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May 10, 2010

David Blumenthal, M.D., MPP
National Coordinator for Health Information Technology
Department of Health and Human Services

[Submitted electronically]

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

Dear Dr. Blumenthal:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the proposed rule guiding establishment of certification programs for health information technology (IT) published on March 10 (*Federal Register*, Vol. 75, No. 46, p. 11327).

America's hospitals share the administration's vision of a health care system where widespread use of interoperable electronic health records (EHRs) supports improved clinical patient care, better care coordination, fully informed and engaged patients, and improved public health, and are taking steps to move toward an e-enabled health care system where all hospitals meaningfully use EHRs. They also work every day to ensure adequate privacy and security protections for patients and their personal health information.

The AHA greatly appreciates the hard work that the Office of the National Coordinator for Health Information Technology (ONC) has put into developing the proposed rule. We also appreciate ONC's close coordination with the Centers for Medicare & Medicaid Services (CMS) to ensure that the certification processes support hospitals and other providers in meeting the meaningful use criteria that will be established under the Medicare and Medicaid EHR incentive programs authorized by the *American Recovery and Reinvestment Act of 2009* (ARRA).

Our comments focus on those aspects of the proposed rule that will affect how providers interact with certification entities, and the attributes of the certified products they purchase and install. We also consider how the proposed rule would affect those

hospitals and physician groups that have developed, in-house, their own EHR systems, which must be separately certified. In both cases, we seek to minimize the burden on providers. While most of these comments concern the permanent certification program, we also reiterate recommendations from our letter on the temporary program that are relevant to the permanent certification process, including the critical need to grandfather as certified currently implemented systems that support providers in demonstrating meaningful use. Our previous letter is attached for reference.

The AHA and many of its member hospitals have participated in the activities of the Certification Commission for Health Information Technology (CCHIT) and see both the merits and limitations of EHR certification. Certification provides a level of confidence to purchasers that products meet a baseline level of performance, and could be a means for ensuring that products support standards that will facilitate information exchange. It is not, however, a guarantee that products will work together, be user-friendly, or be cost-effective to maintain.

We strongly believe that the primary purpose of the federal certification process is to give health care providers a reasonable degree of assurance that the EHR technology products they purchase will perform as promised. That is, certification is meant to support providers in achieving meaningful use. Certification is not intended to impose an additional burden on providers.

There should be a clear distinction between the responsibilities of health care providers and the responsibilities of vendors of health IT products. Health care providers rightfully have been asked to take the lion's share of responsibility for meaningfully using EHR systems and supporting technologies. Vendors of health IT products must ensure that their EHR systems meet the certification criteria to support meaningful use. Certification policy must actively reinforce this division of responsibility.

BUILDING ON THE TEMPORARY CERTIFICATION PROCESS (SECTION I.E.)

ONC proposes a two-stage approach in establishing a federal EHR certification process. The first stage 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 in turn establish their own processes for testing and certification of vendor and self-developed EHRs. The second stage, or the proposed permanent process, would be more complex and involve separate testing laboratories to be accredited by the National Institute of Standards and Technology (NIST), an independent ONC-Approved Accreditor (ONC-AA), and multiple ONC-Authorized Certification Bodies (ONC-ACBs) that would certify products based in part on the independent testing results.

As ONC develops the permanent certification program, we recommend that ONC actively build on the temporary certification program. For example, ONC should support the ONC-ATCBs in obtaining permanent status as ONC-ACBs. In addition, ONC should state clearly that products certified under the provisional program will be considered equal to those certified under the permanent program, with no automatic recertification required when the permanent program is established.

While we understand that the temporary process is meant to provide an expedited process to ensure certified products are available on the market as soon as possible, the two-stage approach for certification will prolong the current instability in the health IT marketplace, which ONC should take steps to limit. In the near term, the market will be negatively affected by queues for certification; rapid growth in demand for vendors' products; limited vendor capacity to support installations; and health IT workforce shortages. Linking the two certification programs and building confidence in the value of certification under the temporary process will provide a measure of assurance for those buying and selling certified products.

