Meaningful Use or Market Abuse?
Required Certification of Electronic Healthcare Record (EHR) Technology

by

Lou Agosta, Ph.D.
Initial Version: January 18, 2010
Updated: January 28, 2010
[comment submitted 2010-02-10: 80a90c3c]
LAGosta@acm.org

Table of Contents

Position ................................................................. 2
Arguments in favor of certification of EHR technology .... 2
Arguments against certification of EHR technology ........ 4
Findings and recommendations ................................. 15
Appendix I: Who Certifies the Certifiers? ................. 17
Appendix II: HITECH (ARRA): ‘Certification’ is ‘Voluntary’ ................................................................. 19
Author Biography .................................................... 20
Detailed Contact Data ............................................... 20
This comment on CMS-033-P is being submitted by Lou Agosta, Ph.D. (biographical and contact data at the end of this doc) electronically via www.regulations.gov to the Centers for Medicare and Medicaid Services, Department of Health and Human Services, attention CMS-0033-P.

Lou would like to thank the Secretary and the HHS staff for the opportunity to provide feedback on the Definition and Criteria of Meaningful Use of the reimbursement for the acquisition of certified Electronic Healthcare Records (EHR) under the HITECH portion of the American Recovery and Reinvestment Act (ARRA).

Position

Information technology (IT) is a key enabler in the transformation of the delivery of high quality, affordable, accessible healthcare in the USA. The proposals for meaningful use contained in the document (hereafter referred to as ‘Meaningful Use Proposal’), on which this paper is a comment, contain much that is useful and validates the management best practice that if a process is to be improved, it must be measured accurately and in a timely way.1 This analysis and commentary contains a single recommendation (suggestion): delete the word ‘certified’ from the requirement for reimbursement under the HITECH portion of the American Recovery and Reinvestment Act (ARRA). In short, implement ‘electronic healthcare technology (EHR)’ pure-and-simple instead of ‘certified EHR’ technology. Although easy to state, this is a radical proposal. Thus, this proposal requires a discussion of the pros and cons of a certification approach to transforming the HIT infrastructure using EHR and acts as a lightning rod to constellate diverse issues and challenges in the market.

Arguments in favor of certification of EHR technology

The subtitle of this comment is intended to be provocative. However, in no way does this comment question the value of requiring providers to demonstrate ‘meaningful use’ of EHR technology in order obtain reimbursements under the proposed rule-making. The question is about the value of ‘certification’ as such as a required part of the process. The question raised here is whether the most objective and unbiased certification process in

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1 CMS-0033-P: DEPARTMENT OF HEALTH AND HUMAN SERVICES, Centers for Medicare & Medicaid Services, 42 CFR Parts 412, 413, 422, and 495; CMS-0033-P; RIN 0938-AP78; Medicare and Medicaid Programs; Electronic Health Record Incentive Program; AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS. ACTION: Proposed rule. SUMMARY: This proposed rule would implement the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5) that provide incentive payments to eligible professionals (EPs) and eligible hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology. Hereafter: The Meaningful Use Proposal.

Page 2 of 20 Comment on CMS-033-P, Criteria of Meaningful Use © by Lou Agosta, Ph.D. Version: January 28, 2010 LAgosta@acm.org 773-203-0269
the world, when made an independent authorizing organization, including a revenue source, inherently distorts the process of building out the infrastructure required to transform healthcare using information technology (HIT). The question of who or what organization certifies the certifiers is a valid one but considered out of scope in this comment. Additional background on this dynamic issue is contained in Appendix I.2

The following are reasons in favor of (required) certification of EHRs. These must be addressed by any comment that proposes to delete the word ‘certified’ from ‘certified EHR’.

1. Market dynamics are enhanced by certification: A market filter (or gate-keeper) is useful to separate the wheat from the chafe. Market discipline has its uses in providing prospective buyers with a short list of contenders. If a vendor is so small and marginal to be unable to get over the bar to afford certification, then just maybe it needs to stay on the sidelines and not try to play with the tried-and-true vendors in the market. This will reduce the likelihood of orphan software, rip-and-replace projects, and surprises that damage the reputation of the software (system development) industry as a whole. Along the same lines, even if critics argue that CCHIT is an organizational bottle-neck (or becomes one at any point), certification as such is a positive requirement and additional resources should be marshaled to make it work.

2. HIT is a complex artifact. Healthcare providers (EPs and hospitals) are in the business of fighting disease, not debugging software. It makes good sense to perform the work of identifying, distinguishing, and testing IT functionality up front. This eases the acquisition process and speeds time to implementation. Although it is shocking to think that such things occur, sales people from would-be EHR/EMR systems are already telling small physician practices and community hospitals that ‘EMR is mandated – you have to buy one – let me give you a deal on mine’. Of course, nothing could be further from the truth. Discipline is required.

3. Certification reduces information asymmetries: Instead of relying on the vendor’s marketing brochure, prospective buyers of complex HIT are able to consult the results of a disinterested third party, for example, downloading detailed testing scripts off the CCHIT.org web site and doing their homework up front. Without certification, the floodgates will be opened to reimbursements as providers address the issue willy-nilly by buying a standard relational database, a data model, and a frontend query and reporting tool. In addition, the transparency and accountability in required system functionality serves a useful educational role.

4. System software quality is promoted, standards are implemented by required certification. There is an argument that the testing that occurs as part of certification has value, especially as part of a conversation about standards and benchmarks. Even given that some controversy about the details is seemingly

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2 See Appendix I for background on the role of CCHIT.org.
inevitable, the amount of information surfaced by the assembly and application of the certification-oriented test scripts is substantial. The certification process can (and will) drive standards promoting interoperability – content exchange, transport, security standards - into the market. Interoperability’ and that lack of it is one of the major challenges facing HIT. Lack of interoperability creates substantial friction and inefficiencies. The incremental implementation of interoperability will go a long way to reducing costs, improving care, and modernizing HIT in the USA.

