IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ADHERIS, INC.,	)	
Plaintiff,	)	
v.	)	Case No _____
KATHLEEN SEBELIUS, *et al.*,	)	
Defendants.	)	

PLAINTIFF'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Adheris, Inc. ("Adheris") brings this action to enjoin enforcement of a regulation issued by the Department of Health and Human Services ("HHS") that will impose unconstitutional content- and speaker-based restrictions on Adheris's truthful, non-misleading, and societally beneficial speech. The regulation's restrictions are plainly impermissible under the Supreme Court's decision *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011). Unless enjoined, those restrictions will irreparably harm Adheris's First Amendment rights, and threaten the continued existence of Adheris's core business—harms for which Adheris has no adequate remedy at law.

Adheris's business consists primarily of helping patients take the medicines that their doctors have prescribed for them. Adheris has developed a refill reminder and therapy-adherence service designed to ensure that patients take prescribed medications at the proper time and in the proper dosages. As part of its service, Adheris provides educational and safety materials that reinforce the importance of adhering to a prescribed therapy, and that identify potential side-effects of prescribed medications and appropriate responses to such side-effects.

Adheris's communications are not only truthful and non-misleading, they promote patient health and reduce health care costs. Studies have shown that patient failure to fill or to stay on prescribed medicines imposes enormous costs on the health care system, often in the form of avoidable hospitalizations. That failure also results in thousands of premature deaths. Adheris's communications combat these problems, by stressing the importance of adhering to a treating physician's prescription.

Adheris has no relationship with the physicians who prescribe the medications. Instead, Adheris's reminders and adherence messages are sent on behalf of the pharmacy where a patient first fills a prescription. The communications are sponsored by the manufacturer of the

medication, and Adheris explains that fact—and the patient's right to opt-out of receiving such communications—in the letters it sends. The overwhelming majority of Adheris's letters do not encourage patients to switch drugs or to purchase other goods or services.

For over a decade, HHS recognized that the kinds of refill reminders and adherence communications Adheris provides constitute "treatment communications," not "marketing," under the regulations that implement the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 42 U.S.C. § 1320d-2, *et seq.* Specifically, HHS had long taken the view that a refill reminder sent by a pharmacy was a treatment communication, not a form of marketing, even when the pharmacy was paid by a third-party to make the communication. Thus, a pharmacy (or an associated business acting on its behalf) could use protected patient information to send such "remunerated" refill reminders without obtaining patient authorization.

HHS continued to adhere to that view in 2010, when it proposed rules to implement amendments to certain HIPAA regulations that Congress had enacted in 2009. Specifically, HHS concluded that Congress had not intended to change the agency's long-standing approach to subsidized treatment communications, such as refill reminders, and HHS therefore proposed rules that would have continued to allow subsidized treatment communications, as long as patients received the kind of notice and opportunity to opt out that Adheris has long provided. In promulgating its final rule in 2013, however, HHS dramatically changed course. It required authorization for all treatment communications that encourage the use or purchase of a product or service where the entity is paid to make the communication by the provider of the product or service, unless the payment is so modest that the entity earns no profit. In adopting this rule, HHS identified no harms or dangers from subsidized refill reminders and adherence communications. Indeed, the regulation leaves governmental speakers and others free to fund

the same communications without the significant burdens and expense of obtaining patient authorization. The final rule thus permits pharmacies and business associates, such as Adheris, to earn a profit in connection with refill reminder programs as long as the program is funded by someone other than the manufacturer whose product is the subject of the refill reminder.

HHS promulgated its rule in January and set a September 23rd deadline for compliance. For months, Adheris and others sought clarification that HHS did not intend to bar subsidized refill reminders and adherence messages provided by entities such as Adheris, or to preclude such entities from recovering more than the limited costs associated with mailing such messages. HHS, however, has failed to act on those requests. With the compliance date looming, a major pharmacy chain notified Adheris that it would not continue its programs beyond August 31, 2013 due to the HHS rule, and substantially all of Adheris's pharmaceutical customers have stated that the rule has caused them to re-evaluate their existing contracts and programs with Adheris and have indicated they will be terminating their existing contracts imminently unless HHS clarifies that refill reminder programs sponsored by pharmaceutical manufacturers and administered at a profit by entities such as Adheris are permissible. As a consequence, Adheris is forced to bring this action, and to seek an injunction barring enforcement of the rule prior to its September 23rd compliance date. As Adheris explains in detail below, it readily satisfies the four-part test governing injunctive relief.

First, HHS's rule plainly violates the First Amendment. The rule restricts protected speech based on its content (*i.e.*, because it encourages the use of a third-party's product or service) and the speaker (*i.e.*, an entity paid by the third-party whose product or service is the subject of the communication). Because Adheris's speech is properly characterized as non-commercial for First Amendment purposes, such content- and speaker-based restrictions are

plainly unconstitutional. But even if Adheris's speech is deemed commercial speech, these restrictions are unlawful under *Sorrell*. HHS identified no dangers justifying restrictions on such speech, and the Supreme Court's decision in *Sorrell* effectively forecloses reliance on other rationales that the agency might have—but in fact did not—propound to justify the rule. Moreover, by abandoning the notice and opt-out mechanism in its proposed rule, and instead effectively requiring pharmacies and their business associates to obtain patient authorization for subsidized refill reminders and adherence messages, HHS restricted more speech than necessary, again without adequate justification. Adheris thus has a more than substantial likelihood of prevailing on the merits of its challenge to the final rule.

Adheris will also suffer irreparable injury in the absence of an injunction. Even a temporary loss of First Amendment rights constitutes irreparable harm justifying injunctive relief. In addition, the recent notifications Adheris has received from a major pharmacy chain and substantially all of its pharmaceutical manufacturer customers demonstrates that Adheris is threatened with the loss of its core business, which accounts for more than 90% of its revenues. Because HHS enjoys sovereign immunity, Adheris has no remedy for these financial harms.

The balance of equities and public interest also weigh decisively in favor of an injunction. While Adheris is faced with imminent risk of extreme harm, neither third-parties nor the public will be harmed if Adheris continues its remunerated refill reminder and adherence communications, as it has done for over a decade. Those communications pose no danger to consumers, and in fact are socially beneficial. And it clearly serves the public interest to ensure that HHS complies with the requirements of the First Amendment.

BACKGROUND

I. HIPAA AND THE EVOLUTION OF THE HIPAA MARKETING RULES.

To understand the constitutional infirmities in HHS's new rule, it is helpful to understand the general structure of HIPAA and how so-called "subsidized treatment communications" such as refill reminders were previously regulated. Adheris will then explain how HHS's new rule significantly alters the regulation of subsidized treatment communications, and how that new regulation threatens Adheris's core refill reminder and adherence message services.

A. The Operation Of HIPAA Prior To The New HHS Rule.

At the federal level, HIPAA governs the use and disclosure of health information in the United States. HIPAA's main objectives are to enhance health insurance portability, reduce waste in health care spending, and improve administrative efficiency. Pub. L. No. 104-191, 110 Stat. 1936, pmbl (1996). To achieve administrative simplification, HIPAA calls for the standardization of certain electronic financial and administrative transactions in health care. 42 U.S.C. § 1320d-2. Because the expansion of these electronic transmissions necessitated greater protections for the privacy and security of patients' health information (and because Congress failed to enact privacy standards by the deadline set forth in HIPAA), HHS exercised the authority granted to it by HIPAA to promulgate the HIPAA Privacy Rule, 45 C.F.R. pt. 160 and pt. 164, subpts. A, E, and later, the Security Rule, 45 C.F.R. pt. 160 and pt. 164, subpts. A, C. (For ease of reference, Adheris uses the term "HIPAA" to refer to the statute and to the Privacy and Security Rules.)

HIPAA imposes restrictions and obligations on "covered entities" with respect to the use and disclosure of "protected health information."[1] "Covered entities" include certain (1) health plans; (2) health care clearinghouses; and (3) health care providers that engage in electronic transactions standardized under HIPAA. *See* definition of "covered entity" at 45 C.F.R. § 160.103. Pharmacies qualify as covered entities because they are health care providers that engage in transactions standardized under HIPAA. *See* definition of "covered entity" at *id*. Patients' prescriptions are considered PHI. *See* definition of "protected health information" at *id.* Accordingly, pharmacies may not use or disclose patients' prescription information unless HIPAA allows for such use or disclosure.