Differential Certification

ONC requested comment on whether the ONC-ACBs should conduct "differential certifications" that test an EHR only to ensure that it has been modified to account for changes in certification criteria, and when differential certifications should begin. In particular, ONC asks whether vendor products should undergo complete certifications at least once under the permanent process or be allowed to complete differential certifications from the beginning of the certification process.

ONC should direct the ONC-ACBs to conduct differential certifications from the beginning of the permanent program. As noted above, market stability requires that ONC take all steps to make the transition to the permanent certification process seamless. If ONC signals that certifications made under the temporary program are somehow inferior to the permanent process, as a wholesale recertification requirement would suggest, then vendors and providers may conclude that they should wait until the permanent process is established to act.

Surveillance of Certified Products

The NPRM proposes to require that ONC-ACBs conduct surveillance of certified EHRs after they have been installed. The proposed purpose of surveillance is to "determine whether the Complete EHRs and/or EHR Modules… certified in a control environment also perform in an acceptable, if not the same, manner in the field as they had performed when they were being certified (p. 11336)."

Surveillance of products to ensure that they continue to comply with certification requirements is important, and certification bodies should have processes in place to

ensure that vendor products sold as certified do, in fact, meet the certification requirements. Surveillance of installed, certified products is, however, a new concept in health IT that, as the NPRM notes, raises many questions. It is difficult for stakeholders to answer those questions, however, without a better understanding of what the process is meant to accomplish, what it will entail, and how the results of surveillance efforts will be used.

We request, therefore, that ONC conduct and make available to the public a thorough study on the purpose, scope and process for surveillance of certified EHRs. The study should involve consultation with all relevant stakeholders and include, among other things:

- A clear discussion of the expected benefits of surveillance;
- A summary of alternative approaches to surveillance;
- A discussion and estimate of the expected impact on stakeholders, including providers whose facilities are chosen for the surveillance process;
- Examples of how surveillance has been conducted in related areas, such as NIST's program to validate cryptographic modules for conformance to Federal Information Processing Standard Publication (FIPS) 140-2;
- A comparison of the surveillance process to other forms of accreditation in health care, such as required accreditations for health care providers to comply with Medicare conditions of participation; and
- A discussion of how the results of surveillance might be used by the federal government, by vendors and by purchasers of systems.

In considering the process for surveillance from the provider perspective, relevant questions include:

- Will surveillance only involve interactions with the vendor, or will the ONC-ACBs also involve providers with installed systems?
- If providers with installed systems are involved, how will the ONC-ACB choose them? What notice will be required?
- If surveillance is conducted at a particular provider site, what activities will take place? Will the ONC-ACB need access to a provider's information systems? If so, how will HIPAA privacy requirements be met? Will a business associate agreement be required? Will the ONC-ACB introduce new data to a provider's system to conduct tests? If so, what assurances will the provider have the ONC-ACB will not negatively impact its system? How will costs incurred by the provider be reimbursed?

A thorough study will, no doubt, bring to light additional questions.

Based on the results of the study, ONC should provide a specific proposal on how it expects the ONC-ACBs to conduct surveillance and how the results of surveillance

will be reported, and seek feedback from stakeholders through a process of public notice and comment.

We also note that, in the context of certification, the results of surveillance activities should accrue only to the vendor product, and not to a provider whose facilities may be chosen for surveillance purposes.

Certification bodies also should be required to provide an open and visible process for feedback from the public on certified products. This would allow purchasers and others to highlight concerns they may have about product conformance. The certification body could then review that feedback and determine whether additional fact finding is needed.

