WHITE PAPER

EHR Certification Alert For Providers

Approached with concerns from hospitals, physicians, vendors and consultants regarding Electronic Health Record (EHR) product certification and the confusion surrounding certification methods and models, and having no sound, defendable answer to impart to any of them, O'Toole Law Group founder William O'Toole researched the issues and published his opinion first in his contributing blog column HITlaw. The outpouring of support and thanks following that posting prompted the creation of this paper. It is hoped that many will benefit from this work, both providers and vendors, and ultimately the patients and taxpayers.

The issue involves the unintentional consequences resulting from the certification of EHR product bundles. The terms bundle and bundles are used throughout this paper to refer to a group of products certified collectively as an Electronic Health Record (EHR) product for the purposes of reimbursement to providers in the healthcare arena under the healthcare stimulus legislation HITECH Act (Healthcare Information Technology for Economic and Clinical Health) and the American Recovery and Reinvestment Act of 2009 (ARRA).

Whether the certified bundle is classified as modular or complete is immaterial for the purposes of this writing, because the absolute heart of the issue is recognizing that in some cases multiple products that are marketed individually by a vendor are grouped together for testing and are ultimately certified together and not separately.

The problem is that not all customers of any given vendor have licensed all component products included in the vendor's certified (and bundled) EHR "product". In fact, no vendor has come forward since the initial blog posting to claim that 100% of its applicable customer base has licensed all components (that are otherwise individually marketed) included in that vendor's certified, yet bundled, product. Inference can be drawn that if that were the case, vendors would have already packaged their products together in their marketing efforts. The fact that they have not supports the premise put forth in this paper.

Unfortunately no accommodation is made in the certification requirements for the reality that some certified EHR products are comprised of separate, individually marketed products and that there are provider customers out there that have licensed only a subset of those individual products. These are the voices screaming the loudest, right along with the smaller niche vendors that are losing business due to the current product registration process. The healthcare technology market mandates availability of the individual products; certification options should mimic the market.

It is not reasonable to suggest that all vendors with bundled certified products have done so in a calculated, purely profit motivated manner, but neither is it reasonable to suggest that no vendor has done so. Time will bear this out. Some vendors have recognized the situation caused by their initial bundled certification and have returned to their certifying body for subsequent certification of the component products that were included in the certified bundle. These vendors deserve heartfelt congratulations, because they realized the issue and its impact on the provider customers involved. Of course the grand scale issue is the unnecessary waste of Federal funding if the current situation is not rectified, as will be explained in detail. With the relatively short time allowed and the huge amount of work involved, the Office of National Coordinator (ONC) should not be criticized too harshly, unless ONC fails to recognize and remedy this situation, and soon.

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This paper illuminates the issue and the solution proposed by O'Toole Law Group.

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CONSIDERATIONS

We know from ONC FAQ #9-10-005-1 that a single certification of a bundle of separately marketed products does NOT propagate certification from the bundled "product" to the subset of individual products. However, ONC also states that vendors may have the subset of products certified individually during the overall certification process. This is the very foundation needed for a very simple solution.

We know that possession of, or a legally enforceable right to use, all components of a certified product permits a provider to add or substitute a product from a different vendor to satisfy a subset of Meaningful Use criteria, as stated in ONC FAQ #12-10-021-1, and that ONC FAQ #9-10-014-1 permits duplicative or overlapping capabilities acquired from different vendors. However, in each case ONC requires the provider to acquire the full product as certified.

THE BEST SOLUTION

Going forward, ONC should require vendors that choose to certify "bundled" EHR solutions to also certify any individually marketed products included in the bundle. Existing certifications of bundled products must be revisited for individual component certification. This is the simplest, most effective method for correcting the situation, and it will work.

ONE ALTERNATIVE SOLUTION

ONC could clarify that providers are not required to obtain all sub-products comprising a vendor's certified product, if marketed individually by the vendor. This would enable the provider to attest to SOME Meaningful Use criteria using SOME of the sub-products that were certified as a bundle by the vendor. This path should also have ONC clarify that attestation by providers that certain Meaningful Use criteria, but not all criteria, are met using a certain certified EHR product does NOT mean that they are attesting to, or representing or warranting that, they have full license or other right to use all components of that certified EHR product, or that they are meeting all possible Meaningful Use criteria associated with that product. This would also require a redo of ONC's Certified Health IT Product List system, because it automatically selects all criteria associated with a certified product and the user is not able to select a subset of criteria met or deselect from the complete list of criteria (this is a topic unto itself). None of this would be necessary with the first solution.

If ONC does not change its policy to require certification of components and in fact maintains the requirement that attestation truly be "all or nothing", meaning that in order to use portions of a certified bundled product for meeting Meaningful Use criteria a provider must acquire, *from that same vendor without regard to choice or market competition,* any components not previously licensed, then:

1. ONC should clarify for the nation's providers and vendors that this is the case *(which would be an egregious ruling),* probably by way of a new FAQ; and

2. Vendors themselves should correct the problem by going back to the certifying entity and retesting their component products (which together were originally certified as a bundled offering) for individual certification as currently marketed. This testing can be done relatively quickly and at less cost than the initial certification, and quite frankly, it is the right thing to do. Some vendors have heard from their customers, listened, and are already doing this.