Arguments against certification of EHR technology

The enabling legislation in the HITECH portion of the ARRA is clear – a certification process is authorized but is unambiguously marked as ‘voluntary’ in at least two key passages. How this got ‘built into’ the rule making process is the equivalent of a typographical error, which may usefully be corrected. In short, there is no language in the initial underlying, enabling legislation that would prevent this comment [to delete ‘certification’] from being accepted and implemented. However, the same result can be obtained semantically by adding the word ‘voluntary’ as in ‘voluntarily certified EHR’. The exact language is of the HITECH portion of the ARRA is cited in Appendix II. As an alternative point of view, acknowledging that certification is voluntary would have many of the same practical results as this proposal to delete the word ‘certified’ from ‘certified EHR’ in the rule-making. Unless otherwise noted, this comment objects to (and opposes) the point of view that ‘certification’ be required as the certification process named in the proposed rule-making is a required one. An alternative point of view that allows ‘certification’ as a voluntary process is called out. Such an approach would capture some of the benefits of standardization and testing without the disadvantages of stifling innovation, distorting the market, and privileging one part of the market at the expense of another. Although such a compromise is feasible, it is not likely to emerge until the pro and con positions have been clearly articulated. This comment focuses on doing that.

1. My research indicates that the current (Q3 2009) market for hospital information systems (HISs) to be some $307 million and growing at a 20% rate, whereas the market for physician practice management systems (PPMS) is $102 million and growing at 25%. Combined, the two markets will reach $1.38 billion by 2014 and surpass $2 billion by 2015. Eliminating the word ‘certified’ from the criteria for reimbursement has the potential approximately to double the size of this growth by 2015, though not directly

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3 For example, for the purpose of submitting lab results to public health agencies, certified EHR Technology must be capable of using HL7 2.5.1. Certified EHR Technology is supposed to be capable of receiving a message with Logical Observation Identifiers Names and Codes (LOINC®) codes from a laboratory, retaining those LOINC® codes, and using LOINC® codes to populate a patient summary record. Certified EHR Technology is only supposed to be capable of using LOINC® codes that are received and retained to populate a patient summary record. For the purposes of performing a drug formulary check, certified EHR Technology must be capable of using NCPDP Formulary & Benefits Standard 1.0 adopted by HHS (73 FR 18918) in order to ensure in circumstances where an eligible professional or eligible hospital electronically prescribes a Part D drug for a Medicare Part D eligible individual, he/she can maintain compliance with applicable law. This list of standards is not complete, but will serve to make the point.

Page 4 of 20 Comment on CMS-033-P, Criteria of Meaningful Use © by Lou Agosta, Ph.D. Version: January 28, 2010 LAgosta@acm.org 773-203-0269
through the actual reimbursement process itself. How then? By allowing increased software competition not just from new, small innovative players, will drive down the prices of HIS and PPMS, putting systems within the reach of the middle and low end of the markets but expanding the outer boundary significantly.  

While the market for run-your-medical-practice (EHR) software is far from perfect, the certification process introduces a substantial distortion into a robust and dynamic market for such EHR software systems at multiple levels. Certification is an anti-competitive and administrative (‘bureaucratic’) barrier to market entry by innovative cloud computing applications, database appliance providers, and those high end hospitals and physician practices that command sufficient IT resources to implement their own in-house solutions using standard off-the-shelf components. In addition to satisfying the criteria of meaningful use and properly reporting quality metrics, all these three types of organization must now go to CCHIT (or its successor organization(s)) and navigate the process of certifying a particular implementation and understanding of how technology maps to meaningful use. I hasten to add that the latter understanding (and implementation) may be quite legitimate and proper without being the only possible one, the optimal one in a given context, or one on which a provider decides to ‘bet the farm,’ resulting in the user in effect being frozen out of the reimbursement process and the market whose outer boundary is defined by the reimbursement process.

![Figure 1](image-url)

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Major Brand</th>
<th>Web Site</th>
<th>Estimated Revenue Attributable to Software (US$ Millions)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allscripts-Misys</td>
<td>Misys</td>
<td><a href="http://www.allscripts.com">www.allscripts.com</a> / <a href="http://www.misys.com">www.misys.com</a></td>
<td>64</td>
<td>Total revenue of $383 million of which some $64 million is system sales (source: 2008 Annual Report)</td>
</tr>
<tr>
<td>Cerner</td>
<td>Millenium</td>
<td><a href="http://www.cerner.com">www.cerner.com</a></td>
<td>22</td>
<td>Total annual revenue of $200 of which about 10% is attributable to software sales of Millenium</td>
</tr>
<tr>
<td>Computer Programs and Systems: ChartLink)</td>
<td>Chartlink</td>
<td><a href="http://www.cpsinet.com">www.cpsinet.com</a></td>
<td>13</td>
<td>Total revenue of $585 million, some 2900 employees including those off shore</td>
</tr>
<tr>
<td>Eclipsys (Sunrise Enteprise)</td>
<td>Sunrise</td>
<td><a href="http://www.eclipsys.com">www.eclipsys.com</a></td>
<td>35</td>
<td>Estimated total revenue of $601 million; privately owned but about the same number of employees as Eclipsys (source: Epic web site)</td>
</tr>
<tr>
<td>Epic</td>
<td>Epic</td>
<td><a href="http://www.epicsystems.com">www.epicsystems.com</a></td>
<td>63</td>
<td>A $17 billion company within a $150 billion company.</td>
</tr>
<tr>
<td>GE Healthcare</td>
<td>Centricity</td>
<td><a href="http://www.gehealthcare.com">www.gehealthcare.com</a></td>
<td>19</td>
<td></td>
</tr>
</tbody>
</table>