Finally, the NPRM cites Section 13 of the International Standards Organization (ISO) Guide 65 as the basis for surveillance of certified products. Although ONC has not summarized Section 13 or provided access to it, it is our understanding that Section 13 speaks to surveillance in the context of ensuring that certification bodies are tracking certified products in the market to ensure that, when a product or manufacturing process is substantially changed, the vendor obtains a new certification, rather than relying on previous certifications of earlier versions. It also requires periodic re-evaluation of certified products, presumably using the same techniques that were deployed in the original certification. Guide 65, Section 13 does not, however, specifically identify post-market surveillance of products in use by purchasers. We also note that Guide 65 is under review by ISO and subject to change. We recommend that ONC clarify whether it anticipates changing its requirements for certification bodies, including surveillance activities, if and when Guide 65 is re-issued.

Certification Beyond EHRs

In the NPRM, ONC asked for comments on whether it should pursue certification of other forms of health IT beyond EHRs, such as personal health records or health information exchanges.

We recommend that ONC defer consideration of additional certification efforts until the permanent certification program for EHRs has been established and operational for a number of years. Implementation of EHRs to achieve meaningful use will be an ongoing process. Ensuring sufficient capacity to meet the vendor demand for certification must be the first priority. ONC should turn its attention to other forms of certification only after that demand has clearly been met and additional certifications against new meaningful use criteria have been successfully accomplished.

In addition, the certification bodies themselves will likely develop additional capacity to certify products for functionality beyond the limited meaningful use criteria and associated standards. CCHIT, for example, has stated its intention to continue and expand its comprehensive EHR certifications. It may be that the private market will

provide sufficient capacity to certify other forms of health IT. ONC should assess the ability of the private market to provide these certifications before undertaking its own efforts.

Certification and Testing of Self-Developed Systems and Coordination with NIST

ONC has proposed that, under the permanent certification program, NIST oversee the testing of EHR products against the federal certification criteria, while ONC will oversee the process of certifying previously tested products. We understand that NIST and ONC have collaborated closely on planning for the certification process and appreciate the involvement of an agency with considerable expertise in this area. We ask, however, that ONC include in its final rule a description of the processes it will use to ensure that the coordination of the testing and certification processes will be ongoing under the permanent certification process. **In particular, we ask ONC to work with NIST to ensure that remote and on-site testing modalities are available for these providers, and to ensure that sufficient testing capacity is deployed to meet the demand for testing timely.**

This coordination is especially important for providers with self-developed systems, who will need to have their systems tested and certified. We are concerned that the two-step process will pose a significant burden and expense for these facilities and ask that ONC keep their needs in mind when finalizing its regulations.

Identification of the ONC-AA

In the NPRM, ONC proposes to "review submissions for ONC-AA status on a first come first serve basis and would 'approve' the first accreditation organization that satisfactorily demonstrated its ability to serve as an ONC-AA (p. 11352)." ONC proposes that the ONC-AA would then be approved for a period of three years.

Given the importance of this organization in ensuring that the accrediting bodies operate in a fair and effective manner, we ask ONC to open a competition for the ONC-AA approval and compare the strengths and weaknesses of all interested parties, rather than choosing the applicant that is first-in-the-door. A competitive process may add a small amount of time to the establishment of the permanent certification system, but will ensure that the process is seen as fair and allow competition to spur organizations to present the best possible applications.

Evaluation of the Permanent Certification Program

We encourage ONC to discuss in the final rule on the permanent certification process how it plans to evaluate the program, including whether the program has engaged the right number of certification bodies, whether sufficient testing capacity exists, and whether both vendors and providers with self-developed systems can

obtain certifications in a reasonable amount of time without excessive costs or burden.

As required by the ARRA, ONC is building a new, federal program for certification of EHRs. As with any new undertaking, program design must include a rigorous ability to evaluate progress and make changes as needed.

PREVIOUS COMMENTS RELEVANT TO THE PERMANENT CERTIFICATION PROCESS

The comments above addressed aspects of the permanent certification program that were not part of our previous comment letter. We would like to take this opportunity to reinforce recommendations from our comments on the temporary program that also are relevant to the permanent process (see the attached letter for expanded treatment of these issues).

