ORAL ARGUMENT NOT YET SCHEDULED

No. 15-1211 (and consolidated cases)

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ACA INTERNATIONAL ET AL.,
Petitioners,

v.

FEDERAL COMMUNICATIONS COMMISSION and UNITED STATES OF AMERICA,
Respondents

CAVALRY PORTFOLIO SERVICES, LLC ET AL.,
Intervenors for Petitioners

ON PETITIONS FOR REVIEW FROM A DECISION
OF THE FEDERAL COMMUNICATIONS COMMISSION

FINAL BRIEF FOR PETITIONER RITE AID HDQTRS. CORP.

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February 24, 2016

CERTIFICATE AS TO PARTIES, RULINGS & RELATED CASES

The following information is provided pursuant to D.C. Circuit Rule 28(a)(1).

A. Parties and Amici.

1. Petitioners are ACA International (No. 15-1211); Sirius XM Radio Inc. (No. 15-1218); Professional Association for Customer Engagement, Inc. (No. 15-1244); salesforce.com inc. and ExactTarget, Inc. (No. 15-1290); Chamber of Commerce of the United States of America (No. 15-1306); Consumer Bankers Association (No. 15-1304); Vibes Media, LLC (No. 15-1311); Rite Aid Hdqtrs. Corp. ("Rite Aid") (No. 15-1313); and Portfolio Recovery Associates (No. 15-1314).

2. The Respondents are the Federal Communications Commission ("Commission") and the United States of America.

3. The Intervenors for Petitioners are listed in the Petitioners' Joint Brief.

4. The entities participating as amicus curiae are listed in the Petitioners' Joint Brief.

B. Ruling Under Review.

The ruling under review is a Declaratory Ruling and Order of the Federal Communications Commission, released July 10, 2015, styled *In the Matter of*

Rules & Regulations Implementing the Telephone Consumer Protection Act of 1991, Declaratory Ruling & Order, 30 FCC Rcd. 7961 (2015) ("*Order*").

C. Related Cases.

All petitions for review of the Commission's *Order* were consolidated in this Court pursuant to the lottery procedures contained in 28 U.S.C. § 2112(a). Rite Aid is not aware of any other pending challenge to the *Order*.

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Petitioner Rite Aid Hdqtrs. Corp. states that it is wholly owned by Rite Aid Corporation, a publicly-held company.

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GLOSSARY

FCC or Commission – Federal Communications Commission

FTC – Federal Trade Commission

HHS – Department of Health and Human Services

HIPAA – Health Insurance Portability and Accountability Act of 1996

TCPA – Telephone Consumer Protection Act of 1991

TSR – Telemarketing Sales Rule

JURISDICTIONAL STATEMENT

Rite Aid petitions for review of the *Order*, which the Court has jurisdiction to review under 47 U.S.C. § 402(a), 28 U.S.C. §§ 2342-2344, and 47 U.S.C. § 706.

STATUTES AND REGULATIONS

The Addendum contains relevant statutes and regulations.

STATEMENT OF THE ISSUE

Whether the Commission improperly adopted TCPA compliance standards for HIPAA-protected telephone communications that vary based on the type of number called and the "exigency" and purpose of the call, where all of the calls are otherwise permissible under HIPAA.

INTRODUCTION

Rite Aid is one of the Nation's largest drugstore chains and cares for millions of patients through approximately 4,600 stores in over 30 States. It communicates with its patients via phone and text concerning, among other things, prescription refills and immunizations. Because Rite Aid cannot feasibly provide notifications to its patients individually through manual dialing, its communications are automated. These communications are lawful, advance important healthcare policy imperatives, and are beneficial to and appreciated by Rite Aid's patients.

But like other healthcare providers, Rite Aid's communications have become the target of abusive litigation alleging violations of the Telephone

Consumer Protection Act of 1991 – a.k.a., the "TCPA" – and threatening staggering statutory damages.[2] Accordingly, it sought clarification from the Commission that its communications do not trigger TCPA liability – as seemed clear from existing regulations. But clarity did not come. Instead, the Commission adopted a patchwork of standards for healthcare communications that will sow confusion, fuel more litigation against providers, and chill communications uniformly recognized to improve clinical outcomes and public health.

