ONC Clarification of "Certified EHR Technology" Raises Questions for Providers Seeking EHR Incentive Funds for 2011

January 10, 2011

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A recent clarification issued by the Office of the National Coordinator for Health Information Technology (the "ONC") has raised issues about the ability of many providers to meet "meaningful use" attestation deadlines (and thus receive EHR incentive payments) for the 2011 period. In a surprise to many providers, the ONC has issued a revised "Frequently Asked Questions" guidance document (an "FAQ") stating, in essence, that all providers will need to possess a "Complete EHR Technology" in order for that technology to be considered "Certified." Providers who had planned to purchase module technology, rather than a "Complete" EHR system, need to carefully consider the ONC's clarified position.

From the inception of the government's electronic health record ("EHR") incentive program, it has been clear that a requirement for the use of "Certified" EHR technology would play a central role in providers' demonstrations of meaningful use. Following the issuance of a much revised (and much softened) final rule, however, many providers understood that they had the option of purchasing either a "Complete" EHR, which may cost more up front, but had the potential to ease compliance with the latter stages of the meaningful use requirements, or to purchase certified "modules" (essentially, individual EHR functionalities amenable to individual, independent implementation). Many providers, concerned with either spreading the costs of a new EHR system over time or with ensuring their system is created to meet only existing standards (with the intention of adding on Stage 2 functionalities, for instance, only when Stage 2 requirements are finalized) planned to purchase only the certified modules necessary to meet the core and "menu set" objectives they intended to implement to demonstrate Stage 1 meaningful use. The ONC's recent clarifications indicate that is not an acceptable means of possessing a "Certified EHR Technology."

On December 23, 2010, the ONC released a revised FAQ 17-2 and FAQ 21, confirming a position, taken in FAQ 17, that appeared to require all providers to purchase “Complete” EHR systems. (FAQ 17 is now listed below FAQ 17-2 on the same page of the ONC’s website). In these FAQs, the ONC appears to definitively take the position that providers can only “possess” “Certified EHR Technology” if that technology is also “Complete.” The American Hospital Association (“AHA”) has already lodged its written objections [PDF] to this interpretation.

In the original FAQ 17, the question posed was whether a provider was required to "implement 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?" The original answer indicated that "this understanding is correct… 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." Many readers read this question, and its answer as asking whether an EHR Technology had to undergo certification on even those functionalities that a provider did not intend to use in order to be considered "Certified." The answer to that question was, unsurprisingly, affirmative.

Not all readers understood the FAQ in this fashion, however. The AHA, shortly after the FAQs release, sent the ONC a letter explaining that it understood this FAQ to require that all providers were required to purchase an EHR system that met "all applicable certification criteria adopted by the Secretary." The AHA, in other words, appeared to read the FAQ to require that all providers "possess" a "Complete EHR Technology" – even where they intended to implement only certain portions of the technology to meet the requirements of Stage 1 of meaningful use. The AHA letter explains in detail the reaction that many providers have had to the ONC's interpretation – that it contradicts the regulatory scheme established by the meaningful use final rule by undermining the flexibility permitted providers. Providers, under such an interpretation, would not be permitted to build an EHR system incrementally from certified modules, adding capabilities as they are required, but would rather be required to purchase a "Complete" (and likely more expensive and complicated) system up front, before Stages 2 or 3 of the EHR incentive program have even been proposed.

The ONC's recent issuances have confirmed the AHA's reading of FAQ 17. In a blog posting on Health IT Buzz (the official blog of the ONC), Dr. David Blumenthal explained that:

> Today on our FAQ page, we are posting a revised Question and Answer regarding an issue that has recently caused confusion in our meaningful use regulations: namely, the flexibility that providers have to defer performance on some Stage 1 meaningful use objectives; and how that squares with the requirement that providers must nonetheless possess fully-certified EHR systems.
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> The new FAQ is meant to clarify this two-part requirement. But we should make it equally clear that our policy has not changed…

In fact, the ONC published two new FAQs. First, a revision of FAQ 17 was issued (FAQ 17-2) clarifying that the ONC interpreted its certification requirement to require that all providers "possess" an EHR system that has been "tested and certified to all applicable certification criteria adopted for the setting (ambulatory or inpatient) for which it was designed." Second, a new FAQ 21 was issued which further detailed the ONC's interpretation of the word "possess."