THREE TAKEAWAY ITEMS

First, Hospital executives and eligible professionals are alarmed by the fact that if their vendor certifies individually marketed products as a bundled, certified EHR solution, and if they have not licensed all of those individual products, then the only solution permitted by ONC is for the provider to acquire the balance of the products from that EHR vendor alone, eliminating all others from consideration, in sharp contrast to market reality. Yes

A Practical Example

Vendor X has certified an EHR solution that is actually comprised of four (4) individually marketed products. The certification is for the "bundle" and not for four (4) individual pieces. Hospital W previously licensed three of the four products but never licensed the fourth piece and now desires to obtain similar functionality (and achieve associated Meaningful Use criteria using that product) from Vendor Q.

However, according to ONC, Hospital W cannot acquire Vendor Q's product (for Meaningful Use reimbursement purposes) without also acquiring Vendor X's fourth piece, regardless of cost or dissatisfaction with the product. Or worse, if Hospital W already acquired Vendor Q's product it now must acquire Vendor X's fourth piece in order to meet ONC's requirements, even if the product will never be used. In the first scenario the hospital has a choice, but in the second the hospital has no option but to invest twice in similar functionality because of a vendor's certification method and ONC's requirements. ONC's suggestions that the provider and vendor negotiate low cost or no cost terms for the missing piece(s) is, in my opinion, off base, as it fails to recognize the issue of the bundled products (see reference to FAQ #12-10-021-1). If the vendor historically offered only the bundled option to its customers, then there would be no issue whatsoever.

Playing this out to the extreme, what if a provider in this situation (probably the small practice) simply makes the right choices for its operation and selects the products that best fit its needs, forgoing incentive money because it chooses not to (or is not able to) duplicate costs for multiple EHR product pieces? In the end, this provider will be penalized, not because they did not implement an EHR (which they did), but because they did not implement a "single-source" EHR that was certified in a manner inconsistent with how the applicable vendor's products are offered in the market. This is admittedly a dramatic interpretation, but it originates in comments received from members of the industry.

they are free to acquire "replacement" products once they have the entire certified EHR, but the initial requirement does not sit well and does not make sense when there is a simpler solution.

Second, providers and smaller vendors are hurt by the bundling of EHR products for certification purposes, because ONC requires providers to obtain all products comprising a vendor's certified (and bundled) product, as stated above. It is not unreasonable to suggest that fair and free competition will be dramatically effected unless this situation is resolved, in which case the incumbent vendors will be unjustly rewarded because providers do not want to risk losing reimbursement.

The solution is simple. Vendors should be required to certify products at the same component level as marketed to the general public. This would solve the problem entirely. They may certainly certify as a bundle, but should also then certify at the component level. Careful caveat; if two or more otherwise individually marketed components must be certified together to meet any Meaningful Use criteria (and neither would meet the criteria on its own) then obviously they cannot be certified separately.

Third, Recognition by appropriate authorities of the absolute need to clarify and correct this situation in a timely and effective manner is essential for the nation's healthcare providers and HIT vendors.

ALERTS TO PROVIDERS

Provider entities must be aware of situations involving certified product bundles. If considering a new vendor relationship, understand what the proposed EHR product includes. If it is a single product offering in the marketplace then the issues presented here are avoided. If however the proposed product is comprised of individual product components, and your organization would prefer one or more components from a different vendor, then the issues presented here are extremely important and the consequences of a certified product bundle, even if unintended, must be clearly understood. Similarly, for provider customers in existing vendor relationships, watch for statements from your vendor warning that selection of a product from a competitor rather than a component product from the vendor's certified *(but bundled)* EHR establishes the risk of losing reimbursement. While the statement may be correct, the vendor itself has the means to rectify the situation. The fact that a vendor elects not to make the correction should be duly noted and should weigh heavily in the selection process. The last example of provider entities highlights the group most at risk and in the most unenviable position. Sound advice and unassailable guidance are imperative for the decision makers involved.

IN CONCLUSION

The very fact that vendors can correct this oversight in the certification process is perhaps the most incredible part of the story. Hopefully there is enough substance here to rouse other voices and ultimately make intelligent minds in all related aspects of the ARRA/HITECH/HIT world take notice and then action. Hopefully the people at ONC and the certification/testing entities step in with a solution that serves as a reward and not a penalty. In this case "go with the flow" is sound advice. The healthcare industry has started the correction on its own. Now it is up to ONC to step in and make it all work.

"ONC should require vendors that choose to certify bundled EHR solutions to also certify any individually marketed products included in the bundle. Existing certifications of bundled products must be revisited for individual component certification. This is the simplest, most effective method for correcting the situation, and it will work."

– William O'Toole

William O'Toole founded the O'Toole Law Group, specializing exclusively in healthcare information technology, following his long tenure as Corporate Counsel at Medical Information Technology (MEDITECH). Known and respected by executives, attorneys and consultants throughout the healthcare industry, O'Toole now represents healthcare provider entities and technology companies in all aspects of technology acquisition, development and distribution with special emphasis on EHR contract creation and negotiation.

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