1. The Patient Authorization Requirement and its Exceptions.

The Privacy Rule provides that covered entities may not use or disclose PHI unless (a) they obtain a valid written authorization from the individual who is the subject of the information, 45 C.F.R. § 164.508(a)(1), or (b) the Privacy Rule permits or requires such use or disclosure without authorization. *Id.* § 164.502(a). Because individual authorization is burdensome and expensive to obtain and administer,[2] in many instances the Privacy Rule's exceptions effectively govern the permissibility of using or disclosing PHI. Importantly, however, many of the uses and disclosures of PHI that are central to the operation of health care

[1] Protected health information ("PHI") is "individually identifiable health information" that is "(i) Transmitted by electronic media; (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or medium." *See* definition of "protected health information" at 45 C.F.R. § 160.103. "Individually identifiable health information" consists of health information, including demographic information, that identifies an individual or could be used to identify an individual, and includes information which "[r]elates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual." *See* definition of "health information" at *id*.

[2] An authorization must be written in plain language and contain certain elements specified under the Privacy Rule, and if a covered entity seeks an authorization from an individual, a copy of the signed authorization must be provided to the individual. 45 C.F.R. § 164.508(c). *See also* Declaration of Mark Dmytruk at ¶ 35 ("Dmytruk Dec.").

providers and health plans are permitted under HIPAA without individual permission. In particular, use and disclosure of PHI is generally permitted under the Privacy Rule without authorization for three broadly defined purposes: treatment, payment, or health care operations activities. *Id*. § 164.502(a)(1)(ii). As explained below, some of these purposes were incorporated into the exceptions to the definition of "marketing" under HIPAA.

"Treatment" is defined as "the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another." *See* definition of "treatment" at *id.* § 164.501. The preamble to the Privacy Rule clarified that third party payors, including health plans, do not perform "treatment" for purposes of the Privacy Rule. *See* HHS, Standards for Privacy of Individually Identifiable Health Information; Final Rule , 65 Fed. Reg. 82462, 82626-27 (Dec. 28, 2000) (the "2000 Final Rule"). Instead, "[o]nly health care providers, not health plans, conduct 'treatment' for purposes of this rule." *Id*. at 82627.

"Payment" includes activities by a health plan to obtain premiums or determine or fulfill its responsibility for coverage and benefits, or the activities of a health care provider or health plan to obtain or provide reimbursement for providing health care. *See* definition of "payment" at 45 C.F.R. § 164.501. "Health care operations" is a broad term that includes activities relating to covered functions, such as quality assessment and improvement activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with

information about treatment alternatives; and related functions that do not include treatment. *See* definition of "health care operations" at *id.*

2. **Use and Disclosure of PHI for Marketing.**

A communication qualifies as marketing under HIPAA if it "encourages recipients of the communication to purchase or use the product or service" that is the subject of the communication. *See* definition of "marketing" at 45 C.F.R. § 164.501. Prior to the new HHS rule, the term "marketing" also included any arrangement between a covered provider and a third party where PHI is shared with the third party, for direct or indirect compensation, in order for the third party to make marketing communications about its products and services. *See* HHS, Standards for Privacy of Individually Identifiable Health Information Part V; Final Rule, 67 Fed. Reg. 53182, 53187 (Aug. 14, 2002) (hereinafter, the "2002 Modifications"); *see* definition of "marketing" at 45 C.F.R. § 164.501 (2009). HIPAA generally requires a covered entity to secure an individual's authorization before using or disclosing the individual's PHI for marketing purposes. *See* 45 C.F.R. § 164.508(a)(3).

Although the definition of marketing under HIPAA was (and still is) broad, several exceptions permitted certain activities without individual authorization. *Id.* First, a covered entity was not required to obtain individual authorization for face-to-face communications or to provide promotional gifts of only nominal value. *See id.* at 164.508(a)(3)(i). In addition, marketing was defined to *exclude* communications made to an individual:

> (i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits[;]

> (ii) For treatment of the individual; or
>
> (iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.[3]

See definition of "marketing" at 45 C.F.R. § 164.501 (2009).

Because of these exceptions, communications by a physician or other health care provider, including a pharmacy, to patients or consumers about health-related products or services were considered "treatment," not "marketing," for purposes of HIPAA and, thus, were not subject to the patient authorization requirement. Such communications were considered "treatment," and therefore were excluded from the definition of marketing, even if they were subsidized by a third party. HHS explained that it did not believe

> that the simple receipt of remuneration should transform a treatment communication into a commercial promotion of a product or service. For example, health care providers should be able to, and can, send patients prescription refill reminders regardless of whether a third party pays or subsidizes the communication. The covered entity also is able to engage a legitimate business associate to assist it in making these permissible communications.

67 Fed. Reg. at 53187. HHS reiterated this position in a Frequently Asked Question, originally issued in December 2002. HHS, *HIPAA Frequent Questions, FAQ 285*, date created Dec. 20, 2002, http://www.hhs.gov/ocr/privacy/hipaa/faq/marketing/285.html (last accessed Aug. 14, 2013) ("HIPAA FAQ 285"). In response to the question: "can a doctor or pharmacy be paid to make a prescription refill reminder without a prior authorization under the HIPAA Privacy Rule," HHS explained that it is not marketing for a doctor to send a prescription refill reminder, even if the refill reminder is paid for by a third party, as a "prescription refill reminder is considered treatment." *Id.* HHS went on to explain that "it is not marketing when a doctor or

[3] As explained in the first Privacy Rule promulgated in 2000, this exception was interpreted as covering communications by both health care providers and health plans in managing the treatment of an individual. 65 Fed. Reg. at 82494.

pharmacy is paid by a pharmaceutical company to recommend an alternative medication to patients" and that "communications about alternative treatments are excluded from the definition of marketing and do not require prior authorization." *Id.* These exceptions were included in the regulations, and incorporated into subsequent FAQ guidance, to ensure that health-related communications, including those between providers and their patients about health issues, were not encumbered.[4]

Thus, while a covered entity had to obtain prior written authorization from an individual to send communications to the individual about non-health related products or services (*e.g.*, home furnishings) or to give or sell the individual's PHI to a third party for marketing, it was permissible for a third party to pay a covered entity to send treatment communications to an individual about the third party's products or services offered by the covered entity and for a covered entity to utilize a business associate to assist in making such treatment communications. Treatment communications were not considered marketing simply because they were funded by a third party.

B. The HITECH Act And The New Marketing Rules

In 2009, Congress enacted amendments to HIPAA as part of the Health Information Technology for Economic and Clinical Health Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 226; 123 Stat. 467 (codified at 42 U.S.C. §§ 300jj *et seq.*; §§ 17901 *et. seq.*) (Feb. 17, 2009) (the "HITECH Act"). Among other things, the HITECH Act extended HIPAA's restrictions to

[4] While the first Privacy Rule promulgated under HIPAA in 2000 required that covered entities explain how patients could opt-out of receiving future communications, the special restrictions on these kinds of communications were deleted in the 2002 modifications to the Privacy Rule. *See* 65 Fed. Reg. 82493, 82545-46; Fed. Reg. at 53185-86. However, in order for a covered entity to provide individuals with information about treatment alternatives or other health-related benefits or services, the covered entity had to include a statement to that effect in its notice of privacy practices. 45 C.F.R. § 164.520(b)(1)(iii)(A) (pre-Omnibus Final Rule); 65 Fed. Reg. at 82549.

"business associates," a term that includes entities that contract with covered entities to perform functions or services involving the use or disclosure of PHI. 42 U.S.C. §§ 17931, 17934. Adheris is a "business associate" and, prior to the HITECH Act, it was required to (and did) enter into Business Associate Agreements that obligated it to safeguard any PHI that has been disclosed to it by the covered entity. Dmytruk Dec. at ¶ 23; *see* 65 Fed. Reg. at 82504; *see also* 45 C.F.R. §§ 164.504(e)(2) (setting forth the Business Associate Agreement requirements). The HITECH Act also heightened enforcement and penalties for violations of HIPAA. 42 U.S.C. §§ 17931, 17934.