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Technology lock in’ refers to the situation in which there is a cost associated with switching from one technology to another. Similar considerations apply to (1) technology lock in (2) increasing the power of selected, dominant sellers. A common example of technology lock in is that you cannot switch from vinyl long plays records (LPs) to compact disks (CDs) for music without incurring the cost of replacing your music collection. There is a common approach to market innovation in software to discount deeply the software at the start of the sales and implementation cycle and recoup some of the discounts through subsequent prices increases that are proportional to switching costs plus the quality cost advantage.⁵ This is a fair approach and results in total revenue to the developer and seller of the software that covers the development costs plus a profit roughly proportional to its marketing success based on the perceived and delivered value. One of the consequences – entirely independent of any certification process – is a standards war – where ‘war’ means ‘competition’ between alternative technology standards. More on the standards (and interoperability) process shortly. By its nature, the certification process advantages existing configurations and whatever standards are thereby implemented. This is not bad in itself; however, it does not promote whatever innovations are occurring in a given market – for example, such as those that are occurring in cloud computing and database appliances.

The requirement to use a certified EHR (EMR) is a de facto barrier to the majority of hospitals under 200 beds that are responsible (according to HIMSS Analytics) for the fact that less than half of US hospitals have clinical provider order entry (CPOE).


Page 6 of 20Comment on CMS-033-P, Criteria of Meaningful Use © by Lou Agosta, Ph.D. Version: January 28, 2010 LAgosta@acm.org 773-203-0269
The certification process addresses functionality without addressing usability, cost, or (downward) scalability. Interoperability is a requirement that the certification process properly targets as critical path, albeit in a context in which none of the larger players such as Cerner, McKesson, and so on succeed in interoperating with one another. (They do not.) Nor is it clear that as of this date (Q1 2010) the established EHR software vendors in the market are unanimously in favor of navigating a required (or even voluntary) certification process. However, the conventional wisdom suggests they would gather advantages in market positioning from such a process, assuming that the certification process incorporated the existing (EHR) functionality they offer individually or collectively.⁶

It is important to note that ‘certification’ does not just advantage the selected large, existing HIS and PPMS systems at the expense of would-be innovators at the low end of the market. At the risk of sounding cynical, it is one thing to throw over the side smaller players who have no constituency – whether in the market or amongst regulatory administrators. However, certification also disadvantages such software, hardware, and system sellers as HP, IBM, Oracle, Microsoft, SAS, SAP as well as a host of large but lesser known players in the enterprise and corporate markets such as Informatica, Pervasive, ParAccel, Teradata. Certification disadvantages these companies and even more importantly the buyers that they might benefit whether they realize it or not. Perhaps IBM, HP, and so on are earning plenty of revenue and the sales staff does not believe they are disadvantages. Well and good – but the real losers are the hospitals and physician practices paying for reduced competition by means of a certification markup. Prospective buyers still need the products offered in a full, robust market and the cost saving that is (would-be) created by full participation. Many of the criteria of meaningful are precisely what the basic technology does best by means of a standard relational database, a frontend query and reporting tool, and a data model that represents the intersection of such basic dimensions as patient data, provider data, diagnosis code, cost, and so on. It strains credibility that well established software products such as IBM, Oracle, Microsoft or well-known brands from Cognos, Business Objects, and Hyperion require ‘certification’. Of course, the healthcare provider’s that buy such products are still properly required to demonstrate meaningful use according to the criteria proposed here and that may require a significant effort (or not); but having these products ‘certified’ adds no value from functional perspective, and the certification steps falls out of the process of acquiring software and demonstrating its meaningful use. The buck starts and stops with the hospital’s demonstration of meaningful use of the software to deliver quality care at lower cost and the certification step falls out of the process as an idle wheel. Case closed.

If HHS and the US Congress want to benefit large established software vendors in the existing market – see Figure 1 for an overview - then proceed with the rule-making in its current form. The result will be that the big will get bigger. The powerful, more powerful. This is not necessarily bad, and a certain amount of consolidation and centralization offers economies of scale in the acquisition and installation of HIS systems at large.

⁶ As of January 20, 2010, requests for comments had not been returned from the list of vendors in Figure 1.
hospital systems and research institutions. What it does not offer is an opportunity to build out the HIT infrastructure at the community hospital level by innovating in affordable, usable, interoperable systems that address the requirement of the struggling constituencies at the community level. Of course, these two scenarios are not mutually exclusive. Just to pick one example, ‘big’ is required if you are HCA (formerly Hospital Corporation of America). My point is merely the latter requires less of a subsidy (and at least at the level of an intuitive sense of fairness is less deserving of one) than the areas of the economy that lack HIS infrastructure altogether.

The situation in the case of so-called Ambulatory systems is different in that there are literally tens of thousands of small physician practices that will not even look up from their stethoscopes to consider a certified EHR technology with the bar being so far above what they can reasonably contemplate proposing, purchasing, and implementing. Once again the large practices such as Mayo, Intermountain, Geisinger, will require big systems that scale to accommodate hundreds of practitioners. Even if they prefer to report quality metrics from existing data warehousing architecture rather than rip-and-replace in favor of a new EHR with redundant functionality, they have resources to manage the alternatives. I hasten to add that it may well be that we may well choose to implement policies that create a practice environment such as that at Mayo where doctors are on salary, are compensated to perform coordination of care, and are incented to talk about patients for the benefit of patients rather than turning the crank on tests and visits. This is certainly the wave of the future in large urban settings. However, we do not want to get there by driving individual and small group practitioners into the ground. These practices require a PPMS (EHR) that resembles what Quicken has done for small scale finance – usable, runs on a PC or small server, requires zero (or minimal) maintenance, and has a correspondingly low price point. Alternatively, the delivery of such a set of capabilities over the Internet as an application service provider (ASP) within a medical cloud infrastructure is a compelling value proposition. Going forward, the possibility of such an initiative flourishing in a ‘certification’ environment is limited, though it is such a compelling value proposition that it may be unstoppable, regardless of certification or reimbursement.

