

April 29, 2010

David Blumenthal, MD, MPP
National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave., SW
Washington, DC 20201

Attention: Certification Programs Proposed Rule

Comments submitted electronically at <http://www.regulations.gov>

Re: Proposed Establishment of Certification Programs for Health Information Technology: Proposed Rule (RIN 0991-AB59)

Dear Dr. Blumenthal:

The College of Healthcare Information Management Executives (CHIME) appreciates the opportunity to comment on the proposed rule guiding establishment of certification programs for health information technology published on March 10, 2010 (*Federal Register*, Vol. 75, No. 46, p. 11327).

CHIME's 1,400 members represent chief information officers (CIOs) and other top information technology executives at many of the nation's largest hospitals. CHIME members have front-line experience in implementing clinical systems, and have learned by trial and error what works and what doesn't in implementing such electronic systems and optimizing the value derived from them. Healthcare CIOs share the vision of an e-enabled healthcare system as described by the HIT Policy Committee, the Office of the National Coordinator for Health Information Technology, and the Centers for Medicare & Medicaid Services.

One of CHIME's primary objectives is to provide educational and other resources to further the adoption of EHR systems across the healthcare continuum. To that end, we have offered numerous educational sessions in past years at our semi-annual meetings, enabling members to share their successes and lessons learned. We plan to re-double our educational efforts in the coming years to support accelerated adoption under the EHR incentive programs, through venues such as our successful CIO Boot Camps and LEAD Forums, which facilitate

information sharing among our members.

This comment letter addresses issues of concern to our members as they seek to implement certified EHR technology and meet the requirements of proposed meaningful use regulations. Although the main purpose of the certification rule is to establish the processes and requirements for the certification program, many aspects of the rule will affect the attributes of the certified products that providers purchase and install. In addition, some hospitals and physician groups may have self-developed electronic health record systems that must be separately certified, so the long-term certification program is of heightened interest to them as well.

We preface our comments on these proposed certification program regulations with the observation that the key purpose of certification is to give healthcare providers a degree of assurance that the products they purchase will perform as promised to support them in achieving the meaningful use objectives for EHRs, thus qualifying to receive stimulus fund payments under the HITECH Act. As such, certification is meant to support providers, not pose an additional burden to them.

Based on this foundational tenet, CHIME believes that regulations surrounding certification must uphold a clear dichotomy of responsibility – healthcare providers are responsible for meaningfully using electronic health records systems and supporting technologies, while vendors of healthcare IT products must ensure that their EHR systems meet the certification criteria to support providers in achieving meaningful use. Any certification policy issued by federal agencies must actively reinforce this division of responsibility.

CHIME previously responded with comments on the temporary certification program (attached as Appendix I), which had a deadline for comments of April 9. Some of our concerns expressed in that letter remain overarching concerns that are especially applicable to the development of the permanent certification program.

We want to emphasize the following major points from our previous comments on the temporary program. The page numbers associated with the following items refer to the pages on which those comments are discussed in detail.

- If ONC pursues a two-stage certification process, as it has currently proposed, it is essential that the two programs be designed to work together in a seamless fashion, so that they mitigate any potential uncertainty from the existence of two separate programs. The temporary program should serve as a provisional or interim effort that is harmonized with the permanent process. Careful design is necessary to limit the uncertainty and eliminate the risk of needless product replacement in the marketplace (Page 4).
- Enabling the certification process to proceed quickly is critical to the industry's efforts to implement clinical systems that providers can use in a meaningful way. We cannot emphasize enough the need for a mechanism that enables the rapid analysis of

currently certified programs so that they can be deemed approved after testing against criteria needed to achieve meaningful use. While the temporary process serves as a stopgap measure intended to provide rapid certification, industry stability will require a permanent program that is quick, yet thorough in its approval of certified systems (Page 5).

- Final regulations must provide more specific language to define what constitutes a self-developed EHR. The current wording of the regulation suggests that any complete EHR or EHR module that is modified by a healthcare provider or a contractor could require re-certification as self-developed. (Page 2).
- Changes in certification requirements should be made only when they are necessary to meet meaningful use evolution or advance interoperability, not for other reasons, such as the mere passage of time (Page 7).
- If CMS maintains the “adoption year” approach originally advanced in proposed regulations, products certified for capabilities beyond this “adoption year” should not be required (Page 9).
- Individual EHR modules should be certified to ensure that they are able to communicate according to adopted standards and that the interoperability of those modules as used by providers be deemed as certified (Page 10).
- HIT vendors should fully disclose functions for which their products are certified and fully disclose known compatibility issues (Page 11).
- In the event that a certification body loses its authority to certify products, vendors should have six months to recertify products, and providers should not be penalized for a change in a product’s certified status if they are still able to demonstrate meaningful use of the technology (Page 12).