Of particular relevance here, the HITECH Act also included a provision that limited the universe of health-related communications that may be considered "health care operations." This provision, codified at 42 U.S.C. § 17936, provides that a "communication by a covered entity or business associate that is about a product or service and that encourages recipients of the communication to purchase or use the product or service shall not be considered a health care operation . . . unless the communication" falls into one of the three exclusions from the regulatory definition of "marketing" discussed above. *Id.* § 17936(a)(1). It then provides that a "communication by a covered entity or business associate" that *does* fall into one of these three exclusions from the marketing definition still "shall not be considered a health care operation . . . if the covered entity receives or has received direct or indirect payment in exchange for the making such communication, except where" the communication satisfies one of two further exceptions. *Id.* § 17936(a)(2).

One such exception is where the communication "describes only a drug or biologic that is currently being prescribed for the recipient of the communication and . . . any payment received by such covered entity is . . . reasonable in amount." *Id.* § 17936(a)(2)(A). Congress authorized

HHS to define the phrase "reasonable in amount" for purposes of this "same drug or biologic" exception. *Id.* § 17936(a)(3). Where this condition is not met, a covered entity must obtain individual authorization prior to making the communication, or if applicable, prior to a business associate making the communication in accordance with the contract between the business associate and covered entity. Finally, subsection (a)(4) provides that the term "direct or indirect payment" shall not include any payment for treatment of the individual. *Id.* § 17936(a)(4).

In proposing rules to implement this provision in 2010, HHS noted that, although the HITECH Act placed subsidized communications about a health-related product or service outside the scope of the *health care operations* exception, "it is unclear whether Congress intended . . . all subsidized communications about products and services, *including treatment communications*," to be treated as "marketing." Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the HITECH Act; Proposed Rule, 75 Fed. Reg. 40868, 40885-86 (Jul. 14, 2010); *see also* HHS, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule, 78 Fed. Reg. 5566, 5593 (Jan. 25, 2013) (the "Omnibus Final Rule") (emphasis added). HHS assumed that this was not Congress's intent. Accordingly, "to avoid undue interference with treatment communications between the individual and a health care provider, [it] proposed to continue to allow subsidized treatment communications, but conditioned on providing the individual with notice and an opportunity to opt out of receiving such communications." 78 Fed. Reg. at 5593 (explaining, in 2013, the 2010 proposal).

In promulgating its final rule, however, HHS abandoned this approach. In the preamble to the final regulations, HHS explained that its regulations required "authorization for all

treatment and health care operations communications where the covered entity receives financial remuneration for making the communication from a third party whose product or service is being marketed." *See* 78 Fed. Reg. at 5595 (emphasis added).[5] HHS deemed this the "best policy" because of a perceived difficulty of distinguishing between health care operations and treatment in all cases. *Id.* HHS stated that the authorization also applied where a business associate, rather than a covered entity, "receives financial remuneration from a third party in exchange for making a communication about a product or service." *Id.*[6]

HHS excepted from the definition of "marketing" those communications made "[t]o provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual," but "only if any financial remuneration received by the covered entity in exchange for making the communication is reasonably related to the covered entity's cost of making the communication." 45 C.F.R. § 164.501 (defining "marketing"). In the preamble, HHS stated that the regulation's "reasonable cost" requirement permits a covered entity or business associate to recover "only the costs of labor, supplies and postage" incurred in providing the communication about a drug or biologic currently prescribed to the individual. 78 Fed. Reg. at 5597. "Where the financial remuneration a covered entity receives in exchange for making a [refill reminder] communication generates a profit or includes payment for other costs, such financial remuneration would run afoul of the Act's 'reasonable in amount' language." *Id.*

[5] The final regulations define "marketing" as "a communication about a product or service that encourages recipients of the communication to purchase or use the product or service," then except from this definition, *inter alia*, communications made for "treatment and health care operations purposes, except where the covered entity receives financial remuneration in exchange for making the communication." *See* 45 C.F.R. § 164.501 (defining "marketing"). "Financial remuneration," in turn, means "direct or indirect payment from or on behalf of a third party whose product or service is being described. Direct or indirect payment does not include any payment for treatment of an individual." *Id.*

[6] HHS explained that the Omnibus Final Rule retains the long standing exceptions to the authorization requirement for (a) communications made face-to-face by a covered entity and (b) promotional gifts of nominal value provided by the covered entity. 78 Fed. Reg. at 5596.

at 5597. Thus, if a pharmacy derives any profit from a drug manufacturer that pays it to send refill reminders, those reminders are subsidized communications and prohibited in the absence of individual authorization. *Id.* HHS stated that the exception (and therefore the limitation on remuneration) also applies to adherence communications encouraging individuals to take their prescribed medication as directed. *Id* at 5596.

HHS further explained that, because the marketing rules were triggered only where financial remuneration was provided in exchange for making the communication from or on behalf of the entity whose product or service is being described, identical speech funded by the government, non-profits, or anyone other than the manufacturer of a product or provider of a service is permissible without individual authorization. Thus:

> an authorization would be required prior to a covered entity making a communication to its patients regarding the acquisition of, for example, new state of the art medical equipment if the equipment manufacturer paid the covered entity to send the communication to its patients; but not if a local charitable organization, such as a breast cancer foundation, funded the covered entity's mailing to patients about new state of the art mammography screening equipment.

Id. at 5593. Accordingly, if a non-profit foundation paid a pharmacy to mail a refill reminder and such payment included a profit for the pharmacy, the payment would be permitted under the Omnibus Final Rule. If a pharmaceutical manufacturer made the same payment for the same program, however, the payment would not be permitted under the Omnibus Final Rule (absent patient authorization or a showing that the pharmacy earned no profit) solely because the manufacturer, rather than the non-profit foundation or charity, funded the same profit to the pharmacy. HHS concluded that this speaker-based restriction was justified by Congress's intent to "curtail a covered entity's ability to use the exceptions to the definition of 'marketing' in the Privacy Rule to send communications to the individual that are motivated more by commercial

gain or other commercial purpose rather than for the purpose of the individual's health care, despite the communication being about a health-related product or service." *Id.* at 5592.

II. IMPACT OF THE NEW MARKETING RULES ON ADHERIS.

A. Adheris's Services.

Adheris was formed in 1993 with the goal of helping patients stay on their therapy. Dmytruk Dec. ¶ 8. A significant number of patients do not take their prescribed medication at all, or fail to take it properly or for the full period prescribed. *Id.* ¶ 6. Fifteen to thirty percent of patients never fill their first prescription for a chronic disease therapy. *Id.* Within the first 90 days, thirty percent of patients will typically drop off their prescription regimen and within 180 days, sixty percent of patients will typically drop off. *Id.*; Dmytruk Dec. Exhibit C.

The consequences of these failures are enormous, for both patients and society at large. Nonadherence and related suboptimal medication practices have been estimated to cost up to $290 billion per year in avoidable medical costs in the United States, with $100 billion in costs for excess hospitalizations alone. Dmytruk Dec. ¶ 7 & Exhibit D at 1. These failures can also be life-threatening for patients, leading to an estimated 89,000 premature deaths every year just for nonadherence to hypertension medication. *Id.* & Exhibit E at 1.

Adheris provides refill reminder and adherence messaging services that are designed to prompt patients to follow their doctor's prescribed medication therapy. *Id.* ¶ 8. Adheris's refill reminder program is focused on chronic diseases such as heart disease, diabetes, osteoporosis, depression, and asthma, where therapy adherence makes a significant difference. *Id.* ¶ 9. Adheris provides these services only to those pharmacies or pharmacy chains that have chosen to participate and have executed an appropriate contract with Adheris. *Id.* ¶ 10.

When patients fill a prescription at a participating pharmacy, the pharmacy sends Adheris the patients' prescription record via a secure communication. *Id.* ¶ 11. Adheris then arranges a series of letters to the patients encouraging adherence to the regime prescribed by their treating health care practitioners. *Id.* Adheris has established strict security and quality control protocols, at great expense, to ensure that PHI is safeguarded consistent with the statutory obligations of the pharmacies involved, including complex quality control systems and employee training to ensure that PHI is protected and that each adherence letter is sent to the appropriate person and relates to the appropriate disease and treatment. *Id.* at ¶ 27, 29, 32.

