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

SOUTH CAROLINA MEDICAL ASSN., ET AL., Plaintiffs, VS. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL., Defendants.	Civil Action No.: 3:01-2965-25

ORDER

Plaintiffs, South Carolina Medical Association, Physicians Care Network, and individual physicians, bring a constitutional challenge to several provisions of Subtitle F, Public Law 104-191, known as the Health Insurance Portability and Accountability Act ("HIPAA"). Plaintiffs filed this action against defendants, United States Department of Health and Human Services ("DHHS") and Tommy G. Thompson, as Secretary of DHHS, specifically alleging that (i) Section 264 of HIPAA is an impermissible delegation of Congress' legislative authority, (ii) that the DHHS privacy regulations exceed the statutory authority granted by HIPAA, and (iii) that Section 264's preemption clause is impermissibly vague and therefore violates the due process clause under the 5th Amendment to the U.S. Constitution.

Plaintiffs request in their complaint a declaratory judgment that the delegation of legislative power under section 264(c) is unconstitutional; that the DHHS privacy regulations promulgated pursuant to Section 264(c) are unconstitutional and in direct

contradiction to the intent of Congress; and, that the preemption provisions of Section 1178(2)(B) of Public Law 104-191 and Section 264(c)(2) are unconstitutionally vague. Pending before this Court is defendants' Motion to Dismiss.

Standard of Review

A motion made pursuant to Fed.R.Civ.P. 12(b)(6) allows a claim to be dismissed for failure to state a claim upon which relief can be granted. The purpose of a motion under Rule 12(b)(6) is to test the legal sufficiency of the statement of the claim. Chertkof v. Baltimore, 497 F.Supp. 1252, 1258 (D.Md.1980). For the purposes of ruling on a motion under Rule 12(b)(6), the Court must accept the allegations contained in the complaint as true, and must liberally construe the complaint as a whole. Jenkins v. McKeithen, 395 U.S. 411, 421, 89 S.Ct. 1843, 1848-49, 23 L.Ed.2d 404 (1969); Finlator v. Powers, 902 F.2d 1158 (4th Cir.1990). Under such an analysis, a Motion to Dismiss for failing to state a claim should only be granted if it is beyond doubt that no relief could be granted, under any set of facts, when the allegations are construed in a light most favorable to the pleader. Hartford Fire Ins. Co. v. California, 509 U.S. 764, 811, 113 S.Ct. 2891, 125 L.Ed.2d 612 (1993); Scheuer v. Rhodes, 416 U.S. 232, 236, 94 S.Ct. 1683, 40 L.Ed.2d 90 (1974); Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957).

BACKGROUND

Congress, in order to "improve portability and continuity of health insurance coverage in the group and individual markets,"[1] enacted HIPAA on August 21, 1996. Pub.

[1]H.R. Rep. No. 104-496, at 1, 66-67, reprinted in 1996 U.S.C.C.A.N. 1865, 1865-66.

L. No. 104-191, 110 Stat. 1936 (1996). Subtitle F of Title II of HIPAA is entitled "Administrative Simplification," and states that the purpose of the subtitle, of which Section 264 is a part, is "to improve the Medicare program . . . the medicaid program . . . and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information." Public Law 104-191, Sec. 261, 110 Stat. 2021. Recognizing the concomitant need to guarantee certain protections to patients' privacy based on the increase in volume of computerized data and the relative ease of accessing health data, Congress included section 264 within Subtitle F, Title II of HIPAA (Public Law 104-191, 110 Stat. 2033-2034) which states:

> **(a) IN GENERAL.**–Not later than the date that is 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Labor and Human Resources and the Committee on Finance of the Senate and the Committee on Commerce and the Committee on Ways and Means of the House of Representatives detailed recommendations on standards with respect to the privacy of individually identifiable health information.
>
> **(b) SUBJECTS FOR RECOMMENDATIONS.**–The recommendations under subsection (a) shall address at least the following:
>
> (1) The rights that an individual who is a subject of individually identifiable health information should have.
>
> (2) The procedures that should be established for the exercise of such rights.
>
> (3) The uses and disclosures of such information that should be authorized or required.
>
> **(c) REGULATIONS.**–
>
> **(1)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).