1) CMS and ONC should "grandfather" as certified EHRs already in use that support hospitals in demonstrating specific "meaningful use" objectives.

2) ONC's definition of what constitutes a self-developed EHR should be modified 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 (see specific language in the attached letter).

3) ONC must take steps to prevent the expense and disruption of needless upgrades by limiting changes to certification requirements and assuming that all certifications are valid until specific certification criteria change. This may mean that certification of certain EHR modules may last for many years.

4) The certification process must, in the future, adopt more rational timelines. We recommend moving forward that new substantial certification criteria be finalized at least three years before providers are expected to use the new functionality covered by new substantial certification criteria.

5) If CMS chooses to implement the "adoption year" approach, the certification process must support that policy by coordinating the validity of certifications with all valid meaningful use phases recognized by CMS. For example, ONC should continue to recognize certifications from "Phase I" through all years in which providers can demonstrate meaningful use by meeting the "Phase I" objectives. Vendors and ONC should provide clear information on which "meaningful use phase" individual certified products support.

6) The retention period for records by certification bodies should be extended to 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, ONC would retain the records handed over by the ONC-ATCBs.

7) Providers who have in good faith installed a product that loses its certified status due to violations by the ONC-ACB, but can demonstrate meaningful use to CMS, should not be

penalized in any way. They should be able to retain that certification until certification requirements change and a new certification is required.

America's hospitals are committed to moving toward an e-enabled health care system and look forward to a stable marketplace of EHR vendors selling certified products that support meaningful use. We will continue to work with you and other federal partners to ensure that the new federal programs being installed to support the transition to widespread use of interoperable EHRs are effective and successful. We encourage ONC to establish a certification process that supports providers in successfully achieving meaningful use of EHRs without adding unnecessary burden.

Thank you for the opportunity to share our concerns and comments. If you have any questions, please contact me or Don May, vice president for policy, at (202) 638-1100 or dmay@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

Enclosure

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April 9, 2010

David Blumenthal, M.D., MPP
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Dear Dr. Blumenthal:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the proposed rule guiding establishment of certification programs for health information technology (IT) published on March 10 (*Federal Register*, Vol. 75, No. 46, p. 11327).

America's hospitals are taking steps to move toward an e-enabled health care system where all hospitals meaningfully use electronic health records (EHRs). They share the administration's vision of a health care system where widespread use of interoperable EHRs supports improved clinical care, better care coordination, fully informed and engaged patients, and improved public health. They also work every day to ensure adequate privacy and security protections for patients and their personal health information.

The AHA greatly appreciates the hard work that the Office of the National Coordinator for Health Information Technology (ONC) has put into developing the proposed rule. We also appreciate ONC's close coordination with the Centers for Medicare and & Medicaid Services (CMS) to ensure that the certification processes support hospitals and other providers in meeting the meaningful use criteria that will be established under the Medicare and Medicaid EHR incentive programs authorized by the *American Recovery and Reinvestment Act of 2009* (ARRA).

Our comments focus on those aspects of the proposed rule that will affect how providers interact with certification entities, and the attributes of the certified products they purchase and install. We also consider how the proposed rule would affect those

hospitals and physician groups that have developed, in-house, their own EHR systems, which must be separately certified. Most of these comments concern the proposed temporary certification program; we also will submit comments on the permanent certification program before that comment period closes on May 10.

The AHA and many of its member hospitals have participated in the activities of the Certification Commission for Health Information Technology (CCHIT) and see both the merits and limitations of EHR certification. Certification provides a level of confidence to purchasers that products meet a baseline level of performance, and could be a means for ensuring that products support standards that will facilitate information exchange. It is not, however, a guarantee that products will work together, be user-friendly, or be cost-effective to maintain.

We strongly believe that the primary purpose of the federal certification process is to give health care providers a degree of assurance that the EHR technology products they purchase will perform as promised. That is, certification is meant to support providers in achieving meaningful use. Certification is not intended to impose an additional burden on providers.

