

2. The Association of American Physicians & Surgeons, Inc. (“AAPS”) and the individual plaintiffs hereby challenge the constitutionality of the Privacy Regulations in requiring physicians to facilitate violations of the Fourth Amendment prohibition against unreasonable searches and seizures. The Privacy Regulations expressly reiterate the traditional expectation of privacy by patients in their medical records. 65 Fed. Reg. at 82464 (“need for security in [Fourth Amendment] ‘papers and effects’ underscores the importance of protecting information about the person, contained in sources such as ... medical records”). But the Privacy Regulations simultaneously allow government virtually unrestricted access to those same records without a warrant. 45 C.F.R. §§ 160.310(c), 164.502(a)(2)(ii), 164.502(b)(2)(iii),(iv). The Privacy Regulations require physicians to aid and abet governmental searches of patient medical records in violation of the Fourth Amendment rights of the patient. 45 C.F.R. §§ 164.502(a), 164.512. The Privacy Regulations also facilitate the construction of a centralized database by government of personal medical records with unique individual identifiers, without patient consent. 45 C.F.R. §§ 164.510, 164.512, 164.514.

3. Plaintiffs also challenge the chilling effect of the Privacy Regulations on patient-physician communications. Government access to these communications without a warrant and without informed, voluntary patient consent interferes with the patient’s right to make full and thorough explanations to the physician in connection with the treatment. The Privacy Regulations contradict the professional Oath of Hippocrates and are in violation of the First Amendment rights of the patient and physician to speak confidentially about the treatment.

4. Plaintiffs challenge the intrusion of the Privacy Regulations into purely

intrastate activities involving a physician and patient. The Privacy Regulations dictate the physician's maintenance and use of medical records, and the patient access to his or her own medical records, in situations that lack any nexus to interstate commerce. 45 C.F.R. §§ 160-64. The Privacy Regulations thereby disrupt traditional state law governing such confidential, intrastate activity, in violation of the Tenth Amendment. 45 C.F.R. §§ 160.202, 160.203; U.S. Const. Amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.").

5. The Privacy Regulations are unauthorized by HIPAA to the extent they extend beyond electronic transmissions. HIPAA limits the statutory authorization for these regulations to electronic transfers, but the Privacy Regulations extend far beyond that limitation. 45 C.F.R. § 164.502; 42 U.S.C. § 1320(d)-2.

6. The Privacy Regulations violate the Paperwork Reduction Act ("PRA"), 44 U.S.C. § 3501 et seq., and Regulatory Flexibility Act ("RFA"), 5 U.S.C. § 601 et seq., by failing to properly estimate the enormous regulatory burden that these regulations impose on small medical practices, and consider more cost-effective alternatives. 65 Fed. Reg. at 82779-795; 45 C.F.R. § 160.310.

7. Plaintiffs seek a declaratory judgment that the Privacy Regulations are unconstitutional to the extent (i) they allow government access to personal medical records without a warrant and chill patient-physician communications and (ii) intrude into purely intrastate activities concerning the maintenance of personal medical records.

8. Plaintiffs seek a declaratory judgment that the Privacy Regulations are in statutory violation of (i) the limited scope of HIPAA and (ii) the PRA and RFA.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this action under the Constitution of the United States and 28 U.S.C. §§ 1331, 1337, and has authority to grant the relief requested under 28 U.S.C. § 2201.

10. Venue is proper in the Southern District of Texas under 28 U.S.C. § 1391(e) because plaintiff AAPS has members here, plaintiff Rex resides here, and defendants are subject to venue here.

THE PARTIES

11. Plaintiff AAPS is a professional, non-profit association founded in 1943. It is organized and existing under the laws of the State of Indiana and has thousands of physician and patient members nationwide, including members in Houston, Texas. AAPS is one of the largest physician organizations which is solely membership funded. AAPS members are themselves patients in addition to being physicians, and AAPS asserts the claims herein on behalf of its members as both physicians and patients.

12. Congressman Ron Paul, M.D. is a member of the United States Congress and also a physician. He resides in Surfside, Texas.

13. Plaintiff Dawn Richardson is a patient who resides in Austin, Texas. She is President of Parents Requesting Open Vaccine Education (P.R.O.V.E.), a Texas-based non-profit association.