The vast majority of healthcare services are delivered by physician practices of 1 to 5 doctors and nurse practitioners. Even though there are some 194 ambulatory EHR choices listed on the CCHIT site, only two are certified – Epic and Pulse Inc – as of this date (2010 Jan 13). The issues is not that there are not enough choices – though that is also the case. The issue is that the certification process presents a gauntlet of requirements for would-be candidates that does not add value, stifles innovation, and creates barriers to market entry that benefits legacy technology.

The market for small physician practices is under-served and will continue to remain so as long as the certification process is dominated by the requirement to demonstrate functionality that is part of a complex system of proprietary products. What is required is what I call a Quicken-class of ambulatory products – possibly delivered over the web in the form of an application service provider (ASP) – where the hardware and software do not even need to be located in the physician office. The 20% of physicians who work for
the Mayo clinic or large hospital chains and research centers will be well-served by the certification requirement, at least in terms of incremental revenue. But not the remainder of the market.

2. As noted above, healthcare providers are in the business of fighting disease, not installing and maintaining software. Still, software is now a part of every business process; and it is on the horizon to become a part of the every process of diagnosing, managing, and treating diseases that occurs in a modern first world setting. The healthcare provider (whether EP or hospital) has to demonstrate meaningful use. That burden cannot be shifted onto a certifying organization, nor would such certifying entity be willing to warrant that its certified EHR system is used in a meaningful way by the provider merely based on its test scripts. Whose job is it to demonstrate that meaningful use is occurring? It is the provider’s job. Presumably that means a cross functional team of healthcare workers and IT staff needed to navigate and document the use of the technology.

How will this occur? The proverbial buck stops with the EP and hospital. The ONC Certification document cautions: ‘Eligible professionals and eligible hospitals that elect to adopt and implement certified EHR Modules should take care to ensure that the certified EHR Modules they select are interoperable and can properly perform in their expected operational environment.’ All the usual disclaimers apply – the certified product is not warranted for any particular purpose and your mileage may vary. In other words, the adoption of a ‘certified’ EHR (EMR) does not create a safe harbor for a provider who purchases, installs, and uses one. Nor is the recommendation of this comment that such a safe harbor be implemented, based on the requirement for provider accountability and the needs to improve quality and efficiency. The provider is still responsible for outcomes, demonstrating quality metrics, and showing that the provider makes meaningful use of whatever technology is acquired. Presumably the ‘certification’ is supposed to provide the provider with guidance (in the market) and ‘a leg up’ on getting over the bar to reimbursement and quality improvement. However, the result is to privilege a certain class of large, existing, dominant players in the market and to complicate the EHR technology acquisition process.

In general, the criteria of meaningful use represent a contract – an agreement – to which the underlying system (whether certified or not) has to conform in terms of producing usable, interoperable output. The provider will work backwards from the interface to assure that the underlying functionality conforms to its attestation – the provider’s sworn testimony (‘attestation’) to the reimbursement office – that the system functions as required. By applying the principles of object-oriented system design and implementation to the challenge represented by meaningful use, the diligent and conscientious provider eliminate the extra step of certification.

The situation is analogous to that encountered in the so-called ERP revolution (enterprise resource planning) in computing. In the run up to the Y2K (year 2000) event in the year 2000, companies such as SAP, Oracle, JD Edwards, PeopleSoft, and many other ERP systems insisted their architectures were robust and flexible enough to support both
transaction processing and BI from the same system architecture and data stores. Fast forward a few years, and by the year 2004 those of these companies that still survived were announcing and delivering revised architectures to support business intelligence. We are on track to repeat an entirely analogous repetition of architectural trial and error. Companies such as Cerner, Epic, Eclipsys, McKesson, GE Centricity, MedSphere, Meditech, and so on predictably claim that their transactional engines based in Mumps and Cache (those are data stores) can handle the job. But the job is complex and is inherently at odds with itself. It is a tad like building a car that gets both good gas mileage and one that has a lot of horsepower. In the software world, the solution is to feed the transactional data into a data warehouse or other business intelligence subsystem and use the latter to optimize the former. (The automotive problem has still not been solved, nor will it be in this paper.)

3. While certification has the potential to reduce information asymmetries by producing test scripts and examples of functionality, this information is less valuable than we may hope. Just as it is often true that some generals prepare to fight the last war, so too it is also the case that certification is getting ready to validate last generation’s client-server technology. The famous example is the construction after World War I of the Maginot Line by France, a series of trench like fortifications in anticipation of trench warfare. Equally famous is (German) General Heinz Guderian’s World War II blitzkrieg that went around (and over) the wall using tanks and aircraft, rendering the Maginot line obsolete. Innovations in cloud computing, the provisioning of web based EHRs (EMRs) and database appliances are the equivalent of an emerging technology blitzkrieg in HIT. While we should not represent different players in the market as sworn enemies, large and established HIT vendors (see Figure 1) are likely to confront a looming innovator’s dilemma. In the 1980s IBM would not look at any sales under $5 million dollars and was nearly driven out of business by upstarts building systems with a copy of SQL Server and a copy of PowerBuilder priced one tenth the cost. The dominant HIS and PPMS vendors are positioning themselves to be the next candidates for the unwelcome category of “too big to fail,” though this time in HIT, not banking. The comment and recommendation? Stop them before they hurt themselves. Stop them by deleting the word ‘certified’.