STATEMENT OF THE CASE

1. Federal law and policy foster automated communications of healthcare information to patients to improve public health. 42 U.S.C. §§ 1320d *et seq.*; 45 C.F.R. §§ 160.101 *et seq.*; Pub. L. No. 108–173, 117 Stat. 2066 (2003). As multiple responsible federal agencies have concluded, and numerous clinical studies confirm, such communications – from appointment reminders to prescription refill notifications – empower patients and improve clinical outcomes.[3]

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[2] *Brady* v. *CVS Pharmacy, Inc. et al.*, No. 15-cv-529 (M.D. La. filed Aug. 11, 2015); *Ondo* v. *Wal-Mart Stores, Inc.*, No. 15-cv-01003-CEM-GJK (M.D. Fla. filed June 18, 2015); *Zani* v. *Rite Aid Hdqtrs. Corp.*, No. 14-cv-09701-AJN (S.D.N.Y. filed Dec. 9, 2014); *Rooney* v. *Rite Aid Hdqtrs. Corp.*, No. 3:14-cv-01249-JAH-NLS (S.D. Cal. filed May 20, 2014); *Kolinek* v. *Walgreen Co.*, No. 13-cv-4806 (N.D. Ill. filed July 3, 2013).

[3] Federal programs aim to improve healthcare outcomes through mobile outreach. Text4baby.org/index.php/about; smokefree.gov/health-care-professionals; http://www.cdc.gov/mobile/registration; *see also* Kati Kannisto, et al., *Use of Mobile Phone Text Message Reminders in Health Care Services: A Narrative*
(footnote continued)

These communications are regulated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Department of Health and Human Services' implementing regulations. 42 U.S.C. § 1302(a); 45 C.F.R. §§ 164.502; .506. A "major goal" of HIPAA is to "allow[ ] the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being." *In the Matter of Rules & Regulations Implementing the Tel. Consumer Prot. Act of 1991*, 27 FCC Rcd. 1830, 1852 n.164 (2012). Indeed, "HIPAA regulations cover *all* communications regarding protected health information and all means of communication regarding such information." *Id.* at 1854 (emphasis added). HIPAA communications by a "covered entity" like Rite Aid regarding treatment or healthcare products are defined as "health care operation[s]." 42 U.S.C. § 17936(a)(1); 45 C.F.R. §§ 164.501; .502(a)(1)(ii). HIPAA specifically exempts these communications from its definition of "marketing." 45 C.F.R. § 164.501.

2. The TCPA is intended to restrict certain calling practices, not further regulate HIPAA-protected communications. Thus, while the TCPA prohibits automated calls to residential and wireless numbers without the called party's

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Literature Review, 16(10):e222 J. MED. INTERNET RES. (2014), *at* http://www.jmir.org/2014/10/e222; Stockwell, Melissa S., et al., *Text Message Reminders for Second Dose of Influenza Vaccine: A Randomized Controlled Trial*, 135(1) PEDIATRICS e83-e91 (2015).

consent, 47 U.S.C. § 227(b)(1)(A)(iii) & (b)(1)(B), the statute does not erect a "barrier" to – let alone *punish* – "normal, expected or desired communications." H.R. Rep. No. 102-317, at 17 (1991).

Indeed, Congress excluded certain kinds of communications entirely from the statute's purview, including a "broad" category of calls "made for emergency purposes." 47 U.S.C. § 227(b)(1)(A); *In the Matter of Rules & Regulations Implementing the Tel. Consumer Prot. Act of 1991*, 7 FCC Rcd. 8752, 8778 (1992). This exclusion encompasses any calls "affecting the health and safety of consumers." 47 C.F.R. § 64.1200(f)(4); *In the Matter of the Tel. Consumer Prot. Act of 1991*, 7 FCC Rcd. 2736, 2745 (1992). Congress also authorized the Commission to exempt other communications. 47 U.S.C. § 227(b)(2)(B)-(C).

