Legal Backgrounder

WLF Washington Legal Foundation

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Vol. 28 No. 8 July 19, 2013

UPDATED MEDICAL PRIVACY RULES UNDER FEDERAL HITECH ACT CONSTITUTIONALLY SUSPECT

by
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In January, pursuant to the HITECH Act,[1] the U.S. Department of Health and Human Services' (HHS) Office for Civil Rights ("OCR" or the "Department") issued long-awaited revisions to the federal medical privacy requirements commonly referred to as the HIPAA Privacy Rule.[2] In a significant departure from the Department's July 2010 Notice of Proposed Rulemaking ("NPRM" or "proposed rule"),[3] the final rule expanded the definition of "marketing" to, absent several exceptions, require patient "authorization" (*i.e.*, affirmative "opt in") for uses and disclosures of a patient's protected health information (PHI) for all "communications where the covered entity receives financial remuneration for making the communications from a third party whose product or service is being marketed."[4] By contrast, the Department's proposed rule sets forth a less restrictive definition of "marketing" that excluded product- and service-specific communications made by covered entities (*e.g.*, pharmacies, physicians, managed care organizations) who received financial remuneration in exchange for making the communication, provided that patients received notice, disclosure of sponsorship, and an opportunity to opt-out.[5]

The final rule requiring "authorization" or "opt-in" will prevent many sponsored patient communications programs from continuing.[6] Indeed, based on uncertainties surrounding the new rule, one major retail pharmacy chain already has discontinued its pharmaceutical company-sponsored programs.[7]

Two potential avenues for First Amendment challenge arise. First, 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 arguably violates the First Amendment. There plainly were less restrictive means available to the government in order to achieve its patient privacy-related goals and the Department's failure to implement those means arguably violates the long-standing judicial precedent of *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*[8] as recently fortified by the Supreme Court in *Sorrell v. IMS Health Inc.*[9] Second, OCR's revised definition of "marketing" imposes independent biases on certain classes of speakers that run afoul of *Sorrell's* application of heightened scrutiny because they exact content- and speaker-based restraints on free speech.

Less Restrictive Means. OCR's final rulemaking appears to run afoul of *Sorrell's* application of *Central Hudson* given that OCR could have adopted a less-restrictive alternative curtailing speech that would still have accomplished its patient privacy objectives. Although *Sorrell's* ultimate imposition of heightened scrutiny appears to raise the bar from *Central Hudson's* "intermediate scrutiny" traditionally applied to First Amendment issues of governmental restrictions on commercial speech, the Court conducted the less strict commercial speech analysis under *Central Hudson* as well and held that the Vermont statute at issue violated the First Amendment.[10] Under that four-pronged "intermediate scrutiny" test, the Court analyzes whether: (1) the speech at issue concerns

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lawful activity and is not misleading; (2) the asserted government interest is substantial; (3) the restriction directly advances the asserted interest; and (4) the interest could not be served by a more limited restriction.[11] The government must justify its content-based law as consistent with the First Amendment by showing "at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest."[12] The government's interests must be proportional to the resulting burdens placed on speech and the law may not intend to suppress a disfavored message.[13]

Sorrell ultimately struck down a Vermont law that prohibited, absent the physician's opt-in, the sale, disclosure, and use of pharmacy records that reveal the prescribing practices of that doctor (*i.e.*, "prescriber identifying information").[14] Vermont cited physicians' desire to maintain confidentiality of prescribing behaviors. The Court, however, rejected that justification given that such confidentiality only applied in certain circumstances (*i.e.*, marketing).[15] The government further maintained that its statute reduced the probability that marketing would result in prescribing decisions at odds with patients' best interests or those of the government itself, protected doctors from harassing sales behavior, and served to improve public health and reduce healthcare costs.[16] Many of those purported interests were unsupported by the legislative history.[17] The Court emphasized that "[a] consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue. That reality has great relevance in the fields of medicine and public health, where information can save lives."[18]

