May 26, 2015

Karen B. DeSalvo, M.D., M.P.H., M.Sc.
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Attention: RIN 0991-AB93
Submitted electronically to: http://www.regulations.gov

Dear Dr. DeSalvo:

The College of Healthcare Information Management Executives (CHIME) appreciates the opportunity to submit comments regarding the regulation proposed by the Office of the National Coordinator (ONC) for Health Information Technology for 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Technology Definition, and ONC Health IT Certification Program Modifications.

CHIME is a professional association representing more than 1,400 chief information officers (CIOs) and other top information technology executives at hospitals and clinics across the nation. CHIME members have frontline experience in implementing the kinds of clinical and business IT systems needed to realize healthcare transformation. Healthcare CIOs share the vision of an e-enabled healthcare system as described by the many efforts underway at the Department of Health and Human Services (HHS).

ONC Health IT Certification Program

Measurement certification criteria

In section IV. B. 2. of the proposed rule, ONC would eliminate the current requirement on ONC-ACBs to certify Health IT Modules to the 2015 Edition meaningful use measurement certification criteria at §§ 170.315(g)(1) and (g)(2) (automated numerator recording and automated measure calculation, respectively). The rationale given for this proposal include (i) stakeholder feedback indicating that these requirements "pose significant burdens on health IT development and come at the cost of improving clinical functionality and usability" and that the criteria "can impact innovation;" (ii) ONC's desire to make the ONC Health IT Certification Program more accessible for health IT certification beyond the EHR Incentive Programs; and (iii) ONC's belief that not all health IT certified under the program require these capabilities. The proposed rule notes that

developers are not precluded from seeking certification to these criteria to support their customers, and encourages developers to consider seeking certification to these criteria.

Among the various proposals of this proposed rule, this policy change raises the greatest concern among eligible professionals (EPs) and eligible hospitals and CAHs (collectively EHs) who require health IT certified to these criteria in order to successfully demonstrate meaningful use for purposes of the EHR Incentive Program. As the EHR Incentive Program moves from financial incentives to the imposition of penalties on EPs and EHs for failure to successfully demonstrate meaningful use for an EHR reporting period, CHIME has enormous concerns that the removal of the requirement on ONC-ACBs to certify health IT to these criteria will lessen the availability of products required for this purpose. The EHR capabilities required through HITECH and PPACA legislation are fundamental to achieving the tripartite goals of improving patient satisfaction and quality, improving the health of communities, and reducing the cost of healthcare. The ONC recommendation to eliminate the mandate that application vendors provide products which meet these goals implements a policy that will limit the effectiveness of health IT products and transfer an unacceptable level of financial risk to healthcare providers.

While ONC's desire to expand the types of products for which certification may be sought under the ONC Health IT Certification Program is a laudable goal, the certification of health IT for different types of care and practice settings should not come at the expense of those EPs and EHs that have relied on, and will continue to rely on, certification of health IT with specific measurement capabilities in order to comply with other provisions of federal law and regulation (such as the EHR Incentive Program). To the extent that ONC believes that measurement certification criteria are not necessary for certain types of care or practice settings, then ONC should make certification of health IT to these criteria optional for those other types of care or practice settings while maintaining the current certification requirement for Health IT Modules intended to support EPs and EHs under the EHR Incentive Program.

ONC indicates in the proposed rule that some stakeholders have cited significant burdens on development at the expense of clinical functionality, but ONC also suggests that these concerns may not be entirely accurate. To CHIME's knowledge, the development of Health IT Modules with these measurement capabilities (either alone or in conjunction with other capabilities) does not pose a significant expense or burden on developers; because the base code already developed and certified should function appropriately for these capabilities, developers should not have to change a significant amount of code to accommodate stage 3 measures and objectives under the EHR Incentive Program. However, these capabilities play a fundamental role for purposes of EP and EH compliance with the requirements of the EHR Incentive Program, and ONC should adhere to its previously adopted policy of requiring certification to the measurement criteria to ensure access to these measurement software products.

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Types of Care and Practice Settings

In section IV. B. 3. of the proposed rule, ONC would make the ONC Health IT Certification Program open and accessible to more types of health IT, including health IT that supports a variety of care and practice settings, various HHS programs, and public and private interests.

