



**American Hospital
Association**

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November 30, 2010

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave., S.W.
Washington, DC 20201

Dear Secretary Sebelius:

The American Hospital Association (AHA) would like to express appreciation for the hard work undertaken by the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) in rapidly setting up the regulatory framework for the Medicare and Medicaid Electronic Health Record (EHR) incentive programs and the new federal certification process. The efforts of both agencies have been impressive, and we appreciate their willingness to listen to our members' concerns in implementing the programs. Like you, we look forward to having as many hospitals as possible qualify for incentive payments by becoming meaningful users of certified EHR technology in 2011.

This letter raises a concern our members have expressed about the extent of certified technology a hospital must have deployed to meet CMS' definition of meaningful use. We recently learned, from ONC's response to a "frequently asked question" (FAQ) posted on its website, that hospitals have significantly less flexibility than they thought they had in meeting the certification requirements for meaningful use. ONC stated that hospitals must have in place EHRs that have been certified against all 24 objectives of meaningful use, not just the 19 that the CMS rule requires them to use to demonstrate meaningful use. This interpretation of the amount of certified technology hospitals must have will delay many hospitals in their efforts to qualify as meaningful users of health IT and, therefore, receive incentive payments. It also will unnecessarily increase costs and negatively impact competition in the vendor marketplace.

Our letter offers two alternative regulatory interpretations that would ensure consistency across the ONC and CMS regulations and give hospitals adequate flexibility in meeting the requirements for meaningful use. We ask your consideration of these alternatives and we request a meeting to discuss our concerns and proposal. The hospital community, ONC and CMS have a common interest in the creation of a vibrant EHR incentive program in which hospitals and the administration work together to encourage the adoption of technology that will improve patient care.



BACKGROUND

In response to concerns from hospitals and physicians that the proposed rule on meaningful use asked for “too much, too soon” and adopted an “all-or-nothing” approach to meeting the requirements of meaningful use, CMS outlined a “flexible” approach to demonstrating meaningful use in its final rule (42 CFR Parts 412, 413, 422 et al). For hospitals, the rule established 14 “core,” or mandatory, objectives and a set of 10 “menu items,” from which hospitals could choose five to demonstrate meaningful use, for a total of 19 objectives. Specifically, CMS noted that “some functionalities are optional in Stage 1” (FR Vol. 75, No. 144, p. 44321) and said, “We believe that establishing both a core and a menu set adds flexibility” (p. 44327). In the final rule, summary documents and press releases, CMS stated that providers could “defer” up to five menu set objectives in Stage 1, implying that they could be delayed until Stage 2. In its July 13 press release announcing the final rule, CMS stated that “this [approach] gives providers latitude to pick their own path toward full EHR implementation and meaningful use.” This flexibility was greatly appreciated, and hospitals interpreted it as addressing their concerns.

Two months after publication of the final rule, however, ONC published an FAQ document (Question 9-10-017-1) indicating that the requirement was certification against all objectives/criteria, not just those used to demonstrate meaningful use. The FAQ reads as follows:

ONC Question [9-10-017-1]: Under the Medicare and Medicaid EHR Incentive Programs Final Rule, eligible health care providers are permitted to defer certain meaningful use objectives and measures and still receive an EHR incentive payment. However, it is our understanding that in order for us to have our EHR technology certified, we must **implement** [emphasis added] all of the applicable capabilities specified in the adopted certification criteria regardless of whether we intend to use all of those capabilities to qualify for our EHR incentive payment. Is our understanding correct?

ONC Answer: Yes, this understanding is correct. The flexibility offered as part of the Medicare and Medicaid EHR Incentive Programs Final Rule is not mirrored in the Initial Set of Standards, Implementation Specifications, and Certification Criteria Final Rule because we believe that it is important to accommodate eligible health care providers’ ability to achieve meaningful use. We recognize that in some circumstances an eligible health care provider may not know which meaningful use measures they will seek to defer until they begin implementation and in others an individual provider (even within a specialty) will want to choose different measures to defer based on their local situation and implementation experience. Thus, in order to possess EHR technology that meets the definition of Certified EHR Technology, it must be tested and certified by an ONC-ATCB to all applicable certification criteria adopted by the Secretary.

IMPACT ON HOSPITAL ADOPTION OF EHRs

Hospitals are concerned that requiring them to have EHR systems that have been certified against the criteria related to all 24 objectives of meaningful use effectively takes away the flexibility to choose how to stage implementations offered by CMS in its final rule.

