

SmithAmundsen Health Care

ALERT

HHS Issues New Rules on EHR and Releases Proposed Modifications to HITECH

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The U.S. Department of Health and Human Services (HHS) has recently announced new rules under the Health Information Technology for Economic and Clinical Health Act (HITECH) to improve health care through expanded use of electronic health records (EHR). The rules provide the defining criteria of HITECH's "meaningful use" requirement and propose additional modifications to HITECH's sweeping revisions to the Security, Privacy, and Enforcement Rules under HIPAA.

Meaningful Use Final Rule

HHS has recently announced the long awaited final rule on achieving "meaningful use" of electronic health records as required under HITECH. Health care providers across the country who successfully demonstrate meaningful use of EHR will qualify for incentive payments through Medicare.

The guidelines for achieving "meaningful use" of EHR are based on a "core" group of requirements that must be met for Stage I (2011-2012) of HITECH's implementation schedule (3 stages total). Initially, under the proposed rule, eligible hospitals (EHs), critical access hospitals (CAHs), and eligible professionals (EPs) were required to implement 23-25 of the core requirements. The modified final rule now requires only 15 for EPs and 14 for EHs/CAHs.

MEANINGFUL USE "CORE" REQUIREMENTS (ALL REQUIRED)

- Use Computerized Provider Order Entry (CPOE)
- Implement drug to drug and drug allergy interaction checks
- E-Prescribing (EP only)
- Record demographics
- Maintain an up-to-date problem list
- Maintain active medication list
- Maintain active medication allergy list
- Record and chart changes in vital signs
- Record smoking status
- Implement one clinical decision support rule
- Report CQM as specified by the Secretary
- Electronically exchange key clinical information
- Provide patients with an electronic copy of their health information
- Provide clinical summaries for patients for each office visit (EP Only)/ Provide patients with an electronic copy of their discharge instructions (Eligible Hospital/CAH Only)
- Protect electronic health information created or maintained by certified

The rule also requires an additional "menu" of procedures from which providers must choose to implement. Unlike the "core" group, the rule allows health care providers to choose 5 out of the 10 criteria to implement. However, at least one of the procedures must concern a population objective.



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MEANINGFUL USE “MENU” SET OF OBJECTIVES (ONLY FIVE REQUIRED WITH AT LEAST ONE POPULATION OBJECTIVE)

- Implement drug-formulary checks
- Record advance directives for patients 65+ years (EH/CAH only)
- Incorporate labs into EHR structure
- Generate patient-lists by specific conditions
- Send reminders to patients for preventative/follow-up care (EP only)
- Provide patients with electronic access to their health information (EP only)
- Use certified EHR technology to provide patient education resources
- Transition medication reconciliation into the care of EP, EH, or CAH
- Provide summary of care records per transition settings
- Become capable to submit data to immunization registries*
- Become capable to submit labs to public health agencies (EH/CAH only)*
- Become capable to submit electronic syndromic surveillance data to public health agencies*

* population objective

It should be noted that the rule defines the criteria above as Stage I requirements only. Because the definition of “meaningful use” under HITECH is designed to be broad and expansive, the rule established the above criteria based on currently available technological capabilities and providers’ practice experience, but CMS will establish additional criteria for demonstrating meaningful use through future rulemaking, consistent with developments in technology and providers’ capabilities.

According to HHS, the rule’s approach (by lowering the number of the “core” requirements, providing options with the “menu” set, and adding future requirements through additional rulemaking) ensures that the most basic elements of meaningful EHR use will be met by all providers qualifying for incentive payments, while at the same time allowing flexibility in other areas to reflect providers’ needs and their individual approach to full EHR use.

However, certain groups in the health care industry, including the American Hospital Association (AHA), have voiced concerns over the new rules. In a letter issued in response to the new rule, the AHA believed barriers still exist for achieving widespread adoption of EHR. The AHA noted, “In particular, individual hospitals in multicampus settings are unfairly excluded from incentive payments. Hospitals within a health care system should each be eligible for incentives.” The AHA also took issue with the rule’s requirement for hospitals to implement CPOE, which can be complicated, costly, and time consuming to some extent. Finally, concern existed over the certification process, which limited how quickly hospitals could adopt certified EHR, due to the limited vendor capacity, workforce shortages, and the fact that currently no certified EHR systems were available.