3. The Commission, like the Federal Trade Commission ("FTC") exercising parallel authority,[4] previously adopted a "hands-off" policy towards HIPAA-protected communications. The Commission exempted from TCPA consent requirements calls that "deliver[ ] a 'health care' message made by, or on behalf of, a 'covered entity' or its 'business associate,' as those terms are defined in the HIPAA Privacy Rule." 47 C.F.R. § 64.1200(a)(2) & (a)(3)(v). On their

[4] The FTC exempted all HIPAA calls. 16 C.F.R. § 310.4 (b)(1)(v)(D); 73 Fed. Reg. 51164-01, 51192 (Aug. 29, 2008). The Commission must "maximize consistency" with the FTC's regulations. Pub. L. No. 108–10, § 3, 117 Stat. 557, 557 (2003).

face, the Commission's regulations – just like the FTC's – exempt HIPAA-protected calls to residential *and* wireless numbers.[5]

The Commission's exemption made perfect sense because calls subject to HIPAA "communicate health care-related information" and are not "unsolicited advertisements." 27 FCC Rcd. at 1856. As the basis for its exemption, the FCC adopted a number of technology-agnostic justifications:

- HIPAA-protected calls are "regulated extensively" and HIPAA "safeguard[s] consumer privacy" through its own enforcement mechanism;
- Additional regulation "could frustrate" HIPAA and "other federal statutes governing" healthcare programs;
- Exemption "ensure[s] continued consumer access to" healthcare information; and
- There is little incentive for "abusive" provider calls.

Id. at 1853-54. The Commission and FTC's respective exemptions covered notifications like "reminders of check-ups, immunizations, or health screenings." 73 Fed. Reg. at 51192; *see* 27 FCC Rcd. at 1855 n.192.

[5] Notwithstanding the plain language of the Commission's regulations, there exists substantial confusion whether the exemption applies to wireless calls. Public Notice, 29 FCC Rcd. 15267, 15267 n.7 (2015).

4. The Commission revisited its TCPA regulations last year against a backdrop of "skyrocketing" wireless phone use[6] and "increasing" class action litigation against legitimate businesses. *Order*, ¶¶6-7. As part of this effort, it adopted different rules applicable to different kinds of healthcare communications, depending on their form and content:

- HIPAA-protected residential calls do not require consent;
- HIPAA-protected wireless calls require prior express consent; and
- Wireless calls that have an "exigen[t] . . . healthcare treatment purpose" and are not charged to the called party do not require consent. *Id.* ¶146.

The Commission did not explain why the same HIPAA-protected communications to different numbers are treated differently or cite record support justifying the different treatment. Nor did it address its own recognition in the *Order* and elsewhere that wireless telephones are increasingly substituting for residential ones, or the importance of mobile telephones for delivering healthcare

[6] *In the Matter of Implementation of Section 6002(b) of the Omnibus Budget Reconciliation Act of 1993: Annual Report & Analysis of Competitive Market Conditions With Respect to Mobile Wireless, Including Commercial Mobile Services*, 29 FCC Rcd. 15311, at *27 (2014); Centers for Disease Control and Prevention, *Wireless Substitution: Early Release of Estimates From the National Health Interview Survey, July–December 2014*, http://www.cdc.gov/nchs/data/nhis/earlyrelease/wireless201506.pdf.

information to underserved populations. *Id.* ¶¶143-146. The Commission expressly declined to address the issue. *Id.* ¶141 n.471.

As the basis for its new exemption, the Commission offered that not all of the calls sought to be exempted are "critical to a called party's healthcare." *Id.* ¶146. It did not define the key terms or scope of the exemption, but offered a non-exhaustive list of calls that "would likely" be exempt. *Id.* ¶146 & n.490.

Two Commissioners dissented, noting the *Order* would encourage abusive litigation and chill healthcare communications. *Id.* at 8072-73; 8084-86.