ONC issued this guidance almost two months after CMS released its final rule, and only 10 days before the official start of the Medicare EHR Incentive Program on October 1. The lack of consistency between CMS and ONC, and the changing interpretation of rules when hospitals are in the middle of planning their meaningful use implementations, creates confusion and will likely delay the progress of hospitals working diligently to comply with the already challenging meaningful use requirements in a very short timeframe. Hospitals have raised the following concerns with ONC's interpretation of the regulations:

- Hospitals will have to commit additional, unplanned financial resources to purchase additional functionality, which may require board approval for additional borrowing.
- Hospitals will be delayed in the achievement of meaningful use because they will have to negotiate contracts with their vendors for additional functionality and wait for the vendor to schedule implementation.
- Hospitals will need to revise and accelerate implementation plans to add additional, unplanned modules, increasing the workload of already stressed health IT implementation teams.
- Hospitals will be forced to purchase relatively new and untested technology that has not yet been widely used in the market. This means that all hospitals seeking to become meaningful users will have to buy and implement first generation technology that may not be effective or best meet their needs. Examples include technology to provide biosurveillance data to public health agencies through the EHR or to identify patient-specific education resources through the EHR.
- Hospitals will be locked into the technology currently on the market, limiting their ability to benefit from innovative solutions that arise in the coming years. It also could limit the number of new vendors offering fresh approaches to meeting specific objectives, such as providing web-based access to patient-specific health information in multiple languages or real-time interfaces to multiple drug formularies.

The question of the scope of required certification for hospitals is also very important for health care systems that have developed their own EHRs – many of which are considered leaders in using EHRs to improve care. For example, Intermountain Healthcare estimated that it would take 24 months of concerted effort to be certified for Stage 1 meaningful use, based on 14 core objectives and five menu set objectives. The system estimates that it will likely have to make significant additional – and unexpected – expenditures to shift course and be certified for all 24 objectives. Resources will need to be diverted from other projects deemed high priority, including ICD-10 preparation and ongoing efforts to improve patient care through innovative uses of EHRs.

Hospitals understand that objectives they initially defer for Stage 1 will likely be required in Stage 2, and plan to add those capabilities over time. Increasing the resources and work they

must devote to purchasing and implementing EHR modules that they do not plan to use to demonstrate Stage 1 meaningful use, however, will impose real stress on top of the existing challenges of extremely short timeframes to achieve meaningful use.

IMPACT ON CRITICAL ACCESS HOSPITALS

While most critical access hospitals (CAHs) find achieving 19 objectives of meaningful use to be a very steep road, for those that are further along in their EHR deployment, the expanded scope of required certification to 24 objectives could result in missed meaningful use incentive payments, as CAHs must be meaningful users by 2012 in order to be eligible to receive all four years of Medicare incentives. For example, Lindsborg Community Hospital, a CAH in Kansas, is working diligently to meet meaningful use and plans to implement computerized provider order entry (CPOE) next spring. The hospital's vendor just released medication reconciliation software, and the hospital believed it could meet meaningful use without it, since it was a menu set item that CMS gave hospitals the flexibility to defer. Installing the medication reconciliation piece will add additional time for the hospital to achieve meaningful use, as the vendor currently takes about six months lead time between the order and the start of implementation for established customers. This piece also adds to their implementation costs – which are already difficult for this small hospital to cover in advance of receiving at least some incentive funds. Finally, the human resources required to implement additional functions will also be a challenge given the hospital's size. Other CAHs are in similar circumstances.

HOSPITALS WOULD BE REQUIRED TO BUY TECHNOLOGY TO SEND DATA THAT PUBLIC HEALTH DEPARTMENTS CANNOT RECEIVE

The AHA is concerned that ONC's interpretation will require hospitals to have technology related to meaningful use objectives for which CMS has provided specific exclusions in its final rule. We do not understand why CMS would provide an exception in these circumstances, but still require hospitals to pay for the acquisition and installation of the technical capacity to meet the objectives. In Section 495.6 of the final rule, CMS outlined exclusions for seven objectives, if hospitals meet the related exclusion criteria. Among these are the following three public health-related objectives:

- Submit electronic data to immunization registries. Exclusion applies if a hospital provides no immunizations during the reporting period or is located where no immunization registry has the capacity to receive the information electronically.
- Submit electronic data on reportable lab results to public health agencies. Exclusion applies if no public health agency to which the eligible hospital submits such information has the capacity to receive the information electronically.
- Submit electronic syndromic surveillance data to public health agencies. Exclusion applies if no public health agency to which the eligible hospital submits such information has the capacity to receive the information electronically.

