
Meaningful Use and Certification of Health Information Technology: What about Safety?

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Introduction

Health information technology (HIT) is becoming increasingly prevalent in medical offices and facilities. Like President George W. Bush before him, President Obama announced a plan to computerize all Americans' medical records by 2014. Computerization is certain to transform American health care, but to ensure that its benefits outweigh its risks, the federal government must provide appropriate oversight.

President Obama's stimulus legislation, the American Recovery and Reinvestment Act of 2009 (ARRA), dedicated \$27 billion to the promotion of health information technology.¹ It provides payments of up to \$44,000 per clinician under the Medicare incentive program and \$63,750 per clinician under the Medicaid program.

In the summer of 2010, the Department of Health and Human Services (HHS) published three sets of regulations to implement ARRA.² This article briefly describes and critiques the regulations, arguing that (1) they fail to appropriately address HIT safety and (2) further steps must be taken to protect patients and serve public health needs in the new digital era.

EHR Systems: Background, Benefits and Risks

The functionality of comprehensive electronic health records (EHR) systems goes far beyond the traditional role of paper medical files. In addition to providing ready access to clinical documentation, these systems transmit diagnostic test images and results to physi-

cians so that the data can be quickly reviewed and shared with patients. They feature computerized provider order entry (CPOE), which allows health care providers to send patient orders, such as those for laboratory tests and medications, electronically to appropriate parties. EHR systems also provide decision support tools, including clinical reminders, drug allergy/interaction alerts, drug-dose recommendations, and suggestions for diagnostic and treatment options. EHR systems may provide secure messaging so that patients can communicate with clinicians electronically. Ideally, they should be interoperable, enabling clinicians to access needed medical information about their patients that is stored remotely on EHR systems of other health care providers. Interoperability is necessary because patients may be unconscious, mentally impaired, forgetful, or otherwise unable to provide needed information themselves.³

The potential benefits of EHR systems, however, are accompanied by significant risks that arise because of software bugs, computer shut-downs, and user errors. EHR software is extremely complex, and it can have defects that endanger patients. Furthermore, poor user interface designs can force clinicians to pore over information that is irrelevant, perplexing, or fragmented. Inflexible electronic templates and confusing checklists can also increase the likelihood that system users will make mistakes entering medical information about patients. Inaccuracies in recorded patient medical histories, drug allergies, or medication lists can lead to serious, even fatal, treatment errors.⁴

EHR systems will exert a pervasive influence on patient care, and hence their quality is critical to patient welfare. With its recent regulations, HHS recognized the importance of responsible oversight.

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However, its regulations fall far short of adequately addressing EHR system safety risks.

The New Federal Regulations

Meaningful Use

EHR systems will not be beneficial if clinicians do not utilize the systems' capacities or if they purchase inferior, low-functioning products. Consequently, HHS issued "Meaningful Use" regulations in July 2010 that delineate what hospitals and clinicians must do to be deemed meaningful users of EHR systems in 2011 and 2012. Those in compliance will be eligible for EHR incentive payments, for which they can register beginning in January 2011. Two additional phases of meaningful use requirements are expected in the coming years.⁵

The rule mandates that physicians meet 15 core objectives and hospitals meet 14 core objectives. Several of these objectives focus on basic data entry, including vital signs, patient demographics, drug and allergy lists, updated problem lists, and smoking status. Others require clinicians to transmit 40% of prescriptions electronically, to enact at least one decision support rule, to use CPOE for at least 30% of medication orders, and more.⁶

In addition, health care providers must comply with five out of a "menu" of 10 additional objectives. Some of the menu capabilities include: performing drug-formulary checks, incorporating laboratory results into patient records, providing patients with reminders for needed care, supplying relevant educational resources, and supporting transitions between care facilities or personnel.⁷

Certification Criteria

To help providers purchase high-quality systems that they can use meaningfully, HHS established certification criteria. The certification regulations detail the capacities that EHR systems must have to enable providers to achieve meaningful use as it is currently constituted in Phase 1 of HHS' regulations.⁸ The regulations feature general criteria in addition to separate criteria for ambulatory and in-patient settings, all of which are based on the meaningful use requirements.⁹

Certification Program

HHS also constructed a mechanism by which EHR systems would be certified. The Temporary Certification Program established in 2010 delegates certification responsibilities to Authorized Testing and Certification Bodies (ATCBs).¹⁰ HHS is accepting applications from prospective ATCBs, which are expected to begin certifying EHR systems in the fall

of 2010.¹¹ The regulations provide that testing will be conducted using "test tools...approved by the National Coordinator" and that ATCBs are to operate their certification programs in accordance with general standards developed by the International Organization for Standardization.¹² The Office of the National Coordinator will oversee ATCBs and receive frequent reports from them and may inspect, suspend, and revoke their status. The temporary program will sunset on December 31, 2011, or at a later time if a permanent EHR certification program is not ready to be launched.¹³

Critique of the Regulations

The 2010 regulations constitute a solid first step towards comprehensive oversight. In an article in the *New England Journal of Medicine*, David Blumenthal, the National Coordinator for HIT, explained that HHS worked hard to strike "a balance between acknowledging the urgency of adopting EHRs to improve our health care system and recognizing the challenges that adoption will pose to health care providers."¹⁴ Clearly, if the government wishes to begin disbursing incentive payments in 2011, it had to limit the number of requirements it imposed and simplify the certification process. Unfortunately, the regulations pay little attention to the safety of EHR systems and the patients whose care they manage.

