



# HIPAA Law Alert

Legal developments affecting HIPAA and medical privacy

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## HHS withdraws breach notification rule from administrative review

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The Department of Health and Human Services (HHS) Office for Civil Rights (OCR) on July 28 withdrew from administrative review its proposed final version of the breach notification rule that requires all health care professionals and other specified handlers of patients' health records to notify patients in the event that their unsecured personal health information (PHI) becomes susceptible to privacy violations by a security breach.

In 2009, pursuant to the Health Information Technology for Economic and Clinical Health (HITECH) Act, HHS issued the Interim Final Rule for Breach Notification for Unsecured Protected Health Information. During the subsequent 60-day comment period, which sparked ample public interest, HHS received over 120 comments.

On May 14, 2010, after consideration and evaluation of the comments, HHS submitted the final rule to the Office of Management and Budget (OMB) for regulatory review. Privacy advocates, and a handful of members of the House of Representatives, including Energy and Commerce Committee Chairman Representative Henry Waxman of California, and Representative Joe Barton of Texas criticized the rule and wrote a letter to HHS Secretary Kathleen Sebelius, insisting that HHS "revise or repeal" a faulty section of the rule "at the soonest opportunity."

The criticized section requires health care providers, researchers, data-miners, and business associates involved in a privacy breach to perform a risk assessment after the breach, and they must inform those individuals whose PHI has been breached *only* if it is determined that harm has been caused by the breach. The criticism centered around the ability of the entity who caused the breach to decide whether or not to disclose the breach.

Dispute arose over the "harm" standard for legislative deliberations because congressional leaders had previously considered and rejected such a standard. Waxman and Barton allege that HHS' inclusion of the harm standard "was not consistent with congressional intent."

OCR has withdrawn the breach notification final rule from OMB review to permit further deliberation over the complex issue of protecting PHI from unauthorized use and disclosure, and "to allow for further consideration given the department's experience to date in

administering the regulations.”

OCR stated in a press release that the rule is a “complex issue” and that it intends to publish a final rule on breach notification “in the coming months.”

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