Within approximately seven days of a pharmacy dispensing a prescription, the patient receives a welcome letter on the pharmacy's letterhead. *Id.* ¶ 11. The letter includes educational information about the medication, safety information, positive reinforcement to stay on therapy, and a direction to follow the treating physician's advice. *Id.* Adheris reinforces these messages with additional letters on behalf of the pharmacy. *Id.* ¶ 12. Patients are sent a reminder to refill the prescription five to seven days before the refill is due; that reminder contains educational and safety materials similar to those sent in the initial letter. *Id.* If the prescription is not refilled, patients are sent an urgent reminder to complete the refill seven to ten days after the missed refill. *Id.*

The educational information included in Adheris's letters may consist of a description of the drug prescribed, the dosage prescribed, and a description of the conditions the drug is commonly prescribed to treat. *Id.* ¶ 13. The letters also provide safety information, such as how to take the drug properly, allergy and side effect information, and instructions to obtain medical help if certain side effects occur. *Id.* Adheris's letters have proved successful as educational tools. *Id.* ¶ 14. Recipients have thanked pharmacies for sending the letters, and some have

explained that they learned through the letters that they were suffering side-effects that prompted them to stop taking the medications. *Id.*

Adheris's letters clearly inform patients about the identity of the entity that sponsors the communication. *Id.* ¶ 15. The letters are printed on the participating pharmacy's letterhead and contain a disclosure that the pharmacy was reimbursed for sending the letter by a named pharmaceutical company. *Id.* The letters also prominently display simple opt-out information if patients do not wish to receive further mailings. *Id.* The overwhelming majority of Adheris's letters serve only to reinforce the treating health care practitioner's prescription, and do not encourage patients to switch drugs or to take alternative or adjunctive therapies. *Id.* ¶ 16.

Adheris's programs have a verifiably significant impact on the percentage of patients still on therapy at the end of a program period, which is a measurable benefit to public health. Adheris conducts randomized tests of the effectiveness of its adherence messaging, and these studies, consistent with governmental studies on other adherence messaging, have found that these communications significantly improve patients' persistency with their prescribed medications. *Id.* at ¶ 17. Because Adheris has contracts with 38 pharmacy chains, a meaningful increase in prescription adherence translates into a significant public health benefit. *Id.* ¶ 18. Indeed, the Congressional Budget Office estimates that a 1% increase in prescription refills in the United States would cause Medicare's spending on medical services to fall by one-fifth of one percent. This translates into more than a billion dollars in annual Medicare cost savings for each 1% increase in prescription refills. *See* CBO, Offsetting Effects of Prescription Drug Use

On Medicare's Spending for Medical Services (Nov. 2012), *available a*t http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf.[7]

These findings are consistent with adherence-promotion activities by the Center for Medicare and Medicaid Services (CMS), a component of HHS. For example, entities that offer Medicare Part D prescription drug plans must have medication therapy management programs "to increase adherence to prescription medications," 42 U.S.C. § 1395w–104(c)(2)(C), and these programs "may include . . . medication refill reminders. *Id.* § 1395w–104(c)(2)(B)(ii). Notably, CMS requires medication therapy management programs for the same chronic diseases for which Adheris provides refill reminders and adherence messages, *compare* CMS, 2012 Medicare Part D Medication Therapy Management (MTM) Programs (Nov. 12, 2012) at 3-4 ("CMS Part D MTM Programs"), *with* Dmytruk Dec. at ¶ 9, and it has deemed refill reminders as a "value added" service. CMS Part D MTM Programs at 6-7.

Similarly, CMS gives bonus payments to Part D prescription drug plans that meet certain quality standards, one of which requires a certain percentage of patients to adhere to prescribed drug therapy for certain oral diabetes, hypertension and cholesterol medications. See CMS, Medicare Health & Drug Plan Quality and Performance Ratings 2013, Part C and D, Technical Notes, p. 91 (Feb. 15, 2013) ("Part D Performance Ratings"), *available at* http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html. Such plans could use Adheris's refill reminder and adherence services to achieve these targets, which in turn could help the plan obtain bonus payments from CMS. In such a circumstance, the Part D prescription drug plan would pay directly, and CMS would indirectly fund, the same adherence

[7] The significance and potential cost savings of adherence programs have also been supported by several other studies. *See* Dmytruk Dec. Exhibit L at 4-5; Exhibit M at 7-11.

communications by Adheris that, under the Omnibus Final Rule, a pharmaceutical manufacturer effectively cannot fund without patient authorization.

B. Impact of the Omnibus Final Rule on Adheris's Business.

The impact of the Omnibus Final Rule on Adheris's business has been dramatic. Dmytruk at ¶ 34. By severely limiting remuneration for refill reminders to "only the pharmacy's cost of drafting, printing, and mailing the refill reminders," 78 Fed. Reg. at 5597, the Omnibus Final Rule effectively prevents Adheris from making a profit on sending written refill reminders and other adherence communications—the core of its business operations. Dmytruk Dec. at ¶¶ 34-37.

In addition, customers are terminating their relationships with Adheris due to concerns that it is not practical or economical to obtain patient authorization, and that, in the absence of authorization, they could face draconian penalties for violating the new regulation. *Id.* at ¶ 35. A major pharmacy chain stopped contracting for most new programs with Adheris in March of 2013, and in July 2013 notified Adheris that it would not continue with its current programs beyond August 31, 2013 due to the Omnibus Final Rule. *Id.* ¶ 36. More recently, substantially all of the pharmaceutical manufacturers that have contracts with Adheris have indicated that the Omnibus Final Rule has caused them to re-evaluate their existing contracts and programs with Adheris and that they will be terminating their existing contracts and programs with Adheris imminently unless HHS clarifies that refill reminder programs sponsored by pharmaceutical manufacturers and administered at a profit by Business Associates such as Adheris are permissible under the Omnibus Final Rule. *Id.* Adheris's business will not survive long without a network of participating pharmacies and pharmaceutical manufacturers broad enough to justify

the substantial overhead costs of its complex and highly secured information processing and program management facilities. *Id.* at ¶ 27-29, 37.

ARGUMENT

A party is entitled to immediate injunctive relief if (1) it has a substantial likelihood of success on the merits of its claim; (2) it will be irreparably injured if relief is not granted; (3) the balance of equities weighs in favor of an injunction; and (4) the public interest will be furthered. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *Nat'l Treasury Emps. Union v. United States*, 927 F.2d 1253, 1254 (D.C. Cir. 1991); *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004). These factors "should be balanced on a sliding scale, and a party can compensate for a lesser showing on one factor by making a very strong showing on another factor." *Biovail Corp. v. FDA*, 448 F. Supp. 2d 154, 159 (D.D.C. 2006). Immediate relief is appropriate if necessary to protect against irreparable injury, to preserve the *status quo* until the Court can rule, and to protect the public interest. *See Barrow v. Graham*, 124 F. Supp. 2d 714, 715-16 (D.D.C. 2000).

As shown below, Adheris is plainly entitled to relief under these standards.

I. ADHERIS HAS A SUBSTANTIAL LIKELIHOOD OF SUCCESS ON ITS CLAIM THAT THE OMNIBUS FINAL RULE VIOLATES THE FIRST AMENDMENT.

The Administrative Procedure Act ("APA") provides that a "person suffering legal wrong because of agency action . . . is entitled to judicial review thereof." 5 U.S.C. § 702. Agency action must be set aside if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with applicable law, *Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005), including if it is "contrary to constitutional right," 5 U.S.C. § 706(2)(B). Adheris has a substantial likelihood of succeeding on its claim that the Omnibus Final Rule is not in accordance with law because it violates the First Amendment.