1. Questions about expanding the certification process

[This section provides comment on Section III.E. of the NPRM.]

The NPRM requests comments on a variety of questions regarding expansion of the certification program to other, related forms of technology. For example, should personal health records (PHRs) be subject to certification?

CHIME firmly believes that there is a need to prioritize certification efforts to focus initial efforts on immediate needs. While there may be good cause to eventually certify PHRs and other technologies to support the flow of health information, the time for considering that expansion is in the future, not now. All certification efforts, whether in the provisional program or the permanent program, need to focus on developing a program to approve clinical applications for achieving meaningful use criteria. In the immediate term, this will represent a significant effort. Because of the crucial role that certification plays in a providers’ eligibility to receive stimulus funds, it is important that all efforts be initially focused on ensuring the success of the certification of IT to achieve meaningful use criteria.

As certification evolves over time, everyone involved in the process will surely learn valuable lessons from this initial certification effort, and that will make it easier to apply that knowledge to certifying other technology. Thus, the federal government needs to carefully develop and stage these certification efforts.

To use a common analogy, this program needs to “walk” and create an effective process for assuring products can help providers achieve meaningful use objectives, before it tries to “run” by expanding scope beyond the immediate needs.

Recommendation:

CHIME firmly believes that there is a need to prioritize certification efforts to focus initially on immediate needs. While there may be good cause to eventually certify PHRs and other technologies to support the flow of health information, the time for considering that expansion is in the future, not now. All certification efforts, whether in the provisional program or the permanent program, need to focus on developing a program to approve clinical applications for achieving meaningful use criteria.

2. Question about the number of Authorized Certification Bodies

[This section provides comment on Section III.G. of the NPRM.]

Any current approach needs to ensure that ONC-Authorized Certification Bodies (ACBs) have enough capacity to handle the urgent and timely need to certify all clinical applications that providers will need to achieve meaningful use objectives.

We believe there is a “sweet spot” for the number of ACBs that can effectively perform certification in both the near and long term. If there are too few certification bodies in the program, they will be unable to effectively handle the demand for certifications that can be expected at the outset of the program. Alternatively, if there are too many ACBs, we question whether all such entities can sustain their businesses after the initial rush of certifications has been awarded.

Key to the success of this program is its ability to certify applications against the proper criteria, and for the various ACBs to achieve consistent results. Every ACB should reach the same conclusion about the certification of every module or collection of modules submitted. The real answer in determining the number of ACBs to handle current and future capacity is ONC’s accurate assessment of their capacity to handle the needs of the industry for certification.

Recommendations:

It is crucial that sufficient certification capacity is available in the market to handle the demand for certification while ensuring that the need for quality and consistency is met.

The real answer in determining the number of ACBs is ONC's accurate assessment of the overall capacity needed.

To ensure the quality and consistency of the certification process, we strongly advise that any ACB determined to be effective and accurate in the temporary certification program be carried forward into the permanent process. By doing so, ONC will provide important protections to those vendors and providers that have installed applications certified under the temporary process.

3. The role of surveillance in certification

[This section provides comment on Section III.D. of the NPRM.]

The preamble of the proposed rule mentions that surveillance will play a role in certification. While we understand the need to ensure that certified products perform as anticipated in live environments, we express significant concerns about the surveillance component, particularly from a practical perspective.

Surveillance already plays an important role in ensuring quality care in healthcare settings, but there is a fundamental difference between these activities. For example, surveillance of MRI or CT devices for radiation doses is of a different scope than overseeing the functionality certified for an EHR system. For clinical systems, it will be important that any type of surveillance activity to measure system safety not become overly prescriptive or stringent.

Potential surveillance of EHR products raises a number of questions that are important to vendors, providers and the industry as a whole. We ask that, before certification bodies are instructed to conduct surveillance, ONC should provide additional information and ensure adequate opportunity for the industry to comment on ONC's positions, particularly on the following questions:

- Is surveillance primarily intended to check on the actual performance of vendors' products?
- If adverse findings are made through a surveillance process, what will the impact be on vendors? On providers?
- What type of surveillance will be done, and how will it be conducted?
- Do adverse results from surveillance only relate to the vendors and their products? What happens in instances in which providers don't use a product properly?
- What will be done with adverse outcomes uncovered by surveillance? Will such information be publicly available?
- What types of remediation or recertification will be required for issues uncovered through a surveillance process?

Recommendation:

More information is needed on how an EHR surveillance program will be conducted. We believe that an overly aggressive surveillance program could have a number of unintended consequences, potentially slowing the pace of product development, and could impede the efforts of CIOs to make IT advancements in their organizations.

We also believe that it is important for any surveillance component to provide a vehicle for providers to offer feedback or voluntarily report problems with certified products. Each ACB should provide a voluntary mechanism for providers to report problems with application functionality intended to achieve meaningful use.