14. Plaintiff Rebecca Rex is a patient who resides in Houston, Texas. She is Vice President of P.R.O.V.E.

15. Plaintiff Darrell McCormick is a patient who resides in Gainesville, Florida. He is a former billing manager for about 500 physicians at the Shands

Healthcare System at the University of Florida in Gainesville, Florida.

16. Defendant HHS is the agency of the United States Government responsible for drafting and promulgating the relevant parts of 45 C.F.R. 160 and 164 pursuant to Public Law 104-191.

17. Defendant Tommy G. Thompson is the Secretary of the U.S. Department of Health and Human Services and is responsible for the administration of the relevant parts of 45 C.F.R. 160 and 164. Defendant Thompson is sued in his official capacity.

BACKGROUND

18. HIPAA includes a Section 264 that instructs HHS to provide “recommendations on standards with respect to the privacy of individually identifiable health information.” HIPAA envisioned Congressional enactment of privacy standards for the electronic transfer of health information based on the recommendations of HHS. 42 U.S.C. § 1320d-2, 42 U.S.C.A. § 1320d-2-note.

19. In the event Congress failed to act, Section 264 provided limited authorization to HHS to regulate electronically transferred health information in protection of patient privacy. 35 U.S.C. § 1320d-2. Section 264(c)(1) of HIPAA mandates that:

IN GENERAL.--If legislation governing standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act (as added by section 262) is not enacted by the date that is 36 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate final regulations containing such standards not later than the date that is 42 months after the date of the enactment of this Act. Such regulations shall address at least the subjects described in subsection (b).

42 U.S.C.A. § 1320d-2-note. Section 1173(a), entitled “Standards to Enable Electronic

Exchange,” mandates that the “Secretary shall adopt standards for transactions, and date elements for such transactions, to enable health information to be exchanged electronically” 42 U.S.C. § 1320d-2 (emphasis added).

20. Likewise, Section 261 of HIPAA states that the statute’s purpose is to improve the health care system by establishing standards and requirements for “the electronic transmission of certain health information.” 42 U.S.C.A. § 1320d-note (emphasis added).

21. Congress failed to enact privacy legislation pursuant to HIPAA, and HHS ultimately promulgated regulations effective April 14, 2001. These Privacy Regulations purport to protect a reasonable expectation of privacy traditionally enjoyed by patients under State law. 65 Fed. Reg. at 82464-68.

22. However, HHS’s Privacy Regulations go far beyond electronic transmissions. 45 C.F.R. §§ 164.500, 164.501 (“*Protected health information* means individually identifiable health information: . . . [t]ransmitted or maintained in any other form or medium.”). They also greatly reduce the privacy in medical records with respect to the government. 45 C.F.R. §§ 160.310(c); 164.502(a)(2)(ii), 164.512, 164.514. While the explanatory comments to the Privacy Regulations detail the need for privacy for medical records in a lengthy section entitled “The Importance of Privacy,” the Privacy Regulations fail to protect patients from intrusions by government. 65 Fed. Reg. at 82464-65; 45 C.F.R. § 164.512(d) (no procedural safeguards to protect patients’ privacy). Moreover, HHS failed to promulgate these Final Regulations within the time period specified above by HIPAA.

23. These Privacy Regulations provide the government with broad access to

highly personal medical records of patients, without a warrant. 45 C.F.R. §§ 160.310(c), 164.502. The Privacy Regulations authorize the government to disseminate such highly personal medical records as “otherwise required by law,” which could even include future FOIA-like laws or local disclosure laws. Id. §§ 160.310(c)(3), 164.501, 164.502. These medical records subject to government access without a warrant would often include highly sensitive patient-physician communications.

24. Although the HHS’s proposed regulations addressed only electronic transfers of information, its final Privacy Regulations regulate all documented patient-physician communications concerning identifiable health information. 65 Fed. Reg. at 82462–829. HHS acknowledged that their regulations extend beyond its Congressional authority as follows:

We proposed in the NPRM to apply the requirements of the rule to individually identifiable health information that is or has been electronically transmitted or maintained by a covered entity. ... In the final rule, we extend the scope of protections to all individually identifiable health information in any form, electronic or non-electronic, that is held or transmitted by a covered entity.

Id. at 82488.