Adheris's refill reminder and adherence communications are constitutionally protected speech. That speech is not properly characterized as "commercial speech" at all. But even if Adheris's speech is deemed commercial, the content- and speaker-based restrictions imposed by the Omnibus Final Rule trigger heightened scrutiny under *Sorrell*. And the rule cannot withstand scrutiny under such standards. Indeed, HHS identified no harms from refill reminders and adherence communications, and *Sorrell* held that cost-containment justifications cannot sustain content- and speaker-based restrictions. Alternatively, Adheris has a substantial likelihood of prevailing on its claim that HHS misinterpreted the HITECH Act, which, properly interpreted, does not limit subsidized treatment communications sent by health care providers or their business associates.

A. The Omnibus Final Rule Is Subject To Heightened Scrutiny, Because It Places Content- And Speaker-Based Burdens On Protected Speech.

1. Adheris's Speech Is Constitutionally Protected Speech.

Adheris's refill reminder and adherence communications are constitutionally protected speech. Indeed, that speech is properly characterized as non-commercial, and thus entitled to the highest level of First Amendment protection. But even if viewed as commercial in nature, Adheris's speech enjoys substantial First Amendment protection.

An essential role of the First Amendment is to protect the "free flow of information." *Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 763 (1976); *see Bates v. State Bar of Ariz.*, 433 U.S. 350, 364 (1977). "That reality has great relevance in the fields of medicine and public health, where information can save lives." *Sorrell*, 131 S. Ct. at 2664. The refill reminders and adherence communications at issue here are purely information, and can, in fact, save lives. Accordingly, Adheris's speech is not properly considered "commercial speech" for First Amendment purposes.

The overwhelming majority of Adheris's communications do not "propose a commercial transaction." *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66 (1983). Indeed, Adheris's communications play no role in a doctor's decision to prescribe a particular medicine, or a patient's initial decision to fill that prescription. Dmytruk Dec. at ¶ 11. Adheris's communications begin only *after* both of these events have occurred. *Compare Sorrell*, 131 S. Ct. at 2659-60 (pharmaceutical salespeople, or "detailers," were engaged in commercial speech where they sought access to information about physicians' prescribing patterns in order to persuade those physicians to prescribe their manufacturer's products).

Nor do Adheris's communications "relate[] solely to the economic interests of the speaker and its audience." *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 561-62 (1980). Instead, Adheris's speech serves the societally beneficial purposes of ensuring that patients adhere to a therapeutic regimen previously prescribed by a health professional with whom Adheris has no relationship. Dmytruk Dec. at ¶ 11. The failure of patients to take medications properly or for the duration of prescription can lead to a wide variety of adverse health consequences, including preventable deaths, and impose enormous costs on the health care system. *Id.* at ¶ 7. Indeed, studies have indicated that failure to take prescription medicines properly causes approximately 89,000 premature deaths per year just for those with hypertension, and imposes anywhere from $100 *billion* to $300 *billion* in additional health care expenses. *Id.* Adheris's communications help to combat these problems by reminding patients to refill their prescriptions and by educating them about the importance of adhering to their prescribed therapy. *Id.* at ¶¶ 8, 11-12. These communications also educate patients about their medicines, including their potential hazards and what to do in the event of adverse side-effects. *Id.* at ¶¶ 8, 11-12. In fact, the information Adheris provides can cause—and in some instances

has caused—patients to *stop* using (and therefore to *stop* purchasing) their prescribed medications. *See id.* ¶ 14.

The fact that pharmaceutical manufacturers fund the communications does not render them in any way less beneficial to patients and the nation's health care system at large. Nor does it make the speech "commercial" in nature. Speech "is not commercial simply because someone pays for it." *Edwards v. District of Columbia*, 765 F. Supp. 2d 3, 13 (D.D.C. 2011) (quoting *Argello v. City of Lincoln*, 143 F.3d 1152, 1153 (8th Cir. 1998)); *see id.* (noting examples of non-commercial "speech-for-profit," including "[t]utoring, providing legal advice, or giving medical advice"). In this case, Adheris is reinforcing the medical advice a doctor has already given a patient: take the medication as prescribed and beware of safety risks. Dmytruk Dec. at ¶ 16. The overwhelming majority of the letters do not urge patients to buy something they have not been prescribed, or contain any encouragement to switch to a different drug, or to buy more of a drug than the amount prescribed. *Id.*

In fact, HHS itself previously recognized that refill reminders and adherence messages were not "marketing" at all, but rather "treatment" communications, even when funded by a third party such as a pharmaceutical manufacturer. *See* 67 Fed. Reg. at 53187 (remuneration did not "transform a treatment communication into a commercial promotion of a product or service"); HIPAA FAQ 285 ("prescription refill reminder is considered treatment" even if the refill reminder is paid for by a third party). As noted above, CMS affirmatively promotes adherence communications for prescription medicines and it can, at least indirectly, fund the very same communications through bonus payments to Part D prescription drug plans. *See supra* at 17-18.

In all events, even if Adheris's refill reminder and adherence communications are properly characterized as commercial speech for First Amendment purposes, they still enjoy

substantial constitutional protection. The Supreme Court recently recognized that "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment." *Sorrell*, 131 S. Ct. at 2659. Because Adheris's speech is truthful and non-misleading, it enjoys at least the same degree of protection as the speech at issue in *Sorrell*, where pharmaceutical salespeople sought to persuade physicians to prescribe their manufacturer's products. *Id.* at 2659-60.

2. The Omnibus Final Rule Places Content- And Speaker-Based Burdens On Adheris's Protected Speech.

The Omnibus Final Rule burdens Adheris's truthful, non-misleading, and beneficial speech solely because it is funded by pharmaceutical manufacturers. *Sorrell* makes clear that the Omnibus Final Rule's restrictions are "content- and speaker-based."

As HHS itself explained, in the absence of individual authorization, the Omnibus Final Rule prohibits communications by a covered entity that "encourage individuals to purchase or use [a] third party's product or service" if the covered entity receives payment from that third party "in exchange for making such communications." 78 Fed. Reg. at 5596. According to HHS, the Omnibus Final Rule excepts refill reminders from this prohibition only if the person making the communication recoups no more than the costs of the labor, supplies and postage incurred in making the communication and derives no profit from the payment it receives for making the communication. *Id.* at 5597. These restrictions are thus plainly content-based. Their application depends on the content of the communication, which must encourage the use or purchase of a product or service. *See Sorrell*, 131 S.Ct. at 2663 (holding that a statute was content-based because it disfavors "speech with a particular content").

"More than that, the [Omnibus Final Rule] disfavors particular specific speakers." *Id.* Indeed, the Omnibus Final Rule makes no secret of the fact that it discriminates against

particular speakers—namely, those who communicate in exchange for payment from or on behalf of "a third party *whose product or service is being described*." *See* definition of "financial remuneration" at 45 C.F.R. § 164.501 (emphasis added). HHS explained that a covered entity could not communicate, without individual authorization, about "new state of the art medical equipment if the equipment manufacturer paid the covered entity to send the communication," but that a covered entity could communicate about the very same equipment and receive the exact same payment "if a local charitable organization, such as a breast cancer foundation, funded the covered entity's mailing." 78 Fed. Reg. at 5593.

Under HHS's reasoning, the government may likewise fund the same communications without limits, and could in fact do so through its Part D Performance Ratings program. *See supra* at 17-18. Entities that provide refill reminders subsidized by anyone other than a pharmaceutical manufacturer may do so without patient authorization. Entities that provide the same reminders in exchange for payments from pharmaceutical manufacturers may not (unless they are willing to do so at a loss). The Omnibus Final Rule is thus openly hostile to those who speak in exchange for payment from the manufacturers of health care products and effectively requires these speakers, but not others, to engage in the cumbersome process of obtaining individual authorization from each recipient of the speech.

Unsurprisingly, these content- and speaker-based restrictions have had a serious chilling effect on Adheris's refill reminders and adherence communications, causing one major pharmacy chain to terminate its contract with Adheris and substantially all of Adheris's pharmaceutical company customers to threaten the imminent termination of their programs. *See* Dmytruk Dec. at ¶¶ 35-36; *see also* 78 Fed. Reg. 5595 ("Several commenters noted that it would be unrealistic to expect a covered entity to perform such non-essential functions as sending refill reminders and

other related communications if they could not recoup both their direct and indirect costs as well as a modest profit"). These heavy financial burdens trigger First Amendment scrutiny. *Simon & Schuster, Inc. v. Members of N.Y. State Crime Victims Bd.*, 502 U.S. 105, 117 (1991) ("[F]inancial burden[s] [that] operate as disincentives to speak" are subject to First Amendment scrutiny); *Citizens United v. FEC*, 558 U.S. 310, 339 (2010) (a "prohibition on . . . expenditures" for speech is the same as "a ban on speech," as it "necessarily reduces the quantity of expression" (citation omitted)).