There should be a clear distinction between the responsibilities of health care providers and the responsibilities of vendors of health IT products. Health care providers rightfully have been asked to take the lion's share of responsibility for meaningfully using EHR systems and supporting technologies. Vendors of health IT products must ensure that their EHR systems meet the certification criteria to support meaningful use. Certification policy must actively reinforce this division of responsibility.

TWO-STAGE CERTIFICATION PROCESS (SECTION I.E.)

ONC 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 second stage in the proposed permanent process would 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 the independent testing results.

The AHA recommends that ONC clearly position any temporary certification program as provisional, rather than temporary. Under a provisional approach,

ONC would actively support the ONC-ATCBs in obtaining permanent status as ONC-ACBs. In addition, ONC should state clearly that products certified under the provisional program will be considered equal to those certified under the permanent program, with no automatic recertification required when the permanent program is established.

The introduction of a two-stage approach for certification is concerning because it will prolong the current instability in the health IT marketplace. In the near term, the market will be negatively affected by queues for certification; rapid growth in demand for vendors' products; limited vendor capacity to support installations; and health IT workforce shortages. Above all else, hospitals and other providers need a stable marketplace in which vendors can quickly offer and support implementation of certified products that will enable providers to provide high-quality, efficient care and meet the meaningful use objectives. The introduction of two separate certification programs – one temporary and one permanent – risks continuing the uncertainty and unintentionally slowing the progress of EHR adoption.

It is critically important, therefore, that the temporary program be seen as laying the groundwork for the permanent program, and be considered provisional rather than temporary. 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 temporary/provisional program would be regarded as equally valid as those certified under the permanent program. This approach would convey more stability and indicate that ONC is building on the temporary program to create something permanent, rather than implementing a stop-gap measure that will be abandoned in short order.

Grandfathering of Current EHRs that Support Meaningful Use

CMS and ONC should "grandfather" as certified EHRs already in use that support hospitals in demonstrating specific "meaningful use" objectives.

The establishment of a provisional/temporary certification process **will not be sufficient** to support providers in achieving meaningful use when the Medicare EHR incentive program begins on October 1, 2010. Even if the provisional/temporary program begins in summer 2010, as proposed, many steps will need to be taken over a period of many months before a pool of certified products is available on the market. For example:

- Providers and vendors will need time to understand the final meaningful use requirements issued by CMS;
- Vendors will need to time understand the final certification criteria issued by ONC;
- Vendors will need time to modify their products to meet the new regulatory requirements;

- Certification agencies will need time to build their capacity to certify products and communicate their processes to vendors and providers;
- Vendors and providers with self-developed systems will need to learn about the specific certification processes and prepare for certification; and
- Vendors and providers with self-developed systems will need to apply for certification and wait in the certification queue.

These steps will result only in certified products being marketed. To ensure that they are making good investments, providers must have a large pool of certified products from multiple vendors from which to compare and select. And, of course, having certified products available only starts the clock on implementation of EHR systems – a multi-million dollar investment that takes years, not months, to achieve.

In our earlier comments on the proposed meaningful use definition, we asked CMS to adopt a "grandfathering provision" under which existing systems that hospitals use to meet meaningful use objectives could be accepted as "certified" for a period of three years. All upgrades to existing systems or deployments of new systems, however, would be required to be certified under the new federal process. Grandfathering will be needed until the permanent program is established, and perhaps for a period of time after that.

It is crucial that current EHR systems that can enable a hospital or physician to demonstrate to CMS that they can meet specific meaningful use objectives be grandfathered as certified. Providers who upgrade complete EHRs, or EHR modules, or purchase new EHR products would be required to install certified products.

A grandfathering approach can relieve some of the pressure on the market to replace or upgrade existing, functional products with certified versions. It also would 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. In addition, it prevents the waste associated with requiring providers to upgrade and/or replace functioning systems simply because they are not certified. Grandfathering products that are currently used to meet meaningful use – as demonstrated through meeting the requirements established by CMS – will help facilitate the transition from a provisional certification program to the permanent program.