4. Testing Under the Permanent Certification Program

It is our understanding that under the permanent certification program, ONC will oversee the activities of the certification bodies, while the National Institute of Standards and Technology (NIST) will oversee the testing bodies for EHRs. As such, the NPRM does not discuss the testing process under the permanent process. We are concerned that this split in regulatory authority, if not managed properly, could unintentionally result in confusion and delay the certification of products.

In addition, CHIME remains concerned about the ability of states to create additional testing requirements, since states have the freedom to customize requirements for their state Medicaid programs. We urge that states be prohibited from requiring redundant individual or separate processes for testing. All testing, whether done at a state or national level, should be consistent with the proposed certification process.

Of key importance to this process is clearly delineating when testing occurs in the certification process. It is our understanding that products will be tested before they are certified, but this is not clearly defined in the proposed rule.

Recommendations:

To provide assurance that the testing and certification processes will work together, we ask that ONC provide detailed information on how ONC and NIST will coordinate efforts to ensure that the testing facilities overseen by NIST are established in a timeframe consistent with the ONC efforts to approve certification bodies and have sufficient technical expertise and capacity to support demand for testing and certification in a timely manner. This level of coordination should not only apply to Medicare, but also for Medicaid at the state level.

We also ask ONC to work with NIST to ensure that all testing methods proposed under the temporary certification process are available under the permanent process as well. Specifically, on-site and remote testing of EHRs will be needed. Providers that require certification of self-developed EHRs will need to have their systems both tested and certified. Therefore, these steps must be well coordinated so that the resulting program

would not prove overly burdensome to provider organizations with self-developed applications.

5. Review of certification process

The development of the certification process is of the utmost importance to the success of this program to expand the use of electronic health records systems and then, subsequently, to reward providers for meaningful use. The certification process needs to be rigorous, so that certifying bodies' results are not subsequently challenged or overturned. Any process that leaves doubt about the quality of the certification process will detract from market stability and confidence, both in the products themselves and in providers' ability to use them to improve care and achieve meaningful use.

We recommend that the temporary certification process be used as a learning experience that is used to foster the development and improvement of the permanent program. Both providers and vendors should be engaged to provide feedback, with an active, ongoing dialogue to assess progress.

Recommendation

We recommend that ONC establish an ongoing, periodic evaluation process for the certification process that includes consultation with providers, vendors and certification bodies. In the process of developing a certification process for these applications, provider input is important because this newly created program will significantly affect providers who are the end users of these certified systems.

Conclusion

In closing, we understand the importance of certification and reiterate our support for this process as an essential ingredient in encouraging the confident and rapid deployment of EHR systems by the nation's providers. We are grateful to participate in activities that can facilitate needed improvements in healthcare quality and efficiency, patient engagement, and public health. As individuals with leadership roles during this promising transformation of information systems, we take this opportunity very seriously and intend to work tirelessly to achieve our collective vision.

Certification can play a positive role in ensuring provider confidence in vendor products. As providers, we emphasize that certification policy should recognize that vendors bear the primary responsibility for meeting certification requirements. We as providers recognize that we will be responsible for meeting and demonstrating meaningful use.

Overall, the industry needs more clarity about and input into whatever oversight process is designed for healthcare IT. All industry segments should provide input into the development of criteria and how certification will take place, so that the resulting system is effective without being overbearing. Such input can make the currently proposed certification process

less of a “one-off” answer to meet the legal requirements for stimulus funding and make it the first step in a process to provide rational, continual improvement in the use of IT among the nation’s providers.

As ONC develops its certification program, we urge you to carefully consider the impact of these regulations on market stability and favor those that offer the most certainty and predictability. We also urge you to ensure that future requirements are laid out as clearly and as early as possible, and are supported by rational timelines that give vendors and providers sufficient time to modify and install products in an orderly fashion.

If you have questions on any of these comments or need more information, please contact Sharon Canner at scanner@cio-chime.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'All', with a long horizontal flourish extending to the right.

Richard A. Correll, President & CEO

Appendix I. CHIME Comments on Temporary Rule



April 7, 2010

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to share their successes and lessons learned. We plan to re-double our educational efforts in the coming years to support accelerated adoption under the EHR incentive programs, through venues such as our successful CIO Boot Camps and LEAD Forums, which facilitate information sharing among our members.

This comment letter addresses issues of concern to our members as they seek to implement certified EHR technology and meet the requirements of proposed meaningful use regulations. Although the main purpose of the certification rule is to establish the processes and requirements for the certification program, many aspects of the rule will affect the attributes of the certified products that providers purchase and install. In addition, some hospitals and physician groups may have self-developed electronic health record systems that must be separately certified, so this rule, and its role in the plan to develop a long-term certification program, is of heightened interest to them as well.