(2)PREEMPTION.–A regulation promulgated under paragraph (1) shall not supercede 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.

(d) CONSULTATION.–In carrying out this section, the Secretary of Health and Human Services shall consult with–

(1) the National Committee on Vital and Health Statistics established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)); and

(2) the Attorney General.

The following definitions are applicable to the analysis:

(4)HEALTH INFORMATION.–The term 'health information' means any information, whether oral or recorded in any form or medium, that–

(A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

Public Law 104–191, Sec. 262, 110 Stat. 2022 (August. 21, 1996).

(6) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.–

The term 'individually identifiable health information' means any information, including demographic information collected from an individual, that–

(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and–

(i) identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe that the

information can be used to identify the individual.

Public Law 104–191, Sec. 262, (Sec. 1171(6)), 110 Stat. 2023 (August. 21, 1996).

By August 21, 1999, Congress had not enacted privacy standards pursuant to HIPAA. Accordingly, on November 3, 1999, DHHS issued a notice of proposed rule-making. After receiving approximately 52,000 public comments, and following publication of several proposed rules and amendments, on February 13, 2001, DHHS promulgated final regulations (the "Privacy Regulations"). Although the effective date of the Privacy Regulations was April 14, 2001, covered entities were given two years, or until April 14, 2003, to come into compliance with the Privacy Regulations. Small health plans were given three years, or until April 14, 2004, to comply.

ANALYSIS

I. Is there an Improper Delegation of Legislative Power?

Plaintiffs first argue that the delegation of legislative power under Section 264(c) is unconstitutional pursuant to Article 1, § 1, because Congress has failed to articulate an "intelligible principle" concerning policies or standards governing DHHS' drafting of Privacy Regulations.[2] In 1989, the U.S. Supreme Court explored the "intelligible principle" and its progeny in Mistretta v. United States, wherein it held that, so long as Congress "shall lay down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform, such legislative action is not a forbidden delegation of legislative power." 488 U.S. 361, 372, 109 S.Ct. 647, 655 (1989)

[2]Plaintiffs argument is based on the "nondelegation doctrine" which is "rooted in the principle of separation of powers . . . ." Mistretta v. United States, 488 U.S. 361, 371, 109 S.Ct. 647, 654 (1989).

(citing J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 409, 43 S.Ct. 348, 352 (1928)). The Supreme Court "has deemed it 'constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of [the] delegated authority.'" Id. at 372-73, (citing American Power & Light Co. v. SEC, 329 U.S. 90, 105, 67 S.Ct. 133, 142 (1946)). In Mistretta, the Court noted that it was not until 1935 that it struck down a statute challenged on delegation grounds, and that since 1935, the Court has "upheld, again without deviation, Congress' ability to delegate power under broad standards." Mistretta, 488 U.S. at 373, (citing Lichter v. United States, 334 U.S. 742, 785-786, 68 S.Ct. 1294 (1948) (upholding delegation of authority to determine excessive profits)); American Power & Light Co. v. SEC, 329 U.S., at 105, 67 S.Ct., at 142 (upholding delegation of authority to Securities and Exchange Commission to prevent unfair or inequitable distribution of voting power among security holders); Yakus v. United States, 321 U.S. 414, 426, 64 S.Ct. 660, 668, 88 L.Ed. 834 (1944) (upholding delegation to Price Administrator to fix commodity prices that would be fair and equitable, and would effectuate purposes of Emergency Price Control Act of 1942); FPC v. Hope Natural Gas Co., 320 U.S. 591, 600, 64 S.Ct. 281, 287, 88 L.Ed. 333 (1944) (upholding delegation to Federal Power Commission to determine just and reasonable rates); National Broadcasting Co. v. United States, 319 U.S. 190, 225-226, 63 S.Ct. 997, 1013-1014, 87 L.Ed. 1344 (1943) (upholding delegation to Federal Communications Commission to regulate broadcast licensing "as public interest, convenience, or necessity" require).