SELF-DEVELOPED EHRS (SECTION I)

The AHA is very concerned that the definition of "self-developed EHR" included in the NPRM is too broad. Some hospitals have developed their own EHR systems, or have developed specific capabilities that could meet the definition of an EHR module. In the proposed rule, ONC provides a mechanism for these hospitals to present their "self-developed" complete EHRs or EHR modules to a certification body for approval under both the temporary and permanent certification programs. The AHA appreciates this

flexibility and notes that it will be important for some providers. However, as currently worded, the definition of "self-developed EHR" included in the NPRM is too broad and the proposed regulations could deem many hospitals' EHR systems and some physician practice systems to be "self-developed." We do not believe that it is in the best interest of hospitals – nor the government – to require large numbers of providers to conduct a separate, self-developed certification.

The NPRM defines a self-developed EHR to be:

> 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)

ONCs definition of what constitutes a self-developed EHR should be modified 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.***

This definition is too broad, particularly given 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 undertake individual certifications than is necessary or effective.

Regulations governing certification should include provisions to enable providers to make modifications to certified products they have purchased without requiring recertification of products. Certified systems may be modified for many reasons. As long as the system can still perform the function for which it was originally certified, and support providers in achieving and demonstrating meaningful use, 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.

ONC has stated clearly that providers bear full responsibility for making certified EHR modules work together. Therefore, they must have the ability to make needed modifications 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 or deviate from adopted standards, they should not affect the certified status of the products.

Many hospitals' EHR systems contain components from more than one vendor. Frequently, hospitals integrate different systems from a number of vendors to implement a comprehensive EHR system. 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 the surgery or the radiology departments. 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. Certification requirements should recognize that some health care organizations are given access to the code underlying the software applications that they have purchased, which they may in turn modify to fit their circumstances.

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 support or extend certified functions, such as quality reporting functions or clinical decision support.

Our concern about this issue is elevated for three reasons. First, the time and money costs of individual certification of self-developed systems will be substantial. Second, the certification process will begin with limited capacity that is unlikely to be able to meet the sizable demand to certify vendor products. If large numbers of hospitals and other providers also must certify self-developed systems, the ability to meet demand for certification will be further diminished. Third, under the Medicare and Medicaid EHR incentive programs, providers will submit attestations to federal and state government 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.

DURATION OF CERTIFICATION AND TRANSITION FROM THE TEMPORARY TO PERMANENT CERTIFICATION PROCESS (SECTION II.E.)

ONC proposes to set 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)." Thus, all certifications provided in 2011 and 2012 would expire in 2013. ONC does not indicate whether these proposed expirations would correspond with the fiscal year (applicable to hospital payment policy) or calendar year (applicable to physician payment policy).

The AHA strongly disagrees with this statement and the proposed approach. Product certifications should not sunset automatically every two years. Upgrades should not be forced on providers based on the calendar 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. It is impossible for all systems everywhere to be upgraded simultaneously on the same, two-year cycle. This approach ignores limitations in the vendor market place, and the time needed to implement new IT systems.

To prevent the expense and disruption of needless upgrades, the AHA recommends that ONC:

1. **Be judicious in making changes to certification requirements and limit them to those that are truly necessary to meet meaningful use or advance interoperability through standards adoption.**

2. **Assume that all certifications are valid until specific certification criteria change. This may mean that certification of certain EHR modules may last for many years.**

3. **Consider certifications achieved under the temporary program to 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. **Instruct the 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 certification criteria.**

These recommendations account for 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 the 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 three years before providers are expected to use the new functionality covered by new substantial certification criteria.

SPECIAL CIRCUMSTANCES UNDER THE ADOPTION YEAR APPROACH (SECTION II.E.)

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. For example, a provider could first achieve meaningful use by meeting the proposed Phase I objectives in 2013, even though existing meaningful users would be expected to meet the Phase II objectives in 2013.