We preface our comments on these proposed certification program regulations with the observation that the key purpose of certification is to give healthcare providers a degree of assurance that the products they purchase will perform as promised to support them in achieving the meaningful use objectives for EHRs, thus qualifying them to receive stimulus fund payments under HITECH legislation. As such, certification is meant to support providers, not pose an additional burden to them.

Based on this foundational tenet, CHIME believes that regulations surrounding certification must uphold a clear dichotomy of responsibility – healthcare providers are responsible for meaningfully using electronic health records systems and supporting technologies, while vendors of healthcare IT products must ensure that their EHR systems meet the certification criteria to support providers in achieving meaningful use. Any certification policy issued by federal agencies must actively reinforce this division of responsibility.

1. Self-Developed EHRs

[This section provides comment on Section I. Background]

In the NPRM, ONC provides a mechanism for providers to present their predominantly self-developed complete EHR or their self-developed EHR modules to a certification body for approval under both the temporary and permanent certification programs. It will be important for many providers to have this kind of flexibility. However, the definition of “self-developed EHR” included in the NPRM is too broad; as currently worded, the proposed regulations could deem many hospitals’ EHR systems and some physician practice systems to be “self-developed.”

The NPRM defines a self-developed EHR as, “A Complete EHR or EHR Module that has been designed, modified or created by, or under contract for, a person or entity that will assume the total costs for its testing and certification and will be a primary user of the Complete EHR or EHR Module. Self-developed (systems) could include brand new

Complete EHRs or EHR Modules developed by a health care provider or their contractor. It could also include a previously purchased Complete EHR or EHR Module *which is subsequently modified by the health care provider or their contractor and where such modifications are made to capabilities addressed by certification criteria adopted by the Secretary.*” (p. 11333, emphasis added)

CHIME is very concerned with the general nature of this definition and the inclusion of the word “modified” without sufficient explanation. A broad interpretation of modification by the agencies charged with enforcing a final regulation on this topic may require more providers to embark on the certification process than is necessary or effective.

Given the likely high level of demand among HIT vendors to have their products certified, and the projected high cost of certification for self-developed EHRs, we do not believe that it is in the best interest of providers – or the government – to require large numbers of providers to conduct separate certification of systems deemed to be self-developed simply because of a broad interpretation of the word “modified.”

Certified systems may be modified for many reasons. As long as the system can still perform the function for which it was originally certified, these modifications should not trigger the need for a self-developed certification, even if the changes are made to the capabilities addressed by the certification criteria.

Currently, many hospitals’ EHR systems contain components from more than one vendor. Frequently, hospitals integrate different systems from a number of vendors to provide the full panel of capabilities they deem necessary to achieve an all-encompassing electronic health record. Even those facilities that install an enterprise system from one vendor routinely supplement it with other products meant to achieve specific needs, such as department-specific systems for surgery or the radiology department. These systems may require the use of interfaces to exchange data, which may necessitate modifications to certified EHR modules to ensure that they work together.

ONC has clearly stated that providers bear full responsibility for making certified EHR modules work together. Therefore, they must have the ability to make needed modifications to modules to achieve that purpose. These modifications may affect, or even enhance, the capabilities addressed by the certification criteria. Modifications may include, for example, introducing new vocabulary sets or employing exchange standards that facilitate the sharing of information among an organization’s entire EHR system. However, as long as these modifications do not negate the certification criteria, deviate from adopted standards or inhibit hospitals’ or eligible providers’ achievement of meaningful use, they should not affect the certified status of the products.

In addition, many hospitals write custom programs to generate specific reports, such as a dashboard of indicators for high-priority quality improvement activities. They also may add custom programs to provide specific decision-support functions, including, for instance,

evidence-based order sets or diagnostic decision trees derived by clinical staff. These programs may enhance certified functions, such as quality reporting functions or clinical decision support, to support or extend them.

Certification requirements also must take into account the fact that some healthcare organizations that purchase certain vendor products are given access to the code underlying software applications, and then slightly change the code to adapt it to their circumstances. Such customization generally does not materially affect the underlying product and its capabilities. Regulations governing certification should include provisions to enable providers to make modifications to certified products they have purchased without requiring recertification of products. Such modifications should not be confused with self-development of applications, where providers conceptualize and then create specific applications from scratch to meet their organizations' purposes.

Our concern about this issue is heightened for two reasons. First, the time and money costs of individual certification of self-developed systems will be substantial. Second, under the Medicare and Medicaid EHR incentive programs, providers will submit attestations to federal and state governments about their certification status, and those attestations are subject to later audit by enforcement agencies. An attestation to a federal or state government conveys a legal compliance burden that could result in significant penalties if hospitals and enforcement agencies have differing understandings of the specific requirements. Therefore, providers must feel confident that the kinds of modifications they routinely undertake will not trigger the need for separate certification.