CHIME is generally supportive of the proposal to expand the ONC Health IT Certification Program to additional types of care and practice settings. The statute establishing the agency includes duties and goals beyond the EHR Incentive Programs. However, as indicated above, CHIME is concerned that the expansion of the scope of the ONC Health IT Certification Program may impact the availability of Health IT Modules for EPs and EHs to demonstrate meaningful use under the EHR Incentive Program. One example described above is the proposal to remove requirements for ONC-ACBs to certify health IT Module for certain measurement capabilities. CHIME recommends that ONC consider establishing different certification tracks for health IT designed for alternative types of care or care settings. This should not be particularly burdensome for ONC; the agency currently provides for different certification tracks for ambulatory settings and for hospital inpatient and emergency department settings for purposes of the EHR Incentive Program.

Principals of Proper Conduct: Surveillance

In section IV.D.1. of the proposed rule, ONC would expand existing surveillance efforts of health IT under the ONC Health IT Certification Program. Beginning January 1, 2016, ONC-ACBs would conduct annual randomized in-the-field surveillance of 10 percent of certified Complete EHRs or certified Health IT Modules to detect patterns of non-conformance that could give rise to a corrective action plan for a product developer. ONC-ACBs would conduct randomized in-the-field surveillance in 10 locations or in 5 percent of all locations at which the technology is implemented and in use, whichever is fewer. ONC-ACBs would also conduct reactive in-the-field surveillance when facts or circumstances indicate issues relating to the continued compliance of certification requirements, which would typically come from user feedback, including complaints. Nonconforming Health IT Modules (including Compete EHRs) could be subject to corrective action plans as well as to decertification.

CHIME fully supports efforts to ensure Health IT Modules meet the criteria to which they have been certified under the ONC Health IT Certification Program after their sale to and deployment by EPs and EHs. Though Health IT Modules are tested in the laboratory for certification, that testing does not necessarily indicate how the health IT will function in the field. While CHIME agrees with the proposed policy, the proposed surveillance program may be difficult to design and implement. CHIME encourages ONC-ACBs to develop clinical testing scenarios for health IT that are created by clinicians who have experience working with the health IT that would be the subject of surveillance; in this way, EPs, EHs, and other consumers may be assured that the health IT capabilities function as promised in the product's marketing materials both in the laboratory setting and in the field.

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CHIME is concerned by the proposed number of locations for in-the-field surveillance. While the proposal to vary locations by practice types, sizes, settings, and locales is good policy, the relatively small number of locations overall may not be sufficient to obtain a representative sample. CHIME welcomes the opportunity to work with ONC to develop an efficient and effective manner in which to select the number and diversity of sites necessary to derive meaningful results from the surveillance effort. Lastly, we urge ONC to be judicious in developing corrective action plans and not assume that failure of one product tested through in-the-field surveillance is indicative of all instances where that product is installed. See comments below regarding our concerns with an over-reliance on decertification.

Principals of Proper Conduct: Transparency and Disclosure

In section IV.D.2. of the proposed rule, ONC would significantly expand health IT developer transparency and disclosure requirements with respect to the Health IT Modules for which they seek certification from the ONC Health IT Certification Program. The goal is to better inform consumers about costs associated with the products they are considering as well as limitations of those products.

CHIME fully supports efforts to improve a consumer's ability to understand the implications of selecting a health IT product beyond the costs to acquire and implement it. Information about the limitations of health IT, especially whether there would be a limitation on a user's ability to implement the health IT consistent with the certification, is essential to consumers who are faced with an increasing array of products from which to choose. CHIME encourages ONC to develop clear standards for these disclosure and transparency requirements that can apply across the spectrum of health IT products. These standards should include, at a minimum, an initial statement of whether a Health IT Module meets requirements for meaningful use for EPs and EHs, and should also include additional information about other requirements that the product may satisfy or capabilities that it includes. ONC should ensure that standards for disclosure and transparency requirements for health IT are readily understandable to both the layperson and individuals with expertise in software products.

Decertification of Health IT

In section IV.E. ONC seeks comment on the use its authority to decertify CEHRT that proactively blocks information sharing, consistent with congressional intent under recent provisions of the Consolidated and Further Continuing Appropriations Act, 2015 (Public Law 113-235).

CHIME agrees that an issue of this complexity requires separate rulemaking, and we appreciate the agency's measured approach by soliciting comment on a number of issues and engaging stakeholders in further discussions of the establishment of procedures to implement decertification of products for information blocking concerns.

CHIME agrees with ONC that decertification of Health IT Modules would be extremely burdensome on health care providers. The decision process in which EPs and EHs engage for the

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selection of their health IT is a complex one that requires consideration of myriad issues. Once that decision is made, time, effort and resources are dedicated to the implementation of the health IT, including implementation, training and requisite upgrades. The entire process is enormously time-consuming (often a multi-year process) and is resource intensive.

