

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**

REPLY BRIEF FOR PETITIONER RITE AID HDQTRS. CORP.

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GLOSSARY

<i>2012 Order</i>	<i>In the Matter of Rules & Regulations Implementing the Tel. Consumer Prot. Act of 1991, Report & Order, 27 FCC Rcd. 1830 (2012)</i>
Commission	Federal Communications Commission
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH Act	Health Information Technology for Economic and Clinical Health Act
<i>Order</i>	<i>In the Matter of Rules & Regulations Implementing the Tel. Consumer Prot. Act of 1991, Declaratory Ruling & Order, 30 FCC Rcd. 7961 (2015)</i>
TCPA	Telephone Consumer Protection Act of 1991

ARGUMENT

The Commission mistakes Rite Aid's challenge. Rite Aid is not seeking an exemption for "non-treatment telemarketing" calls – whatever that term may mean. Br. 68. It argues the Commission unlawfully bent a generic call statute to impose a confusing patchwork of regulations on healthcare communications that are protected and promoted by federal law and policy to the detriment of providers, patients, and public health. The Commission's overreach is backed by no rational justification (it conflicts with its prior sound regulation) or record evidence (which supports "hands off" treatment of HIPAA-protected communications), and is compelled by no statutory mandate (the TCPA permits exclusion of HIPAA-protected communications). If the Commission's crazy-quilt regulations of HIPAA-protected calls stand, they will create a deeper compliance quagmire, spark more litigation against legitimate providers, and impede lawful communications that benefit patients and improve clinical outcomes. The Commission's efforts to prop up its regulations on brief fall short.

1. The Commission thinks it is free under the TCPA to layer additional regulations on communications extensively regulated under HIPAA because they are "separate statutes that serve different purposes." Br. 72. But HIPAA strikes a careful balance between the privacy needs of patients and ensuring the flow of information necessary to promote high quality healthcare and protect the public's

health and well-being. 67 Fed. Reg. at 53182-83. HIPAA’s Privacy Rule regulates *all* communications between providers and patients and is carefully calibrated to “avoid interfering with, or unnecessarily burdening communications about, treatment or about the benefits and services of health plans and health care providers.” *Id.* at 53183; 65 Fed. Reg. at 82462-01. This is not news to the Commission: “HIPAA regulations cover *all* communications regarding protected health information and *all* means of communication regarding such information.” 2012 Order, ¶ 61 (emphases added).

2. The Commission nevertheless justifies its attempt to further burden HIPAA-protected communications by arguing HIPAA does not “supersede” the TCPA. Not so. Both HIPAA and the HITECH Act¹ were enacted *after* the TCPA and *supersede* the TCPA when it comes to regulating the flow of healthcare information. The Commission cannot use a blunt instrument – the TCPA – to curb healthcare communications already regulated using a finer statutory tool – HIPAA. *Crawford Fitting Co. v. J. T. Gibbons, Inc.*, 482 U.S. 437, 445 (1987) (“[A] specific statute will not be controlled or nullified by a general one.”).

The Commission misses the bigger problem too: Its regulations *conflict* with HIPAA, forcing providers to face the Hobson’s choice of complying with HIPAA

¹ The HITECH Act expanded HIPAA’s protections. 78 Fed. Reg. at 5566.

or coming within the cross-hairs of TCPA litigation bounty hunters.² Covered entities (which include retail pharmacies) may undertake a host of health-related communications without authorization because they are not “marketing” – and therefore not “telemarketing” when made by phone. 45 C.F.R. § 164.501. These communications include those made for:

- treatment purposes;
- describing health-related products or services (including payment options); and
- case management. *Id.*

According to HHS, the expert agency charged with implementing federal healthcare law and policy, these exemptions “facilitate . . . communications that enhance the individual’s access to quality healthcare.” 67 Fed. Reg. at 53186.

But the Commission restricted these communications to wireless lines to those that are “exigent” and serve a “healthcare-treatment purpose.” It defined neither critical term (nor is it qualified to do so) and its exemption breaks from HHS’s definition of “healthcare” and frustrates the very communications HHS

² This argument is properly before the Court. *Appalachian Power Co. v. EPA*, 135 F.3d 791, 818 (D.C. Cir. 1998). Rite Aid and others made arguments below about HIPAA and the need to defer to HHS. AAHAM Pet. 2-4 & 10; Rite Aid Comments 2 & nn.9 & 15. The Commission considered calls “subject to HIPAA” and analyzed the statute’s applicability. *Order*, ¶146 & n.472-73.

sought to “enhance.” 45 C.F.R. § 160.103. Its exemption blocks lawful communications, concerning, among other things:

- Physician referrals;
- Alternative medications and treatment;
- Available services and products;
- Drug interactions and medication restrictions;
- Case management;
- Preventive screenings;
- Refill-reminders; and
- Immunizations and flu shots.

