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National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue
Washington, DC 20201

RE: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications [RIN 0991-AB93]

Dear Dr. DeSalvo:

The American College of Cardiology (ACC) appreciates the improvements the Office of the National Coordinator for Health Information Technology (ONC) provided to the Health Information Technology (Health IT) Certification Criteria in the final rule dated October 16, 2015. The ACC is a 49,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, provides professional medical education, promotes cardiovascular research and bestows credentials on cardiovascular specialists who meet stringent qualifications. The *Journal of the American College of Cardiology* (JACC), which publishes peer-reviewed research on all aspects of cardiovascular disease, is the most widely read cardiovascular journal worldwide. JACC is ranked No. 1 among cardiovascular journals worldwide for its scientific impact. The College had called on ONC to make many of the changes finalized in the rule and wanted to outline the vast improvements finalized along with the opportunities for improvement which still exist.

The College has long been supportive of the creation of a nationwide health information infrastructure driving interoperability that would provide for improved patient outcomes and increased population health. The creation of a nationwide health information infrastructure requires coordinated efforts by the government, private payers, providers and patients, and while the ACC is aware that it will not happen overnight, if any of the affected groups is removed from the equation, this major transformation will not occur. In order to establish such a critical infrastructure many changes in the health IT certification process have occurred. The ACC appreciates ONC responding to our calls for increased usability, product transparency, interoperability, data

portability, and registry participation in the final rule which are outlined below.

Usability
The College recognizes the time and energy dedicated to improving the functionality of certified EHR technology (CEHRT). Given the perpetual advancement of technology, this aspect will continuously require updating. However, with each new vendor development cycle, the ACC requests that an ample and thorough testing period is provided. As finalized, the rule could require vendors and providers to implement untested technology at a time when physicians are fed up with their EHRs. Although 60 new criteria and 25 revised criteria for certification have been finalized, it is hazardous to mix such new guidelines into technology that is rolled out to market before it may be ready. While the vast number of new criteria accounts for various functional needs across specialties or healthcare settings, it instead manifests as overwhelming and muddles the path to certification.

In addition, there needs to be further prioritizing of user-centered design, not simply tweaking EHRs designed around charge capture. EHRs need to be adapted to the clinical environment because it is dreadfully apparent that emergency room physicians want different functionality than cardiologists. To date, the certification standards have focused on ensuring that specific functionalities are included in EHRs and are actually being used. However, these functionalities are meaningless without ensuring that they and the EHRs are actually usable and safe. The ACC urges ONC to advance effective, clinically relevant EHR standards created with specialty medical societies in these areas to assist physicians and hospitals in determining which EHRs constitute the small subset that are truly high-quality and will assist them in improving the quality of patient care while minimizing the administrative burden of EHR adoption, implementation and use on physicians and hospitals. Ensuring usability is the key to successful physician adoption of EHRs. The rule as finalized gives no consideration as to the clinician decision-making process or practice workflow. To ensure that EHR system vendors take these concerns into account, the ACC urges ONC to continue the advancement of standards for usability testing.

In previous comments, the ACC called for ONC to conduct post-market surveillance of EHR products to assure the implemented system encompasses the usability elements tested in the pre-market stage. While the final rule includes new “in the field” surveillance of EHRs and would require developers to take corrective action if the technology wasn’t meeting CEHRT requirements, the ACC calls for further clarity on what exactly would be tested in the field, understanding that the ONC has finalized the following “in-the-field” surveillance requirements under the ONC Health IT Certification Program:

- ONC-ACBs should ensure that certified Health IT Modules can perform certified capabilities in a production environment (when implemented and used)
    - Reactive surveillance (e.g., complaints)
    - Randomized surveillance (2% of annually certified health IT at one or more location)
- Enhanced surveillance of mandatory transparency requirements
- Non-conformity and corrective action reported to the ONC’s Certified Health IT Products List (CHPL) beginning in CY 2016

As an example, the College is requesting the following be addressed in post-market surveillance: who would be accountable for product failure (vendors/developers or users/providers); how well systems perform with regard to interoperability, usability, and patient safety in the real world after products have been deployed.