The ONC's clarified interpretation essentially requires all providers to possess "Complete EHR Technology" before they may attest that they possess "Certified EHR Technology." This requirement applies even where the stand-alone EHR modules providers possess are, in fact, "Certified." FAQ 17-2 goes on to imply that Certified EHR modules are meant to supplement or enhance an existing Complete EHR. A provider may, for instance, replace a certain functionality of a purchased Complete EHR with a Certified module that provides the same functionality but is obtained from a different vendor. The ONC

specifies that, in that circumstance, it would not require that the provider pay for both functionalities, so long as the provider was, in the end, in possession of a Complete EHR.

Providers are also given the option of building an EHR from modules – but not in the slow and steady fashion envisioned by many. Rather, an EHR assembled from individually certified modules will still be required to meet "all applicable certification criteria adopted by the Secretary." In short, an EHR may be assembled from modules, but only where the provider purchases *all* the modules necessary to assemble a Complete EHR *before* attesting to Stage 1 meaningful use. For some providers, this will likely prove impractical.

FAQ 21 provides the ONC's further explanation of the term "possess." Although the original FAQ 17 used the term "implement," FAQ 21 makes clear that the ONC will not require providers to "implement" or use *all* functionalities of a Complete EHR, so long as they "possess" them. FAQ 21 goes on to explain that:

> We consider "possession" of Certified EHR Technology to be either the physical possession of medium on which a certified Complete EHR or combination of certified EHR Modules resides, or a legally enforceable right by an eligible health care provider to access and use, at its discretion, the capabilities a certified Complete EHR or combination of certified EHR Modules includes. **An eligible health care provider may determine the extent to which it will implement or use these capabilities, which will not affect the provider's "possession" of Certified EHR Technology.**

(Emphasis added). Further, FAQ 21 explains that providers need not pay for functionalities until they are installed or used:

> While we recognize that eligible health care providers may enter into various business arrangements depending on their particular needs and circumstances, we would expect that such arrangements could potentially include agreements with EHR technology developer(s) to access and use the capabilities included in Certified EHR Technology. **Further, that these business arrangements could make an eligible health care provider's payment for a particular capability contingent on its use or implementation of that capability in a production environment or the provider's request for maintenance or technical support.**

(Emphasis added). FAQ 21, then, appears to state that a provider is in "possession" of a Certified EHR Technology where the provider has obtained the legally enforceable right to access and use the technology, even where it has not accessed, installed, used, or even paid for the functionality in question. While it is not clearly stated in the FAQ, providers who hope to take advantage of this feature of the definition should be certain to retain some evidence that they have, in fact, purchased the legally enforceable right to access and use the non-installed functionalities.

Ober|Kaler's Comments

The issuance of FAQs 17-2 and 21 has come as a shock to many in the provider community. Upon first reading, the interpretation advanced in these FAQs appears to directly conflict with the "piece-by-piece" EHR development strategy that many providers believed was permitted under the final meaningful use

rule. Providers may, however, be able to maintain some features of that strategy by carefully negotiating purchase agreements with vendors that permit them a "legally enforceable right to access and use" *all* of a Certified, Complete EHR's functionalities while also deferring payment for the unused functionalities until they are actually implemented. The availability of this option, of course, will depend on both market demand and a willingness amongst EHR vendors to negotiate sufficiently flexible purchase terms.

It should also be noted that the meaningful use of EHR systems is an area that is still under development. If providers feel that the ONC's interpretation of "Certified" will prevent them from being able to attest to meaningful use on a reasonable schedule, they should let their thoughts be known. Both the ONC and CMS have, in the past, been responsive to thoughtful and practical provider concerns — this may be yet another instance where the responsible agencies need to hear provider feedback to clarify why a particular requirement is viewed as problematic or overly burdensome.

Finally, providers who had elected a strategy of selective EHR module purchasing should reevaluate, and quickly. While the initial stages of meaningful use attestation will be available through 2012, the negotiation, customization, and installation process for EHR technology can be time consuming. Especially for large providers, the attestation clock has already begun to tick; any implementation strategy changes should be accomplished as quickly as possible.