25. HHS acknowledged that it purposely structured its definition of “protected health information” to “emphasize the severability of this provision. . . . We have structured the definition this way so that, if a court were to disagree with our view of our authority in this area, the rule would still be operational, albeit with respect to a more limited universe of information.” 65 Fed. Reg. at 82496.

26. The HHS Privacy Regulations go far beyond the scope of addressing the privacy of electronic communications governed by HIPAA to regulate all forms of speech involving individually identifiable health information. 45 C.F.R. §§ 164.501,

164.502. The HHS Privacy Regulations apply to all communications involving individually identifiable health information, whether or not the information is in electronic form. Id. § 164.501.

27. The Privacy Regulations apply to purely intrastate transactions and communications between physicians and their patients, and between physicians and other health care providers.

28. Plaintiff AAPS has physician members who have already expended time and money in order to comply with the new HHS Privacy Regulations. Plaintiff AAPS has physician members who will be subject to severe criminal and civil penalties for violations of the HIPAA Privacy Regulations. 42 U.S.C. § 1320d-5 (imposing fines of \$100 per occurrence up to \$25,000 per year for even accidental violations of the HHS Privacy Regulations); 42 U.S.C. § 1320d-6 (imposing fines of up to \$50,000, and imprisonment of up to one year, or both, on a person found in knowing violation of the HHS Privacy Regulations). Plaintiff AAPS has patient members who are already reluctant to provide information to their physicians due to the broad access to such information provided by the Privacy Regulations to the government. Plaintiff AAPS has members in California who are subject to that state's constitutional and statutory privacy protections, with which the Privacy Regulations conflict.

29. The individual plaintiffs are patients subjected by the Privacy Regulations to invasions of their privacy that are unconstitutional and in violation of HIPAA.

30. The effective date of April 14, 2001 for the HHS Privacy Regulations was nearly 56 months after the enactment of HIPAA and over one year after the delegation to HHS to promulgate final regulations expired under the express terms of Section 264(c)(1)

of HIPAA. 65 Fed. Reg. at 82470. The compliance date for initial implementation of the privacy standards for health care providers is April 14, 2003.

**FIRST CLAIM FOR RELIEF
(BASED ON FOURTH AMENDMENT)**

31. Plaintiffs incorporate herein all statements and allegations contained in paragraphs 1 through 30.

32. The Fourth Amendment protects patients and physicians against unreasonable searches and seizures. U.S. Const. Amend. IV (“the right of the people to be secure in their persons, houses, papers and effects, against unreasonable searches and seizures, shall not be violated”). The Privacy Regulations, however, provide government with broad access to the most personal information concerning medical treatment provided to patients, without a warrant. 45 C.F.R. §§ 160.310(c), 164.512(c). The Privacy Regulations require physicians to turn over to the government medical records in which patients and the physician have a reasonable expectation of privacy. 45 C.F.R. §§ 164.508(a)(2)(ii), 164.512. The Privacy Regulations promote construction of a centralized database of personal medical records through assignment of unique individual health identifiers (analogous to a social security number), without prior patient consent. 45 C.F.R. § 164.514(c). The Privacy Regulations even allow government to disseminate such highly personal information pursuant to other local, state or federal surveillance, database or disclosure laws. Id. §§ 160.310(c)(3), 164.502, 164.512. Finally, the Privacy Regulations prevent access by the patients themselves to disclosures about the extent of the disclosures. 45 C.F.R. § 164.528(a)(2). To the extent consent forms provided to patients as a condition for treatment disclose this governmental access without a warrant,

such consent is coercive and cannot constitute a valid waiver of Fourth Amendment rights. 45 C.F.R. § 164.508(b)(4)(ii).

33. Plaintiffs seek a declaratory judgment invalidating the Privacy Regulations to the extent they require physicians to facilitate Fourth Amendment violations of patient medical records, and subject patients to such privacy violations, without prior patient consent or a warrant. Plaintiffs also seek a declaratory judgment invalidating the Privacy Regulations to the extent they authorize the governmental construction of a centralized database of personal medical records with unique individual identifiers, without prior patient consent or a warrant, and to the extent they authorize the governmental dissemination of this personal information pursuant to other laws.

