

Health and Human Service to Issue Guidance on Remuneration for Refill Reminders under Health Insurance Portability and Accountability Act (HIPAA) Final Rule

Article By:

Healthcare Department Barnes Thornburg

In response to a lawsuit by Adheris Inc. challenging marketing provisions under the HIPAA Final Rule (“Final Rule”) issued earlier this year, the **Department of Health and Human Services (“HHS”)** will issue guidance on remuneration for refill reminders and other communications about drugs or biologics before the Sept. 23, 2013 compliance date of the Final Rule.

In a suit filed on September 5, 2013 in the U.S. District Court for the District of Columbia, Adheris argued that the Final Rule violated its First Amendment free speech rights as Adheris generates most of its revenue from sending refill reminders and other communications to patients on behalf of pharmaceutical companies. According to Adheris, the marketing provisions of the Final Rule, which require patient authorization for refill reminders and other communications about drugs or biologics for which remuneration is provided that exceeds the reasonable cost of such communications would essentially put it out of business. Additionally, Adheris claimed that these provisions discriminated based on whether a refill reminder was sent by a for-profit or not-for-profit entity.

Filed on Sept. 11, 2013, a joint motion between HHS and Adheris requests the suspension of the schedule on Adheris’ motion for a preliminary injunction on the restrictions on refill reminders and other communications on drugs and biologics. HHS and Adheris filed the joint motion as the parties determined that the forthcoming guidance from HHS has “obviated any need for the parties to provide further briefing on, or for the Court to resolve, plaintiff’s motion” prior to Sept. 23. Further, the joint motion notes that HHS Secretary, Katherine Sebelius, in exercising her discretion, has decided not to enforce the restrictions on remuneration for refill reminders and other communications about drugs or biologics for a period of forty-five (45) days following the compliance date, or until Nov. 7, 2013.

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