HHS Publishes HITECH Final Ruling: One Big Loophole Closed, Breach Fines Modified

By: Bill Palisano, Lincoln Archives

Important Dates: Final Ruling Published: 1/25/13. Effective Date: 3/26/13, Compliance Date: 9/23/13.

On January 25, 2013 the Office of Civil Rights ("OCR") of the Department of Health and Human Services ("HHS") published the HIPAA/HITECH 'Final Ruling' in the Federal Register. This replaces the Interim Final Ruling ("IFR") which was published back in 2009.

Per HHS Secretary Kathleen Sebelius: "The new rule will help protect patient privacy and safeguard patients' health information in an ever-expanding digital age."

Per OCR Director Leon Rodriguez: "This final omnibus rule marks the most sweeping changes to the HIPAA Privacy and Security Rules since they were first implemented." He goes on further to say: "These changes not only greatly enhance a patient's privacy rights and protections but also strengthen the ability of my office to vigorously enforce the HIPAA privacy and security protections, regardless of whether the information is being held by a health plan, a healthcare provider, or one of their business associates."

Now, the Final Ruling modifies each of the Privacy, Security, Enforcement and Breach Notification (for Unsecured Protected Health Information) Rules contained in HITECH. But in an effort to get at least one very important change across (in this article), I'm going to speak only on one change. Perhaps the most significant changes in the Final Ruling are those pertaining to 'Business Associates' ("BA") and the definition of a BA.

Previously, when a Covered Entity ("CE") contracted with a BA who had access to PHI, and that BA subcontracted some function to another (third) party (who in turn had access to that PHI), the protections under the IFR lapsed between the BA and his/her contracted third party. Hence there was that loophole, a gray area. If there was a downstream breach, the CE was normally on the hook to OCR/HHS. But in some cases the primary BA could avoid liability altogether. And, if the contracted third party was not aware of his/her possession of PHI and his/her obligations to protect the PHI a 'plead ignorance' argument could be made. Hence, the chain of responsibility was broken. Lots of finger pointing.

But, that all changes now. The Final Ruling expands the definition of "Business Associate" to cover certain organizations, some which have only indirect relationships with the healthcare industry (and may have little awareness of their compliance obligations). The "Business Associate" designation now follows subcontractors "down the chain" of custody of the PHI. For example, if a BA contracts a function involving the disclosure of PHI to a subcontractor, that subcontractor is now a BA as well. If that subcontractor delegates a function (involving the PHI) to another third party, that third party is now a BA of the subcontractor. Both the subcontractor and third party are now subject to the DIRECT COMPLIANCE obligations of HHS/OCR under HITECH. Now, everyone touching that PHI is 'on the hook' to OCR/HHS directly.

Continued on page 8

Aligning Value-Based Reimbursement With Physician Compensation

Compensation May Become Dependent on Case Outcome

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Third-party and governmental payers are moving rapidly to value-based reimbursement — in effect, leading to a shift from the traditional physician compensation model toward a new focus on quality outcomes. If you haven't moved in that direction, start thinking about how you should change compensation plans to reflect an environment that emphasizes pay for performance and accountability.

Accountable care

The Patient Protection and Affordable Care Act (PPACA) offer practices and hospitals multiple options for providing care and paying providers, such as forming accountable care organizations (ACOs). CMS will reward ACOs that can reduce costs while still meeting performance standards on quality of care. Provider and patient participation in an ACO is strictly voluntary.

But even if you don't plan on forming a CMS-inspired ACO, you can still develop a compensation system that works toward improving outcomes and cutting costs. This will probably require new physician performance metrics that put less emphasis on volume and greater focus on quality factors, such as patient satisfaction, efficiency and readmission rates. (Keep in mind that any new compensation plan that involves nonemployee physicians will need to comply with the Stark Law and the antikickback statute requirements regarding commercial reasonableness and fair market value.)

Compensation models

Several value-based compensation models are gaining attention, including:

- ***Bundled payments.*** CMS is running a pilot program for the bundled payment model in several hospitals. It makes a single discounted payment to hospitals and physicians for a defined group of services provided to a patient within a specified episode of care, such as heart bypass surgery. Instead of a surgical procedure generating multiple claims from multiple providers, the entire team is compensated with a bundled payment.
- ***Pay-for-service / fee-for-service.*** In this model, physicians are paid a negotiated amount for each service, with additional incentives based on quality, costs and patient experience.
- ***Shared savings.*** With this model, providers that work together to meet quality standards based on outcomes and care coordination share in the savings they achieve on the targeted costs.

The path to success

Physicians might want to fight change, especially if it involves their compensation. But, by following the steps below, you can smooth out the transition:

1. ***Define your practice's strategic goals.*** Start by defining the strategic goals so you can align the incentives to accomplish those goals. Part of your physicians' compensation could be based on their individual patient survey scores.
2. ***Get physician buy-in.*** Physician buy-in is critical to the long-term success of organizational change. Make sure you engage your physicians in the process by, for example, giving them representation on the accountable care team that will identify the optimal clinical practices and establish performance metrics.
3. ***Offer feedback.*** Give your physicians feedback on their performance before they see the consequences of any underperformance in a smaller paycheck. Track their performance regularly and offer timely reports in one-on-one meetings. Solicit feedback on any performance hurdles they're confronting, and provide physicians aggregated reports of clinical data that demonstrate how their efforts are improving quality.
4. ***Proceed with Caution.*** Although the change to value-based reimbursement seems inevitable, don't rush into such a dramatic and alarming change. Make sure you take a step-by-step approach, introducing a few new components at a time.

HHS Publishes HITECH Final Ruling

Continued from page 5

The Final Ruling also requires BA's to enter into BA agreements with their direct subcontractors. There is no provision that the CE is required to police BAA's with every downstream entity now considered a BA; but that every BA is required to enter into a BAA with its' direct subcontractors (that may have access to BA's PHI).

OK, so that's pretty encompassing. No more broken chain of liability/responsibility. If you touch PHI, you fall under HIPAA, Period. And, remember what Mr. Rodriguez said, above: 'vigorously enforce'. Now I didn't mention the increases in minimum fines (and the fact that the words: that the government may be required to impose civil money penalties for a violation due to willful neglect, were replaced with: the government will be required to impose civil money penalties for a violation due to willful neglect. There is no more discretion.) Those may be in a future article.

Now, when you start thinking of subcontractors who support your operations, you probably already have good solid BAA's in place, right? Talk with your legal counsel and ask them if/how you advise your BA's that they now need to have BAA's in place for any subcontractor that THEY USE (who might have access to your PHI).

Now this is purely my opinion, not that of my company, nor that of the Medical Society, but I have to say it. Although I'm not generally in favor of more government control, tracking, fines, etc., nor higher fines for breaches. I do applaud one part of this Final Ruling; responsibility. Anyone that touches PHI has an obligation to protect it. No more hiding in gray areas, no more hiding in loop holes. If someone has entrusted PHI to you, you have to protect it, no matter who you got it from, or how. You are on the hook, period. That is coming from an industry veteran with over twenty years experience in protecting PHI. The things I've seen some CE's, BA's and their subcontractors do would make you ill. Yes, for some, these new regulations may be 'a bitter pill to swallow.' Those companies that 'cut corners' may not survive very long. But for those companies who take responsibility, act responsibly and exercise (good judgment), it can be a long, healthy life.