**SECOND CLAIM FOR RELIEF
(BASED ON FIRST AMENDMENT)**

34. Plaintiffs incorporate herein all statements and allegations contained in paragraphs 1 through 33.

35. The Privacy Regulations authorize governmental access to virtually all patient-physician communications without consent, a warrant, or a compelling state interest. These Regulations allow dissemination of the substance of those communications to others. Under the Privacy Regulations, patients can no longer communicate with their physicians in a truly privileged manner. The patient-physician privilege is of ancient origin, emphasized even in the Oath of Hippocrates in ancient Greece. The Privacy Regulations have a chilling effect on patients' speech to their physicians, physicians' speech to their patients, and the longstanding professional oath of physicians in violation of the First Amendment protection for free speech. U.S. Const. Amend. I.

36. Plaintiffs seek a declaratory judgment invalidating the Privacy Regulations to the extent they authorize government access to patient-physician communications without prior patient consent.

**THIRD CLAIM FOR RELIEF
(BASED ON FEDERALISM AND TENTH AMENDMENT)**

37. Plaintiffs incorporate herein all statements and allegations contained in paragraphs 1 through 36.

38. Personal activity that is purely *intrastate* in nature, such as maintaining confidential communications by patients to their town physician, is beyond the scope of federal power to regulate. Physician use of patient information in providing care is typically *intrastate* in nature and traditionally within the exclusive jurisdiction of state law. State and common law currently guarantee nearly immediate access by patients to their medical records, yet the Privacy Regulations purport to preempt state law for such purely intrastate activity and impose a lengthy 30-day delay on access by patients to their own medical records. 45 C.F.R. §§ 160.203, 164.524(b)(2); Florida Statute § 456.057(4) (requiring patient access to their own records “in a timely manner,” with the Florida Agency for Health Care Administration providing a toll-free number for patients who are delayed).

39. Access by patients to their own personal medical records when they volunteer for medical research is likewise within the province of state law for intrastate activity. The Privacy Regulations arbitrarily intrude on state law by denying access by patients to their own medical records if they once waived such access. 45 C.F.R. 164.524(a)(2)(iii). For intrastate medical treatment, patients’ access to their own medical records is governed by state, not federal, law.

40. Many States, such as California, have provisions governing the protection of privacy in medical records. Cal. Const. Art. I, Section I (“All people . . . have inalienable rights. Among these are enjoying and defending life and liberty, . . . and pursuing and obtaining safety, happiness, and privacy.”); Confidentiality of Medical Information Act, Civil Code § 56 et seq. In particular, California requires that “any waiver by a patient of the provisions of this part, except as authorized by Section 56.11 or 56.21 or subdivision (b) of Section 56.26 shall be deemed contrary to public policy and shall be unenforceable and void.” Id. § 56.37; see also id. § 56.20. The Privacy Regulations require physicians, including many members of AAPS, to allow certain governmental and third party access to medical records without patient consent, as referenced herein, in violation of applicable State law and the Tenth Amendment. The Privacy Regulations also subject patients to the same unconstitutional privacy invasions.

41. The Constitution of the State of Florida, where plaintiff McCormick resides, includes a Declaration of Rights. Its Section 23, entitled “Right to Privacy,” guarantees that: “Every natural person has the right to be let alone and free from government intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided in law.” The Privacy Regulations interfere with this right of Florida residents by allowing government access to medical records without patient consent and without protecting patient privacy.

42. Privacy and confidentiality between doctor and patient, and the practice of medicine generally, have been traditionally regulated by the states and that, by not legislating itself on the matter, Congress has failed to show that there is a substantial

adverse effect upon interstate commerce to justify federal regulation of privacy of medical records.

43. Plaintiffs seek a declaratory judgment invalidating the Privacy Regulations to the extent they regulate purely intrastate medical care and, in some cases, conflict with applicable State law.

**FOURTH CLAIM FOR RELIEF
(BASED ON HIPAA)**

44. Plaintiffs incorporate herein all statements and allegations contained in paragraphs 1 through 43.

45. Even though HIPAA only authorizes regulation of communications transmitted electronically, the HHS Privacy Regulations regulate the communication of any individually identifiable health information whether in electronic form or not. 42 U.S.C. § 1320d-2; 45 C.F.R. § 164.502. The HHS Privacy Regulations are thus unauthorized by the statutory context and purpose of HIPAA.