SUMMARY OF ARGUMENT

The Commission implemented a statute intended to curb certain calling practices in a way that interferes with and undermines protected non-telemarketing communications that further core national healthcare policy objectives. The confusing patchwork of regulations governing HIPAA-protected communications to patients by telephone is supported by no rational explanation or record evidence, conflicts with HIPAA and the agency's existing regulations, and departs from its sound prior hands-off policy. The Commission exceeded its jurisdiction in restricting HIPAA-protected communications to wireless devices and its new

regulations will fuel more abusive litigation against providers and chill beneficial patient communications.[7]

STANDING

Rite Aid participated in the proceedings culminating in the *Order*. The *Order* impedes its patient communications and vacatur of the *Order* would redress that harm. *Massachusetts* v. *EPA*, 549 U.S. 497, 517 (2007).

ARGUMENT

I. THE COMMISSION IMPROPERLY ADOPTED DIFFERENT STANDARDS FOR THE SAME BENEFICIAL HIPAA-PROTECTED COMMUNICATIONS.

1. Just a few short years ago, the Commission exempted HIPAA-protected communications from consent requirements based on sound policy justifications. This exemption was enshrined in its regulations. 47 C.F.R. § 64.1200(a)(2) & (a)(3)(v). But now, the Commission installed three different standards for the same HIPAA-protected communications based on the telephone number called. In doing so, it overlooked the plain, and controlling, language of its existing regulations. 47 C.F.R. § 64.1200(a)(2) & (a)(3)(v). This alone is fatal. *S. California Edison Co.* v. *FERC*, 195 F.3d 17, 28 (D.C. Cir. 1999).

But the Commission offered no explanation – none – for its departure from the justifications supporting its earlier exemption either. While the Commission is

[7] Rite Aid supports Joint Petitioners' arguments.

entitled to change course, it must acknowledge and explain the change. *FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). The Commission did not do that here; it did not purport to revisit its hands-off policy. It offered no explanation why the technology-agnostic rationales that supported its earlier exemption of HIPAA-protected calls did not apply equally to all wireless calls (especially given its recognition they are substituting for residential lines), or why an exemption applied only to "exigent" calls for "healthcare treatment purposes" where the called party is not charged. This was not a "tolerably terse" "swerve from prior precedent[ ]"; rather, in the face of "inconvenient precedent," the Commission stood "intolerably mute." *Jicarilla Apache Nation* v. *U.S. Dep't of Interior*, 613 F.3d 1112, 1120 (D.C. Cir. 2010). This "*sub silentio*" departure is arbitrary and capricious. *Fox*, 556 U.S. at 515.

2. Even on its own terms, the Commission's new regime for HIPAA-protected communications is not supported by any reasonable explanation or evidence. *Order*, ¶¶143-146. The Commission's rationale for exempting HIPAA calls was based on the type of call, not the type of number called. 27 FCC Rcd. at 1853. Yet, the Commission offered no reason or record support for subjecting wireless calls to requirements different from residential calls. *Order*, ¶¶143-146.

The record shows there is no basis for any formalistic distinction: There are important reasons for treating residential and wireless telephone lines the same

when it comes to delivering healthcare information. Mobile phone use has grown dramatically and these devices substitute for residential lines. *Id.* ¶7. Wireless lines are also critical for reaching underserved populations.[8]

Nor did the Commission consider whether HIPAA-protected communications—whether to residential or wireless numbers—are even subject to regulation under the TCPA. But the statute clearly excludes calls for "emergency purposes." 47 U.S.C. § 227(b)(1)(A)-(B). HIPAA-protected communications qualify for this exemption under the Commission's regulations. 47 C.F.R. § 64.1200(a)(1)-(3). The Commission's refusal even to consider this issue is particularly glaring given its obligation to "maximize consistency" with the FTC's exemption of all healthcare calls.[9] 16 C.F.R. § 310.4(b)(1)(v)(D); 73 Fed. Reg. 51164-01, 51189-92. The Commission's determination to treat HIPAA-protected communications to residential and wireless lines differently is irrational, unsupported, and unlawful. 5 U.S.C. § 706(2)(E); *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

3. Nowhere is the irrationality of the Commission's new regime for healthcare communications on greater display than with its newly-minted but ill-defined exigent healthcare treatment purpose exemption. It does not define any of

[8] *Supra* note 3.