The ONC has made critical changes to the 2015 usability requirements including requiring health IT developers to submit specific information about the user-centered design processes used and applied along with increased safety-enhanced design requirements, which provides the opportunity for vast improvement on user-centered design. However, in comments the ACC called on ONC to mandate that EHR certification criteria require the EHR produce be reviewed by a 15 person panel (consisting of clinicians). The ONC responded by establishing a minimum 10 test participants for summative usability testing. While this shows a promising intent to improve the usability of health IT, in an effort to streamline requirements across various government bodies, the College would like to reiterate it's preference for ONC to adopt the National Institute of Science and Technology's recommendation that at least 15 participants engage in user-centered design testing.

Product Transparency

The need for price transparency is a key component to achieve interoperability**.** The ACC called on ONC in comments on the 2015 CEHRT proposed rule to require EHR vendors to publish prices for each service a user may need, such as interfaces, data transmission requirements, and health information exchange fees. In the final rule, ONC responded to this by requiring that: ONC-Authorized Certification Bodies (ONC-ACBs) ensure health IT developers conspicuously disclose in plain language on their website, in all marketing materials, communication statements, and other assertions related to certified heath IT:

- Additional types of costs users may incur to implement or use health IT for any purpose within the scope of its certification (not just for achieving MU objectives);
- Limitations (including contractual, technical, or other limitations) that are likely to limit a user's ability to implement or use health IT for any purpose within the scope of its certification;
- Provide a hyperlink for all disclosures, which will be published via CHPL; and
- Make a "transparency attestation" indicating whether or not they will provide the required information to other persons and organizations (e.g., customers, prospective customers, and associations representing consumers or providers) upon request.

The ACC applauds ONC for providing these much needed transparency improvements to the certification process and looks forward to the improved health it landscape that improvements may lead to. Additionally, the ACC calls on ONC to make public a list of complaints and failure rates for all future testing of certified EHRs to inform purchasers of potential hurdles in the implementation, upgrade, or use of the products. This would require ONC to continue its work to promote transparency of vendor contracts by prohibiting the use of "gag clauses" or no non-disparagement language in EHR contracts so that providers could openly discuss problems with their systems without facing repercussions. This must include the ability of end users and health IT safety researchers to post screen-shots. Research on EHR screens used by clinicians in patient care and adverse event reporting to patient safety organizations and accrediting

organizations is inhibited unless corrective action is taken which allows problems with poor usability at the human-computer interface to persist and sometimes result in serious patient harm.

Furthermore, once this information can be shared it needs to be posted in a common format that is easily discernable to provide ease in comparing items so physicians, hospitals, and other purchasers make more informed choices and can lead to a more naturally competitive marketplace. The ONC responded to this request to "Open Data" by converting the CHPL to an open data file to make the reported product data (e.g., test results) more accessible for product analysis and by requiring that ONC-ACBs report an expanded set of information about health IT products for increased product transparency. In comments, the ACC called on ONC to enforce the EHR vendor certification requirement that they post user centered design reports generated during EHR testing. While the ACC appreciates ONC taking this corrective action, the College further requests that ONC conduct a satisfaction survey of providers that outline barriers to interoperability, including costs. The College has received many accounts of EHR vendors charging excessive fees for data exchange. Next to the well-known technical exchange limitations of EHRs, cost is the other major barrier to interoperability for small to medium sized physician practices.

Interoperability
The final rule appears to lack specifics of how the newly created interoperability standards will apply to the certification process, if the certification process will be streamlined to mainly, or even solely, focus on interoperability, along with discrete timelines for these changes. **The ACC calls on ONC to provide further clarity.**

The College also strongly cautions ONC on enforcing interoperability through the threat of decertification. Physicians have invested significant funds, not to mention time and resources, into purchasing and implementing certified EHRs, expecting that these systems will be compliant. Decertification places the burden not on the non-compliant vendor but on the physician who must buy a new product, transfer patient data (which is a considerable expense), and devote staff time to training and implementing a new system. If an EHR becomes decertified, physicians have no recourse but will simply own a product that is deficient and can no longer be used to satisfy Meaningful Use. One remedy is to establish a hardship exemption that allows for temporary use of the decertified technology on a case-by-case basis. While this does reduce the monetary burden, providers are still chained to dedicating vast amounts of time to complete the exemption process along with updating and retraining staff once the new technology is released.

