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The Limits of Certification and Guarantees in Buying Electronic Health Records in the U.S.

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It is important not to rely on product certification to ensure that the buyer of an electronic health record (EHR) will qualify for incentive payments under the American Recovery and Reinvestment Act of 2009 (ARRA). Executives, CIOs, chief medical information officers (CMIOs) and application managers in care delivery organizations (CDOs) should understand the limits of certification, and evaluate vendor guarantees accordingly.

Key Findings

- Certification ostensibly ensures that a CDO *can* achieve meaningful use if it implements and uses EHR technology properly. However, it is likely that the federal certification program will only evaluate nominal functional capabilities in this regard.
- CDOs will frequently need more than one product to fully meet certification and meaningful-use requirements. Certification provides no assurance that multiple products will work together.
- Most vendors that offer guarantees with respect to the ARRA incentive program only guarantee that their products will be certified.

Recommendations

- Do not use certification as a proxy for a thorough product selection, even if this might imply a delay in achieving meaningful use.
- Look for additional certification or third-party implementation services that provide greater assurance that a product is capable of providing a successful implementation.
- When vendors offer guarantees of being certified, ensure that such guarantees apply to future software releases and future certification criteria.

ANALYSIS

It is important to recognize that certification and meaningful-use requirements are related but very different. Certification provides some assurance that the software *could* be used to meet meaningful-use requirements. The actual meaningful-use requirements, however, measure what the CDO *is doing* with the software. Confusion on this point can lead a CDO to poor product choices.

Recent Regulatory Actions

On 13 January 2010, the U.S. Department of Health and Human Services (DHHS) issued two important regulations about the incentive payments for the meaningful use of certified EHR technology (see Notes 1, 2 and 3).

Gartner's "Meaningful Use and Certification of EHRs: Tracking Evolving Targets" predicted many specifics of these regulations and provides important background information for this research.

Certification vs. Achieving Meaningful Use

To receive the payment under the ARRA, an eligible provider or hospital must achieve "meaningful use" of "certified EHR technology." Both criteria must be met, and they are different. For example, a certifying body (see Note 4) might ask the vendor of a product to show that its demonstration system has been configured to collect orders entered by a physician. However, when the CDO takes the next step to qualify for the incentives, the CDO must show that its physicians actually used the software to generate 80% of ambulatory orders or 10% of inpatient orders during Stage 1 of the incentive program.

An individual product does not have to meet all the criteria required of EHR technology to be certified. The product will be considered a "module" of EHR technology if it has been certified to enable an eligible physician or hospital to meet at least one of the criteria for meaningful use set out in the interim final rule (IFR).

A few examples of programs that might help meet the criteria in specific modules are described in the IFR. They include:

- An interface program that provides the capability to exchange electronic health information
- A patient portal
- A clinical decision support rule engine
- A program to submit public health information to public health authorities
- A quality reporting service or program

For an eligible provider or hospital to be deemed as having certified EHR technology, it must have a complement of products in place that, when taken together, have been certified for all the criteria in the IFR.

A regulation yet to be issued will describe how a CDO can achieve certification for software that was not certified by its vendor. Such CDOs may have a legacy version of a product, may have self-developed part of its EHR functions or may have used an open-source product. In this case, the software at the specific CDO is certified, rather than the products.

The Limits of Certification

Buying EHR products that are certified by the processes in regulations does not ensure that a CDO can have a successful implementation or use them to meet meaningful use. Certified products can fail to meet the requirements of the CDO in two ways:

- A product that meets certification requirements may not meet the needs of the CDO.
- An assemblage of certified products may not work together.

Certified vs. Usable

Certifying bodies will inspect a product in a test environment and verify that features are present that could meet one or more of the criteria listed in the IFR. In the interest of fairness and inter-rater reliability, they will use very concrete scripts for this. For example, a specific inspection script might tell the judge to enter an allergy to penicillin for a patient and then attempt to enter an order for penicillin. If the user is warned, then the product passes that test. However, the script may have no requirement that the user be informed of the severity of the allergy or the source of the information about the allergy. There will be no judgment on whether the manner of alerting is more likely to cause "alert fatigue."

Another example of the difference between a product that is certified and one that will enable a CDO to meet the requirements for meaningful use is the manner in which a product enables reporting on general and specialty-specific quality measures. A vendor (or a CDO that is self-certifying) will have to show an example of a documentation template that captures the necessary discrete data elements and a report that produces the data necessary to calculate the measure.

However, the value proposition of an EHR product includes a library of prebuilt templates for documentation. CDOs use them as a starting point in adapting the system to meet their needs. It is unlikely that the certifying entity will verify that that the entire library has been modified with the appropriate entries to collect the data. It is even more unlikely that the certifier will verify the availability of clinical decision rules to capture contraindications, such as patients for whom aspirin prophylaxis would not be an appropriate therapy, or to detect which other medications in the patient's active record act as anti-thrombotics.

Integration Risks

Under the current approach to certification, a CDO cannot assume that an arbitrary assemblage of certified products will work together to enable it to achieve the meaningful-use criteria. The certification process does not require standard interfaces among the modular products and does not test the products working together.

In "In Healthcare, Application Integration Does Not Produce Fully Integrated Applications," we discuss the difference between using a single product with a common architecture and database and interfacing separately designed products. The latter approach carries the likelihood of delays, the risk of failure and ongoing operational issues. It is up to the CDO to determine whether multiple products work together well enough to meet its needs and whether multiple vendors will work cooperatively if a problem develops.