Hence, the government failed to show that the statute directly advanced its purported interests; nor was the law drawn to achieve those interests.[19] Vermont was specifically unable to offer any "explanation why remedies other than content-based rules would be inadequate."[20] It is important to note that Vermont argued that the marketing at issue somehow undermined the clinician-patient relationship by influencing treatment decisions. The Court held, in no uncertain terms, that "pharmaceutical marketing is also entitled to the protection of the First Amendment [and a]bsent circumstances far from those presented here, the fear that speech might persuade provides no lawful basis for quieting it."[21] Fear that the recipient of a truthful message will make a poor decision can never justify content-based burdens on speech.[22]

In its July 2010 proposed rule implementing HITECH, OCR proposed to exclude from the definition of "marketing" written, product-specific "treatment" communications made by a covered entity to specific individuals where the covered entity had received financial compensation in exchange for making the communication, provided three ***new*** requirements were satisfied:

- The pharmacy's ***notice of privacy practices*** would have to explain separately that: (i) the pharmacy may send "treatment" communications for which the pharmacy had received compensation, and (ii) the patient can opt-out of receiving such communications.

- The "treatment" communication itself would have to ***disclose that compensation was received***.

- The "treatment" communication would have to provide an ***opt-out*** mechanism.[23]

Ultimately, OCR's decision to require "authorization" or "opt-in," instead of the significantly less burdensome notice/disclosure/opt-out proposed requirements, appears to run afoul of *Sorrell's* application of *Central Hudson*. OCR clearly proposed a workable, less restrictive alternative which would have accomplished its patient privacy objectives. Yet, the Department offers almost no justification in the preamble to the final rule regarding the basis for its decision to reject the less restrictive proposed approach. There also is very little support for the final rule's approach in the public comments on the NPRM. Indeed, OCR noted that "many commenters were generally in support of not requiring authorization for treatment communications" and only "several commenters expressed concern . . . ."[24] Rather than providing guidance or clarification, however, OCR simply implemented a more restrictive authorization requirement for sponsored treatment communications because "the distinction between what constitutes a treatment communication versus a health care operations communication may be difficult to make with precision in all cases."[25]

Regardless of whether precision is difficult, OCR plainly had a less restrictive means available to achieve the goal of protecting an individual's health information. In this instance, OCR's content-based regulation prevents physicians from sending treatment communications only in instances when those communications are sponsored, with little justification and disregard for a less onerous, proposed, and widely endorsed, alternative.

Viewpoint Discrimination. The HITECH Act and final rule also impose two other, separate biases on select speakers, giving rise to a complementary challenge under *Sorrell*. First, OCR's revised "marketing" definition distinguishes between sponsored and non-sponsored communications and, therefore, precludes certain speakers (*i.e.*, those whose product or service is the subject of the message) from sponsoring covered entity-run communications programs. Second, the "refill reminder" exception precludes those manufacturers whose drugs or biologics are not currently being prescribed from sponsoring covered entity-run programs that use PHI to communicate with the patients concerning their products and services. These independent biases may run afoul of the Supreme Court's decision in *Sorrell* because they exact content- and speaker-based restraints on free speech that cannot withstand heightened scrutiny.

The *Sorrell* Court held that speech in support of pharmaceutical marketing was protected expression under the First Amendment and the statute imposed more than an incidental burden on that speech: "[b]oth on its face and in its practical operation, Vermont's law impose[d] a burden based on the content of speech [marketing] and the identity of the speaker [pharmaceutical manufacturers]."[26] The law specifically "disfavor[ed] specific speakers – namely pharmaceutical manufacturers. . . ."[27] – going "beyond mere content discrimination, to actual viewpoint discrimination."[28] Heightened judicial scrutiny under the First Amendment is appropriate in such cases where the government establishes "a regulation of speech because of disagreement with the message it conveys."[29] Under the ordinary case of heightened (strict) scrutiny, it typically is dispositive to conclude that the law at issue "is content-based and, in practice, viewpoint-discriminatory."[30]

Subject to certain exceptions, the final rule requires authorization for communications where the covered entity receives financial remuneration for making the communications from a third party whose product or service is being marketed. OCR's distinction between sponsored and non-sponsored communications is suspect under *Sorrell*'s heightened scrutiny analysis. Although *Sorrell* involved restrictions on prescriber-identifiable information as opposed to the use of patient-identifiable information, OCR's restriction is plainly content-based and viewpoint-discriminatory depending on the subject of the communication and who pays for it.