The prospective buyers of EHR technology are physician practices (eligible professionals (EP)) and hospitals. They are best protected from the unprofessional practices of a small – very small - minority of system sales people through their own professional procurement practices, diligently reviewing written proposals, specifications, and contracts. It is unlikely to be the basis of a legal claim against a software vendor installed

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7 Clayton Christensen, The Innovator’s Dilemma. Boston: HBS press, 1999. Professor Christensen tells the story of how successful companies – across incredibly diverse and different industries - are single-mindedly motivated to listen only to their biggest and best customers (in general, not a bad thing to do), and are, thereby, blind to innovations that get a foothold at a price point down market and subsequently disrupt the standard market dynamics, leading to the demise of the ‘big guys.’ Note that IBM, mentioned in the next sentence, is one of the few companies to have succeeded in turning itself around, admittedly in a painful and costly process led by the now legendary Lou Gerstner, and to have brought itself back from the brink. Watch for this dynamic to continue in HIT, albeit at a slower pace due to the friction caused by large government participation and with results such as that at IBM being the rare exception.
at a given site that failed to satisfy meaningful use criteria for provider that the software system or modules were certified. The provider receives the reimbursement (if any is forthcoming) and is responsible for attaining and demonstrating a use of the system that delivers healthcare services in a more effective way according to the criteria of meaningful use. From such a perspective, certification may be of value to the vendor but it furnishes a false sense of security to the prospective buyers (such as hospitals and eligible physicians).

On the one hand, some of the meaningful use criteria, including those that capture basic clinical transactions, are best delivered by an underlying system consisting of a standard relational database, a frontend query and reporting tool, and a data model that represents the patient demographics, diagnoses and procedures, and related clinical nomenclature. The user interface at which the meaningful use of the technology, including the capturing of data electronically, reporting of data electronically, and the manipulation of quality measures is the contract at which the meaningful use is delivered. Multimillion dollar HIS systems are candidates for “over kill” from a transactional perspective in addressing such use yet at the same time lack the necessary infrastructure to support quality metrics through aggregation and inquiry via a data warehouse function.

On the other hand, some of the meaningful use criteria – in particular the requirement to report about 100 quality measures – are poorly accommodated by the vast majority of HIS system on the market today. I do not know of a single exception where the HIS system provides for the aggregation and analysis of metrics in a way similar to what business intelligence (now ‘clinical intelligence’) does in business verticals such as retail, finance, telecommunications. Once again, the user interface at which the quality measures are surfaced is (in effect) the contract, but it will prove impractical to generate such a result. If these systems propose to perform the aggregations of a year’s worth of data based on transactional detail, the predictable result will be a long, slow process. Reinventing the wheel is hard work, but that is the path on which existing HIS and PPMS (EHR) systems have embarked. I hasten to add that the quality metrics are critical path and required. However, the path to the efficient and effective production of them does not lie through certification.

Those providers that are currently reporting quality metrics from a data warehouse that gets its data from the transactional EHR are concerned that they are out of compliance. It is widely reported that Intermountain Healthcare is one such enterprise. Are they now supposed to certify their data warehouse? Where is the value-added in that?

A long list of clinical quality measure requires reporting a percentage of a total aggregate of a given diagnostic condition; for example, percentage of patients aged 50 years and older who received an influenza immunization during the flu season (PQR1 110 / NQF 0041). These are what other business operations such as retail or finance call “business intelligence” questions. In the context of healthcare, we might call them “clinical intelligence” – or just plain quality measures – but the function is similar – to make possible the tracking of improvements in the delivery of care. To manage enhancements

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*8 For example - http://www.healthcareitnews.com/news/meaningful-use-criteria-too-high-and-too-many*
by measuring outcomes in aggregate. The periodic calculation of some 94 percentages requires scanning the entire database and performing an analysis, review, and aggregation of a totality of the diagnostic data. Even though most records will not satisfy a given diagnosis – whether coronary artery disease of diabetes mellitus – they will have to be examined. The lessons of some two decades of computing in finance, telecommunications, retail, manufacturing, and fast food are clear, but not always obvious to those medical professional who have spent their time in healthcare IT. When you attempt to perform business intelligence (BI) against the operational, transactional system, then something has got to give. Either the performance of the transactional system is brought to its knees or the BI process has to wait. In fact, system design for high performance transactions processing are poorly adapted to generate the results required to perform business intelligence. The difference is between update intensive operations and query intensive ones, between updating and scanning. That is why the data warehouse was invented – in order to collect and aggregate the data required for reporting in optimal format, allowing the transactional system to do its job supporting clinical process whereas clinical intelligence is used to guide process improvements.

The counter-argument that certification of the functionality around clinical data warehousing ought to be rolled up into the certification process is the reduction to absurdity of the process itself. There will always be some such functionality – if not data warehousing, then cloud computing, database appliances, artificial intelligence in clinical decision support, and so on. The list is limited only by our imagination and that of our fellow innovators. The Meaningful Use Proposal has got it basically right (though one can (and should) argue about details). The reporting of quality measures, based on aggregated clinical detail is a proven method in other disciplines of driving improvements in outcomes by surfacing, managing, and reducing variability from the quality norm. (‘If you can’t measure it, you can’t manage it’) However, this value is provided by implementing systems that directly address the superset of meaningful use criteria captured in the proposal, not by driving the process up stream into one particular system architecture that happens to have emerged in the early 1990s and gotten some significant traction.

