IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

SOUTH CAROLINA MEDICAL ASSOCIATION, PHYSICIANS CARE NETWORK, DR. J. CAPERS HIOTT, M.D., DR. JOHN R. ROSS, SR., M.D., DR. GORDON E. PENNEBAKER, M.D., DR. CAROL S. NICHOLS, M.D., DR. DANNETTE F. MCALHANEY, M.D., DR. HERBERT MOSKOW, M.D., AND LOUISIANA STATE MEDICAL SOCIETY	)
Plaintiffs,	)
vs.	)
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND TOMMY G. THOMPSON, AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES	)
Defendants.	)

Complaint for Declaratory Relief

Introduction

1. This case is a constitutional challenge to several provisions of Subtitle F, entitled "Administrative Simplification," found in Public Law 104-191, known as the Health Insurance Portability and Accountability Act ("HIPAA"), enacted by Congress on August 21, 1996. This case also challenges the regulations promulgated pursuant to HIPAA by the Department of Health and Human Services ("HHS") found at 45 C.F.R. Parts 160 and 164. The challenged

HHS regulations promulgated in Parts 160 and 164 and entitled "Standards for Privacy of Individually Identifiable Health Information" and will be referred to as the "HHS Privacy Regulations."

2. This Complaint challenges the constitutionality of Section 264 of Public Law 104-191 ("Section 264"). The Plaintiffs seek a declaratory judgment that Section 264 is an unconstitutional delegation of legislative powers in violation of Article I, § 1 of the United States Constitution. Plaintiffs seek a declaratory judgment that Section 264 violates the separation of powers envisioned by the United States Constitution because the statute allowed HHS, an executive agency, to act as federal legislators in drafting and enacting the executive regulations referred to as the HHS Privacy Regulations, 45 C.F.R. Parts 160 and 164. As enacted by Congress, Section 264 contains no intelligible principle to guide or limit HHS in the drafting of the regulations.

3. Plaintiffs also challenge the facial constitutionality of Section 264 on the grounds that the preemption clause in Section 264(c)(2) is so impermissibly vague that it violates the Due Process guarantee of the Fifth Amendment. Section 264(c)(2) states:

> A regulation promulgated under paragraph (1) shall not supersede a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation.

4. As drafted, the preemption clause of Section 264(c)(2) is impermissibly vague because a person of ordinary intelligence is unable to determine whether state privacy protections are "more stringent" than the HHS Privacy Regulations. Prior to HHS's Privacy Regulations, upon information and belief, most states already have taken the initiative to pass laws protecting

medical privacy. Many of these states have comprehensive initiatives governing the issues of medical privacy. Whether a state law is pre-empted is unclear under the statute. As a result, persons in states that already have significant privacy laws are not on notice as to whether they must comply with the HHS Privacy Regulations.

5. This action is also a challenge to the federal regulations enacted by HHS pursuant to Section 264. In the event the Court upholds the constitutionality of Section 264, the regulations promulgated thereby are unconstitutional because they violate the clear intent of Congress that limited the application of any HHS regulations to electronic communications. Furthermore, the HHS Privacy Regulations as enacted are not a permissible construction of the statute.

6. Plaintiffs do not dispute the benefits of protecting the privacy of individually identifiable health information. Furthermore, Plaintiffs would not challenge Congressional privacy legislation that considered the recommendations of HHS issued pursuant to Section 264. However, the failure of Congress to provide any standards or limits in Section 264 in conjunction with the failure of Congress to enact any legislation has left the regulations promulgated by HHS constitutionally infirm.

Jurisdiction and Venue

7. 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.

8. Venue is proper in the District of South Carolina under 28 U.S.C. § 1391(e) because Plaintiffs South Carolina Medical Association (the "SCMA"), Physicians Care Network, Dr. J. Capers Hiott, M.D., Dr. John R. Ross, M.D., Dr. Gordon E. Pennebaker M.D., Dr. Carol S.

Nichols, M.D., Dr. Danette F. McAlhaney, M.D., and Dr. Herbert A. Moskow, M.D. reside there.

The Parties

9. The SCMA is a professional association organized and existing under the laws of the State of South Carolina with its principal executive offices in Columbia, South Carolina.

10. The Louisiana State Medical Society is a professional association organized and existing under the laws of the State of Louisiana.

11. Physicians Care Network is a corporation formed under the laws of South Carolina with its principal place of business in Columbia, South Carolina.