[9] Nor did it consider exercising its "forbearance" authority to ensure regulatory parity for healthcare communications. 47 U.S.C. § 160(c).

the exemption's critical terms. Nor does it articulate the exemption's parameters beyond offering the cold comfort of a partial list of calls that "would likely"—not *do*—fit the exemption. *Order*, ¶146 n.490. Worse still, the Commission's exemption conflicts with HIPAA's definition of "health care," which is not keyed to "exigency" and encompasses *all* calls concerning "care, services, or supplies related to the health of an individual." 45 C.F.R. § 160.103.

The Commission does not even explain from whence its new "exigency" requirement springs. To be sure, it is not the record, or the Commission's healthcare expertise. The Commission's supposition that only *some* healthcare messages are critical to a person's well-being finds no roots in its expert judgement, record evidence, or the TCPA. *Order*, ¶146. The TCPA does not require any "exigency" finding to exempt a class of calls. 47 U.S.C. § 227(b)(2)(B)-(C). Nor is the Commission's existing exemption for healthcare calls, and the underlying rationales for it, tied to exigency. 47 C.F.R. § 64.1200(a)(2) & (a)(3)(v); 27 FCC Rcd. at 1852-56. The Commission's exemption makes no sense, is unworkable, and should be set aside. *State Farm*, 463 U.S. at 43; 5 U.S.C. § 706(2)(C) & (E).

4. The TCPA does not empower the Commission to restrict HIPAA calls and it cannot interpret the TCPA in conflict with HIPAA. *Scheduled Airlines Traffic Offices, Inc.* v. *Dept. of Def.*, 87 F.3d 1356, 1361 (D.C. Cir. 1996); *Yukon-*

Kuskokwim Health Corp. v. *NLRB*, 234 F.3d 714, 718 (D.C. Cir. 2000). But that is just what the Commission did. HIPAA does not restrict calls based on the type of number dialed and does not limit calls to those that are "exigent" or for "treatment purpose[s]." 45 C.F.R. §§ 164.501; .502(a)(1)(ii); .506(a). By restricting otherwise permissible HIPAA communications, the Commission acted unlawfully and in excess of its authority and, in effect, exposed providers to liability for communications otherwise protected by HIPAA. It is the Federal *Communications* – not *Healthcare* – Commission and it does not have "untrammelled freedom to regulate." *Nat'l Ass'n of Regulatory Util. Comm'rs* v. *FCC*, 533 F.2d 601, 617 (D.C. Cir. 1976). And because the Commission's regulation "conflicts with another federal law," the Court should "invalidate" it. *NextWave Pers. Commc'ns, Inc.* v. *FCC*, 254 F.3d 130, 149 (D.C. Cir. 2001).

5. The high stakes of misdials only make matters worse for providers that must comply with the Commission's crazy-quilt regulations. The TCPA affords steep penalties, and legitimate businesses are increasingly in the cross-hairs of plaintiffs' counsel. 47 U.S.C. § 227(b)(3); *Order*, ¶6; *id.* at 8072-73. Retail pharmacies' patient communications have indeed been widely targeted. By subjecting HIPAA-protected communications to different compliance standards and exposing providers to TCPA liability for making them, the Commission has

exacerbated this problem and inadvertently chilled beneficial patient communications.

CONCLUSION

The Court should grant Rite Aid's Petition.

Respectfully Submitted,

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February 24, 2016

CERTIFICATE OF COMPLIANCE

1. This brief complies with the Court's Order of October 13, 2015, setting forth the briefing schedule for this case, because it contains 2,500 words, excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii) of the Federal Rules of Appellate Procedure and Circuit Rule 32(e)(1).

2. This brief complies with the typeface requirements of Rule 32(a)(5) of the Federal Rules of Appellate Procedures and the type style requirements of Rule 32(a)(6) of the Federal Rules of Appellate Procedures, because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point font and Times New Roman type style.

