



Written Testimony Provided By Cerner Corporation

**To the Implementation Workgroup of the Health Information Technology Standards Committee
(HITSC)**

On Cerner's Certification Experience with the EHR Certification in the 2011-2012 ONC-ATCB Program

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Cerner wishes to thank the Implementation Workgroup of the HITSC for the opportunity to provide testimony on Cerner's experiences participating in the 2011-2012 ONC-ATC Program for certification of EHRs. By way of background, Cerner participated in both the Hospital and Eligible Provider certification programs offered through the Certification Commission on Healthcare Information Technology (CCHIT) in October, 2010, and we successfully completed that certification as a Complete EHR for both of the programs. In this written testimony, we will provide response to the discussion questions provided by the Implementation Workgroup, and we will provide summary of those responses in oral testimony.

- *Identify your challenges, barriers, and successes when certifying a software vendor (for certifiers) or when being certified (for software vendors).*

Cerner has participated in CCHIT's traditional "comprehensive" certification program since 2005 in the core ambulatory program, in 2007 in the inpatient program and in 2008 in the ED program. As a result of these experiences, we felt that we had a pretty good perspective on the due process that we could expect for the 2011-2012 ONC-ATCB temporary certification program for meaningful use. While the ONC-ATCB program differed in certain aspects from those prior experiences, we still had a pretty good idea of what we needed to do to organize and prepare our certification team for going through the experience.

As to challenges, we highlight the following:

- Certification is a team effort that draws on a many parts of the organization. Perhaps like many vendors, Cerner assembled a team of subject matter experts and demo specialists from across the organization from within our development, technical sales support, system integration/interface, security, ASP hosting, quality analytics, and compliance and physician services teams. The process for getting ready for certification can never start too early. This is an internal



challenge more than an external one, but as advice to other vendors contemplating going through certification, prepare early and often.

- Information on detailed criteria development, conformance tool development and test procedure availability and stability are critical and impact development requirement every bit as much as do the proposed and final rules for the certification criteria. We have three particular observations that reflected our experience with this:
 - Vendors have to be prepared to respond to development requirements that start with the earliest iteration of the Health Information Technology Policy Committee's (HITPC) first draft recommendations on meaningful use objectives through all of the stages of rule making through to the test procedures published by the National Institute for Standards and Technology (NIST). Every iteration of requirement begat potential new development requirement as the changes were material in at least some respects throughout the process.
 - There must be a better change control process for all facets of the test procedure development by NIST. There was not much advance definition of how vendors were to expect changes in test procedures to be communicated. The particular issue lay with the conformance test tools referenced within the test procedures. We found that while there was advance notice of when test procedures were effective, the underlying conformance test tools could change almost without notice. We offer the particular example with the conformance test tools used by NIST for the Continuity of Care Document (CCD). It was updated four times after the test procedures were first finalized in mid August 2010 through the completion of our certification in late October, and three times within a two week period in late September and early October. One update occurred on one of the very testing days we went through certification, and was effective for our certification testing that day. The changes in some cases were material to the conformance test, and would not have been experienced in any of our dry run preparation leading up to our inspection date because we never saw the version of the conformance test tool used the day of our inspection. This absolutely cannot be the case in the future. There has to be an advance warning with adequate lead time for vendors to be able to conduct dry runs with new versions of conformance test tools. A change in the version of a conformance test tool IS a change in the test procedure itself, and therefore should be subject to a change control process that affords adequate advance notice to vendors on par with changes in the test procedures themselves.
 - There must be stability in the test procedures prior to certification program launch. We realize that everything was moving very fast from final rule making in June 2010 through launch of the certification program in September 2010. However, for vendors who participated



early in the certification program in September and October 2010, the test procedures changed significantly after program launch. We believe this has two deleterious effects:

- Vendor preparation efforts to conduct dry runs and to “lock down” their preparation is undermined and cycle time extended to attempt to have final stage dress rehearsals practicing against the test procedures, and if these change in the middle of that process, vendors are left to redo significant parts of their preparation. This is an issue because vendors schedule their inspection dates weeks in advance, and work to schedule them counting on stability in their preparation in their final dry runs. Most vendors do not schedule their inspection date unless they are pretty certain of their ability to pass. If the test procedures change materially between the time a vendor asks for an inspection date and the inspection date, it plays havoc with the vendors’ ability to prepare absent a possible reschedule.
- Substantive change in the test procedures can mean a substantive change in the certification test even while the certification criteria supposedly remain unchanged. Systems that certify early in the process can be held to a significantly different requirement in certain cases than systems that certify later on. Now we understand that over time, test procedures may need to change, but change has already been substantive, and for those aware of the certification requirements, it can raise questions as to what abilities a system has been certified to having if one certified early on in the program versus later on, and it raises the specter of not all certifications being necessarily equal. CCHIT has historically piloted their certification programs by engaging with vendors to test the certification criteria and test scripts they use for their comprehensive program before engaging in a final program launch. We have participated in this a couple of times, and have found it useful both ways (vendor and certifying body), and we suggest ONC and NIST consider such a process to improve certification in the future.

As to barriers and differentiating them from challenges, there were a number of areas where we had a lot of questions that we had to work around given the short time frame. Most compelling were the following, and may have to do with the clinical quality measures and the related process for selection and maintenance of their specifications:

- In general, the need for specific guidance as to the definition, interpretation and intent of the quality measures is critical since as CMS looks to move to e-submission in the near future (2012), and specific intent and specific statements



of specification requirements are important to the actual certification of the quality measures.

- For the EP program and the clinical quality measure requirements for it that vendors must certify against, we have specific suggestions as follows:
 - For the use of the PQRI .xml specification – for the applicable NQF measures with multiple numerators and populations, we would like to see clear guidance in the future around how to report them
 - We would like to see better change control as the NQF measure specifications have continued to be updated on the CMS website since the certification program started. There is a change control log that is published that reflects the changes within the human readable .pdf specifications and/or content spreadsheets, but the .pdf specifications themselves are not updated with a new version number, and the same supplemental specifications zip file is continually updated without clear indication from the main page when the last update occurred. For example, most recently the log was updated with a change that is not reflected in the actual .pdf specification for NQF 0038. This is a core measure that all vendors have already certified and also leaves it subject to vendor interpretation as to what we are expected to change.
 - We suggest that a way of automatic vendor notification such as a e-mail notification service such as what ONC has done for their FAQs be implemented to provide a way to be automatically notified when new/updated content is posted relative to the NQF measures.
 - Please consider including an additional column with codes and descriptions within the content spreadsheets. This would make it much easier to get a quick feel for the measure when doing requirements and would also make identification of mistakes within the content much easier.
 - Please consider including a “key” to indicate the intent of the concepts that are used across the various measures. For instance, Medication active vs. Medication order vs. Medication dispensed. These may seem straightforward but are subject to interpretation across different vendors and our providers.
 - The number of changes that has been published indicates the specifications were not well vetted prior to publishing. There should be a process to vet them in advance of making them final and having vendors certify the measures based on specifications that have been adopted into final form.
 - There should be a more formal process such as which exists through the PQRI program to log questions and clarifications, publicly document these questions, hold regular mandatory vendor calls, etc. It is important for all vendors to be implementing the measures as consistently as possible.