Recently, the Supreme Court in Whitman v. American Trucking revisited the nondelegation doctrine and held that the Clean Air Act was not unconstitutional because

Congress had articulated an intelligible principle in the statute which limited the discretion of the agency–the EPA–charged with drafting the regulations. 531 U.S. 457, 472-73 (2001). The Supreme Court noted that it found an intelligible principle lacking in only two statutes in the history of its existence:

> . . .[O]ne [statute] provided literally no guidance for the exercise of discretion, and the other . . . conferred authority to regulate the entire economy on the basis of no more precise standard than stimulating the economy by assuring "fair competition." . . . In short, [the Supreme Court has] 'almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law.'

Whitman, 531 U.S. at 474-75, (citing Panama Refining Co. v. Ryan, 293 U.S. 388, 55 S.Ct. 241 (1935), A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 55 S.Ct. 837 (1935)); Mistretta v. United States, 488 U.S. 361, 416, 109 S.Ct. 647 (1989). Although the "intelligible principle" was found lacking in only two statutes by the Supreme Court since the early 1930s, this Court is required to carefully consider its application to this case.

To determine whether the statute is an unconstitutional delegation of legislative power to the Executive branch, the Court must decide whether Congress articulated an intelligible principle. After reviewing the applicable statutory language and case law, this Court concludes that Congress has sufficiently articulated an intelligible principle to guide, and limit the discretion of, the Department of Health and Human Services when it drafted the Privacy Regulations.

The starting point for the analysis should be the language of the statute itself. First, Congress directed DHHS to implement regulations containing standards regarding the privacy of individually identifiable health information, addressing at least the following

subjects: "(1) [t]he rights that an individual who is a subject of individually identifiable health information should have;" (2) "[t]he procedures that should be established for the exercise of such rights;" and (3) "[t]he uses and disclosures of such information that should be authorized or required." Section 264(b). However, this statutory verbiage alone does not comprise, nor does it reveal, the entire "intelligible principle" Congress conveyed to DHHS when it granted DHHS the authority to draft the Privacy Regulations. When gleaning an intelligible principle from a statute, the law permits the Court to look outside the verbiage of Section 264. "It is a familiar rule that the constitutionality of a part of an act or statute is not to be resolved in isolation from other parts of the statute and from the purposes of the statute as a whole, particularly if the section in question refers to or embraces other sections of the Act . . . ." United Hospital Center, Inc. v. Richardson, 757 F.2d 1445,1451 (4th Cir 1985).

To discern the intelligible principle set forth by Congress, the statutory language in Section 264 can be read together with the other statutory provisions in Subtitle F, such as Section 261, which sets forth the purpose of Subtitle F:

> It is the purpose of the subtitle [of which Section 264 is a part] to improve the Medicare program . . . the medicaid program . . . and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.

Public Law 104-191, Sec. 261, 110 Stat. 2021. Section 261, read together with Section 264, causes the undersigned to conclude that Congress provided DHHS with an intelligible principle to guide the drafting of privacy regulations. Congress directed DHHS to draft Privacy Regulations that would not harm federal medical entitlement programs or the

efficiency and effectiveness of the health care system. See Section 261. Congress also directed DHHS to avoid drafting privacy regulations that would discourage the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information. See id. Furthermore, DHHS could not draft privacy regulations that would affect the rights of a person who is the subject of individually identifiable health information in such a manner that would impede or hinder the electronic transmission of certain health information. See id. The Section 264(c) delegation is not overladen with detailed guidance. However, these statutory provisions provide a sufficient limitation on DHHS' discretion. Therefore, Section 264(c) meets the "constitutionally sufficient" standard allowing for the delegation of authority to DHHS to draft the Privacy Regulations.