4. While there is general agreement that testing is valuable and while the certification step(s) can provide evidence that the functionality promised by the technology is actually available, the number of variables introduced by implementing the software in a specific context is significant enough that the buyer should beware and require its own proof points in its specific context. In short, the certification step drops out. It is an idle wheel that does nothing. At the margin, a jury of disinterested observers, volunteers in work groups from stake-holders in the process, viewing a software demonstration over a remote video conference – which is exactly what is required by the certification process – may be better positioned to testify that functionality is or is not available as promised in the vendor’s marketing brochure. Yet the granularity of the testing that occurs falls significantly short of that required to say whether the functionality will actually deliver meaningful use in the context of its target environment. Healthcare providers should not be required to pay for highly variable, potentially useful information – on the order of ‘better than a marketing brochure’ – unless they decide to do so.
Whether or not there is a certification process, the would-be buyer of EHR technology that deploys the minimum necessary HIT procurement intelligence will write its request for proposal (RFP) with selection criteria that map one-to-one with the criteria published by the CMS-033P document on which this is a commentary. The diligent buyer will further request that the supplier of the software system or technology show the user in a live, hands-on demonstration that the software provides the functionality required to attain meaningful use. Just as a test drive is a best practice prior to purchasing a car; just as a test listening is a best practice prior to buying a stereo system; likewise, a software demonstration, preferably with a live system, is a best practice in purchasing or upgrading any software. Precisely since the buyer remains accountable for meaningful use, the ‘certification’ process becomes a trap for the unwary. If the certification process shifted both costs and accountability from the provider to the vendor, it might be worth considering it; but the cost gets recouped by the vendor due to market limitations and the accountability remains where it started (and arguably properly belongs) with the provider.

One of the intentions of the US Congress in enacting reimbursements for the purchase of an electronic medical (healthcare) record (system) is to prime the pump and, in effect, jump start the arduous process of upgrading the technology infrastructure of the healthcare delivery system in the USA. So where are we at collectively in terms of market readiness? HIMSS Analytics has developed a capability maturity model (CMM) that positions hospitals along a continuum of functionality relating to the mission to which hospitals are dedicated. Roughly, reimbursement Stage 1 that begins in 2011 maps to HIMSS Analytics CMM Phase 4, especially if the latter is understood to require entry level CDSS (clinical decision support) and partial CPOE (clinical provider order entry). The answer is that there is a lot of work to be done. According to HIMSS Analytics, the majority (67%) of hospitals are at CMM Phase 2 or 3 with some 27% not yet at that level and not quite 6% beyond it. What does that mean? If CMM Phase 4 maps to Meaningful Use Stage 1, then some 6% of hospitals are ready for Meaningful Use Stage 1. That is not necessarily a bad thing, since the entire point of the reimbursement is to prime the pump and build out the infrastructure. But what infrastructure?

More of a concern is that the HIMSS CMM points to a significantly different system architecture than the one envisioned and institutionalized in the certification process. In particular, the role of data warehousing – call it ‘clinical’ information warehousing, if

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9 HIMSSAnalytics.org. The CMM phases extend from (0) no support (1) ancillaries installed – lab, rad, pharmacy (2) clinical data repository, controlled medical vocabulary, clinical decision support system, document imaging (3) clinical document (CDSS), work flow, CDSS (Error checking), PACS available outside radiology (4) CPOE, CDSS (e.g. if one patient service area has implemented CPOE with physicians entering orders and completed the previous stages, then this stage has been achieved.) (5) Closed loop medication administration (6) physician documentation, full CDSS (physician variation and compliance), R-PACS (7) medical record fully electronic, HCO able to contribute CCD as by product of EMR; data warehouse in use. It should be noted that each of these CMM phases (also sometimes called ‘stages’) is different from what is meant by Stage 1, Stage 2, and Stage 3 of the demonstration of meaningful use of certified EMR (EHR) under the incentives in the ARRA. As noted, in general, Stage 1 that begins in 2011 maps to HIMSS Analytics Phase 4, especially if the latter is understood to require entry level CDSS and partial CPOE.
you prefer - in aggregating the quality metrics is critical path. Such a best practice for aggregating and managing quality metrics is not certified, but it is required. This is not so much a matter of the perfect being the enemy of the good enough as the tendency of the certification process to institutionalize a system architecture that emerged prior to data warehousing systems. As with any dynamic, rapidly changing technology, certification comes too late.

Compliance with requirements for quality reporting and reimbursement (these are related) will constrain and act as a forcing function in the adoption of standards. However, this comment is skeptical – highly skeptical – that building standards into a required certification process will cause anything other than loss of agility, constraining innovation, and validating last generation technology. For better or worse, HHS and its regulatory partners in public health, CMS, and so in government will have a decisive influence on setting standards in the following way: by requiring that in bound messages for quality reporting, processing, and (where applicable) reimbursement use a given set of standards.

This comment agrees whole-heartedly that promoting interoperability – content exchange, transport, security standards – in the healthcare delivery system(s) will drive down costs, improve service, enable a 360 degree view of the patient across coordination of care, and enhance the quality of outcomes. It may well be that government agencies, due to their size and procurement constraints, represent a ‘lowest common denominator’ in the adoption of standards. The market may, on its own, favor alternative standards that will eventually ‘percolate’ up to the reporting function. But in the meantime, building standards into a certification process is at best redundant and at worst validating of yesterday’s technology. I hasten to add this is entirely consistent with the view expressed on all sides of the discussion that interoperability and that lack of it is one of the major challenges facing HIT. Lack of interoperability creates substantial friction and inefficiencies. The gradual (or rapid) implementation of interoperability will go a long way to reducing costs, improving care, and modernizing HIT in the USA.