45 C.F.R. § 164.501; 42 U.S.C. § 17936(a)(1).

The Commission is wrong that “the fact that some alleged ‘non-treatment’ calls are covered by HIPAA [does not] mean that the TCPA must treat them the same as healthcare-treatment calls.” Br. 70-71. It has no expertise or authority to regulate what constitutes “healthcare treatment” and “non-treatment” – invented terms with no fixed meaning – and it cannot exercise its TCPA authority to restrict HIPAA-protected communications and stymie healthcare policy imperatives.

NextWave Pers. Commc’ns, Inc. v. FCC, 254 F.3d 130, 149 (D.C. Cir. 2001) (APA “requires [court] to invalidate agency action not only if it conflicts with an agency’s own statute, but also if it conflicts with another federal law.”); *Murphy*

Expl. & Prod. Co. v. U.S. Dep't of the Interior, 252 F.3d 473, 479 (D.C. Cir. 2001) (“[I]f an agency has promulgated a regulation outside the scope of its specialized knowledge, courts will not defer to it.”). The Commission’s foray into healthcare regulation is misguided and will impede beneficial communications, create a compliance morass for providers, and encourage abusive litigation.

3. The Commission’s regulation of HIPAA-protected communications is an unlawful jurisdictional frolic and detour. And its dabbling in healthcare is unreasonable on its own terms given its prior “hands off” policy, an administrative record that does not support additional regulation, and an *Order* with nary a word of justification for such regulation. While the Commission argues its regulations reflect no “unexplained change,” in 2012 it offered robust justifications for exempting HIPAA-protected communications from TCPA regulation. Those justifications were rooted in HIPAA’s protections, not the type of call. *2012 Order*, ¶¶60-61. The Court will search the *Order* in vain for any hint why those sound reasons do not apply equally to wireless calls. *Order*, ¶¶143-46. The record makes clear they do. NACDS Comments 7-8.

The Commission’s explanations on brief do not hold up. It plainly adopted a “narrower” wireless call exemption. 47 C.F.R. §§ 64.1200(a)(2) & (3)(v). It cannot fall back on the statute to defend that exemption; it does not – and cannot –

assert the TCPA precludes equal treatment of HIPAA-protected communications.³ 47 U.S.C. §§ 227(b)(1)(A)(iii) & (b)(1)(B). And it cannot defend the *Order* with post-hoc suppositions about differences between wireless and wireline calls. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983) (“[T]he courts may not accept appellate counsel’s post hoc rationalizations for agency action.”).⁴

The Commission’s assertion that it cannot be unreasonable to distinguish between “healthcare-treatment purpose” calls and “telemarketing” makes no sense and misses the point. Br. 70. It never explained why *all* HIPAA-protected communications are not “healthcare-treatment purpose” calls and not “telemarketing” or why such communications to wireline and wireless numbers should be regulated differently. These critical conclusions find no support in the Commission’s expert judgment, the record, the TCPA, its own policy pronouncements, or common sense.

³ The “emergency purposes” exclusion was raised below. NCLC letter 4-5; Owens Reply Comments 2-3. The Commission necessarily had to consider it to bring HIPAA-protected calls within the TCPA, and Rite Aid’s point is that the statute permits equal treatment of such calls.

⁴ Rite Aid has standing as a “party” aggrieved by the *Order* because it participated in the rulemaking. 28 U.S.C. § 2344; *S. Pac. Transp. Co. v. ICC*, 69 F.3d 583, 587 (D.C. Cir. 1995). It also will suffer actual injury since the *Order* restricts its calls. 5 U.S.C. § 702; *Omnipoint Corp. v. FCC*, 78 F.3d 620, 628 (D.C. Cir. 1996).

CONCLUSION

The Court should grant the Petition.

Respectfully Submitted,

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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 1,250 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.

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ADDENDUM

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5 U.S.C. § 702

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.

* * *

28 U.S.C. § 2344

On the entry of a final order reviewable under this chapter, the agency shall promptly give notice thereof by service or publication in accordance with its rules. Any party aggrieved by the final order may, within 60 days after its entry, file a petition to review the order in the court of appeals wherein venue lies. The action shall be against the United States. The petition shall contain a concise statement of-

- (1) the nature of the proceedings as to which review is sought;
- (2) the facts on which venue is based;
- (3) the grounds on which relief is sought; and
- (4) the relief prayed.

The petitioner shall attach to the petition, as exhibits, copies of the order, report, or decision of the agency. The clerk shall serve a true copy of the petition on the agency and on the Attorney General by registered mail, with request for a return receipt.

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;

* * *

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:

* * *

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.

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.

CERTIFICATE OF SERVICE

I hereby certify that on February 16, 2016, I caused to be electronically filed the foregoing Reply 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

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