Additionally, the applicability of the Privacy Regulations are further limited to health plans, health care clearinghouses, health care providers, and applicable business associates, who transmit any health information in electronic form in connection with certain transactions. Pub. L. No. 104-191, Sec. 262, 110 Stat. at 2023 (Aug. 21 1996); 42 U.S.C. § 1320d-1. Thus, DHHS could not regulate health care communications, whether confidential or not, between people who have no connection to health plans, health care clearinghouses, health care providers, or to covered entities who do not transmit health information in electronic form in connection with certain transactions. Congress created a framework within which DHHS' could establish privacy regulations and in doing so provided an intelligible principle to guide the drafting of such regulations. Furthermore, Congress defined a general policy, the public agency which was to apply it, and the boundaries of the agency's delegated

authority. Mistretta, 488 U.S. at 372-73 (citing American Power & Light Co. v. SEC, 329 U.S. 90, 105, 67 S.Ct. 133, 142 (1946)). Pursuant to the foregoing analysis, because this Court finds that, accepting the allegations in the complaint as true, this claim is subject to dismissal because it cannot survive under any set of facts set forth by the plaintiffs. Hartford Fire Ins., 509 U.S. at 811.

II. Did DHHS Exceed the Scope of Authority Granted by Statute?

Plaintiffs next argue that DHHS' decision to regulate paper records exceeds the scope of the authority granted by HIPAA. The Court carefully considers this important argument. The undersigned notes the plaintiffs make a logical argument in regard to this issue. However, the undersigned concludes this argument is not sufficiently persuasive for two reasons: (1) the regulation is reasonably related to the purposes set forth in the enabling legislation; and, (2) the term "health information," as defined in HIPAA, can reasonably be read to conclude Congress intended to cover non-electronic records.

Regulations promulgated by an administrative agency are presumptively valid and will be sustained "so long as [they are] 'reasonably related to the purposes of the enabling legislation.' " Harman Mining Co. v. United States Dept. of Labor, 826 F.2d 1388, 1390 (4th Cir. 1987) (quoting Mourning v. Family Publication Servs., Inc., 411 U.S. 356, 369, 93 S.Ct. 1652, 1660 (1973)). "Thus, deference is to be accorded to the interpretation given to a statute by the agency charged with its administration." Id. (citing Udall v. Tallman, 380 U.S. 1, 16, 85 S.Ct. 792 (1965)); United Hospital Center, Inc. v. Richardson, 757 F.2d 1445, 1451 (4th Cir. 1985). The enabling legislation states that the purpose of "Subtitle F–Administrative Simplification" is to improve government sponsored medical benefits programs and the

efficiency and effectiveness of the entire health care system through the encouragement of an electronic health information system. 110 State. 2021; Public Law 104-191, Section 261. DHHS has drafted Privacy Regulations in keeping with Congress' purpose.

DHHS drafted regulations that cover electronic records and extended that coverage to corresponding paper records. It did so apparently to prevent a potential loophole which may allow disclosure of health information contained in paper records. Without extending coverage to paper records, paper records could be maintained and shared with no electronic transmission of those records to avoid the restrictions imposed by the regulation. DHHS argues that the regulation of paper records under HIPAA, in addition to electronic records, is reasonably related to the enabling legislation. The undersigned finds this argument sufficiently persuasive.

After a careful review of the enabling legislation, the statutory language employed in HIPAA can also be reasonably interpreted to indicate that Congress intended for the regulations to extend privacy protection to paper records. A court must examine the statutory language to give effect to the legislative will that is expressed in the language. United States v. Murphy, 35 F.3d 143, 145 (4th Cir. 1994), cert. denied, 513 U.S. 1135, 115 S.Ct. 954 (1995). A court's inquiry must cease if the " 'statutory language is unambiguous and the statutory scheme is coherent and consistent.' " Murphy, 35 F.3d at 145 (quoting United States v. Ron Pair Enters., Inc., 489 U.S. 235, 240-41, 109 S.Ct. 1026. 1030 (1989)). The duty of interpretation does not arise if the statutory language is plain and admits of no more than one meaning. Id. (quoting Caminetti v. United States, 242 U.S. 470, 485, 37 S.Ct. 192, 194 (1917)).

Plaintiffs argue that since the transactions described in section 1173(a) of the Social Security Act, which are referenced in Section 264(c)(1), involve only the electronic exchange of health information, then the Privacy Regulations should only cover electronic health information. While the argument of the plaintiffs warrants careful consideration and analysis, the undersigned reaches a conclusion unfavorable to plaintiffs' position.