It is extremely disruptive for an EP or EH to make an unplanned change in health IT systems for reasons outside its control and outside the parameters of its business plan. Additionally, it is an expensive and time-consuming undertaking to migrate to another vendor's systems. Thus, it is paramount that ONC build in sufficient protections for users in what CHIME hopes would be the rare exercise of this proposed authority to decertify a Health IT Module, especially in the case of CEHRT. While CMS is the agency for establishing EHR reporting periods and hardship exemptions under the EHR Incentive Programs, we urge ONC to consider carefully the impact that such a decertification would have on EPs and EHs as the Incentive Programs will increasingly involve payment adjustments for failure to meaningfully demonstrate use of CEHRT. The establishment of reasonable procedural time frames and deadlines under this proposed new authority to accommodate generally accepted implementation guidelines is crucial to avoid disruption to health care providers and their patients. These time frames should also vary taking into consideration the nature of the enterprise of the particular health IT that is proposed for decertification as well as the migration to another health IT product. Again, while we understand that such policies are the purview of CMS, CHIME recommends that any EP or EH whose CEHRT is subject to decertification be held harmless for the EHR reporting period during which the certification was withdrawn and for an additional 12 months following the end of such period. We also recommend that providers have the ability to seek two additional hardship exceptions covering a 12-month calendar year should their CEHRT be subject to decertification.

Health IT Module Certification Criteria

Privacy and Security

ONC proposes a new approach to privacy and security (P&S) requirements which will vary based on the regulatory functional area and will not require each criterion to meet all P&S functionalities. Rather, a certification criterion within each regulatory functional area would be required to meet a minimal set of P&S functionalities that ONC determines would afford users the appropriate safeguards.

CHIME generally supports the revised P&S policy and appreciates efforts to reduce burden on health care providers where possible, in this case by requiring vendors to assure that their Health IT Modules have the requisite P&S functionalities rather than imposing that burden on health IT users. The policy approach is both logical and feasible.

However, the proposal does raise some concerns. For example, with respect to end-user device encryption, it is unclear how a software vendor could guarantee that functionality. Additionally, there are already barriers built into health IT to the transmission of patient information among

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providers. If the precision of the P&S requirements vary significantly among Health IT Modules and electronic health records, CHIME is concerned that the patient information will not be easily transferrable among providers. We encourage ONC and software developers to avoid or eliminate software functionality restrictions that block patient information transfers among providers to the greatest extent practicable.

Transitions of Care

ONC proposes to expand on the 2014 Edition transitions of care criterion by using updated C-CDA standard; by requiring capabilities to detect valid and invalid C-CDA documents; and by requiring a Health IT Module certified to SMTP-based edge to accept and process XDM packages it receives.

CHIME is generally supportive of the proposed modifications to this criterion. We would urge ONC to ensure as part of the testing for certification to this criterion that the exchange of information (both sending and receiving) is the exchange with valid content. Because there is significant variability in the manner in which content is formatted, there should be no assumptions in ONC-ABC testing that the content sent or received will be valid.

CHIME respects the precision with which ONC uses and updates terminology and nomenclature in the language of the regulations under its jurisdiction. As in previous rulemaking cycles, this rule proposes to rename a number of items for clarity and appropriateness. Along these lines, ONC should update some of the terminology under the proposed patient matching data elements to reflect current practice. For example, ONC should substitute the term "birth name" for the term "maiden name." Likewise, the name of the proposed data field "middle name (including middle initial)" should be modernized to recognize that where an individual's middle name is one letter, it is an initial. This is consistent with current industry nomenclature.

Additionally, some proposed data fields should provide for more specificity. For example, the proposed data element place of birth should include fields for city, state, and country. Where possible, ONC should adopt standard approaches for these fields to reflect current practice. It would be more helpful to specify the format for the phone number and to include additional fields, such as a filed for a patient's email address.

CHIME strongly urges ONC to include in the patient matching quality data functionality a field for a voluntary national safety identifier. Users would be permitted to assign for themselves a national safety identifier for use for every provider. This national safety identifier could be consistent with an email address and would facilitate communication of data among providers and the patient.

Data Portability

ONC proposes to enhance requirements for data portability to facilitate the accessibility and exchange of data. ONC revises the focus of this criterion; the capability would need to be user-focused and user driven (i.e., users must be able to set the configuration options and be able to

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execute these capabilities at any time the user chooses and without subsequent developer assistance to operate).