5. A practical objection to the comment to delete ‘certification’ requires considering. One concern by the payer of the incentive (tax payers) might be that by dispensing with the certification of the EHR the flood gates would be opened to more payments, thus straining the available funds. However, the overall result would just as likely be a reduction in total costs of the system along with a broadening of the base of those receiving the benefits of payment due to the adoption of EHR technology. This may seem counter-intuitive at first. Why reduction? Current EHR systems from Figure 1 vendors are multi-million dollar investments. Those large hospitals already operating such systems will continue to do so and will be incented (financially) to upgrade. This will drive sales and the installation of upgraded technology. However, there is a vast middle market that is under-served and unserved. The big guys have struggled to move “down market,” with limited success because they end up cannibalizing their own business. This presents obstacles internal to the Figure 1 organizations as the sales force try to compete with one another, but then are properly just told to stop by their executive management, ending the ‘down market’ initiative from within. Open source (Medshere, VistA) have
moved to fill the gap, but is still a multi-million dollar proposition, albeit significantly less than the proprietary players. The transformational opportunity – where it may require just a spark of reimbursement to ignite a conflagration of infrastructure improvement activity – is in this under-served area of small physician practices and community hospitals. Intense competition in the development of what I call a Quicken-class of software (possibly on a data cloud or appliance infrastructure) to serve this market will be delayed but not stopped by reimbursing a certification process that validates last generation’s system architecture. Why incur the delay?

Findings and recommendations

The requirement for ‘certification’ does not increase the choices or power of prospective buyers such as Eligible Professionals in healthcare or inpatient hospitals. It funnels them into a process that limits choices to large, already dominant providers with legacy, early 1990s system architectures. In short, the criticism being aimed at the certification process is that it creates an administrative lock, increases switching costs by artificially reducing the choices of replacement products, subsidizing the prices of existing dominant software sellers in the market.

If the meaningful use criteria are finalized and implemented requiring ‘certified’ EHR, then large, multi-million dollar hospital systems and eligible professionals that are already operating complex HIS and PPMS will make upgrades to existing infrastructure, but smaller community hospitals and small physician practices will not participate. This is because they will be unable to afford the purchase price of the high end offering and the delivery of what might be described as ‘kinder, gentler’ down market solutions will be inhibited until the market distorting incentives expire. Such community and small practice prospects will fall into the market gap between high end EHR systems whose price has been driven up by high end functionality (and a certification process to validate such functionality) and simpler Quicken-class EHRs – including solutions from upstarts as well as established giants such as HP, IBM, and so on - that have chosen not to run the certification gauntlet. I predict the latter inevitably will get a toe-hold in the market and march up market in the next three to seven years. However, this disruption of the established players Figure 1 vendors footnoted in my research will occur as other credible competitors such as HP, IBM, Oracle, Microsoft, SAS, SAP and so on awaken to the market opportunity.

The best way (not the only way) to combat fear, uncertainty, and doubt (FUD) in the market, including unscrupulous sales claims that ‘you have to buy an EHR’ is not through required certification but through education based on the power of the meaningful use of healthcare information technology (HIT). For example, there is a crucial role for community colleges to play in creating HIT jobs that address the information technology needs of community hospitals and small physician practices. This is a marriage made in heaven between physicians whose job it is to treat patients and Geek Squad class technical associates [this is an example, not an endorsement] who...
know how to keep the printers running, the network connection in tact, and backup the local database against a system crash.\textsuperscript{10}

From the perspective of semantics, substantially the same result can be obtained by substituting the word ‘voluntary’ as in ‘voluntary certification’ as envisioned in the initial legislation (see Appendix II) as by deleting the word ‘certification’ from EHR. The arguments pro and con and similar. However, for purposes of simplification and reducing the word count, this comment urges the latter. To the extent that certification facilitates an educational function, it should be voluntary as indeed called out in the initial legislation (Appendix II).

When approached from the perspective of object-oriented systems design where the user interface is the contract, ‘certification’ becomes an ‘idle wheel’ that does not drive any part of the process of the demonstration of meaningful use relative to the context in which the EHR system is implemented. ‘Certification’ does nothing, and it falls out of the process. Hence, this comment: delete ‘certification’.

Appendix I: Who Certifies the Certifiers?

At the present time (Q1 2010), there is a single organization, the Certification Commission for HIT (www.CCHIT.org), authorized by the ONC to perform the certification process. Going forward, the authority to perform certification will not be restricted to a single organization; but for the foreseeable future CCHIT is the only certification organization in town.

CCHIT came into existence in 2004 as a way to qualify the kinds of interoperable software and hardware that could be given to physicians without violating the anti-kickback provisions of the Stark Law:

In August 2006, HHS published two final rules in which CMS and the Office of Inspector General (OIG) promulgated an exception to the physician self-referral prohibition and a safe harbor under the anti-kickback statute, respectively, for certain arrangements involving the donation of interoperable EHR software to physicians and other health care practitioners or entities (71 FR 45140 and 71 FR 45110, respectively). The exception and safe harbor provide that EHR software will be “deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the [physician/recipient]. ONC Certification Criteria: page 16 of 136. 11

What was initially a relatively brief “sanity check” that the physician referrals to hospitals (or other health providers) were based on the exchange of real goods – legitimate interoperable information technology with standing in the market and not, for example, a trip to the Caribbean - evolved into a more elaborate and potentially useful “good house-keeping seal of approval” for HIT. My analysis does not suggest eliminating the safe-harbor or the perfunctory process required to check that any technology goods being exchanged are legitimate. Under such a regime, once the safe-harbor is attained, the certification has no other enforceable or revenue generating role besides a marketing benefit similar to a good house keeping seal of approval. In short, there is no necessary connection between allowing physician self-referral and detailed testing of functionality, nor is the former enabled by the latter or the latter required by the former. A legal, safe

11 The definition of EHR is assumed as in the ONC Certification Criteria without qualification: ‘Definition of Qualified Electronic Health Record (EHR) Qualified EHR is defined at section 3000(13) of the Public Health Service Act (PHSA) as “an electronic record of health-related information on an individual that: (A) includes patient demographic and clinical health information, such as medical history and problem lists; and (B) has the capacity: (i) to provide clinical decision support; (ii) to support physician [36 of 136] 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.”’ This comment accepts the statutory definition of Qualified EHR without modification.
harbor for physician self-referral is logically, legally, and functionally independent of verifying the detailed functionality of complex EHRs such as health information systems or physician practical management systems.