The statutory language at issue is reasonably plain and can be read to cover paper records. In Section 262, "health information" is defined as "any information, *whether oral or recorded in any form or medium*, that–

> (A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
>
> (B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

Public Law 104-191; 110 Stat. 2022 (emphasis added). Section 264 is entitled, "Recommendations with Respect to Privacy of Certain *Health Information*." Public Law 104-191; 110 Stat. 2033 (emphasis added). In Section 264(b)(1), Congress states that, "[t]he recommendations under subsection (a) shall address . . . (1) [t]he rights that an individual who is a subject of individually identifiable *health information* should have." See id. (emphasis added). Under Section 264(c), Congress states that if legislation governing standards with respect to the privacy of health information transmitted in connection with certain transactions is not enacted by a certain date, the Secretary is charged with promulgating final regulations, which were to address at least the subjects described in Section 264(b),

containing such standards.

The statutory definition of "health information" and reference to the term "health information" in the privacy provision of the statute indicates that Congress likely sought to delegate authority to DHHS to regulate more than electronic information. Congress chose to include the last sentence in Section 264(c)(1), which incorporates by reference Section 264(b). "When 'interpreting a statute, the court will not look merely to a particular clause in which general words may be used, but will take in connection with it the whole statute . . . and the objects and policy of the law, as indicated by its various provisions, and give to it such a construction as will carry into execution the will of the Legislature' . . . ." United Hospital Center, 757 F.2d at 1451. This Court notes the references to other statutory sections and would have to ignore those references to reach the conclusion sought by the plaintiffs.

Congress could have simply limited the definition of "health information" to electronic information, but it chose to include the phrase "any information, whether oral or recorded in any form or medium." 110 Stat. 2022; Public Law 104-191. Congress, however, apparently recognized that limiting the definition of the term "health information" would have narrowed the privacy regulations to such an extent as to render them ineffective. A finding that Congress chose to limit the regulation to electronic information would appear to deny the intent sought by Congress. Accordingly, this claim does not survive dismissal pursuant to Rule 12(b)(6).

III. Is Section 264's Preemption Clause Impermissibly Vague and Does It Violate the Due Process Clause Under the 5th Amendment to the U.S. Constitution?

The undersigned next analyzes vagueness and due process claims raised by the

plaintiffs.

HIPAA's preemption provision, 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.

Plaintiffs argue that "Section 264(c)(2)'s preemption clause is so vague that a person of ordinary intelligence will not know whether the regulations will apply to his or her communications or not." See Reply to Defendant's Motion to Dismiss at 30. Plaintiffs state in their complaint that the term "more stringent" is unclearly defined in Section 264(c)(2). See Complaint at ¶ 50. Plaintiff's predicate their argument that the term "more stringent" is vague and that "it will be impossible to know for certain until a court rules authoritatively whether the state law or HHS Regulation is 'more stringent.' " See id. at 32. Plaintiffs also argue in their memorandum of law that this Court should apply a strict standard of review because the Regulations grant to DHHS unfettered access to every American's private health information without a warrant or probable cause.

The Supreme Court has held in a long line of cases that "it is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined." Grayned v. City of Rockford, 408 U.S. 104, 92 S.Ct. 2294 (1972). The Supreme Court in Grayned noted concerns raised by vagueness and explained:

> Vague laws offend several important values. First, because we assume that man is free to steer between lawful and unlawful conduct, we insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warning. Second, if arbitrary and discriminatory

> enforcement is to be prevented, laws must provide explicit standards for those who apply them . . . . Third, but related, where a vague statute 'abuts upon sensitive areas of basic First Amendment freedoms,' it 'operates to inhibit the exercise of (those) freedoms.'

408 U.S. at 108-109.

This Court begins its vagueness analysis by determining whether the preemption provision " 'abuts' upon sensitive areas of basic First Amendment freedoms," as Grayned instructs. See id. The undersigned is unable to conclude that sensitive areas of First Amendment freedoms are sufficiently affected by the preemption statute. The Court, after a review of the allegations in the complaint, finds no basis to conclude that the regulations will stifle or infringe upon rights guaranteed by the U.S. Constitution. As discussed below, the provisions at issue cannot reasonably be interpreted to conclude they will inappropriately regulate free speech in regards to health information.