Recommendation:

We recommend that ONC modify its definition of what constitutes a self-developed EHR to better reflect the realities of the market and to limit the scope of provider EHR systems that would otherwise be subject to an expensive and burdensome certification process. Specifically, we recommend that the second half of the definition read: “Self-developed (systems) could include brand new Complete EHRs or EHR Modules developed by a health care provider or their contractor. It could also include a previously purchased Complete EHR or EHR Module which is substantially and materially modified by the health care provider or their contractor in such a way that the capabilities addressed by certification criteria adopted by the Secretary are negated, preventing the achievement of Meaningful Use objectives.”

2. Two-Stage Certification Process

[This section provides comment on Section I.E. Factors influencing the proposal of both temporary and permanent certification programs]

The NPRM proposes a two-stage approach in establishing a federal EHR certification process. The first is designed as a temporary stage that would include a process by which ONC establishes a method for evaluating the capabilities of various entities to test and certify

EHR products. ONC then would recognize these ONC-Approved Testing and Certification Bodies (ONC-ATCBs), which would establish their own processes for certification of vendor and self-developed EHRs.

In the proposed rule, ONC states that it designed the temporary process to create an expedited way to make certified products available to the market. The permanent process is expected to be more complex and involve separate testing laboratories (to be accredited by NIST), an independent ONC-Approved Accreditor, and multiple ONC-Authorized Certification Bodies (ONC-ACBs) that would certify products based in part on their independent testing results. The current comment period (and this comment letter) addresses issues with the temporary certification program; a separate, longer comment period will cover the permanent certification program, and CHIME plans to respond to those proposed regulations separately.

We are very concerned that the introduction of a two-stage approach for certification will prolong the current instability in the health IT marketplace, which exists because of the unfinalized status of meaningful use and certification regulations. Above all else, providers need a stable marketplace in which vendors can quickly offer and support implementation of certified products that will enable providers to use those products meaningfully in the course of providing care. However, neither providers nor vendors feel confident in their ability to make design changes and investment decisions when the final meaningful use requirements and certification criteria are not known. Even when those regulatory requirements are known, the introduction of two separate certification schemes – one temporary and one permanent – carries a risk of continuing the uncertainty and promoting needless product replacement in the marketplace.

We also anticipate that the market will continue to be affected by queues for certification; rapid growth in demand for vendors' products; limited vendor capacity to support installations; and HIT workforce shortages.

It is critically important that the two stages of this process work together, so as to promote the adoption of EHR technology in the marketplace, and diminish and eventually eliminate the uncertainty surrounding product certification for both providers and vendors. To achieve that, any interim approach toward certification should be positioned as provisional, an approach by which the philosophy ungirding the first phase of the approach is building toward and logically can be extended to harmonize with the permanent process. In implementing a provisional program, ONC would actively support and encourage the organizations that achieve approval as certification bodies under the provisional program to transition as smoothly as possible to being recognized under the permanent program. As part of this approach, products receiving certification under the provisional program would be seen as equally valid as those certified under the permanent program.

We note that the establishment of a provisional certification process will **not** be sufficient to support providers in achieving meaningful use under the Medicare EHR incentive program

that will begin on October 1, 2010. Providers must have a large pool of certified products available in order to intelligently select the application that best fits their organization's circumstances. Even having certified products available only starts the clock on implementation of EHR systems – a process that takes years, not months.

In our previous comment letter to CMS on standards and certification, CHIME had asked for consideration of a “grandfathering provision,” with the intent that existing systems that hospitals use to meet meaningful use objectives could be accepted as “certified.” We believe that the proposed temporary certification process could essentially achieve the same purpose, if currently certified systems can be rapidly approved if they achieve the requirements to be set through the interim final rule (IFR).

However, we cannot emphasize enough the need for a mechanism that enables the rapid analysis of currently certified programs so that they can be deemed approved after testing against criteria needed to achieve meaningful use. This will allow for the rapid certification and deployments of certified systems. It also could enable providers to focus on those aspects of their EHR systems that must be added or modified (using certified products) to meet meaningful use objectives, rather than undertaking wholesale system upgrades across all functionalities.

Recommendations:

1. We urge that the provisional certification process include existing certification mechanisms augmented to include gap analysis of capabilities specified by ONC's interim final rules. This will allow for the rapid development of certified solutions. A quick and nimble provisional approach is urgently needed because getting certified products into providers' hands quickly is essential if they are to meet demanding implementation windows for installing EHR applications that can meet meaningful use objectives.

2. In establishing temporary certification, ONC should clearly position it as provisional, meaning that it will lead logically into a permanent certification process. ONC should actively support the ONC-ATCBs in obtaining permanent status as ONC-ACBs. In addition, ONC should clearly state that products certified under the provisional program will be considered equal to those certified under the permanent program, with no automatic recertification required.