- Last, there should be more consistency between how the specifications are written for the measures. It is easier to make mistakes when there is inconsistency. We understand that the measures have been originally developed by different measures developers/organizations, but even within a measure developer there are inconsistencies. Timeframes should always be clearly indicated and should be reflective of the intent of the measure and good clinical practice. For instance, expected timeframes for various results differ and it may make sense to extend the measurement period prior to the start of the reporting period for meaningful use. This is especially true for 2011 where the measurement period is limited to 90 days.
- As to the Hospital clinical quality measures, there was very limited guidance as to how the 2009 PQRI Registry XML was to be used for Hospital clinical quality measures. We found the selection of this specification strange for its use for hospital measures, and almost nothing was originally published as to how to adapt its fields for use that were PQRI specific. We ultimately did get our answers, but this is something that should have been addressed in the selection of it for use with hospital quality measure reporting and not in the middle of certification.
 - Also applicable to the hospital program, how are the measure specifications to be managed for the selected clinical quality measure areas (Stroke, VTE and ED Throughput) on an ongoing basis? For the other areas of measurement that are a part of the National Hospital Quality Measures that form the basis of the Report of Hospital Quality Data for the Annual Payment Update (RHQDAPU), specifications are updated in accordance with The Joint Commission/CMS agreement every six months. Vendors certified based on the version of specification in effect as of the time of final ONC rule making on the certification criteria for the 2011/2012 ONC-ATCB temporary program. Should vendors expect that they will need to update their certified capabilities as the National Hospital Quality Measure specifications are updated every six months during the course of 2011/2012? Will providers need to report their quality measures based on the version of specification in effect depending on when their reporting period occurs? Based on the version in effect when their reporting period starts? Do they remain on the version in effect as of the time of the final certification criteria and incentive rules?
- The vagueness of the statements of requirement for the automated calculated measures. We had to work with the regulatory text as best as we could, and even now, material change is occurring to some key concepts with the measures. CMS has recently changed the definition of how ED visits are to be considered for the unique patient concept for example by allowing for “plain language” and “FAQ” based approaches that are significantly different. Vendors have to code to a



particular expectation under the hope that they are on the mark, and we certainly hope that there is reasonable latitude in judging provider attestations allowing for good faith effort in getting these measures right.

As to successes, we had a successful outcome. We have to highlight the role of CCHIT as our ONC-ATCB in that success. CCHIT's staff worked tirelessly to help us with clarification, guidance, interpretation, confirmation and assistance with what I am sure was to them an endless barrage of questions from us. I cannot speak for the other ONC-ATCBs and vendor experience with them, but we had a very good experience with CCHIT. I commend them for their hard work to try to make smooth a process that was very subject to rapid change. They did not have all of the answers and were honest with us about what they could or could not provide comment on given their role as the ONC-ATCB, and what we would need to take directly to NIST, ONC or CMS.

We also do have to commend the staff at NIST, ONC and CMS for their assistance. In all we say that may be taken as critical of the certain aspects of the process, all the federal agencies involved were working with a very short time frame and were working to launch the certification program within a very short span of time going from no recognized certification program and no final set of test procedures in June 2010 to program launch by September 2010.

The best single policy aspect of the program was the support for inheritance that allows vendors to extend certification attained on one software version to another. Without that provision, vendors would be faced with the frustrating experience (and possibly wasting their time to be honest) going through repeat inspections on software that was substantially equivalent in all respects for the sake of the capabilities inspected. We think this a critical element to retain come time for the permanent program. All vendors desire to have their current and go forward production versions of software in good standing as certified, and when the substance of the capabilities important to meaningful use remain materially the same version to version, this avenue of being able to leverage the certified status to more than one version is incredibly valuable to both vendors and their clients.

- *Outline the certification process from your point of view. Include what worked and didn't work, as well as any real-world user stories, illustrations, or examples.*

We have highlighted above what we felt did not work so well, but to summarize it:

- The instability of test procedures within a short span of time impacting vendor preparation and dry runs
- The lack of advance notification and change control for changes in conformance tools embedded within the test procedures



- The lack of clarity or availability of guidance on how to make use of some of the specifications or statements of requirement for quality and automated calculated measures leaving vendors to make good faith assumption as best as they can
 - In particular, because there still was scrutiny in the conformance review of the output files for both of these types of measures, this cannot be left vague and subject to vendor interpretation – more structure is needed earlier in the process for future stages

One area that deserves additional comment is the impact of the pacing and incremental change in the development of the criteria itself. If Stage 2 repeats the history of Stage 1 as we fear it likely will, the fast paced and iterative nature of the criteria and test procedure development throughout the process that most often contained material change does not leave lot of time for vendor response