CHIME supports the proposed change to a user-focus for the criterion. One concern we have is whether a health care practitioner will be able to identify whether the information that is downloaded relates to the correct patient. While this could pose a challenge to developers, this capability would be a meaningful requirement to include for purposes of patient safety and practice efficiency. Additionally, it is not clear from the proposed requirements how a patient would migrate his or her health care data from one practitioner or provider to another. As a practical matter, the criterion does not appear to permit practitioners and providers to access all of the patient's data. We recognize that this may involve more than multiple years of data and thus may complicate efforts of developers; however, incomplete data unnecessarily complicates the provision of health care and increases risks of adverse events.

Data Segmentation

ONC proposes two new certification criteria for data segmentation in order to separately track or "segment" individually identifiable health information in an EHR that is protected by federal and state privacy rules that are more restrictive than the HIPAA Privacy Rule, and to apply privacy metadata tagging at the document level.

To our knowledge, ONC has not proposed such a criterion in previous rulemaking, and there is not much practical experience with this type of effort. The policy goal here is sound; however, we believe this will be a particularly complicated product to develop. This is in part due to the specificity required to address the myriad privacy rule rules and their interaction; another issue is the degree to which tagging is done. For example, would tagging be done at the patient level, the encounter level, or some other level? We believe these policies require more study and testing before proposing to include them as certification criteria.

View, Download, Transmit to 3rd Party (VDT)

ONC proposes a number of revisions to the VDT criterion, such as clarifying that it is patient-facing and for patients to use; including the Common Clinical Data Set (CCDS) and diagnostic image reports; requiring that the same API capabilities applicable to the CCDS apply to this criterion; providing patient laboratory test reports; and for the view capability, to be compliant with Web Content Accessibility Guidelines (WCAG) 2.0 Level A.

CHIME believes that the proposed modifications to the VDT criterion are helpful, especially the clarification of the patient-centered focus of these capabilities. As patients become more educated about health care, it is essential that they be given the tools to better understand and communicate their care options and goals. Patients should take an active role in the decisions about their care, and this criterion could be modified to help achieve that policy goal. For example, we believe this criterion would be far more meaningful in the inpatient setting if it included the capability to deliver information during the course of the inpatient stay. Thus, the patient could become an active

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participant in his or her course of treatment, rather than being an observer, if the patient were able to view, download and transmit patient information in real time. Real-time records are available at a number of hospitals, and ONC has an opportunity to further encourage this capability through the VDT certification criteria. Should ONC conclude that it would not be feasible to include this functionality for this rulemaking cycle, it should propose to include it in future rulemaking.

With respect to the requirement that the data should be in their English (i.e., non-coded) representation, CHIME is concerned that although a patient may be able to read the data, he or she may not understand its meaning. Because most patients are not conversant with the technical language of medical practice, the data required to be provided in English should meet a plain-English standard. In other words, there is an opportunity here to further engage the patient in his or her care by making the data available to the patient in a format and language that the patient can readily understand. Consistent with proposals to make this criterion more focused on the patient, data should be represented using patient-centric language. Again, if ONC determines that this type of requirement is not feasible for this rulemaking cycle, it should be included in the next rulemaking cycle.

Application Access to Common Clinical Data Set

ONC proposes a new certification criterion for application programming interfaces (API); health IT would have to demonstrate that an API responds to data requests for any one, and for all, of the data referenced in the Common Clinical Data Set (CCDS). The criterion would rigorously assess a product's C-CDA creation performance (for both C-CDA version 1.1 and 2.0) when presented for certification for exchange capabilities.

CHIME commends ONC's efforts to require and validate continued interoperability of certified health IT and the ability to exchange health information. The use of APIs should help meet that policy goal, but this depends in part on how APIs are integrated into different health IT products. In the proposed capabilities of the criterion, ONC does not specify the event that permits an API to send or receive data (i.e., the trigger event) so that a user may meaningfully use the data. Additionally, the proposed criterion does not specify the point at which an API will be activated when sending or receiving data. Finally, the criterion does not address the case where there is no API available to collect the data to answer a patient's query.

CHIME hopes the above comments are helpful. Should you have any questions about these comments or need more information, please contact Leslie Krigstein, Interim Vice President of Public Policy, at lkrigstein@chimecentral.org. We look forward to continued partnership and dialogue.

Sincerely,

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