/s/ Paul Werner
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ADDENDUM

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42 U.S.C. § 17936(a)(1)

(a) Marketing

(1) In general

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 for purposes of subpart E of part 164 of title 45, Code of Federal Regulations, unless the communication is made as described in subparagraph (i), (ii), or (iii) of paragraph (1) of the definition of marketing in section 164.501 of such title.

47 U.S.C. § 227(b)

(b) Restrictions on use of automated telephone equipment

(1) Prohibitions

It shall be unlawful for any person within the United States, or any person outside the United States if the recipient is within the United States--

(A) to make any call (other than a call made for emergency purposes or made with the prior express consent of the called party) using any automatic telephone dialing system or an artificial or prerecorded voice--

(i) to any emergency telephone line (including any "911" line and any emergency line of a hospital, medical physician or service office, health care facility, poison control center, or fire protection or law enforcement agency);

(ii) to the telephone line of any guest room or patient room of a hospital, health care facility, elderly home, or similar establishment; or

(iii) to any telephone number assigned to a paging service, cellular telephone service, specialized mobile radio service, or other radio common carrier service, or any service for which the called party is charged for the call;

(B) to initiate any telephone call to any residential telephone line using an artificial or prerecorded voice to deliver a message without the prior express consent of the called party, unless the call is initiated for emergency purposes or is exempted by rule or order by the Commission under paragraph (2)(B);

* * *

(2) Regulations; exemptions and other provisions

The Commission shall prescribe regulations to implement the requirements of this subsection. In implementing the requirements of this subsection, the Commission--

(A) shall consider prescribing regulations to allow businesses to avoid receiving calls made using an artificial or prerecorded voice to which they have not given their prior express consent;

(B) may, by rule or order, exempt from the requirements of paragraph (1)(B) of this subsection, subject to such conditions as the Commission may prescribe--

(i) calls that are not made for a commercial purpose; and

(ii) such classes or categories of calls made for commercial purposes as the Commission determines--

(I) will not adversely affect the privacy rights that this section is intended to protect; and

(II) do not include the transmission of any unsolicited advertisement;

(C) may, by rule or order, exempt from the requirements of paragraph (1)(A)(iii) of this subsection calls to a telephone number assigned to a cellular telephone service that are not charged to the called party, subject to such conditions as the Commission may prescribe as necessary in the interest of the privacy rights this section is intended to protect;

* * *

16 C.F.R. § 310.4(b)

(b) Pattern of calls.

(1) It is an abusive telemarketing act or practice and a violation of this Rule for a telemarketer to engage in, or for a seller to cause a telemarketer to engage in, the following conduct:

* * *

((v) Initiating any outbound telephone call that delivers a prerecorded message, other than a prerecorded message permitted for compliance with the call abandonment safe harbor in § 310.4(b)(4)(iii), unless:

* * *

(D) This paragraph (v) shall not apply to any outbound telephone call that delivers a prerecorded healthcare message made by, or on behalf of, a covered entity or its business associate, as those terms are defined in the HIPAA Privacy Rule, 45 CFR 160.103.

45 C.F.R. § 160.103

Except as otherwise provided, the following definitions apply to this subchapter:

* * *

Health care means care, services, or supplies related to the health of an individual. Health care includes, but is not limited to, the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

45 C.F.R. § 164.501

As used in this subpart, the following terms have the following meanings:

* * *

Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined in 42 CFR 3.20); 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;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;

(3) Except as prohibited under § 164.502(a)(5)(i), underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of § 164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.

* * *

Marketing:

(1) Except as provided in paragraph (2) of this definition, marketing means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

(2) Marketing does not include a communication made:

(i) To provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual, 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.

(ii) For the following treatment and health care operations purposes, except where the covered entity receives financial remuneration in exchange for making the communication:

(A) For treatment of an individual by a health care provider, including 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;

(B) 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; or

(C) For case management or care coordination, contacting of individuals with information about treatment alternatives, and related functions to the extent these activities do not fall within the definition of treatment.