- This is a lesson we feel must be learned for future meaningful use criteria development – we have listened to the growing voice in the proceedings of the HITPC Meaningful Use work group on the need to build in lead time for the industry – and this is true both for the vendors and the providers - we offer our own lead time as an example – we develop and release versions of our software about 1-2 times a year, and work off of a rolling 15-18 month cycle for each release start to end that works something like the following:
 - Month 1-2 – Development planning is initiated to consider what major release themes and priorities should be considered for prioritization
 - Month 3-4 – The proposals as to the release themes and priorities are debated, approved and funding for them identified, and assignments made to particular development teams
 - Month 5-10 – Active development from design through construction
 - Month 11-12 – Internal testing and quality assurance processes are applied
 - Month 13-16 – Early testing partner and adopter phase occurs
 - Month 17-18 – Final packaging and general availability occurs
- We are always working on 2-3 releases on a rolling basis, and they commence about 6-9 months apart and so are on different trajectories at different points in time – but our key point is that the release that would hit the market in early 2012 which may be our basis of certification for the next stage is *already about to enter the active development phase* – so if there are new requirements, there is not a lot of opportunity to respond to them if not already capabilities being planned for
 - Now we can adjust and will adjust, but this is the kind of situation vendors find themselves in – we need good early clarity and



statement of requirement that at least allows us to be mostly on target as criteria development refines and evolves

We have also highlighted what we thought worked well which included

- The professionalism, patience and dedication of the staff at both the ONC-ATCB we worked with and from the federal agencies involved – we know that this was a difficult program to launch in the circumstances it did
 - The inheritance provision of the ONC-ATCB program which allows for vendors to be able to extend certification to versions of the software that are materially substantially equivalent to the version subjected to inspection
 - The guidance that has come out has generally been helpful and both ONC and CMS have shown a willingness to listen and be responsive within the constraints of what the HITECH statute and their own final rules allow
- *Discuss your outcomes/results. Include any surprises or unexpected outcomes and how you addressed them?*

We achieved the outcome we expected which is to say that we obtained certification as a complete EHR for both the EP and Hospital incentive programs. We have commented earlier on the things about the process that caused us struggle or concern.

One additional thing we should like to comment on is that we understand from our ONC-ATCB (and as has been confirmed by ONC) that ONC intends to add additional listings to the Certified Health IT Products Listing (CHPL) that reflect any reported certification result made by ONC-ATCBs for vendors who may have initially achieved modular certification on their way to complete EHR certification and/or who made changes in wording on their listing. All of these interim statuses and changes will now be reflected as additional listings on the CHPL for that vendor. We fear any value anticipated from this will be outweighed by the confusion it may cause. We understand ONC believes this required by the temporary certification program final rule for the sake of transparency. However, our own situation highlights that this may only lead to cluttering the listings. We tested over a period of a few weeks in October with the full intent of becoming a complete EHR. We have that certification status now. What value does all the interim history add to that? If ONC wishes to portray that history, consider putting it within the body of the detail page available for any given vendor listing, but do not clutter up the main CHPL page with it. It could as easily (and as valuably) be reflected in a change history within the vendor's certification listing page. ONC believes they are obligated to provide the listings in this way based on their own final rule. If it must be done, we strongly urge it be done in such a way so as not to clutter up the main listing for a vendor. If not within a details page once a CHPL user clicks on a listing, then indented underneath the main listing. Do not clutter up the clarity of the main current effective vendor listing. The risk is that a provider sees an interim state that



reflects the modular certification initially achieved by a vendor which has been succeeded by a complete EHR status, and thinks it a modular certification. It is not. If that same vendor comes back and does certify something on a modular level, how is the CHPL user to distinguish that in a face up view from something that was only an interim status for that vendor on the way to complete EHR certification? We are considering pursuing modular certification on certain objectives, and have concern this will clutter up the CHPL and will lead to confusion. We have raised this concern with ONC, but they remain unconvinced.

- *Describe your experience using the ONC, CMS and NIST communications regarding the meaningful use criteria, standards specifications and measurement.*

We have found the communications on the whole helpful and of clarity. We have found the staff at ONC, CMS and NIST to be helpful and open to communicating with us. We realize they operate within the constraints of time and authority that serve to limit what guidance they can provide and how fast as they have to follow their own clearance processes.

We have offered previous comment on issues we encountered with the NIST test procedures – particularly relative to the question of the change control needs around updates to the test procedures for conformance test tools. We have also offered previous comment on the need for clarity and guidance early and often around the automated calculated measures.