46. In addition, HIPAA does not authorize the temporary or permanent denial of access by patients to their own medical records. The Privacy Regulations allow health plans to withhold medical records from patients for at least 30 days, and medical records from certain patients who volunteered for medical research forever. 45 C.F.R. §§ 164.524(a)(2)(iii), 164.524(b)(2). Such denial of access is anticompetitive and overly protective of corporate interests at the expense of patients.

47. HHS failed to promulgate its final regulations with the proscribed 42 months of the enactment of HIPAA, missing the deadline by over a year. HHS did not continue to retain the statutory delegation of power by Congress beyond that period.

48. HIPAA mandated that “[t]he Secretary shall adopt standards for

transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for ... other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and **reducing administrative costs.**” 42 U.S.C. § 1320d-2 (emphasis added). Moreover, HIPAA requires that “[t]he Secretary shall adopt standards that ... take into account ... the needs and capabilities of small health care providers and rural health care providers” Id. The Privacy Regulations violate both of these requirements.

49. Plaintiffs seek a declaratory judgment invalidating the Privacy Regulations to the extent they regulate individually identifiable health information in non-electronic form, were not promulgated in final form within the time period expressly required by the statutory delegation, and increase administrative costs.

FIFTH CLAIM FOR RELIEF (BASED ON RFA AND PRA)

50. Plaintiffs incorporate herein all statements and allegations contained in paragraphs 1 through 49.

51. The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small businesses. The comments to the Privacy Regulations purport to address the RFA in Section V, entitled “Final Regulatory Flexibility Analysis.” 65 Fed. Reg. at 82779-793. Using a methodology that fails to recognize economies of scale unavailable to small businesses, Section V estimates a cost of compliance for small businesses of \$4,188 per establishment in the first year and approximately \$2,217 thereafter. Id. at 82789. However, the Privacy Regulations, even as underestimated, impose unjustified costs on small medical practices to the detriment of patients. The

Privacy Regulations are based on the baseless assertion that “[t]hese costs may be offset in many firms by the savings realized through requirements of the Transactions Rule.” Id. at 82789.

52. Similarly, the Paperwork Reduction Act (PRA) requires the government to estimate the impact on small businesses of new regulatory burdens. The Privacy Regulations, however, fail to comply with the PRA in a meaningful manner. 45 C.F.R. § 164.506 (“While this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).”).

53. One AAPS physician reasonably estimates his cost of compliance with the Privacy Regulations to include charges of \$8,000 for new computer hardware and \$5,000 to \$12,000 for new software. Moreover, there would be a cost of \$800 in seminar fees and another \$2,000 in lost revenue while attending the seminars. This overall cost of compliance would total between about \$16,000 and \$23,000 for the first year alone, and substantially more if an additional employee or consultant is necessary to manage the new software. The ongoing cost of maintaining the software would probably be another \$2,500 per year, plus further costs in attending seminars, hiring consultants, and otherwise keeping up with the inevitable revisions to the complex Privacy Regulations.

54. Plaintiffs seek a declaratory judgment invalidating the Privacy Regulations to the extent they impose regulatory burdens on physicians without a realistic assessment of the costs of those regulatory burdens, and without meaningful consideration of more cost-effective alternatives, for small medical practices.

Prayer For Relief

Wherefore, plaintiffs respectfully request a declaratory judgment that the Privacy Regulations:

(i) violate the Fourth Amendment to the extent they require physicians to allow government access to personal medical records without a warrant or patient consent, subject patients to such privacy invasions, and authorize governmental construction of a centralized database of personal medical records with unique individual identifiers;

(ii) violate the First Amendment to the extent they chill patient-physician communications by requiring them to be subject to warrantless review by government;

(iii) violate the Tenth Amendment to the extent they govern purely intrastate activities by physicians in using and maintaining medical records for patients;

(iv) violate HIPAA and lack statutory authorization to the extent they regulate medical records other than electronic transmissions, were not promulgated within the time period expressly required by Congress, and increase administrative costs;

(v) violate the Paperwork Reduction Act and the Regulatory Flexibility Act to the extent they impose an immense and unjustified regulatory burden on small medical practices; and

(vi) such other relief as the Court may deem appropriate, including attorneys' fees.

Respectfully submitted,

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