The AHA urged CMS to replace the "adoption year" approach with a more rational transition that requires hospitals to meet a lower bar in the early years of the program, but increase requirements over time. This would promote more widespread adoption of EHRs, while also preventing the difficulties the "adoption year" approach poses for the certification program. Therefore, we reiterate that recommendation here.

If, however, CMS does adopt the "adoption year" approach, the certification process must support that policy by coordinating the validity of certifications with all valid meaningful use phases recognized by CMS. For example, ONC should continue to recognize certifications from "Phase I" through all years in which providers can demonstrate meaningful use by meeting the "Phase I" objectives.

To limit confusion about which certifications are valid, ONC also should direct the certification bodies to require vendors to clearly state the "Meaningful Use Phase" their products support. In addition, ONC should ensure that its proposed website

providing a "master list" of certified products clearly identifies this information for providers.

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. 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. Although this approach is complex, the steps outlined above will help to limit confusion while supporting the flexibility offered by the "adoption year" approach.

WHEN PRIVACY AND SECURITY CERTIFICATION CRITERIA APPLY TO EHR MODULES (SECTION II.E.B.)

The NPRM requests comment on when EHR modules should be certified against privacy and security criteria. **The AHA recommends that ONC specify that, for EHR modules submitted for certification, each privacy and security certification criterion shall be deemed "addressable" in the same way that certain implementation specifications in the HIPAA Security Rule are addressable.** This approach would require that, for each addressable security criterion, each EHR module submitted for certification would either include that security capability or the submission must provide an explanation of why the security criterion is not relevant to the module's EHR functionality and the context of its purpose and operation.

ONC's interim final rule (IFR) on standards and certification criteria (45 CFR Part 170) provides for the certification of EHR modules as well as complete EHRs. An EHR module is defined in section 170.102 of the rule as "any service, component or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary." The EHR module approach raises questions about how an integrated set of modules will work together to provide the core capabilities related to privacy and security that cross-cut an EHR system of an organization and, therefore, how eligible hospitals and professionals can be assured that their certified EHR technology when it is assembled from these multiple modules "may assist . . . to improve their overall approach to privacy and security."

Since the current definition requires that an EHR module meet only one certification criterion, it would seem that a hardware or software product designed specifically to provide an EHR-specific functionality that includes no security capabilities could be an EHR module. In addition, a hardware or software product whose sole purpose is to meet a single security criterion like encryption and decryption might be an EHR module. Under the interim final rule, however, combinations of EHR modules used together are not required to be certified together and it is the clear responsibility of the eligible hospital or professional to assure that the selected modules will work together.

Certification under these circumstances ignores the complexities of security integration and the importance of assuring that security policy can be enforced consistently across all of the integrated modules. Such certification provides no guarantee to eligible hospitals and professionals that any specific combination of modules will be sufficient to assist them in improving their overall approach to privacy and security, and offers no assurance that any module designed solely to provide security functionality will integrate and work effectively with any specific or combination of modules providing EHR-related functionality. The IFR further complicates the process by including a definition of "certified EHR technology" in section 170.102 that seemingly contemplates that only "complete EHRs" or a "combination of EHR modules" (as a whole) can be certified.

Security and privacy functionality is a cross-cutting set of requirements that can only be evaluated as a complete system. In some cases, a module may rely on its environment to provide the necessary security functionality, while in other cases a module may offer some specific security functionality while leveraging the general EHR platform to provide more broad-based security functions. A requirement that each module meet all of the security criteria would introduce unnecessary complexity and may not guarantee – or might inhibit – integration necessary to achieve uniform level of security enforcement throughout the organization's EHR system. On the other hand, a requirement that only some EHR modules provide the security related functionality without assuring that the other EHR modules selected would use – and not undermine – this security functionality does not guarantee effective security protection within the organization's EHR system.

SHOULD CERTIFICATION TEST WHETHER EHR MODULES WORK TOGETHER? (SECTION II.D.)