Nor is the Omnibus Final Rule saved by the fact that pharmaceutical manufacturers may fund the communications if consumers sign individual authorization forms. While "private decisionmaking can avoid governmental partiality and thus insulate privacy measures from First Amendment challenge" under some circumstances, "that principle is inapposite" where the government imposes the authorization requirement "only on terms favorable to the speech the State prefers." *Sorrell*, 131 S.Ct. at 2669. Here, as in *Sorrell*, the authorization requirement "burden[s] disfavored speech by disfavored speakers," *id.*; pharmacies and their business associates need not obtain authorizations if the speech does not encourage the use of medical products, or if it is not funded by pharmaceutical manufacturers.

B. The Regulation Fails Heightened Scrutiny.

Because Adheris's speech is properly viewed as non-commercial treatment communications, *see supra* at 21-23, the content- and speaker-based restrictions imposed by the Omnibus Final Rule are presumptively unconstitutional. *R.A.V. v. St. Paul*, 505 U.S. 377, 382 (1992). Indeed, "it is all but dispositive to conclude that a law is content-based and, in practice, viewpoint discriminatory." *Sorrell*, 131 S. Ct. at 2667.

But, as *Sorrell* make clear, even when content- and speaker-based restrictions are imposed on commercial speech, such restrictions are still subject to heightened scrutiny. The

Court did not decide the precise level of heightened scrutiny applicable to such restrictions on commercial speech, however, because the restriction at issue in that case could not satisfy even the baseline requirements for regulation of commercial speech—*i.e.*, that the government demonstrate "at least that the [restriction] directly advances a substantial governmental interest and that that measure is drawn to achieve that interest" in a manner that was "proportional" to the government interest's and "does not seek to suppress a disfavored message." *Id.* at 2667-68. So too here, the Omnibus Final Rule fails these threshold requirements.

1. HHS Identified No Substantial Government Interest That The Regulation Serves.

HHS identified no governmental interest—substantial or otherwise—that is served by the restriction on refill reminders and adherence communications. HHS pointed to no harms or dangers from subsidized refill reminders and adherence communications, and cannot attempt to do so now. *See SEC v. Chenery Corp,* 318 U.S. 80, 87-88 (1943); *see also Williams Gas Processing—Gulf Coast Co. v. FERC,* 373 F.3d 1335, 1345 (D.C. Cir. 2004). The agency's failure in this regard is telling: if subsidized treatment communications were harmful, those harms should have come to light in the years HHS allowed such communications without patient authorization.

Moreover, the regulation leaves pharmacies free to send such communications as long as they do not receive more than a "reasonable" amount of funding from pharmaceutical manufacturers. HHS incoherently continues to allow remuneration for face-to-face communication of the same material. And it allows business associates such as Adheris to profit from adherence communications as long as those communications are funded by someone other than the provider of the product or service discussed in the communication. These various exceptions and inconsistencies "bring into question the purpose of" the regulation. *Rubin v.*

Coors Brewing Co., 514 U.S. 476, 489 (1995); *Greater New Orleans Broadcasting v. United States*, 527 U.S. 173, 190 (1999) (regulatory regime could not advance asserted governmental interests when the regime was "pierced by exemptions and inconsistencies").

HHS stated only that the restriction is designed to effectuate Congress's purported intent to "curtail a covered entity's ability to use the exceptions to the definition of 'marketing' in the Privacy Rule to send communications . . . that are motivated more by commercial gain or other commercial purpose rather than for the purpose of the individual's health care." 78 Fed. Reg. at 5592. This is not a legitimate governmental interest at all. The fact that speech is motivated by profit does not remove its First Amendment protection and is not itself a basis for the government to discriminate against such speech. As *Sorrell* makes clear, "[c]ommercial speech is no exception" to the First Amendment's limits on content-based laws: "While the burdened speech results from an economic motive, so too does a great deal of vital expression." 131 S.Ct. at 2664-65. Burdening speech because it is commercially motivated is not a "neutral justification." *Id.* at 2664.

HHS's cryptic explanation appears to reflect the view that those who are "motivated more by commercial gain . . . than for the purpose of the individual's health care" will encourage the consumption of unnecessary products or services, thus driving up health care costs. Insofar as HHS was justifying the Omnibus Final Rule on cost-reduction grounds, this justification is unavailing. First, it is inapplicable to Adheris and thus, even if legitimate, would serve only to highlight that the Rule is drawn too broadly. Second, and more fundamentally, *Sorrell* squarely rejects cost-saving justifications for speaker-based restrictions.

The overwhelming majority of Adheris's communications simply reinforce the advice of a physician who, acting in the best interests of his or her patient, has independently prescribed a

prescription medicine. Again, the overwhelming majority of these communications do not encourage patients to consume more medicine than the physician has prescribed; to take the medicine for longer periods than prescribed; to switch to higher-priced medicines; or to purchase ancillary or auxiliary products or services. Dmytruk Dec. at ¶ 16. Adheris's speech thus does not distort the market or encourage unnecessary consumption that drives up health care costs. To the contrary, its reminder and adherence messages affirmatively promote patient health, helping to save lives and to reduce health care costs. *See id.* at ¶¶ 8, 11-12, 17. Indeed, the government itself recognizes this, which is why it promotes therapy adherence. *See supra* at 17-18.

But even if HHS had identified evidence that refill reminders and adherence messages increased health care costs, that still could not justify the Omnibus Final Rule. "[T]he fear that speech might persuade provides no lawful basis for quieting it." *Sorrell*, 131 S.Ct. at 2670; *see id.* at 2671 ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good") (quoting *44 Liquormart, Inc., v. Rhode Island*, 517 U.S. 484, 503 (1996)); *Va. State Bd.*, 425 U.S. at 770 ("[I]nformation is not in itself harmful, . . . people will perceive their own best interests if only they are well enough informed, and . . . the best means to that end is to open the channels of communication rather than to close them."); *Buckley v. Valeo*, 424 U.S. 1, 48–49 (1976) ("[T]he concept that government may restrict the speech of some elements of our society in order to enhance the relative voice of others is wholly foreign to the First Amendment."). Thus, even if HHS could show that refill reminders and adherence messages "distort" the market for prescription drugs when made by those paid by drug manufacturers (though not when made by others), HHS "can express that view through its own speech," but it "may not burden the speech of others in order to tilt public debate in a preferred direction." *Sorrell*, 131 S. Ct. at 2671.

2. The Regulation Does Not Directly Advance Any Legitimate Privacy Interests, Or Do So In A Proportional Manner.

Protecting the privacy of individuals' medical information is a legitimate government interest, but the Omnibus Final Rule does not directly advance that interest, much less do so using the least restrictive means. The Rule has no impact on the privacy of individuals' medical information. Before that rule went into effect, pharmacies had access to prescription information and pharmaceutical manufacturers did not. The Omnibus Final Rule does not change this situation: pharmacies still have access to prescription information, and pharmaceutical manufacturers still do not have access to that information. Nor does the rule promote privacy interests by ensuring that PHI cannot be used to contact patients who do not wish to receive communications encouraging them to take their prescribed medications: Under the Omnibus Final Rule, pharmacies and their business associates can still make such communications, as long as they are funded by someone other than the manufacturers of the medicine, or if the pharmacy or business associate is willing to provide the refill reminder and adherence communications at a loss.

Moreover, even if some people would prefer not to receive the communications, that provides no legitimate governmental interest in burdening the speech. "Many are those who must endure speech they do not like, but that is a necessary cost of freedom." *Sorrell*, 131 S.Ct. at 2669; *see Cohen v. California,* 403 U.S. 15, 21 (1971). In any event, HHS points to no evidence that customers feel "coerced" or "harassed" by refill reminders or adherence communications. *Sorrell*, 131 S.Ct. at 2669. Indeed, these reminders are widely considered beneficial, *see* Dmytruk Dec. at ¶¶ 14, 17, which is why HHS itself promotes them. *See supra* at

17-18. And people may simply discard the communications if they do not find them useful. *Sorrell*, 131 S.Ct. at 2670.

