website could be considered "advanced" integration. Both examples allow the physician to enter and access data, however, the level of cognitive burden on the physician may be substantial. Depending on the use case, launching a new window may be more efficient and cost effective. However, as in the case with accessing Prescription Drug Monitoring Program (PDMP) information, the "window swapping" and hand-keying of information between applications detracts from physician-patient time. As the demand on physician time increase (along with the influx of data), physicians will require tighter integration with third-party applications and services. A simple matrix comparing EHR products, prevalent third-party systems (PDMPs, HIEs, state immunization registries, etc.), and their integration level (basic, intermediate and advanced along with a description and examples of each level) would benefit physicians and could be useful in helping to establish a baseline of system-to-system interoperability.
	What other domains of interoperability (beyond those already identified and referenced above) would be useful for comparative purposes?	Reporting criteria should: (1) Be automated wherever possible; (2) initially, target high-value standards/use cases; and (3) deliver value to those stakeholders being measured. Other domains of interoperability should include the complexity of the product integration and the product's connectivity with networks such as CommonWell, Carequality, and/or the forthcoming Trusted Exchange Framework.
	Of the data sources described in this RFI,	CMS program data is more reflective of how clinicians are told to use the product rather than the capabilities of the product and whether the

	which data sources would be useful for measuring the interoperability performance of certified health IT products? • Comment on whether State Medicaid agencies would be able to share detailed attestation-level data for the purpose of developing reports at a more detailed level, such as by health IT product. If so, how would this information be useful to compare performance on interoperability across health IT products? • How helpful would CMS program data (e.g., Quality Payment Program MIPS Promoting Interoperability Category, Inpatient Hospital Promoting Interoperability Program, Medicaid Promoting Interoperability Programs) related to exchange and interoperability be for comparative purposes? What measures should be selected for this purpose? Given that some of these data may be reported	product helps a physician accomplish a task. For example, the HIE measures in the PI category measure whether a physician is using the CEHRT's HIE functions but are not necessarily indicative of whether the CEHRT is helping the physician meet the measures in intuitive, usable ways that fits into the physician's workflow. Additional information can be found in the cover letter comments and past AMA responses to QPP Notices of Proposed Rulemaking.

	across providers rather than at the individual clinical level, how would this affect reporting of performance by health IT product?	
	What other data sources and measures could be used to compare performance on interoperability across certified health IT products?	Additional data sources and measures could include data from regional and state HIEs, data from public and private sources, and data from registries. Although health care user and patient experience data can be subjective, it is still important to include such information in comparing products. If a product design is not intuitive to the user and patient, it will not be used optimally. This data is especially important in determining what specific functionally may negatively impact use.
Conformance to Certification Testing	What additional information about certified health IT's conformance to the certification testing (beyond what is currently available on the CHPL) would be useful for comparison purposes? What mechanisms or approaches could be considered to obtain such data? What barriers might exist for developers and/or end users in reporting on such data?	While ONC's current certification program focuses on product non-conformities, it could be enhanced by focusing on real-world production data related to interoperability, usability, and security performance in a live environment. We acknowledge these data may not provide a detailed picture of performance; however, we must understand and leverage real-world production data currently available through CEHRT, identify what real-world production data should be available through CEHRT, and work towards building a post-implementation surveillance ecosystem to improve CEHRT security, usability, and interoperability. Real-world production data is a reality in most, if not all, CEHRT. For example, one well-known CEHRT 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 (such as if there is no known Direct address), if the failure occurred in transit (e.g., a Health Information Service Providers (HISP) failure), and whether the transaction was received and acknowledged by the recipient system.
Other Categories for Consideration	Please comment on different types of information, or measures, in this area that would be useful to acquisition, upgrade, and customization decisions in the ambulatory setting as opposed to inpatient settings?	CEHRT developers should publish specific costs, or a range of costs, that physicians must pay to meet requirements for all federal programs requiring the use of CEHRT. This information is vital to help physicians be more empowered consumers. Physicians need to be better informed prior to purchasing or upgrading products. Furthermore, they need to know if they can use the system "as is" or if they need to (a) upgrade the system, (b) switch to another system, or (c) configure or customize the system in a way which changes the original or intended use. Ultimately, physicians need a better understanding of the return on their investment.

	Please comment on other categories, if any, besides those listed in this RFI that should be considered to be included in the EHR Reporting Program. Why should these be included, and what data sources exist to report on performance for the suggested categories?	Attestation data reported as part of certification, such as encryption and hashing algorithms used to comply with certification criteria, is not publicly available. Additionally, CEHRT developers do not typically disclose which HISP they support for physicians to exchange Direct messages. This has impacted the adoption of Direct and added to the confusion and cost associated with secure message exchange. Further, CEHRT developers are not expected to share the addresses of their customers using Direct, which limits the availability of a national Direct address directory. Sharing this information would increase the utility of Direct and further support the foundation of secure data, while also not being overly burdensome to procure since it is already maintained by the CEHRT developer. The 21st Century Cures Act requires the EHR Reporting Program to include reporting criteria across four prescriptive measure categories and "other categories as appropriate to measure the performance of electronic health record technology." We recommend that ONC prioritize a measure that provides a patient or an authorized designee with a complete copy of the patient's health information from an electronic record in a computable format. Recent policies established by CMS seek to improve patients' access to their data through APIs. However, this access will only provide a limited data set (currently the common clinical data set) which is insufficient to be considered a complete copy. Policy efforts should be made to define what a complete copy is, and technical requirements should deliver this newly defined concept to patients in a computable format, so that their data can be used once made available. Federal agencies must coordinate their efforts to ensure that a "complete copy" of records is defined consistently across agencies, particularly when fines and regulatory penalties are a factor. For example, HIPAA requires that a patient have access to his or her entire designated record set in a manner of his or her choosing; however, the common clinical data set only provides a subset of the designated record set's information. Physicians who provide a patient's health information to them via an API should not be penalized by OCR for failing to provide the patient with a "complete copy" of their medical record because technology currently does not allow them to do so.