The purpose of the Privacy Regulations promulgated by DHHS is to regulate the maintenance and disclosure of patients' private health information contained in medical records and related documents, such as payment invoices and explanation of benefits. The attempt to characterize this case as one relating to free speech under the First Amendment is not sufficiently persuasive. Private health information is highly regulated and protected by both state and federal statutory law and, in many instances, state common law. It is not disputed that state laws currently provide some form of governmental access to patient records, mandatory reporting requirements for public health purposes, and limitations on disclosure of health information. The Privacy Regulations were promulgated to provide uniform protection from wrongful disclosure of an individual's health information when it is

in the possession of a covered entity. The undersigned concludes these regulations do not directly impede or impair a patient's right to explain his or her health problems to a physician, nor do they unduly impede the disclosure of that information by a health care professional to those who should be aware of such information.

In light of the First Amendment analysis, to successfully challenge a law as unduly vague on its face, in violation of due process, "the complainant must demonstrate that a law is impermissibly vague in all of its applications." Village of Hoffman Estates, v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498, 102 S.Ct. 1186 (1982). The plaintiffs in this case are unable to make such a showing.

A court is not to mechanically apply the Grayned standards set forth above. See id. The enactment itself will dictate the degree of vagueness and the relative importance of fair notice and fair enforcement that is tolerated by the Constitution. See id. The undersigned concludes it is appropriate to apply a less strict vagueness test to regulations affecting, as they do here, business interests. Because businesses, such as hospitals, physician offices, and health plans are in a position to plan and prepare for compliance carefully through consultation of relevant regulations well in advance of the regulation's enactment, the less strict vagueness standard would apply. See Village of Hoffman Estates, 455 U.S. at 498. Plaintiffs' facial challenge does not prevail because the preemption provision of the HIPAA statute and its correlating regulations are sufficiently clear as applied to health care providers and to the plaintiffs in this action.

This Court should additionally determine whether health care providers have a reasonable opportunity to know what conduct is prohibited under the HIPAA Privacy

Regulations; that is, do the plaintiffs have fair warning of the law? The undersigned cannot lightly dismiss these concerns raised by the plaintiffs. However, the undersigned finds that there are sufficient reasons why the plaintiffs would have a reasonable opportunity to know what is prohibited with respect to the preemption provision in the HIPAA statute: (1) the plain and ordinary meaning of the term "more stringent" is not, while not precisely clear and easily applied in all situations, overly vague; (2) DHHS expressly defines the term "more stringent" in the privacy regulations and specifically sets forth criteria concerning the type of state privacy law that might preempt a federal privacy law; (3) HIPAA provides that covered entities, such as health care providers, participate in HIPAA training and provide HIPAA training to their employees; (4) HIPAA provides that each covered entity designate a privacy official; and, (5) individuals can only be prosecuted if they "knowingly" violate the privacy regulations. Applying these reasons or factors sufficiently demonstrates there is the requisite "fair warning" as to when a federal law will not preempt a "more stringent" state law.

In summary, the undersigned concludes that health care providers can, by virtue of the plain meaning of the term "more stringent," and the reasons set forth, when presented with a situation where a state law is contrary to a federal law, determine and follow the more stringent, or more strict, of the two laws.

Next, plaintiffs allege in their complaint (¶ 50) that the term "more stringent" is unclearly defined, thereby leaving a person of ordinary intelligence uniformed by the statute as to whether a HIPAA Privacy Regulation or state privacy law would govern his or her actions. Again, this concern is one that warrants careful analysis. As noted, the DHHS Privacy Regulations sufficiently define the term "more stringent," and also provide specific

criteria as to when certain state laws should preempt federal laws:

> More stringent means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under Subpart E of this subchapter (the subchapter containing the privacy regulations), a State law that meets one or more of the following [six] criteria.