Proposed Rule on Modifications to HIPAA under HITECH

HHS has also recently issued a notice of proposed rulemaking on modifications and clarifications to HIPAA Privacy, Security, and Enforcement Rules under HITECH. Through the proposed rule, HHS seeks to, among other things, strengthen privacy and security protection of health information, and improve the overall effectiveness of HIPAA.

One significant aspect of the proposed rule concerns business associates under HIPAA. A business associate is a person or entity that performs functions or activities on a covered entity’s behalf, or provides specified services to the covered entity, that involve the use or disclosure of protected health information (PHI). The proposed rule expands HITECH’s liability provisions by imposing liability and duties on subcontractors of business associates in the same manner as the primary business associate. The proposed rule clarifies that covered entities are required to enter into business associate agreements (BAA) with their business associates, but not with subcontractors (agents). However, the business associate who engages the subcontractor (which includes expert witnesses retained by law firms who act as business associates to covered entities) is now responsible for entering into a BAA with that subcontractor. The subcontractor BAA would need to comply with the same Privacy and Security Rule requirements as the original BAA between the business associate and covered entity. Depending on HHS guidance and further clarification, which is likely to come, this may mean that business associates will be charged with the duty of entering into a comprehensive subcontractor BAA whenever PHI is disclosed to a specific agent of that business associate.

Significantly, HHS stated that its proposed rule would clarify that **a person is a business associate if he/she/it meets the definition of a business associate, even if there is no required business associate agreement in place**, and direct liability under the Privacy and Security Rules would attach regardless of the existence of such an agreement.



Confusion also existed under HITECH as to the effect HITECH had on the actual HIPAA business associate agreement. Disagreement existed as to whether the BAA needed to be amended to reflect the changes under HITECH, or whether HITECH was retroactively applied to all existing BAAs. HHS stated that the business associate is required under HITECH to (1) comply, where applicable, with the HIPAA Security Rule with respect to electronic PHI, (2) report breaches of unsecured PHI to covered entities as required by the HHS Breach Notification Rule, and (3) ensure that any subcontractors agree to the same restrictions. Thus, it appears HHS will require that all pre-existing BAAs be amended. However, to “prevent rushed and hasty changes to thousands of on-going existing business associate agreements,” HHS proposed a transition period for amendments which appears to be no longer than one year and 240 days after the date of publication of the final rule.

The proposed rule also supplements HITECH by making a number of modifications to the HIPAA Privacy Rule with respect to fundraising. The rule, for example, would require each fundraising communication to include a clear and conspicuous opportunity for the individual to elect not to receive further fundraising communications (HHS suggests a toll-free number, email address, or “other simple, quick and inexpensive way to opt out”). HITECH also called for the prohibition against the sale of PHI, and the proposed rule would require a covered entity to obtain the individual’s authorization prior to disclosing PHI in exchange for direct or indirect compensation.

Finally, the proposed rule responds to concerns raised regarding the difficulty of protecting decedents’ PHI indefinitely. The rule would require covered entities to protect a deceased individual’s PHI for 50 years following the date of death, and also permit a covered entity to disclose PHI to individuals involved in a person’s care or payment for that care after the individual has died even when that person may not qualify as a personal representative under applicable law.

Comments on the Proposed Rule are being accepted through Sept. 13, 2010. Covered entities, business associates and others affected by the Administrative Simplification Regulations are being asked to consider submitting comments in order to shape the final rule. SmithAmundsen intends to participate in the process of submitting comment on the proposed rule, as our job of providing legal counsel to various covered entities designates us a business associate under HIPAA and HITECH.

Our concern with the proposed rule is focused on the rule’s reliance on the business associate agreement. It is difficult to determine the effect this proposed rule will have on the relationship and workflow which exists with covered entities, business associates of those covered entities, and the agents of the business associates. If the main purpose of HITECH is to make business associates directly liable for complying with the Privacy and Security Rules of HIPAA, must the covered entity obtain assurances from business associates through a BAA to effectuate that goal? The requirement of the BAA in our opinion should be limited to narrow circumstances rather than expanded to additional parties, as the proposed rule intends. If HITECH has the effect of imposing liability on business associates directly, it should consequentially de-emphasize the significance of the BAA as the vehicle for regulating business associates’ use of PHI. Requiring covered entities and business associates to implement BAAs to the extent that the rule proposes places an undue burden on the health care industry that is unnecessary under HITECH and HIPAA. We invite your comments.

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