3. Length of certification and transition from the temporary to permanent certification process

[This section provides comment on Section II.E. ONC-ATCB performance and testing of certification.]

ONC is proposing a two-year time limit on the certified status of Complete EHRs and EHR Modules because it believes “the planned two-year schedule for updates to meaningful use objectives and measures and correlated certification criteria creates a natural expiration for the ‘certified status’ of Complete EHRs and EHR Modules.” ONC further notes that those certified products “would need to be recertified in order for the eligible professionals and eligible hospitals to continue to possess HIT that meets...the definition of Certified EHR Technology (p. 11346).”

CHIME strongly disagrees with this statement and this approach of a predetermined sunset of certification every two years, to be timed with evolving stages and MU criteria changes. Upgrades should not be forced on providers for calendar-based reasons alone. The need to require additional certifications must be kept to a minimum to ensure market stability and avoid significant costs and disruption for unnecessary upgrades. We do not believe that all of the certification criteria will merit changes on a two-year cycle, even if meaningful use requirements change. Examples of certification requirements likely to remain static include drug-drug and drug-allergy checks, recording demographics, recording vital signs, recording smoking status, and generating lists of patients by specific conditions.

Avoiding an automatic expiration of certified status every two years is especially important in the context of modular certification. A provider using multiple EHR modules will find it very difficult to coordinate upgrades across modules and ensure that upgraded products work together. It is also important in the context of a market where providers must wait in vendor queues and undergo lengthy installations. Given the realities of the vendor marketplace and the time needed to implement systems, many providers will finish installations at the end of any given year. It is impossible for all systems everywhere to be upgraded to the same status on the same day, or even the same quarter of a given fiscal or calendar year.

Recommendations:

- 1. ONC should be judicious in making changes to certification requirements and limit them only to those that are truly necessary to meet meaningful use or advance interoperability through standards adoption.**
- 2. All certifications should be assumed to be valid until specific certification criteria change. This may mean that certification of certain EHR modules may last for many years.**
- 3. Certifications achieved under the temporary program should be as valid as those made under the permanent program. A product certified under the temporary program should not need to be recertified until significant changes are made in the meaningful use criteria.**
- 4. ONC should instruct certification bodies it approves to allow for “differential certifications” that test an EHR only to ensure that it has been modified to account for changes in Meaningful Use certification criteria.**

These recommendations are made in the context of current market realities. As noted in our comment letter on the interim final rule on certification criteria, providers need long lead times to implement complex EHR systems, change workflows and train clinicians in how to use these applications. As a result, it will become increasingly important for vendors developing and seeking certification of these products to work far in advance of the deadlines to which providers will be held responsible under meaningful use regulations. Insufficient lead time for product development and certification places an unfair burden on hospitals and eligible professionals, raising implementation costs and potentially jeopardizing patient safety.

While the timelines established in the ARRA make it difficult for the first round of certification criteria to be established well in advance of the date by which providers must use certified products, future timelines must be more rational. We recommend that in the future new substantial certification criteria be finalized at least two years before providers are expected to use the new functionality covered by new substantial certification criteria.

Recommendation:

When certification requirements change and new final requirements are available, we suggest allowing at least six months for vendors to incorporate the changes and an additional 18 months for providers to implement or upgrade their existing environments to meet the new meaningful use criteria that the certification criteria is intended to support. For example, if providers are expected to submit data to a personal health record (PHR) in 2015, the certification criteria should be established by 2013 to ensure that vendors have updated products, giving providers sufficient time to then install that capability.

4. Special circumstances under the adoption year approach

[This section provides comment on Section II.E. ONC-ATCB performance and testing of certification.]

In its proposed rule, CMS established an “adoption year” approach that would allow providers that are late adopters to achieve meaningful use based on earlier requirements.

CHIME recommended in its comment letter to CMS that the “adoption year” approach be replaced with a more rational transition that requires providers to meet a lower bar in the early years of the program, but increase requirements over time. We believe that this recommendation also would prevent the difficulties the “adoption year” approach poses for the certification program. Therefore, in this letter we affirm our previous recommendation to CMS.

If, however, CMS does adopt the “adoption year” approach, CHIME believes that the certification process must be synchronized with that policy. Providers that take advantage of

the “adoption year” approach should not be penalized by having to purchase certified products that are beyond the capabilities of their stage of meaningful use. ONC must continue to recognize certifications from “Phase I” through all years in which providers can demonstrate meaningful use by meeting the “Phase I” objectives. It is no more difficult for ONC to implement and manage multiple sets of certification requirements than it is for CMS to implement and manage multiple sets of meaningful use requirements.

That said, ONC will need to give clear guidance to certification entities about the certifications that are valid. ONC also will need to carefully outline the requirements to vendors to clearly state the “Meaningful Use Phase” their products support and ensure that the website that catalogues certified products clearly identifies this information for providers.