When focusing in on clinical decision support, comments were sought on whether "utilization alerts" received by a provider when a patient is admitted, seen in an emergency room, or discharged from a hospital should have been included in measure two or as a separate measure. Such alerts are ideal when a patient remains in the same health system for all of their interactions and EHR vendors across the system remain homogenous. However, if either of these elements is missing, quality patient care could be compromised due to the lack of a unique patient identifier. Without the assurance that patients across varying health systems and varying EHRs have been matched

appropriately, sending a utilization alert could become detrimental to a patient's health. The integration of health IT into care settings drives us towards the goal of providing the right information at the right time to the right patient, but only if those items are correct. **The ACC strongly cautions ONC on integrating any required utilization alerts into the program unless an effective patient matching plan is outlined alongside it. By the next certification cycle, the ONC needs to begin development of provider directories and facilitate patient matching.** Developing these tools will ensure that when exchanging information among records that the intended recipient and patient are easily and correctly identified.

Data Portability

The ACC believes data portability between EHRs and clinical databases such as specialized registries is critical. It is equally critical that physicians and hospitals have the ability to port data between EHRs. To do otherwise restricts physicians and hospitals to the EHRs they adopt at the outset. Today vendors employ methodologies for restricting access to the data that make it challenging to change EHRs. This is made even more challenging by the market consolidation that has begun to occur and that we expect to continue. Physicians and hospitals that adopt EHRs created by vendors that later go out of business or are purchased by others that elect to cease providing the necessary updates and support for those products need solutions to this dilemma that are cost-effective, create as little burden as possible and have minimal effects on the quality of patient care.

Medical record retention laws, as well as those governing fraud and abuse investigations, largely determine the amount and type of information that must be retained, and therefore, needs to be portable. However, there also may be other reasons for retaining longitudinal information on patient care, such as clinical trial participation, post approval study requirements and others. As such, the ACC believes that it should be left to physicians and hospitals to determine the type and amount of information that should be ported from one EHR to another. **For these reasons, the College urges ONC to adopt the standards and certification criteria on the portability of data stored within an EHR that allow physicians and hospitals to determine what information and the amount of it that needs to be ported to another EHR or clinical database.**

Registries

Regardless of ACC's support for the use of specialized registries, data collection directly from EHRs remains hampered by the lack of data standards and technical interfaces to IT systems. Different EHRs and applications use different clinical and technical definitions, so it can be challenging to determine what information is needed. To overcome this barrier, the PINNACLE Registry works with an application that performs back end "system integration" data mapping. Additionally, clinical staff helps to identify key terms and phrases that may be used to describe critical elements. As cited earlier in our comments, to ultimately solve this problem, the ACC has been working with the AHA to attempt to ultimately solve this problem. Through these efforts we have identified the key data elements and definitions of a base cardiovascular vocabulary for EHRs. The subsequently generated document contains less than 100 terms that are commonly used in cardiovascular care. The ACC is now in the process of building out

those terms and the necessary specifications for them; however, this ultimately takes time and will not be ready immediately for use. **As such, the ACC urges ONC to adopt a standard that will ease the movement of data from EHRs to registries for these purposes.**

In today's modern practice of medicine, physicians rely heavily on imaging for diagnosis and treatment. Yet, CMS fails to work towards encouraging the development of standards for transmission of images and information pertaining to those images. For instance, standards for the transmission of 3-D echocardiography images continue to lag behind in this area. Additionally, most EHRs remain incapable of handling images. Images embedded in reports such as Microsoft Word documents may be difficult to view with adequate resolution on some systems and with some hardware such as smart phones. Physicians continue to receive studies on disk that cannot be read by a PACS system, let alone an EHR.