CMS provided these exclusions in the final rule because the agency recognizes that “many areas of the country currently lack the infrastructure to support the electronic exchange of information” (p. 44366). In fact, Dr. Peter Briss of the Centers for Disease Control and Prevention recently

stated that “connections between health departments and EHR systems are still largely developmental” (Testimony to the HIT Policy Committee Meaningful Use Workgroup, July 29, 2010, available at healthit.hhs.gov). Nevertheless, many hospitals are submitting data to public health departments, but not necessarily in the standardized formats required by CMS and ONC, and often using systems other than their EHRs. Even if hospital systems could generate data from their EHRs in the standardized formats, many, if not most, public health departments lack the capacity to receive them. As noted by Dr. Briss, while public health departments are working toward that goal, currently state health departments have identified “funding constraints, workforce needs, the lack of system support, and the absence of best practices as significant barriers to accepting data from EHRs and using it for public health purposes.” Under the guidance in ONC’s FAQ, however, all hospitals would be expected to purchase the capacity to send public health data today, even when the data cannot be received by a public health department, solely to meet a certification requirement.

As illustrated by these examples, coordination across departments within HHS is needed to ensure that the infrastructure exists to support the flow of health information to both improve care and meet public health objectives. The end goal of interoperable health information technology requires that all entities sharing data have the capacity to send and receive data. Placing requirements on hospitals to send information without ensuring that the entire system is functional risks imposing burden without realizing benefit.

ALTERNATIVE INTERPRETATIONS

The AHA continues to believe that hospitals should be required to have EHR technology certified against only those objectives they will use to demonstrate meaningful use, so that they can exercise the flexibility CMS offered in its final rule. In looking carefully at the regulatory text in both the ONC and CMS final rules, the AHA believes that there are alternative interpretations of the existing regulations that address this problem. Those alternatives, which we believe can be addressed through sub-regulatory mechanisms such as an FAQ or guidance document, are described in the Attachment. Given that the hospital Medicare EHR Incentive Program started October 1, speedy resolution is required.

If the department feels rulemaking is necessary, we urge the department to promulgate an interim final rule as quickly as possible that clearly allows hospitals and CAHs to qualify for EHR incentive payments if they have implemented certified EHR modules needed for all of the objectives they use to demonstrate meaningful use. In other words, this regulatory change, if required, would explicitly allow hospitals to defer adopting certified EHR modules that they do not immediately need or plan to use. Similar flexibility also could be provided to eligible professionals.

CONCLUSION

The requirement that hospitals have EHRs certified against all 24 measures of meaningful use is inconsistent with the CMS final rule on meaningful use, which states that a hospital may “defer” up to five objectives of meaningful use in 2011 and 2012. Effectively, the ONC interpretation means that hospitals will need to purchase and implement technology beyond that required to comply with the meaningful use requirements, delaying many hospitals’ efforts to become meaningful users.

The AHA asks that the department take a consistent approach to meaningful use that requires hospitals to have EHR technology certified against only those 19 objectives they will use to demonstrate meaningful use.

Hospitals want to move to an e-enabled health care system that supports the best possible care, informed and engaged patients, and improved population health. Ensuring real flexibility in meeting the requirements of meaningful use is critical for hospitals to build on early successes with EHR deployment and accelerate greater levels of adoption over time.

We look forward to working with the department to resolve this issue. If you have any questions, please do not hesitate to contact me or Chantal Worzala, director of policy, at (202) 626-2313 or cworzala@aha.org.

Sincerely,



Rich Umbdenstock
President and CEO

Attachment

cc: David Blumenthal, M.D., Office of the National Coordinator for Health IT
Tony Trenkle, Office of E-Health Standards and Services, CMS

ATTACHMENT

Regulatory Provisions Addressing Certification Requirements for Hospitals

The AHA has carefully reviewed the final regulations from CMS and ONC. In considering the options available to the department, we believe that there are at least two alternative interpretations that would reconcile the Certification Criteria Rule and the Meaningful Use Criteria Rule with the reduction from 24 to 19 meaningful use objectives that providers are required to meet in the final Meaningful Use Rule.

The first approach would clarify the ONC certification rule and the second approach would clarify the CMS meaningful use regulation.

Clarifying the Current Certification Criteria and Meaningful Use Rules

1. Clarifying part (2) of the definition of “certified EHR technology”

In the final Certification Criteria Rule, adopted by ONC, “certified EHR Technology” was defined as:

(1) A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, or

(2) A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

45 C.F.R. § 170.102. While the preambles to both the interim final Certification Criteria Rule and the final Certification Criteria Rule suggest that a Complete EHR must meet all the relevant certification criteria for either an inpatient or ambulatory system, the language in the final Certification Criteria Rule provides a separate scheme for groupings of EHR Modules to be considered “certified EHR technology.” In this portion, part (2), of the definition, the Certification Criteria Rule requires that:

[E]ach constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary . . .

