

# UPDATED MEDICAL PRIVACY RULES CHALLENGED AS UNCONSTITUTIONAL

by

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Adheris, Inc., a provider of prescription drug-focused adherence and compliance messages for patients (*i.e.*, “refill reminders”) sued the U.S. Department of Health and Human Services (“HHS” or the “Department”) last month on grounds that the long-awaited revisions to the federal medical privacy regulations (the HIPAA Privacy Rule)<sup>1</sup> violate its First Amendment rights to free speech.<sup>2</sup> In its complaint and motion for a preliminary injunction, Adheris asks the U.S. District Court for the District of Columbia to immediately enjoin HHS enforcement of its final rule under the HITECH Act<sup>3</sup> as an unconstitutional imposition of content- and speaker-based restrictions on truthful, non-misleading, and societally beneficial speech.<sup>4</sup>

Adheris, on behalf of retail pharmacies and pharmacy chains, seeks to promote the public health and reduce health care costs by using patient prescription records to provide customized adherence and compliance messaging to patients encouraging them to take and refill their clinician-prescribed medications. As explained in the letters to patients, the messages are sponsored by the product manufacturers. The patient is given notice of the funding and has the opportunity to opt-out of receiving future communications at any time.

HHS’s January 2013 final rule expanded the definition of “marketing” to, absent several exceptions, require patient “authorization” (*i.e.*, “opt in”) for such uses and disclosures of patient information for all “communications where the [pharmacy] receives financial remuneration for making the communications **from a third party whose product or service is being marketed.**”<sup>5</sup> The lawsuit argues that the final rule is subject to, and fails, the test of heightened judicial scrutiny announced in the Supreme Court’s 2011 decision in *Sorrell v. IMS Health, Inc.*,<sup>6</sup> because it imposes impermissible restraints on non-commercial speech in violation of the First Amendment. Specifically, plaintiff asserts, the rule restricts protected speech based on its content (*i.e.*, encouraging the use of a third-party’s product or service) and speaker (*i.e.*, an entity paid by the third-party whose product or service is the subject of the communication).<sup>7</sup> In other words, the rule treats those speakers who accept payment from manufacturers differently than other speakers (*e.g.*, those who accept payment from the government or a non-profit). The final rule, according to the suit, unconstitutionally burdens truthful, non-misleading, and beneficial speech solely because it is funded by pharmaceutical manufacturers.<sup>8</sup>

In support of its principal argument, and citing the longstanding Supreme Court precedent of *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, Adheris also asserts that, even if HHS’s restriction advanced a substantial government interest, that restriction must be “narrowly drawn” and cannot “completely suppress information when narrower restrictions on expression would serve [the government’s] interest as well.”<sup>9</sup> The Department’s July 2010 proposed rule set forth just such a narrowly drawn definition of “marketing” that excluded product- and service-specific communications made by pharmacies and other HIPAA covered entities that received financial remuneration in exchange for making the communication, provided that patients received notice, disclosure of sponsorship, and an opportunity to opt-out.<sup>10</sup> Adheris asserts that OCR’s decision to reject its proposed—and less onerous—notice/disclosure/opt-out procedure for sponsored communications and to impose a mandatory opt-in process for such communications violates the First Amendment. Because HHS could have adopted a far less burdensome approach as it originally

proposed, its final rule is, likewise, unconstitutional under this theory.

The government agreed to stay enforcement of the HITECH rule for 45 days (until November 7, 2013) as it pertains to refill reminders and, on September 19, 2013, issued its long-awaited guidance clarifying certain aspects of the “refill reminder” exception to the patient authorization requirement.<sup>11</sup> The guidance broadens what communications are considered “refill reminders” and significantly expands what constitutes “reasonable costs” that sponsors can pay to covered entities. The guidance does not, however, address the fundamental First Amendment issues raised in the suit.

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### **ENDNOTES**

<sup>1</sup> 78 Fed. Reg. 5566 (Jan. 25, 2013).

<sup>2</sup> *Adheris, Inc. v. Sebelius*, No. 1:13-cv-01342 (D.D.C. filed Sept. 5, 2013).

<sup>3</sup> 42 U.S.C. §§ 17921 *et. seq.*

<sup>4</sup> Plaintiff’s Memorandum In Support Of Its Motion For A Preliminary Injunction, *Adheris, Inc. v. Sebelius*, at 21-32.

<sup>5</sup> 78 Fed. Reg. at 5595 (emphasis added).

<sup>6</sup> 131 S. Ct. 2653 (2011).

<sup>7</sup> Pl.’s Memo at 3.

<sup>8</sup> Pl.’s Memo. at 24.

<sup>9</sup> Pl.’s Memo. at 31 (citing *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 565 (1980)).

<sup>10</sup> 75 Fed. Reg. 40,868, 40,885-886 (July 14, 2010).

<sup>11</sup> HHS, Guidance, “The HIPAA Privacy Rule and Refill Reminders and Other Communications about a Drug or Biologic Currently Being Prescribed for the Individual” (Sept. 19, 2013), available at <http://www.hhs.gov/HHS/privacy/hipaa/understanding/coverentities/marketingrefillreminder.html>.

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