12. Dr. J. Capers Hiott, M.D. is a health care provider with an ear, nose, and throat practice in Sumter, South Carolina; Dr. John R. Ross, M.D. is a health care provider with a general practice in Bamberg, South Carolina; Dr. Gordon E. Pennebaker M.D. is a health care provider with a family practice in Batesberg-Leesville, South Carolina; Dr. Carol S. Nichols, M.D., is a health care provider practicing medicine in Spartanburg, South Carolina; Dr. Danette F. McAlhaney, M.D. is a health care provider with a family practice in Bamberg, South Carolina; and Dr. Herbert A. Moskow, M.D. is a health care provider with a family practice in Bamberg, South Carolina. (Hereinafter the "Plaintiff Doctors"). The Plaintiff Doctors are all physicians residing, licensed, and practicing medicine in the State of South Carolina.

13. 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.

14. 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

Privacy Regulations

15. As part of HIPAA's Administrative Simplification, Congress recognized the desirability of protecting the privacy of individually identifiable health information that would be electronically transferred pursuant to the new standards for electronic transmission.

16. Section 264 is found in the Administrative Simplification section of HIPAA enacted by Congress on August 21, 1996. Initially, Congress did not intend for HHS to author the standards governing electronic privacy. When Congress enacted HIPAA, the statute provided that Congress itself would enact legislation to protect the privacy of individually identifiable health information. Section 264 only charged HHS with the responsibility to provide "recommendations on standards with respect to the privacy of individually identifiable health information." Based on those recommended standards, Congress would enact privacy protections for the electronic transfer of health information.

17. As a default position, Section 264 contained a provision that if Congress failed to pass any privacy legislation in the thirty-six months following HIPAA's enactment, then HHS would promulgate final regulations for the protection of electronically transferred health information. Unfortunately, Congress failed to enact any privacy legislation within the proscribed period of time.

18. Without any guidance whatsoever from Congress, HHS has drafted and promulgated executive regulations creating an overreaching administrative regime to regulate individually identifiable health information. 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. Furthermore, through the regulation of business contracts, the HHS Privacy Regulations go beyond HIPAA's regulation of health care providers, health plans, and health care clearinghouses to regulate all persons doing business with such entities who would receive either electronic or non-electronic communications of individually identifiable health information.

19. The HHS Privacy Regulations ignore the realities of current medical practices and will delay and impede critical health care operations. Among the major consequences of the HHS Privacy Regulations will be increased costs of health care, massive new paperwork requirements for all involved in the field of health care, and serious inconvenience to all patients in the health care system.

20. Foreseeable problems include such things as delays in filling prescriptions, impediments to hospital pre-admission procedures, and difficulty in using archived patient information. Furthermore, doctors and other health care providers working under this totally new and highly complex administrative regime face severe criminal and civil penalties for non-compliance with the HHS Privacy Regulations.

21. Unlike the major federal privacy statutes previously enacted by Congress (as opposed to a federal agency), HHS chose not to provide the individual harmed by a disclosure with a right to

bring a federal lawsuit to enforce the regulations or recover damages. The other major federal privacy laws, such as the Privacy Act of 1974 (5 U.S.C. 522a), Electronic Communications Privacy Act (18 U.S.C. 2701), Fair Credit Reporting Act (15 U.S.C. 1681), Cable Communications Act (47 U.S.C. 551), Videotape Privacy Protection Act (18 U.S.C. 2710) and the Driver's Privacy Protection Act (18 U.S.C. 2721), permit individuals to bring federal suits.

22. HHS's choice to draft the regulations such that HHS is the only entity that can enforce the privacy provisions empowers the HHS bureaucracy instead of the aggrieved individual. Fines imposed for the improper release of individually identifiable health information are paid to the federal government and the individual actually harmed by the disclosure is not provided *any* personal relief by the HHS Privacy Regulations. Such a self-serving regulatory regime can be expected where Congress fails to place any meaningful boundary on the legislative authority delegated to the federal agency responsible for drafting the regulations.

23. The only Congressional directive for potential HHS regulations that can be found in Section 264 is that any HHS regulations should address individually identifiable health information transmitted in electronic form.

23.1 Section 264(c) states unequivocally that any HHS privacy regulations should address health information "transmitted in connection with the transactions described in Section 1173(a) of the Social Security Act (as added by Section 262)." This Section 1173(a) is entitled "Standards to Enable Electronic Exchange" and states that the "Secretary shall adopt standards for transactions,

and date elements for such transactions, to enable health information to be exchanged electronically . . ." (Emphasis added).

