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HIPAA Update Will Shake Up Marketing, Fundraising Efforts

By **Rachel Slajda**

Law360, New York (January 23, 2013, 7:46 PM ET) -- Under a new overhaul to the Health Insurance Portability and Accountability Act, health providers and insurers must change the way they use protected information to target patients for fundraising and third-party marketing, which could improve donations but make it harder for drug companies and others to market to patients.

The final rule, which will be published in the Federal Register on Jan. 25, implements scores of changes made to the Health Insurance Portability and Accountability Act in 2009. The biggest change is making the vendors and contractors covered entities use, known as business associates, directly subject to HIPAA's privacy and security rules.

But the final rule also includes plenty of changes for covered entities, such health care providers, plans and clearinghouses that have long been subject to HIPAA. Covered entities have nine months to come into compliance with the rule's myriad tweaks regarding exactly how they can use patients' protected health information.

One significant area, experts say, is communications between covered entities and patients that are subsidized by third parties. Under the final rule, any communications for which the covered entity receives payment from a third party — for example, a pharmaceutical company — constitute marketing. The use of a patient's protected health information in marketing, such as communications about cancer drugs targeted toward patients newly diagnosed with cancer, must be authorized by the patient.

"I think it's going to be a significant administrative burden," said Dianne Bourque, a member at Mintz Levin Cohn Ferris Glovsky & Popeo PC. "You have to reach out, get [the patient's] authorization in advance, then keep track of who has authorized among your population. You have to make sure the people who haven't authorized don't get the communication. And the magical thing about authorizations is they can be revoked."

Under the new rule, the only third-party-subsidized communications that will be allowed without such authorization are refill reminders for patients who have already been taking a medication, as long as the amount paid by the third party covers the communication but no more, as well as "face-to-face" communications given directly from a provider to a patient, in person.

"It's a lot, administratively, to manage that, so I think it's going to be a huge disincentive" for covered entities to continue using subsidized communications, she said.

The final rule is a departure from the proposed version, taking some observers by surprise. In the proposed rule, regulators attempted to draw a distinction between subsidized

communications regarding the "treatment" of a patient and broader communications regarding "health care operations" more generally.

In the final rule, the U.S. Department of Health and Human Services' Office of Civil Rights said the distinction would create too much confusion for covered entities trying to determine which communications required a patient's permission and which didn't.

Experts say the idea behind the rule was to balance the desire for providers to tell patients about potential treatments with the threat of patients' information being exploited for profit. Information sent to a patient with a new cancer diagnosis about potential treatments, how to deal with side effects from drugs, nutrition information and the like, for example, can be useful, Bourque said.

"But at the same time, if money is changing hands to prompt that communication to the patient population, and a company is benefiting from that communication, you can see where that's kind of exploitative," she said.

The new rule is not all restrictions, however. In other areas, it expands the sorts of information covered entities can use. Under current rules, for example, covered entities can only target donation solicitations to patients based on their demographic information, such as age and gender, and the dates they were treated. The new rule will allow entities to more specifically target fundraising pleas, using information on the department a patient was treated in and the treating physician.

Experts say that will allow nonprofits to more specifically target their solicitations to potential donors. For example, a hospital looking to raise money for a new cancer center could target patients treated in its oncology department.

The final rule also allows entities to use information on treatment outcomes. Regulators said they only intend this information — limited to the death of a patient and other "suboptimal results of treatment" — to be used so entities can weed out patients who would, due to that suboptimal result, be less inclined to donate.

"You can use information about outcomes, how things turned out for patients, which is good, because you want to make sure they had a good outcome before you ask them for money," said Shannon Salimone, a health care partner at Holland & Knight LLP and co-chair of the firm's data privacy and security team.

The new regulations also include some positive changes for the research community, such as allowing researchers to get a single patient authorization for a range of related research activities. For example, a single compound authorization could allow researchers to have access to both a patient's tissue sample and his corresponding health information. Compound authorizations can also include permission for unspecified future research using a patient's information.

Previously, researchers had to get a separate authorization for each step of the process, which created a burden. The allowance for future unspecified research is especially important, Bourque said, because scientists cannot always know now where their research will take them.

"You don't know upstream what is going to be important as medicine advances," she said. "If you can't use what you have, you have to get new samples, which is expensive [and] time-consuming, and it's a hassle for patients."

In addition, health information for people who have been deceased more than 50 years will no longer be protected, opening up historical data for researchers.

The long-awaited final rule implements provisions of the Health Information Technology for Economic and Clinical Health Act, passed in 2009. The final rule will officially be enacted in March, with a six-month grace period for covered entities and business associates to come into compliance with the new regulations.

--Editing by Elizabeth Bowen and Katherine Rautenberg.

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