Recommendation:

Providers should not be required to have products certified beyond their specific adoption/meaningful use stage.

5. When Privacy and Security Certification Criteria Apply to EHR Modules

[This section provides comment on II.E.B.]

The NPRM requests comment on when EHR modules should be certified against privacy and security criteria. This is a difficult question that depends to some extent on the specific functions being performed. We believe security and privacy should be required in the certification process to the point where it is reasonable, based on the scope and use of that particular module. Systems that are limited in scope, such as a program that aggregates public health surveillance data and is operated by one or two individuals, would not have sufficient scope to warrant separate privacy and security protections. By contrast, a product that combines four base EHR modules and will be used by multiple individuals could warrant certification of accompanying privacy and security protections.

Recommendation:

Certification against security and privacy criteria should be required to the extent to which it is reasonable, based on the scope and use of a particular module.

6. Testing of whether EHR modules work together

[This section provides comment on II.D. Temporary certification program approval process.]

The NPRM asks for comment on whether certification could include testing to determine if EHR modules work together. While the end goal of a “plug-and-play” environment is widely shared and desired, the temporary certification program can only address this issue in a limited way.

Given the immature development of interoperability standards, we believe that the ability of EHR modules to work together should be tested and certified only when multiple modules are presented as an integrated bundle. Individual EHR modules should be certified to ensure that they are able to communicate according to adopted standards. Individual providers, however, should not have to separately certify the interoperability between two certified EHR modules that they have chosen to use together.

Rather, when certified systems are used together by a provider, they should be deemed certified. For example, lab systems are subject to rigorous and thorough CAP (College of American Pathologists) inspections to ensure the integrity of data as it flows between systems. As more providers use these accredited lab systems to share data with electronic health records, providers should not be required to certify the interface between the two systems.

Recommendation:

Individual EHR modules should be certified to ensure that they can communicate according to adopted standards. When certified modules are used together by a provider, they and their interoperability should be deemed as certified.

7. Types of ONC-ATCB Authorization

[This section provides comment on II.D.1.b.]

ONC asked for comment on whether certification bodies should be required to certify all types of complete EHRs and EHR modules or if they should be able to specialize by setting – for example, ambulatory or inpatient – or by function – such as e-prescribing.

“Niche” certifications could expand the pool of certified products available for implementation. Flexibility in vendor offerings also carries benefits for innovation. The ability to certify a product for a collection of EHR Modules, however, also provides vendors with an opportunity to certify against all but the most difficult to achieve meaningful use objectives, such as quality reporting or biosurveillance.

We are very concerned that this strategy, if adopted by vendors, could leave a provider with difficult and unfair choices, such as paying large sums for third-party applications that a provider will need for its “almost complete” EHR, or filling the gap through self-development, which would require the provider to pay for and conduct a separate self-developed certification. This is particularly problematic in the area of quality reporting, where data residing in the base EHR must be accessed to generate quality measures. Given the current lack of standardization, it is hard to envision a third-party product that could, in fact, pull that data easily.

It also is possible that, with the ability to certify a single EHR module or a collection of EHR modules, there may be some meaningful use objectives for which no vendors seek certification of their products. Alternatively, only one or two vendors may create certified products for those objectives, leading to monopoly or quasi-monopoly situations.

Recommendations:

1. It is important to providers that HIT vendors fully disclose the functions for which their products are certified, and to also fully disclose any compatibility issues of which they are aware.

2. In the event that no – or very few – vendors offer certified products to support a meaningful use objective, providers should not be held accountable for having certified products for those modules or for meeting those meaningful use objectives.

8. Authorized testing and certification methods

[This section provides comment on Section II.E.3.]

ONC proposes requiring ONC-ATCBs to have the capacity to test and certify products at their own facilities. ONC also proposes requiring that ONC-ATCBs also have the capacity to certify product through at least one of the following secondary means – at the site where the EHR was developed; at the site where the EHR resides, such as a hospital; or remotely, for example through secure electronic transmissions and automated web-based tools. ONC asks for comment on this proposal.

From the perspective of providers that need to certify a self-developed system, all of the secondary means for providing testing site options must be available to them. The proposed primary method – testing and certification at the ONC-ATCBs’ own facilities – is less important. If a provider has a unique self-developed system, there is no difference between the site where the EHR was developed and the site where the EHR resides – therefore, both options for testing sites are needed. Furthermore, it is our understanding that CCHIT, the only organization with existing experience in certifying EHRs, uses only remote methods for testing and certification. This approach has been deployed to lower the time and money costs of certification, a very important consideration for providers seeking certification of self-developed systems.

Recommendation:

CHIME recommends that ONC require ONC-ATCBs to have the capacity to certify products through all of the secondary means mentioned.

9. Retention of Records

[This section provides comment on II.D. and III.D. Application process, and applies to both the temporary and permanent programs.]