The incorporation of scanned images into EHR records is generally ineffective at improving patient care. When images are scanned into EHRs, physicians cannot manipulate the data, which may prevent them from truly seeing the images or from understanding what the images represent. Additionally, it represents an additional burden imposed by CMS on physicians, one that will not improve the quality of patient care. The ACC supports inclusion of the DICOM standard as a requirement for EHR certification, as well as certification of DICOM compliance for the storage and transmission of images. Many vendors of cardiovascular imaging equipment claim that the format of stored files is DICOM compliant; however, the reality is that this is frequently not the case. Specifically, it is the ability to view a "DICOM compliant" study created by one vendor with a second vendor's DICOM viewer that is not guaranteed. This problem permeates the market, and failure to specify conformance to the DICOM format for storage and retrieval as a least common denominator functionality will only serve to exacerbate this situation. To execute successfully, the specific components of DICOM compliance need to be specified. Requiring DICOM standards as a component of EHR certification will galvanize industry towards adoption and implementation of the standard. After this has occurred, then CMS can consider requiring electronic transmission of images as a component of the EHR Incentive Program. **Because of this, the ACC urges ONC to include this requirement in the final rule.** Additionally, the ACC recommends that ONC require that the viewer application maintain the aspect ratio of the original image (i.e., square should remain square), rather than reflect the aspect ratio of the monitor.

Patient Generated Data

The College worries that the technology landscape surrounding patient generated health data (PGHD) is still evolving. Currently EHR vendors are not capable of handling PGHD and while this is a mandated functionality under the 2015 CEHRT rule, there are no fully-developed standards for incorporating this information. Furthermore, the ACC does not believe the timeline finalized in the regulations will accommodate a smooth transition. As highlighted in a Jason report published for the Agency for Healthcare Research & Quality (AHRQ) in November 2014:

> "There is insufficient openness of data formats and algorithms for these devices, preventing interoperability and innovation in synthesis of individual health data. Although many of today's activity monitors include some open protocols, the data are usually locked in data structures that make it difficult for individuals to directly use the data. For example, service agreements have significant restrictions on how individuals may use what is in fact their own health data…
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> While standards such as the IEEE Personal Health Data Standards (ISO/IEEE 11073) do exist, the accuracy of the devices appears to be based on mostly proprietary algorithms and calibration processes. As a result, devices from different vendors measuring the same health or fitness activity will provide significantly different and thus incomparable data, e.g., numbers for steps, distance, and calorie counts. In fact, even the same device used in a slightly different way (e.g., attached to one's hip as opposed to one's wrist) will produce different results…
>
> To truly enable patients to improve their health and wellness with better knowledge from such devices, the industry should establish meaningful statements of uncertainty for both fitness measurement and fitness calculations so that data are comparable and interpretable. Metrics and standards should be independently reproducible from raw sensor data."

Additionally, the College is concerned that the incorporation of PGHD into the EHR will exacerbate the information overload which already occurs without proper context or data segregation – despite ONC's data segmentation for privacy effort in the final rule. It is not clear how data will be tagged so that it is obvious to the physician where external data originated. Tagging is also an important feature to ensure information is not inadvertently mixed in with clinically generated data.

Unique Device Identifiers

The ACC is pleased to see a response to our request for an implantable device list incorporating fields within the common clinical data set (CCDS) for the insertion of unique device identifiers (UDI). The inclusion of the UDI into patient medical records can lead to the facilitation of high quality care, the reporting of adverse events and the surveillance of medical devices after FDA approval. The College applauds ONC's finalized data fields required under the certification criteria for UDIs in Stage 3 but looks to ONC to coordinate working with the appropriate federal agencies to advance the opportunities provided by the collection of this information. The greatest benefit is to decrease the number of adverse events and increase the ability to provide more effective corrective and preventative action in response to device recalls and alerts, which is not outlined in the final rule.

Conclusion

The ACC believes that ONC should be commended on the efforts to further advance the EHR Certification Program. This is not an easy feat and while the final rule addressed here has many available areas of improvement, the College recognizes the amount of thought and work that went into its development. The College has outlined vast improvements along with areas which cause great concerns about the

practicability, adaptability, deliverability, and ability of physicians to leverage health IT in the means expected come 2018. The College appreciates the opportunity to furnish input on these critical regulations and we would welcome the opportunity to discuss this and other relevant issues with ONC. Please direct any questions or concerns to Julie Brown at (202) 375-6351 or jbrown@acc.org.

Sincerely,

Kim Allan Williams, Sr., MD, FACC, FAHA, FASNC
President

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