Fall Preview: A Look at the Season's Expected Rules

By Kevin Heubusch

Perhaps one of the biggest jobs related to implementing the ARRA provisions right now is keeping track of the moving parts. Publication of the act in 2009 was a kind of Big Bang-an explosion of provisions that rocked the healthcare universe. Since then, however, the pieces have traveled at different speeds and in differing trajectories.

By the end of the year, however, at least two major pieces should come into view: a final rule on the privacy rule modifications and a proposed rule on stage 2 of the meaningful use program. Other rules could accompany them, making this waiting period a good time to review the major regulations in motion.

Breach Notification

ARRA directed the Federal Trade Commission to issue breach notification regulations for noncovered entities, which it did in August 2009. FTC issued a final rule, which became effective in September, with full compliance beginning in February 2010.

The preceding day the Office for Civil Rights had issued a rule related to covered entities, which followed the same dates. OCR, however, has yet to publish a final rule.

The office did submit a final rule for internal review by the Office of Management and Budget in the spring of 2010, a standard procedural step, but it withdrew the rule that July with little explanation.

One assumption has been that OCR would reconsider the most controversial aspect of the interim rule, the "harm threshold," which Congress had not specified in ARRA. The provision allows an entity to forego notifying patients of breaches that it deems unlikely to cause harm.

There also was speculation that OCR withdrew the rule in expectation that a more comprehensive law on breach notification was coming from Congress. Such a law, however, has not materialized to date. There is a possibility that OCR will release a final rule when it publishes a final rule on other modifications of the HIPAA privacy rule.

HIPAA Modifications

Following publication of the breach notification rule, nothing further surfaced from OCR for nearly a year. In July 2010, however, the office published a proposed rule covering a variety of privacy rule modifications called for in ARRA.

The changes have significant implications on HIM operations, including expanded consumer rights to access and restrict disclosure of information. Business associates will be subject to the same regulation under HIPAA as covered entities, as will their subcontractors. Emerging entities such as health information exchanges will be considered business associates.

Other ARRA changes expand the definition of electronic media, cover investigations and the application of civil money penalties, and change authorization requirements related to research. New restrictions apply to marketing and fund raising and the sale of an individual's protected health information.

It is not clear whether OCR will proceed directly to a final rule. Given the complexity of some of the issues and amount of commentary that it requested, there is a possibility it could next issue an interim final rule, which would allow it to solicit another round of comments and potentially make further changes when issuing a final rule.

Once the final rule is published, covered entities and business associates will have 180 days to comply. There will be an exception for updating business associate agreements under certain circumstances.

Accounting of Disclosures

OCR chose to manage the modifications to the HIPAA accounting of disclosure provisions in a separate rule. In May 2010 OCR published a request for information on accounting of disclosures. A silence of a year ensued, and then in May 2011 OCR published a proposed rule.

OCR proposed a new "access report" that it expected would be easier for covered entities to maintain and more likely to provide individuals with the information they want. The report would not distinguish between use and disclosure; instead it would identify anyone inside or outside the facility who accessed an individual's information.

The report would be restricted to protected health information contained within the individual's designated record set and existing in electronic format.

The access report received mixed reviews. While many industry groups in principle supported the spirit of the report, some also judged it too burdensome, and others felt it required considerable refinement.

Again, OCR can proceed to an interim final rule that would take effect but be subject to modification, or it could issue a final rule. Presumably it will consider revisions to the proposed access report in light of the many comments it received.

Regulation Watch

Regulation	Publication date	Status	Next Up
Privacy and Security			
Breach notification, noncovered entities	August 2009	Final rule	N/A
Breach notification covered entities	August 2009	Interim final rule	Final rule
HIPAA privacy modifications	July 2010	Proposed rule	Interim final or final rule
Accounting of disclosure	May 2011	Proposed rule	Interim final or final rule
EHR Incentive Program			
Certification program, temporary	June 2010	Final rule	Sunsets with effective date of permanent program

Certification program, permanent	January 2011	Final rule	Scheduled to begin January 1, 2012
EHR Standards, certification criteria	July 2010	Final rule	New rule to reflect stage 2
Meaningful use, stage 1	July 2010	Final rule	N/A
Meaningful Use, stage 2	N/A	Under discussion	Proposed rule expected late 2011; final rule expected summer 2012

Meaningful Use

Much of the meaningful use regulations appeared in a rush last summer: final rules on stage 1 of the program, EHR standards and certification criteria, and a certification program.

Rulemaking on the certification program is complete, with the permanent program scheduled to be January 1, 2012.

By far the most widely awaited rule this fall is a proposed rule on stage 2 of the incentive program. The policy advisory committee to the Office of the National Coordinator released a glimpse of its work in January 2011, and that preview and the committee's subsequent discussions have set the industry's expectations of what may be coming.

It is expected that all objectives in stage 1 will become mandatory under stage 2, and a limited number of new objectives will be added. Many of the measures in the committee's early draft increased, but not all.

The stage 2 start date is a closely watched item. By the time the committee submitted its final recommendations, it seemed likely that stage 2 would be delayed in some manner. There was prevailing concern that vendor and providers would not have time to implement the final requirements before the reporting period began in 2013.

Another item on the watch list is the quality measures to be reported under stage 2. The committee did not offer a preview of its recommendations, but it is expected that the number and the scope will increase.

Once the requirements become final, revised standards and certification criteria must be published.

The Centers for Medicare and Medicaid Services has indicated it will release a proposed rule by end of the year, with a final rule targeted for summer 2012.

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