The NPRM asks for comment on whether certification should include testing of whether 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 also should be certified to ensure that they can communicate according to adopted standards. Individual providers, however, should not have to separately certify interoperability between two certified EHR modules because that connection is deemed to be self-developed.

ONC should, however, instruct certification bodies to require that EHR vendors carefully and accurately state the areas in which a given product has been certified and disclose all information it has on the compatibility of that product with other products on the market (including its own and those of other vendors). ONC should include that information on the master "certified health IT products list" it plans to post and maintain on its Web site. The AHA commends and thanks ONC for proposing this service, which will greatly increase transparency in the EHR market.

As the development and implementation of standards for interoperability continues, certification of vendor products also could include testing of whether EHR modules work together, as well as usability and other factors that impact the ease and cost of implementation.

TYPES OF ONC-ATCB AUTHORIZATION (SECTION 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 (ambulatory or inpatient) or function (such as e-prescribing).

The AHA supports allowing flexibility in the types of products a certification body reviews for certification, but notes that this flexibility also raises some potential concerns. "Niche" certification bodies 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. 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.

Therefore, 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.

If vendors choose to certify their products against all but the most difficult meaningful use objectives, providers will be faced with difficult and unfair choices, such as paying large sums for third-party applications or filling the gap through self-development, which would require the provider to pay for and conduct a separate self-developed certification. This situation seems especially 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.

AUTHORIZED TESTING AND CERTIFICATION METHODS (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 products 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.

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

For providers choosing to certify a self-developed system, all of the secondary means for providing testing site options would be relevant. However, the proposed primary method – testing and certification at the ONC-ATCBs' own facilities – is likely to be very difficult to do. 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 reduce the time and money costs of certification, a very important consideration for providers seeking certification of self-developed systems.

RETENTION OF RECORDS (SECTIONS II.D. AND III.D.)

ONC asks for comment on how long certification bodies should be required to keep their records regarding certified products.

The retention period for records by certification bodies should be extended to 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.

In the temporary program, ONC proposes to require ONC-ATCBs to hand over its 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 the 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 several additional years to ensure records are available during an audit process.

IMPACT OF THE REVOCATION OF A CERTIFICATION BODY'S STATUS ON PROVIDERS (SECTION II.E.5)

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

120 days. ONC also proposes that providers who have installed the affected products would no longer meet the meaningful use requirements, as a portion of their EHR system would no longer be certified.

Providers who have in good faith installed a product that loses its certified status but 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.

If, however, 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 during the replacement process.

ONC also should give affected EHR vendors at least six months to get their products recertified by another certification entity if the body that certified their product has its status revoked. During this time, the vendor should not be able to sell the product to new providers or begin new installations. The vendor also should be required to take steps to remediate any problems with installed systems.

The AHA 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 devolve onto providers unless an improperly certified product poses real risks to patient safety. Even in those cases, providers will need much more than 120 days to replace a product that has had its certification revoked, and should be exempted from having to meet the affected meaningful use objectives during the replacement process.

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, EHR vendors should be given six months to get the application recertified. The affected vendor should not be able to sell the product to new customers, or proceed with new installations, until recertification is achieved. The vendor should, however, work with its current clients to remediate any problems.

Providers that purchased and installed that 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 would 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 when implemented. 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.

America's hospitals are committed to moving toward an e-enabled health care system and look forward to a stable marketplace of EHR vendors selling certified products that support meaningful use. We will continue to work with you and other federal partners to ensure that the new federal programs being installed to support the transition to widespread use of interoperable EHRs are effective and successful. We encourage ONC to establish a certification process that supports providers in successfully achieving meaningful use of EHRs without adding unnecessary burden.

Thank you for the opportunity to share our concerns and comments. If you have any questions, please contact me or Don May, vice president for policy, at (202) 626-2356 or dmay@aha.org.

Sincerely,

Rick Pollack
Executive Vice President