23.2 Furthermore, 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." It is undisputed that the final HHS Privacy Regulations regulate speech beyond electronic transmissions. (Emphasis added).

24.

HHS has explicitly recognized that the statutory authority to regulate speech far beyond the limits of electronic transmission under HIPAA is highly suspect. The proposed rule by HHS addressed only electronic transfers of information. In direct contrast to the proposed rule, HHS's final rule, published at 65 Fed. Reg. 82462 - 82829, attempts to regulate *all* forms of speech involving individually identifiable health information. HHS recognized their unilateral decision to extend the scope beyond of 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.

See 65 Fed. Reg. 82488.

25. In the final rule, HHS acknowledged that it purposely structured the HHS definition of "protected health information" such that it anticipated court intervention to limit the privacy regulations to the authority actually granted by the statute. HHS explains that the structure of its

"protected health information" definition is "set out in this form 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." *See* 65 Fed. Reg. 82496.

THE PLAINTIFFS HAVE BEEN AND WILL BE AGGRIEVED

BY THE PRIVACY AND ELECTRONIC TRANSACTION REGULATIONS

26. The SCMA was established in 1848. Its membership is comprised of physicians in the State of South Carolina who practice medicine and pursuant to their practice will acquire individually identifiable health information. As such, the SCMA is a representative organization of health care providers whose members will be forced to comply with HHS's newly enacted Privacy Regulations.

27. The Louisiana State Medical Society has a membership is comprised of physicians in the State of Louisiana who practice medicine and pursuant to their practice will acquire individually identifiable health information. As such, the Louisiana State Medical Society is a representative organization of health care providers whose members will be forced to comply with HHS's newly enacted Privacy Regulations.

28. The SCMA formed the Physicians Care Network ("PCN") in March 1993. PCN is a statewide health care provider network with the primary goal of reducing medical costs and maintaining quality medical care for its participants. As a provider network, PCN receives and processes claims from its subscribers that include individually identifiable health information.

29. The Plaintiff Doctors are all physicians practicing in South Carolina. These Plaintiffs are health care providers who will receive and transmit individually identifiable health information as defined by the HHS Privacy Regulations.

30. In anticipation of the enforcement date, the Plaintiffs have already expended, and will continue to expend, time and money in order to comply with the new HHS Privacy Regulations. Furthermore, all Plaintiffs in this matter may be subject to the severe criminal and civil penalties for accidental violations of the HIPAA Privacy Regulations.

31. The effective date for the HHS Privacy Regulations was April 14, 2001. The compliance date for initial implementation of the privacy standards for health care providers is April 14, 2003.

FIRST CLAIM FOR RELIEF

Facial Violation of the Constitution--Section 264 Is an

Impermissible Delegation of Congress' Legislative Authority

32. Plaintiffs repeat and reallege, as is fully set forth herein, each and every statement and allegation contained in paragraphs 1 through 31.

33. Article I, § 1 of the United States Constitution vests "all legislative Powers" in the Congress. Article I, § 8 further assigns to Congress alone the "Power . . . to make all laws for carrying into Execution the foregoing [Article I] Powers."

34. Congress may not constitutionally delegate to the Executive Branch or any Executive Agency the powers and functions vested in the Congress by Article I of the Constitution. While Congress may seek assistance from its coordinate Branches, it must lay down by legislative act a

substantive, intelligible principle to which the person or body authorized to act is directed to conform.

35. As is clear from Section 264's plain language, Congress has not put forth any policy or standard to govern the drafting of privacy regulations as an intelligible principle. The plain language of Section 264 acknowledges that it does not contain any guiding principles. The *very purpose* of the recommendations by the Secretary of HHS requested in Section 264(a) and (b) is to assist Congress in the development of such a policy or standard.

36. The statutory language does not provide an intelligible principle to guide HHS. More importantly, the only boundary set forth in the Congressional act is that the regulations apply only to electronic communications.

37. Due to the failure of Congress to enact any legislation within the statutory time frame, HHS promulgated proposed and final regulations containing standards governing the privacy of individually identifiable health information.

38. Section 264 fails to contain any intelligible principle to which HHS is directed to conform. Section 264 fails to delineate any general policy or the boundary of HHS's authority in enacting privacy regulations. Any regulations promulgated by HHS under this excessively broad grant of legislative power is the result of an unconstitutional delegation of Article 1, § 1 powers.