Moreover, even where a restriction advances a substantial government interest—which is not the case here—that restriction must be "narrowly drawn," and cannot "completely suppress information when narrower restrictions on expression would serve [the government's] interest as well." *Central Hudson*, 447 U.S. at 565. The Omnibus Final Rule fails this test because HHS could have chosen far less burdensome approaches, such as mandating opt-out notices and disclosures that pharmaceutical manufacturers funded the communications—both of which HHS initially proposed when it first proposed rules to implement HITECH, *see* 75 Fed. Reg. at 40884, and both of which Adheris already provides. Regulations designed to protect consumer privacy by requiring opt-in consent to marketing communications violate the First Amendment because, even if the regulation were to materially advance privacy goals, requiring opt-in consent is not narrowly tailored. *See US West, Inc. v. FCC*, 182 F.3d 1224, 1238-39 (10th Cir. 1999) (barring a FCC opt-in requirement for communications personal data because an opt-out approach was viable).

HHS sought to justify its more restrictive approach based on its view that it can be difficult to distinguish between health care operations communications and treatment communications in certain circumstances. *See* 78 Fed. Reg. at 5595. But the lack of clarity in the agency's own regulations cannot justify content- and speaker-based restrictions on protected speech. Indeed, for over a decade, HHS recognized that refill reminders and adherence messages constituted treatment, not marketing, regardless of how such communications were funded. And in its promotion of medication adherence, CMS requires program sponsors to enroll eligible Medicare Part D beneficiaries into a medication therapy management program, which as noted

may include refill reminders, *see* 42 U.S.C. § 1395w–104(c)(2)(B)(ii), "using an opt-out approach only." Agency for Healthcare Research and Quality (AHRQ), Effective Health Care Program, Evidence-based Systematic Review Protocol: Medication Therapy Management (July 24, 2013), at 2, *available at* http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayProduct&productID=1601. HHS has completely failed to justify the far more speech-restrictive opt-in requirement for adherence communications subsidized by pharmaceutical manufacturers.

Finally, to the extent HHS believes that the HITECH Act compelled a different result, that is not a substantial governmental interest that justifies infringement of Adheris's First Amendment rights. Instead, it is an argument that the statute itself is unconstitutional for all of the reasons just discussed. But as Adheris demonstrates next, the statute does not compel the constitutional violation that Adheris challenges here.

C. HHS Misinterpreted The HITECH Act And Improperly Failed To Implement It In A Manner That Would Avoid The Constitutional Violation At Issue Here.

The Omnibus Final Rule is "not in accordance with law" for the alternative reason that HHS misinterpreted the HITECH Act. The provisions of the HITECH Act placed no limits on the pre-existing ability of health care providers to make *treatment* communications, including those funded by pharmaceutical manufacturers. Instead, the HITECH Act restricted the scope of HIPAA's *health care operations* exception to the patient authorization requirement. The "same drug or biologic" exception to this *health care operations* restriction can be read as simply allowing health care plans (which can never engage in treatment communications) to provide subsidized adherence communications at cost. Because statutes should be construed, where possible, to avoid serious doubts as to their constitutionality, *Int'l Ass'n of Machinists v. Street*,

367 U.S. 740, 749 (1961), HHS's failure to adopt this narrower interpretation of the "same drug or biologic" provision renders the marketing provisions of the Omnibus Final Rule invalid.

The HITECH Act states only that a communication "that encourages recipients of the communication to purchase or use [a health care] product or service *shall not be considered a health care operation* . . . unless the communication" falls into one of HIPAA's three exclusions from the regulatory definition of "marketing." 42 U.S.C. § 17936(a)(1). It then provides that a "communication by a covered entity or business associate" that falls into one of these three exclusions from the marketing definition still "shall not be considered *a health care operation* . . . if the covered entity receives or has received direct or indirect payment for making such communication," unless the communication satisfies further exceptions, one of which pertains to communications about the same drug or biologic that has already been prescribed for an individual. *Id.* § 17936(a)(2). Thus, the HITECH Act limits the extent to which a remunerated "communication . . . that encourages recipients of the communication to purchase or use [a health care] product or service" falls within the scope of HIPAA's health care operations exception. Regardless of whether the speaker is a covered health care provider or a health plan, remunerated communications that encourage the purchase or use of products cannot qualify as a health care operations communication, unless they satisfy the HITECH Act's exceptions.

This restriction on the scope of HIPAA's *health care operations* exception has no bearing on the ability of health care *providers* to provide refill reminders and other adherence messages. This is because the Privacy Rule treated subsidized communications about health care-related products or services by health care *providers* as falling within HIPAA's *treatment* exception, and the HITECH Act does not purport to amend the Privacy Rule's definition of "treatment" at all.

The HITECH Act thus does not seek to restrict treatment communications, including refill reminders and adherence messages by health care providers, even when funded by a third party.

The "same drug or biologic" exception to the HITECH Act's restriction on health care operations communications *is* relevant, however, to subsidized adherence messages made by or on behalf of health *plans*. As noted earlier, communications by health care plans never qualify as *treatment* communications. Thus, insofar as health care plans provide remunerated refill reminders or adherence messages, the HITECH Act's "same drug or biologic" exception would allow such communications, provided the remuneration satisfies the Act's "reasonable in amount" restriction on remuneration.

Several factors weigh in favor of this interpretation. First, if Congress had intended to alter HHS's long-standing view that subsidized refill reminders by health care providers were "treatment" and not marketing, Congress could have, and presumably would have, chosen to amend the definition of "treatment" itself, or the definition of "marketing." An amendment to the definition of "health care operations" is a singularly circuitous and opaque way of overturning HHS's conclusion that subsidized refill reminders by health care providers such as pharmacies were "treatment."

Second, the HITECH Act provides that the term "direct or indirect payment" shall not include any payment for treatment of the individual. 42 U.S.C. § 17936(a)(4). HHS had already concluded that third-party payments for refill reminders by health care providers were direct or indirect payments for "treatment." *See* 67 Fed. Reg. at 53187 ("The Department does not agree that the simple receipt of remuneration should transform a treatment communication into a commercial promotion of a product or service. For example, health care providers should be able to, and can, send patients prescription refill reminders regardless of whether a third party pays or

subsidizes the communication."); HIPAA FAQ 285 ("It is not marketing for a doctor to make a prescription refill reminder even if a third party pays for the communication. The prescription refill reminder is considered treatment."). The HITECH Act's definition of "payment" thus merely codifies the pre-existing safe harbor for subsidized treatment communications. Accordingly, the "same drug of biologic" exception must be limited to adherence messages by health plans, which is a health care operations function that would otherwise be prohibited without authorization.

Third, and most importantly, this narrow interpretation avoids the constitutional violation that HHS's broader reading inflicts on Adheris. Under a narrow reading, refill reminders and adherence communications by health care providers and their business associates are not restricted at all. Because this interpretation avoids infringing the First Amendment rights of health care providers and their business associates who engage in speech in exchange for remuneration by manufacturers, HHS was obligated to adopt it. *Int'l Ass'n of Machinists*, 367 U.S. at 749 ("Federal statutes are to be so construed as to avoid serious doubt of their constitutionality. When the validity of an act of the Congress is drawn in question, and even if a serious doubt of constitutionality is raised, it is a cardinal principle that this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided.") (internal citation omitted); *United States v. Clark*, 445 U.S. 23, 27 (1980) (same). Its failure to do so renders the Omnibus Final Rule invalid, as not in accordance with law.

* * *

In short, Adheris is likely to prevail on its claim that the Omnibus Final Rule is unlawful.