In designing the temporary program, ONC proposes requiring ONC-ATCBs to give their records to ONC when the program sunsets. The NPRM does not state how long ONC would keep those records. In the permanent program, ONC recommends that certification bodies keep records for five years. However, CMS has proposed requiring providers to maintain records demonstrating meaningful use, which includes use of a certified EHR, for 10 years. In the event of an audit, providers may need to go back to the certification body (or ONC, in case of the temporary program) to verify that a particular product was indeed certified at a particular point in time. Therefore, the retention period for certification bodies needs to be equal to the length of time that providers must maintain records, plus two additional years to ensure records are available during an audit process.

Recommendation:

We recommend that the retention period for records by certification bodies should be extended to at least match the duration of time that CMS requires providers to keep records, plus an additional two years to ensure records are available for potential audits. For products certified under the temporary program, it is ONC that would retain the records handed over by the ONC-ATCBs.

10. Impact Of The Revocation Of A Certification Body's Status On Providers

[This section provides comment on II.E.5.]

ONC has proposed that if a certification entity has its status revoked, any product whose certification is considered compromised would only retain its certification status for 120 days.

CHIME supports the goal of ensuring a fair and honest certification process and understands the need for sanctions in the event that certification entities violate the law or the rules of the program. However, it is not clear that an improper certification process actually would mean that a product fails to support providers in achieving meaningful use. Embezzlement or fraud by corporate officers, for example, does not inherently suggest that certified products cannot perform their designated functions. Therefore, we believe that the impact of violations by certification entities should not impact providers unless those violations negatively affect their ability to demonstrate meaningful use to CMS. Even in those cases, providers will need much more than 120 days to replace a product that has had its certification revoked.

In the event of a certification entity losing its status to certify records, ONC should test products to determine whether a faulty certification process has negatively and substantially impacted the performance of an application in achieving a meaningful use objective. If certified products are shown to have been affected by a certification body losing its status, HIT vendors should be given six months to recertify the application. The affected vendor

should not be able to sell the product to new customers, or proceed with new installations, until recertification is achieved.

Providers that purchased and installed a certified product in good faith, however, should not be negatively impacted by a faulty certification process. All providers able to demonstrate meaningful use to CMS using the product in question should continue to receive incentive payments and should not be required to replace the product out of the regular upgrade cycle. Providers should replace the product when new certification criteria have been finalized for the affected meaningful use criteria, or when their own strategic and technical requirements necessitate an upgrade, whichever comes first. The only exception to this approach should be when ONC or another federal agency determines that the improperly certified product poses a real and demonstrable risk to patient safety. If that rare circumstance occurs, providers that have installed the faulty product should be required to replace it as quickly as possible (which may take more than 18 months for some products), but be given an exemption for the affected meaningful use objective(s) under the Medicare and Medicaid EHR incentive programs so that their meaningful use status is not affected.

Recommendations:

- 1. If a certification entity loses its authority to certify products, ONC should give HIT vendors at least six months for product recertification by another certification entity.**
- 2. If a vendor fails to have its product recertified, the vendor should not be able to sell the product to new providers or begin new installations.**
- 3. Providers who have previously installed a product that loses its certified status and can demonstrate meaningful use to CMS should not be penalized in any way by a change in that product's certification status. They should be able to retain that certification until certification requirements change and a new certification is required.**
- 4. If ONC determines that an improperly certified product poses a real and demonstrable risk to patient safety, then providers that have installed the faulty product should be required to replace it as quickly as possible (which may take more than 18 months for some products), but be given an exemption for the affected meaningful use objective(s) under the Medicare and Medicaid EHR Incentive Programs so that their meaningful use status is not affected.**

Conclusion

In closing, we understand the importance of certification and reiterate our support for this process as an essential ingredient in encouraging the confident and rapid deployment of EHR systems by the nation's providers. We are grateful to participate in activities that can facilitate needed improvements in healthcare quality and efficiency, patient engagement, and public health. As those with leadership roles during this promising transformation of

information systems, we take this opportunity very seriously and intend to work tirelessly to achieve our collective vision.

Certification can play a positive role in ensuring provider confidence in vendor products. As providers, however, we emphasize that certification policy should recognize that vendors bear the primary responsibility for meeting certification requirements. For their part, providers will be responsible for meeting and demonstrating meaningful use.

As ONC develops its certification program, we urge you to carefully consider the impact of these regulations on market stability and favor those that offer the most certainty and predictability. We also urge you to ensure that future requirements are laid out as clearly and as early as possible, and are supported by rational timelines that give vendors and providers sufficient time to modify and install products in an orderly fashion.

If you have questions on any of these comments or need more information, please contact Sharon Canner at scanner@cio-chime.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'All', with a long horizontal flourish extending to the right.

Richard A. Correll, President & CEO