Who certifies the certifiers is itself a process that is undergoing transformation. Initially, the Office of the National Coordinator (ONC) of HIT published separately a Certification Guidance Document (CGD) (71 FR 44296) to explain the factors ONC would use to determine whether or not to recommend to the Secretary a body for recognized certification body status. The CGD serves as a guide for ONC to evaluate applications for recognized certification body status and provides the information a body would need to apply for and obtain such status. However, that document seems to have been withdrawn from the web and searches have failed to turn it up, though perhaps someone has saved the PDF and can send it (or a URL) to me. In section VI of the CGD, ONC notified the public and potential applicants that the recognition process would be formalized through notice and comment rulemaking. Now certification will be separately handled under the Public Health Services Act (PHSA). Section 3001(c)(5) of the Public Health Service Act (PHSA) expressly requires the National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, to “keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted” by the Secretary [of HHS] under section 3004. Well and good. What does this mean in plain English? I suspect there is still a lot of rule-making that has to occur prior to an organization being certified to pass judgment on what health information technology is in compliance. Stand by for update on that!

I hasten to add that all evidence available to this reviewer – especially inspection of the web site (www.CCHIT.org) and notwithstanding some controversy in the ‘Blogosphere’ - indicates that the methods and processes at CCHIT are transparent, accountable, and available to anyone who can afford the fees associated with the services. In general, the approach is to conduct demonstrations of functionality in settings that support live software using a mixed of volunteers and compensated CCHIT staff. According to Sue Reber, ‘CCHIT Marketing Director, CCHIT operates with a paid staff of about 20 personnel who support the work of the Commission and it’s 15 volunteer work groups, administer the certification inspections and provide outreach to its diverse stakeholders.’ For example, the Ambulatory EHR Work Group develops criteria and test scripts for certifying electronic health record (EHR) products used in physician offices - large and small - where most Americans get their care. Volunteers include a mixture of professionals from providers, vendors, and (in some cases) independent consultants or related professional stakeholders. The professionalism of CCHIT and its staff is unquestioned in this comment, and indeed acknowledged.12

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12 CCHIT has always been open about the fact that it was initially created in relationship with the Health Information Management Software Society (HIMSS), the National Alliance for Health Information Technology and the American Health Information Management Association. One of the bloggers has done some background research on CCHIT’s finances, contracts, and consultants, all from data that is a matter of public record, and it can be found under ‘More on CCHIT’ at http://histalk2.com/2009/02/21/monday-morning-update-22309/. [Web sites checked on 2010-01-15.] All the usual disclaimers apply.
Appendix II: HITECH (ARRA): ‘Certification’ is ‘Voluntary’

There is nothing in the HITECH portion of the ARRA that requires, mandates, or forces the use of ‘certified’ EHR in order to qualify for reimbursement. The act clearly states the Office of the National Coordinator of HIT and National Institute for Standards and Testing (NIST) should set up a voluntary program to coordinate, define, and test standards and candidate standards. The key term is ‘voluntary’. For example:

HITECH Act: Sec. 13101 - ONCHIT
The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end the following:
‘TITLE XXX—HEALTH INFORMATION TECHNOLOGY AND QUALITY
SEC. 3000. DEFINITIONS. . . .
‘(5) CERTIFICATION.—
‘(A) IN GENERAL.—The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle. Such program shall include, as appropriate, testing of the technology in accordance with section 13201(b) of the Health Information Technology for Economic and Clinical Health Act.’ [emphasis added]
[. . . . ]

(b) Voluntary Testing Program.—In coordination with the HIT Standards Committee established under section 3003 of the Public Health Service Act, as added by section 13101, with respect to the development of standards and implementation specifications under such section, the Director of the National Institute of Standards and Technology shall support the establishment of a conformance testing infrastructure, including the development of technical test beds. The development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing.’ [emphasis added]

Any rule-making that changes ‘voluntary’ to ‘mandatory’, ‘required’, or ‘necessary’ is at variance with the enabling legislation. Given the complex and dynamic nature of the process, the introduction of such a requirement is the moral equivalent of a typographical error and usefully should be corrected – typographically. While legal action is rarely a desirable use of resources, if a public interest group is aroused by such changes in wording between the initial legislation and the rule-making, then such word play provides a cause for engagement.
Author Biography

Lou Agosta, Ph.D. is an independent industry analyst specializing in the role of data warehousing in healthcare information technology. He publishes regularly as the “Channel Expert” on Healthcare Information Technology on the BeyeNetwork. He is the author of over seventy substantial reports and five hundred research notes on the role of data warehousing across numerous industry verticals including but not limited to healthcare. Lou has been employed as an industry analyst, database administration, and developer for Forrester Research, Giga Information Group, IBM, Greenbrier and Russel, Computer Power Group. Blue Cross of Illinois (HCSC), Washington National Insurance, and Leo Shapiro Market Research. As an employee of one or other of the above mentioned firms, Lou has consulted to numerous corporations about data management, data warehousing, and information technology across diverse industry verticals, including healthcare. In his research on transforming healthcare using information technology, Lou has interviewed and seeks research opportunities with healthcare providers, payers, system integrators, and vendors. He is the author of The Essential Guide to Data Warehousing (Prentice Hall) and received his Ph.D. from the University of Chicago.

Detailed Contact Data

Lou Agosta, Ph.D.
5801 N. Sheridan Rd 8C
Chicago, IL 60660
LAGosta@Uchicago.edu
1-773-203-0269