EHR System Safety

While advocates argue that computerization will reduce errors, numerous recent reports have demonstrated that the opposite can be true. Hospitals have experienced incidents in which doctors' orders were posted to the wrong patient charts and electronic drug orders were not delivered to nurses who needed to dispense them to patients.¹⁵ A published 2009 review of almost 56,000 CPOE prescriptions found that approximately 1% of them contained errors.¹⁶ Patients who do not receive needed medication or whose treatment is otherwise mismanaged because of software or usability problems can suffer catastrophic consequences.

General system safety is a property that is attainable only through rigorous processes for development and evaluation.¹⁷ However, the regulations do not address certification of EHR vendors' software development processes or even require vendors to analyze and mitigate potential safety hazards. Furthermore, ATCBs will use testing requirements developed by the National Institute of Standards and Technology (NIST) that are apparently intended only to determine whether systems include certain features.¹⁸ Passing such tests is not sufficient to ensure that those features function properly in the long term and under varied operating conditions.

Appropriate Evaluation Requirements

Meticulous testing of EHR products is critical to their safety. Because of the government's lucrative incentive payments, many new vendors may attempt to enter the market and to quickly produce EHR systems whose quality is unproven and perhaps dubious. Before such systems are approved, they should be carefully monitored during clinical use at several facilities over an extended period of time.¹⁹ HHS or NIST should specify the evaluation methodology, including the types of system failures and adverse events to be considered, how they should be detected, reported, and confirmed, and what failure rates and adverse event rates are unacceptable (rates of zero are not realistic). Even veteran companies whose EHR systems are already in use should be required to demonstrate a track record of safety for purposes of certification, though they could forego clinical testing.

Admittedly, clinical evaluation of new products poses challenges for vendors who would need to find facilities willing to accept the administrative burdens of assessing systems that may ultimately fail. Such facilities would also experience delays in receiving incentive payments because they would use uncertified systems during the evaluation period. However, certification of HIT that has not been thoroughly evaluated is no more responsible than approval of medications or devices that have not been carefully scrutinized by the FDA.

Certifiers must assume that providers will use whatever system they purchase for many years and that the system will affect the care of thousands of patients. After investing substantial money, time, and effort in purchasing and adopting a particular system, it is simply too difficult for providers to switch products even if significant flaws are discovered.

Continuing Review and ATCB Oversight

Because the regulations focus only on establishing a certification program, they are silent about monitoring EHR systems after approval and about adverse event reporting by EHR system vendors and users. HHS (or ATCBs) must engage in continuing oversight, including review of incident reports, so that the government can intervene if a product turns out to be defective despite certification. In addition, purchasers may not be able to make educated decisions about which products have the strongest safety record without publicly available records of system problems.

HHS must also recognize that providers can customize and configure EHR systems differently. Thus, a system that is safe at one facility can experience safety problems when customized by other users.²⁰ Hence, the meaningful use criteria should be expanded to

require providers to establish: (1) a process for ensuring the safety of their EHR system's implementation and ongoing operation; and (2) a body, such as a system oversight committee,²¹ responsible for overseeing the process.

The delegation of EHR approval responsibilities to ATCBs will ease HHS's regulatory burdens and likely supply an adequate pool of experts for HIT testing. HHS is authorized to monitor ATCBs through on-site visits, reports, and review of documentation.²² It remains to be seen if these measures will ensure that ATCB members are qualified, competent, and free of conflict of interest. These issues will become more critical if HHS eventually requires rigorous clinical testing of EHR systems as described above.

Conclusion

The federal government is understandably eager to build momentum in the HIT area and to complete the digitization of medical records as quickly as possible. However, it is naive to assume that any use of HIT is better than no use of HIT.²³ EHR systems constitute complex technology that can introduce errors as well as prevent them. Medical errors can occur because of computer bugs, computer shut-downs, or user mistakes that may be attributable to a flawed user interface. Through communication tools, electronic ordering, decision support features, and data management, EHR systems will guide many aspects of patient care. Treatment success will often depend on their proper functioning.

HHS' new regulations constitute positive first steps and a laudable reversal of a relatively lawless approach to EHR system design and deployment. Previously, the only certification program was offered by the Certification Commission for Health Information Technology, a private industry group that was not subject to regulation.²⁴

Still, much more work must be done to protect public health in the digital era. We urge that future meaningful use and certification criteria and the post-2011 permanent certification program be more attentive to safety issues. EHR system approval should be no less rigorous than the FDA's process for drug and device approval²⁵ because HIT is as safety-critical for patients. A prime criterion for certification should be a documented history of safe operations in a number of clinical environments. The federal government would be wise to focus less on the speed of EHR adoption and more on product quality. Only through sufficient safeguards for EHR system safety can this technology fulfill its promise to dramatically improve individual and public health outcomes.

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