A parallel First Amendment concern arises in the context of the HITECH Act's "refill reminder" exception to patient authorization. As *Sorrell* recognized, one fatal flaw in the Vermont statute was that it had "the effect of preventing [pharmaceutical manufacturer] detailers – and only detailers – from communicating with physicians in an effective and informative manner."[31] Likewise, absent patient authorization or an exception thereto, the HITECH Act's "refill reminder" exception effectively prevents all competing manufacturers (*i.e.*, those whose drugs or biologics are ***not*** "currently being prescribed for the recipient of the communication") from using PHI to communicate with patients concerning alternative therapies.[32] This seemingly biased statutory restriction raises First Amendment concerns as it favors one manufacturer's message over another's.[33] A competing manufacturer is no longer permitted to subsidize communications to patients without authorization.

Conclusion. Thus, OCR's final rule under HITECH requiring patient "opt-in" will prevent many sponsored patient communications programs from continuing. Accordingly, for the foregoing reasons, the new restrictions appear susceptible to a First Amendment challenge.

ENDNOTES

[1] 42 U.S.C. §§ 17921 *et. seq.*

[2] 78 Fed. Reg. 5566 (Jan. 25, 2013).

[3] 75 Fed. Reg. 40,868 (July 14, 2010).

[4] 78 Fed. Reg. at 5595.

[5] 75 Fed. Reg. at 40,885-886.

[6] The final rule codified the HITECH Act's statutory exception from patient opt-in for so-called "refill reminders" and similar communications about a drug or biologic that is "currently being prescribed for the individual," 45 C.F.R. § 164.501 (definition of "marketing," provision (2)(i)). 78 Fed. Reg. at 5596. It also strengthened the regulatory "face-to-face" exception for oral and written "in-person" communications. *Id.* ("For example, a health care provider could, in a face to face conversation with the individual, recommend, verbally or by handing the individual written materials such as a pamphlet, that the individual take a specific alternative medication, even if the provider is otherwise paid by a third party to make such communications.").

[7] Joseph Conn, *CVS Cancels Pharma-Funded Rx Reminders Citing New HIPAA Rule*, ModernHealthcare.com (May 6, 2013), *available at* http://www.modernhealthcare.com/article/20130506/NEWS/305069954.

[8] 447 U.S. 557 (1980) (applying "intermediate scrutiny" to cases of restrictions on commercial speech).

[9] 131 S. Ct. 2653 (2011).

[10] *Id*. at 2667-68 (citing *Central Hudson*, 447 U.S. at 566).

[11] 447 U.S. at 560.

[12] 131 S. Ct. at 2667-68.

[13] *Id*. at 2668.

[14] *Id*. at 2659-60, 2672.

[15] *Id*. at 2668.

[16] *Id*.

[17] *Id*. at 2670.

[18] *Id*. at 2664 (internal quotation omitted).

[19] *Id*. at 2671 ("That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers [and] may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, nonmisleading advertisements that contain impressive endorsements or catchy jingles.").

[20] *Id*. at 2670.

[21] *Id*.

[22] *Id*. at 2670-71 (internal quotation omitted).

[23] Proposed 45 C.F.R. §§ 164.501, 164.512(f)(2), and 164.520(b)(1)(iii)(A); 75 Fed. Reg. at 40,885-886.

[24] 78 Fed. Reg. at 5594.

[25] *Id*. at 5595.

[26] 131 S. Ct. at 2663, 2665.

[27] *Id*. at 2663.

[28] *Id.* (quoting *R.A.V. v. St. Paul*, 505 U.S. 377, 391 (1992)).

[29] *Id*. at 2664 (quoting *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989)).

[30] *Id*. at 2667.

[31] *Id*. at 2663.

[32] 42 U.S.C. § 17936(a)(2)(A).

[33] 131 S. Ct. at 2663 ("the law's express purpose and practical effect are to diminish the effectiveness of marketing by manufacturers of brand-name drugs. . . . Here, the Vermont legislature explained that detailers, in particular those who promote brand-name drugs, convey messages that 'are often in conflict with the goals of the state.'").