SECOND CLAIM FOR RELIEF

The HHS Privacy Regulations Exceed the

Statutory Authority Granted by HIPAA

39. Plaintiffs repeat and reallege, as is fully set forth herein, each and every statement and allegation contained in paragraphs 1 through 38.

40. As drafted, HIPAA clearly limits its application to electronic transfers of information. The HHS Privacy Regulations go well beyond the limits of HIPAA in attempting to regulate all forms of speech involving individually identifiable health information, not just the electronic transfers governed by HIPAA.

41. As discussed above, Section 264(c) requires that any HHS privacy regulations address health information "transmitted in connection with the transactions described in Section 1173(a) of the Social Security Act (as added by Section 262)." Section 1173(a) is entitled "Standards to Enable Electronic Exchange" and states that the "Secretary shall adopt standards for transactions, and date elements for such transactions, to enable health information to be exchanged electronically . . ." Furthermore, 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. The HHS Privacy Regulations clearly ignore Congress' intent because the HHS Privacy Regulations as enacted apply to *all* communications involving individually identifiable health information, whether or not the information is in electronic form, even though HIPAA limits its application to only information transmitted electronically.

43. As such, even though HIPAA's "Administrative Simplification" only addresses those communications transmitted electronically, the HHS Privacy Regulations go well beyond this statutory context to regulate the communication of any individually identifiable health information whether in electronic form or not. Therefore, the HHS Privacy Regulations are

contrary to the statutory context and purpose of HIPAA and are arbitrary and capricious in nature.

THIRD CLAIM FOR RELIEF

Facial Violation of the Constitution--Section 264's Preemption Clause is Impermissibly Vague and Therefore a Violation of Due Process under the 5th Amendment

44. Plaintiffs repeat and reallege, as is fully set forth herein, each and every statement and allegation contained in paragraphs 1 through 43.

45. The 5th Amendment to the United States Constitution states "No person shall . . . be deprived of life, liberty, or property, without due process of law." U.S. Const. Amend. 5. Due process of law requires that a statute give persons fair notice as to what conduct is prohibited.

46. Section 1177 of Public Law 104-191, codified at 42 U.S.C. 1320d-6, contains penalties for the wrongful disclosure of individually identifiable health information. Under this section, a person found in violation of the HHS Privacy Regulations may be fined up to $50,000, imprisoned up to one year, or both. If the violation is found to be under false pretenses, the fine is up to $100,000 and the jail sentence may be up to five years. If the offense is found to be committed with the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, then the penalties can reach up to $250,000 and ten years in prison.

47. Section 1178(2)(B) of Public Law 104-191 contains a preemption clause providing that "A provision or requirement under this part . . . shall not supersede a contrary provision of state law, if the provision of state law--(B) subject to section 264(c)(2) of the Health Insurance

Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information."

48. Section 264(c)(2) then contains a clause preempting all state privacy laws that are not "more stringent" than the HHS Privacy Regulations. As such, covered entities in states with state privacy laws that are "more stringent" are not subject to the penalty provisions addressed above.

49. If the Court upholds the constitutionality of Section 264(c)(2) and the HHS Privacy Regulations, most states, including South Carolina, already have legislation protecting patients' medical privacy which may or may not be pre-empted by the HHS Privacy Regulations. *See e.g.*, S.C. Code Ann. § 44-115-40 (1987).

50. The pre-emption clauses of Section 1178(2)(B) of Public Law 104-191 and Section 264(c)(2) are impermissibly vague because it is unclear which state laws will be preempted by the HHS Privacy Regulations. The term "more stringent" is unclearly defined in Section 264(c)(2) and a person of ordinary intelligence is left uninformed by the statute if the HHS Privacy Regulations or state privacy law would govern his or her actions.

51. As such, Section 1178(2)(B) of Public Law 104-191 and Section 264(c)(2) violate the due process of law guaranteed by the 5th Amendment in that any of the Plaintiffs may be subject to criminal penalties without fair notice if their actions are covered by the HHS Privacy Regulations.

Prayer For Relief

Wherefore, Plaintiffs request:

52. A declaratory judgment that Section 264(c)'s delegation of legislative power is unconstitutional.

53. A declaratory judgment that the HHS Privacy Regulations promulgated pursuant to Section 264(c) are unconstitutional and in direct contradiction to the intent of Congress.

54. A declaratory judgment that the pre-emption provisions of Section 1178(2)(B) of Public Law 104-191 and Section 264(c)(2) are unconstitutionally vague.

55. Such other relief as the Court may deem appropriate.

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