45 C.F.R. § 170.102. In this sentence, the word “applicable” cannot logically have the same meaning as in part (1) of the definition of “certified EHR technology” in the

Certification Criteria Rule, which applies to Complete EHRs. If the word applicable here meant that each constituent EHR Module would have to meet every certification criteria applicable to an EHR in either an inpatient or ambulatory setting, there would be no such thing as an EHR Module, as each individual Module would have to meet all of the same criteria as a Complete EHR. Nowhere in the text of this definition is it contemplated that the combination of EHR Modules must together meet all of the certification criteria applicable to either an inpatient or ambulatory EHR. The Rule goes on to require that, “the resultant combination also meets the requirements included in the definition of a Qualified EHR.” *Id.* The definition of “qualified EHR” lists these requirements:

An electronic record of health-related information on an individual that:
(1) Includes patient demographic and clinical health information, such as medical history and problem lists; and (2) Has the capacity: (i) To provide clinical decision support; (ii) To support physician order entry; (iii) To capture and query information relevant to health care quality; and (iv) To exchange electronic health information with, and integrate such information from other sources.

Id. Under this definition, then, a combination of certified EHR Modules used to demonstrate meaningful use that together meet the requirements imposed by the definition of a “qualified EHR” reasonably could be read to meet the definition of “certified EHR technology.” Any hospital or CAH that is capable of qualifying for meaningful use incentive payments could use such a combination of certified EHR Modules to meet the requirements set forth in the definition of “qualified EHR” as well as the definition of “certified EHR technology” that applies to EHR Modules.

ONC revised the definition of “certified EHR technology” between the interim final Certification Criteria Rule and the final Certification Criteria Rule. In the preamble to the final Rule, ONC explains that one of the reasons for this change was “to state explicitly the two distinct ways the definition can be met.” 75 Fed. Reg. 44590, 44597 (July 28, 2010) (emphasis added). In the preamble to the interim final Certification Criteria Rule, ONC had suggested that a grouping of EHR Modules would have to meet all of the applicable certification criteria for either an ambulatory or inpatient EHR. However, there is no similar language accompanying the revised definition of “certified EHR technology” in the preamble to the final Certification Criteria Rule. Indeed, the revised definition, along with an important scaling back of the meaningful use requirements for Stage 1, suggests that such a standard would not apply to the final definition of “certified EHR technology.”

There was a major shift in meaningful use objectives between the proposed Meaningful Use Rule and the final Meaningful Use Rule. This shift allows hospitals and CAHs to qualify for meaningful use incentive payments by satisfying a core set of objectives and meeting a certain number of objectives from a menu set rather than meeting all of the objectives, as originally had been proposed. Given this shift, a logical reading of the revised and final definition of “certified EHR technology”, which outlines a separate way

for groupings of EHR Modules to be considered “certified EHR technology,” is that a combination of EHR Modules needs to meet the certification criteria applicable to each constituent EHR Module, but that the combination does not need to constitute a Complete EHR or all applicable certification criteria required for a Complete EHR.

This interpretation would give full force to the flexibility that the department has accorded hospitals and CAHs in adopting the menu set of meaningful use objectives while still requiring that each and every EHR Module used to meet these meaningful use objectives has been tested and certified according to ONC’s standards for the relevant objectives.

Further, we believe this interpretation need in no way change the fact that a Complete EHR must necessarily be certified as meeting all applicable certification criteria; doing otherwise would lead to confusion in the EHR marketplace. However, since EHR Modules are certified as meeting specific criteria for different objectives (but not all objectives), it is both feasible and prudent to allow hospitals and CAHs to adopt only those Modules needed to satisfy meaningful use requirements during a specific EHR reporting period. Eligible professionals (EPs) could be accorded the same flexibility.

Finally, because this interpretation flows logically from the regulatory language, the only change necessary to ensure this flexibility is a clarification of ONC’s FAQ on this topic.

2. Clarifying the definition of “meaningful EHR user” in the Meaningful Use Rule

Another option, based on only the final Meaningful Use Rule, would focus on the existing regulatory definition of “meaningful EHR user” found in 45 C.F.R. § 495.4, the language in 45 C.F.R. § 495.6 specifying that an eligible hospital or CAH must satisfy “five objectives” from the menu set of objectives, and the language in 45 C.F.R. § 495.8 specifying that an eligible hospital or CAH must attest that it “used certified EHR technology” and satisfied the required objectives and associated measures under 45 C.F.R. § 495.6. The definition of “meaningful EHR user” clearly indicates that a hospital or CAH would need to meet the “applicable objectives and associated measures under §495.6,” which necessarily implies “five” menu set objectives (but not all objectives). 45 C.F.R. § 495.4 (emphasis added). Taken all together, we believe there is adequate regulatory authority for CMS to conclude that a hospital or CAH could qualify for EHR incentive payments by attesting that they used all the certified EHR Modules required to satisfy the requirements of 45 C.F.R. § 495.6. EPs could be accorded the same flexibility. CMS could make clear that hospitals and eligible professionals may meet the attestation requirements for having “used certified EHR technology” by meeting the definition of certified EHR technology relevant to EHR Modules, as described above. Once again, we believe this interpretation is appropriately derived from the regulations and does not require a regulatory change.