(3) Financial remuneration 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.

Payment means:

(1) The activities undertaken by:

(i) Except as prohibited under § 164.502(a)(5)(i), a health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or

(ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to:

(i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth;

(C) Social security number;

(D) Payment history;

(E) Account number; and

(F) Name and address of the health care provider and/or health plan.

45 C.F.R. § 164.502

(a) Standard. A covered entity or business associate may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) Covered entities: Permitted uses and disclosures. A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of §§ 164.502(b), 164.514(d), and 164.530(c) with respect to such otherwise permitted or required use or disclosure;

(iv) Except for uses and disclosures prohibited under § 164.502(a)(5)(i), pursuant to and in compliance with a valid authorization under § 164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and

(vi) As permitted by and in compliance with this section, § 164.512, § 164.514(e), (f), or (g).

* * *

45 C.F.R. § 164.506

(a) Standard: Permitted uses and disclosures. Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) through (4) or that are prohibited under § 164.502(a)(5)(i), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(b) Standard: Consent for uses and disclosures permitted.

(1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.

(2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under § 164.508, is required or when another condition must be met for such use or disclosure to be permissible under this subpart.

(c) Implementation specifications: Treatment, payment, or health care operations.

(1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to other participants in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

47 C.F.R. § 64.1200(a)

(a) No person or entity may:

(1) Except as provided in paragraph (a)(2) of this section, initiate any telephone call (other than a call made for emergency purposes or is made with the prior express consent of the called party) using an automatic telephone dialing system or an artificial or prerecorded voice;

(i) To any emergency telephone line, including any 911 line and any emergency line of a hospital, medical physician or service office, health care facility, poison control center, or fire protection or law enforcement agency;

(ii) To the telephone line of any guest room or patient room of a hospital, health care facility, elderly home, or similar establishment; or

(iii) To any telephone number assigned to a paging service, cellular telephone service, specialized mobile radio service, or other radio common carrier service, or any service for which the called party is charged for the call.

(iv) A person will not be liable for violating the prohibition in paragraph (a)(1)(iii) of this section when the call is placed to a wireless number that has been ported from wireline service and such call is a voice call; not knowingly made to a wireless number; and made within 15 days of the porting of the number from wireline to wireless service, provided the number is not already on the national do-not-call registry or caller's company-specific do-not-call list.

(2) Initiate, or cause to be initiated, any telephone call that includes or introduces an advertisement or constitutes telemarketing, using an automatic telephone dialing system or an artificial or prerecorded voice, to any of the lines or telephone numbers described in paragraphs (a)(1)(i) through (iii) of this section, other than a call made with the prior express written consent of the called party or the prior express consent of the called party when the call is made by or on behalf of a tax-exempt nonprofit organization, or a call that delivers a “health care” message made by, or on behalf of, a “covered entity” or its “business associate,” as those terms are defined in the HIPAA Privacy Rule, 45 CFR 160.103.

(3) Initiate any telephone call to any residential line using an artificial or prerecorded voice to deliver a message without the prior express written consent of the called party, unless the call;

(i) Is made for emergency purposes;

(ii) Is not made for a commercial purpose;

(iii) Is made for a commercial purpose but does not include or introduce an advertisement or constitute telemarketing;

(iv) Is made by or on behalf of a tax-exempt nonprofit organization; or

(v) Delivers a "health care" message made by, or on behalf of, a "covered entity" or its "business associate," as those terms are defined in the HIPAA Privacy Rule, 45 CFR 160.103.

47 C.F.R. § 64.1200(f)(4)

The term emergency purposes means calls made necessary in any situation affecting the health and safety of consumers.

CERTIFICATE OF SERVICE

I hereby certify that on February 24, 2016, I caused to be electronically filed the foregoing Brief for Petitioner with the Clerk of the Court for the U.S. Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. All participants are registered CM/ECF users, and will be served by the CM/ECF system.

/s/ Paul Werner
Paul Werner
Counsel for Petitioner Rite Aid Hdqtrs. Corp.