II. ADHERIS WILL SUFFER IRREPARABLE HARM IN THE ABSENCE OF INJUNCTIVE RELIEF.

Unless this Court enjoins the Omnibus Final Rule prior to the September 23 compliance date, Adheris will suffer irreparable harm. First, "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (citing *New York Times Co. v. United States*, 403 U.S. 713 (1971)); *see also Quaker Action Grp. v. Hickel*, 421 F.2d 1111, 1116 (D.C. Cir. 1969) ("any delay in the exercise of First Amendment rights constitutes an irreparable injury to those seeking such exercise"). Because First Amendment rights are intangible and are fundamental, violations of such rights cannot be compensated by money damages. Injunctive relief is thus appropriate whenever "First Amendment interests [are] either threatened or in fact being impaired." *Elrod*, 427 U.S. at 373. "'Where a plaintiff alleges injury from a rule or regulation that directly limits speech, the irreparable nature of the harm may be presumed.'" *Am. Freedom Def. Initiative v. Washington Metro. Area Transit Auth.*, 898 F. Supp. 2d 73, 83-84 (D.D.C. 2012) (quoting *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 301 (D.C. Cir. 2006)).

These principles are fully applicable even if this Court concludes that Adheris's communications constitute commercial speech. *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 15-17 & n.17 (D.D.C. 2002) (applying *Elrod* to commercial speech and rejecting the argument that "commercial speech, unlike political speech, is more durable and not easily chilled"). Indeed, the facts of this case vividly illustrate why this is so. Although the Omnibus Final Rule does not require compliance until September 23, 2013, Adheris's speech is already being impaired. Dmytruk Dec. at ¶¶ 34-35; *see also England*, 454 F.3d at 301 ("moving parties must also establish they are or will be engaging in constitutionally protected behavior to demonstrate that the allegedly impermissible government action would chill allowable individual conduct").

A major pharmacy chain stopped contracting for most new programs with Adheris in March of 2013, and in July 2013 that chain notified Adheris that it would not continue with its current programs beyond August 31, 2013 due to the Omnibus Final Rule. Dmytruk Dec. at ¶ 36. More recently, substantially all of the pharmaceutical manufacturers that have contracts with Adheris have indicated that the Omnibus Final Rule has led them to re-evaluate their existing contracts and programs with Adheris, and that they will be terminating those existing contracts and programs imminently unless HHS clarifies that refill reminder programs sponsored by pharmaceutical manufacturers and administered at a profit by Business Associates such as Adheris are permissible under the Omnibus Final Rule. *Id.* These customers fear that, without patient authorization, their use of Adheris's service could expose them to legal penalties and sanctions and reputational harms for unauthorized use or disclosure of PHI under HIPAA. *Id.* ¶ 35.

As large pharmacy contracts are cancelled, and as pharmaceutical manufacturers reallocate their budgets away from refill reminders, the continued existence of Adheris's core business of providing written adherence communications is threatened. *Id.* at ¶ 37. In light of the substantial technology and other costs needed to run that core business, Adheris would not have the level of sales necessary to continue this core business (from which it derives over 90% of its revenues) should any other significant pharmacy or pharmaceutical partners make good on their promises to cancel their contracts. *Id.* Moreover, any attempt to measure the harms that the Omnibus Final Rule is inflicting on Adheris would be extremely difficult to quantify. *Id.*

Second, because the loss of these customers "threaten[s] the very existence of" Adheris's core business, Adheris is suffering the threat of irreparable business harm wholly apart from the separate—and legally sufficient—irreparable harm to its First Amendment rights. *Cardinal*

Health, Inc. v. Holder, 846 F. Supp. 2d 203, 211 (D.D.C. 2012) (quoting *Wisconsin Gas Co. v. F.E.R.C.*, 758 F.2d 669, 674 (D.C. Cir. 1985)); *see also Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 43 (D.D.C. 2000) (irreparable harm can be established where a movant makes "a strong showing that the economic loss would significantly damage its business above and beyond a simple diminution in profits"); *Gulf Oil Corp. v. Dep't of Energy*, 514 F. Supp. 1019, 1025 (D.D.C. 1981) (stating that irreparable harm can be established where the harm "cause[s] extreme hardship to the business, or even threaten[s] destruction of the business"). Indeed, over 90% of Adheris's revenue is at risk of being lost if Adheris is not allowed to continue its adherence programs. Dmytruk Dec. at ¶ 37. Thus, while Adheris is exploring alternative commercial models that may reposition its business, irreparable impairment of Adheris's core business is highly likely in the absence of injunctive relief. *Id*.; *see also Gulf Oil*, 514 F. Supp. at 1026 (noting that an element of irreparable harm is that the economic damage "cannot be estimated in terms of money and cannot be redressed by money").

Finally, Adheris cannot obtain money damages from HHS, as it enjoys sovereign immunity from such relief. *See* 5 U.S.C. § 702. As this Court has explained, where "the plaintiff in question cannot recover damages from the defendant due to defendant's sovereign immunity . . . any loss of income suffered by plaintiff is irreparable *per se*." *See Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2009); *see Nalco Co. v. EPA*, 786 F. Supp. 2d 177, 188 (D.D.C. 2011) ("EPA's actions threaten a loss of sales and goodwill for which Nalco will have no right of recourse against the federal government"); *accord Brendsel v. Office of Fed. Hous. Enter. Oversight*, 339 F. Supp. 2d 52, 66 (D.D.C. 2004).

Unless enjoined, the Omnibus Final Rule will impair Adheris's speech and jeopardize its business. These consequences constitute irreparable injury justifying a preliminary injunction.

III. THE BALANCE OF EQUITIES FAVORS ADHERIS.

Further, a preliminary injunction is justified because "the balance of equities tips in [Adheris's] favor," *Winter*, 555 U.S. at 20. Adheris will suffer severe irreparable injury in the absence of a preliminary injunction, as discussed above, and "an injunction [will] not substantially harm" third parties if preliminary relief is granted, *Cobell*, 391 F.3d at 258. Refill reminders and adherence communications funded by pharmaceutical manufacturers are not false or misleading, and HHS identified no dangers to consumers or patients from such communications. To the contrary, HHS permitted these subsidized communications for years. Indeed, studies show that refill reminders and adherence communications improve patient health and lower health care costs, which is undoubtedly why HHS itself promotes their use. *See supra* at 17-18.

Furthermore, any "injury that could flow to consumers cannot compare, as a matter of law, with the First Amendment injury" to Adheris. *Pearson v. Shalala*, 130 F. Supp. 2d 105, 119 (D.D.C. 2001). Adheris's communications will "at worst . . . result simply in consumers spending money" to take their medications as prescribed. *Id.* Even if this result could somehow be considered an injury, it "cannot compare to the harm resulting from the unlawful suppression of speech," *id.*, nor to the threat of irreparable damage to Adheris's business.

IV. AN INJUNCTION WILL FURTHER THE PUBLIC INTEREST.

Finally, a preliminary injunction is warranted because it will further the public interest. "In exercising their sound discretion, courts of equity should pay particular regard for the public consequences" of an injunction. *Winter*, 555 U.S. at 24 (citation omitted). "[I]t is clearly in the public interest to ensure that governmental agencies . . . fully comply with the law, especially when that law concerns the parameters of a party's First Amendment rights to effectively

communicate its health message to consumers." *Pearson*, 130 F. Supp. 2d at 119; *see Gordon v. Holder*, 826 F.Supp.2d 279, 297 (D.D.C. 2011) (noting strong "public[] interest in avoiding enforcement of an unconstitutional law"). Here, as explained above, HHS's rule imposes severe content- and speaker-based burdens on protected expression, thereby violating Adheris's First Amendment rights and preventing Adheris from communicating its health message to consumers.

Furthermore, a preliminary injunction is in the public interest because the rule chills speech that is highly beneficial to the public. Failure to take medications as prescribed causes serious health consequences, including an estimated 89,000 premature deaths every year from those with hypertension alone. Dmytruck Dec. ¶ 7. In addition, failure to take medications as prescribed imposes costs of up to $290 billion per year, with $100 billion in costs for preventable hospitalizations. *Id.* Adheris's refill reminders and adherence communications are an effective means of encouraging people to take their medications as prescribed by their doctors, thereby improving health outcomes and reducing medical costs. *Id.* ¶ 17. Without a preliminary injunction, Adheris will likely be forced to shut down these programs. *Id.* ¶ 37. A preliminary injunction should be granted to protect this valuable speech.

Respectfully submitted,

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September 5, 2013