The Value of a Meaningful-Use Guarantee

Vendors frequently offer guarantees with respect to the ARRA incentive program. The purpose is to ensure that the vendor has some "skin in the game" — a financial commitment to ensure that the product will support the client in obtaining incentive payments. Generally, the vendor guarantees to suspend subscription fees or maintenance payments for a given release of the

software until that release has been certified. Given the limitations of certification, however, the guarantees provide only minimal assurance that a CDO can qualify for incentive payments.

The guarantee will be of more value if it applies to future software releases and to the requirements for meaningful use in future stages of requirements for compliance.

Increasing the Odds of Getting It Right

A discussion of guarantees misdirects the buyer's attention to a minor risk (not getting the incentive money), whereas it should be focused on the bigger risk (not getting value from the EHR). The cost to practices or hospitals of not choosing a product that works for them or rushing an implementation is far higher than the stimulus amounts. It includes lost billing, loss of patient satisfaction and severe backlash by the physicians or staff. Patient safety could be at risk as well.

We recommend that practices and CDOs include the following features in their approach to choosing an EHR:

- Don't overdelegate the decision. Invest time among physicians and staff users in the decision.
- Find an "expert" member of the CDO — one who has prior experience *successfully* implementing an EHR and using it afterward.
- If you do not have an expert, get one. In many cases, local hospitals and health information exchanges (HIEs) are offering to assist in selection. Regional health IT extension centers may be of assistance, but they also may have limitations — for example, being new or having associations with only a few vendors. Boutique consultancies in many communities offer such expertise.
- Using your expert, prepare a list of must-have features.
- Insist that the vendor demo the system performing your must-have functions. Challenge the vendor with questions. Have the vendor come back if it missed your intent in the first demonstration.
- Choose vendors that have a multiyear track record serving organizations similar to yours in size and medical services offered.
- Reach out to colleagues and other organizations that have successfully implemented an EHR under consideration. Find out how long they've used it, and get their candid evaluation.
- Consider third-party sources of input, including professional organizations that have done satisfaction surveys and analyst firms that cover the EHR market.
- Check whether vendors have the Certification Commission for Health Information Technology (CCHIT) comprehensive certification. This is a superset of the meaningful-use criteria and provides some added assurance that the system will meet the needs of a CDO. However, do not use this certification as a proxy for the other decision measures described here.

For many practices and hospitals, it will be necessary to buy multiple certified products to meet the full gamut of meaningful-use requirements. If so, include the following features in your approach:

- Do not use components from multiple vendors simply to reduce costs. The risk of delay or failure during implementation is high.
- Use this approach sparingly. The best candidates for separate components are the billing/patient accounting system and products that provide interfaces to instruments or interoperability for transitions of care, receiving diagnostic reports, participation in registries or transmission to a personal health record.
- Avoid the situation where a single user, particularly a clinician, must regularly use the user interface of multiple products. Even if the user interfaces are quite similar, there are likely to be subtle differences in the data integration, which will lead to inconvenience and errors.
- Avoid assembling different products for the core functions of an EHR — documentation, ordering, e-prescribing (see Note 5) and clinical decision support (see Note 6).
- Seek references that have used the specific products together.
- Attempt to buy multiple components from a single vendor that takes responsibility for integration and support.

Keep the Real Goal in Mind

The incentive money from the ARRA can be substantial, and most CDOs have sufficient Medicare business, so the prospect of reduced payments for not having an EHR in 2015 is also important. The money notwithstanding, a CDO is unlikely to survive and certainly will not thrive if it approaches implementing an EHR in a manner that is driven mainly by meeting meaningful-use requirements. If it is not possible to implement EHR technology fast enough to get the maximum incentive payments, then consider the cost of forgoing some of incentive payments.

RECOMMENDED READING

"Meaningful Use and Certification of EHRs: Tracking Evolving Targets"

"Proposed Rules to Promote EHRs Stress 'Meaningful Use'"

Note 1
Proposed Rule on Meaningful Use

The Proposed Rule: Medicare and Medicaid Programs: Electronic Health Record Incentive Program sets criteria, policies and procedures for payments for the meaningful use of certified EHRs under the ARRA. It also describes measures of meaningful, specific criteria that an eligible provider or hospital must achieve to qualify for the payments. Comments will be accepted through 15 March 2010, and a final rule will be issued later this year.

Note 2
Interim Final Rule on Certification

The "Standards and Certification Interim Final Rule: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology" specifies standards for interoperability, security and privacy that must be used to qualify for the payments. The IFR will be effective 12 February 2010. The word "interim" in IFR indicates that the DHHS will accept comments. The comments may be offered through 13 March 2010, and it is likely that a final rule will be issued later, with some changes.

Note 3
Electronic Health Record Defined

In "Global Definitions of EHR, PHR, E-Prescribing and Other Terms for Healthcare Providers," Gartner lists various definitions of the term "EHR" in the U.S. vs. other countries. This research, which describes a U.S. program, uses the U.S. definition of the term.

Note 4
Potential Conflict of Interest

The author of this research is a member of the Board of Trustees of the CCHIT. This is a nonprofit organization that provides certification services, as described here. The author receives no remuneration at all for participation in CCHIT and has no financial interest in its success.

Note 5
Order Entry vs. E-Prescribing

In the federal rules, computer-based order entry is the module that the physician uses to enter orders, and e-prescribing is the module that transmits prescriptions to the organization that fills it.

Note 6
Clinical Decision Support

There are strong reasons — both economic and in terms of knowledge management — that external clinical decision support systems could become feasible. However, at this point, Gartner is not aware of successful product pairings like this, other than for evaluating the advisability of ordering expensive diagnostic procedures.

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