45 C.F.R. § 160.202 (2001). The six criteria, set forth in detail in the Privacy Regulations, eliminate undue confusion about the type of state law that federal law should not preempt, and when the state law should yield to the federal law. For example, the second criteria states:

> (2) With respect to the rights of an individual who is the subject of the individually identifiable health information of access to or amendment of individually identifiable health information, [a state law that] permits greater rights of access or amendment, as applicable; . . . .

See id. Thus, any state law that permits a patient greater access to, or amendment of, their own medical records should be followed, if it is contrary to a HIPAA Privacy Regulation concerning access and amendment to records. The Court concludes that those who routinely handle health information, and who must undertake privacy regulation training, should be able to understand and apply the language set forth in criteria (2), and would not need an interpretation of a court of law for guidance. The other five criteria should be understood and applied by health care professionals such as the plaintiffs. Even if there were no training rule, those who have access to individually identifiable health information can consult the Privacy Regulations to clarify the application of the regulations, as is done with state regulations. See Village of Hoffman Estates, 455 U.S. at 498.

The Privacy Regulations also provide for the designation of a privacy official to assist in the understanding of differences between state and federal privacy regulations. The

Privacy Regulations require that every covered entity designate a privacy official "who is responsible for the development and implementation of the policies and procedures of the entity." 45 C.F.R. § 164.530(a)(1)(i). Therefore, if a person is unable to determine which privacy law to follow, state or federal, he or she can contact the privacy officer, who should be knowledgeable about such distinctions. While not a complete solution to making distinctions between state and federal law, consultation with the privacy official can be useful and a reasonable conclusion can be reached.

Again, the regulations set forth a framework that militates against a finding of vagueness. Hence, the undersigned concludes that the regulations provide sufficient notice and guidance to health care providers to overcome the vagueness concerns raised in this case.

In regards to applying the "more stringent" standard, there is some question as to whether or not a criminal prosecution would lie for making the wrong decision about following federal or state privacy laws. Section 1177 provides for criminal prosecution if a person "knowingly . . . obtains . . . or . . . discloses identifiable health information to another person . . . ." The focus of the criminal prosecution is the unlawful obtaining or disclosing health information. It is not clear to the undersigned that a person could be prosecuted for making the wrong judgment call as to whether state law is "more stringent" than federal law. However, the defendants in footnote 21 of their Memorandum in Support of their Motion to Dismiss refer to the risk of prosecution if plaintiffs are "unable to discern which state laws are more stringent." Apparently, the defendants acknowledge the possibility of prosecution if a person cannot "discern" correctly. The undersigned finds this somewhat troubling. Again, there remains uncertainty by the undersigned whether or not a prosecution would lie for a

wrong judgment call when trying to discern if a state or federal law is more stringent. At this time, there is no prosecution before the Court for a failure to properly "discern" which law is "more stringent." Should there be a criminal prosecution for making the wrong judgment, a court would then have to determine whether Section 1177 would reach such conduct. It would be premature to rule on such an issue until an actual case arises so the relevant facts and law can be fully analyzed at that time.

Moreover, if education, personal inquiry, and resort to a privacy officer all fail to provide an adequate determination concerning which law to follow, state or federal, to an individual who is employed by a covered entity, there is also protection from a criminal sanction by virtue of the scienter requirement. A scienter requirement "may mitigate a law's vagueness, especially with respect to the adequacy of notice to the complainant that his conduct is proscribed." Village of Hoffman Estates, 455 U.S. at 499. The Privacy Regulations state that to warrant punishment, a person who wrongfully discloses individually identifiable health information must do so "knowingly." Public Law 104-191, Sec. 262, (Sec. 1177(a)(Aug. 21, 1996)); 42 U.S.C. 1320d-6. Accidental disclosures due to a lack of knowledge of the preemption provision will not result in criminal penalties for plaintiffs.

The next factor in the Grayned analysis is whether the preemption provision and its clarifying regulations provide explicit standards to prevent a court from applying the law in an arbitrary and discriminatory manner resulting in conflicting decisions. Courts need only refer to the plain and ordinary meaning of the term "more stringent" and the detailed definition of "more stringent" when applying the law in situations where there may be a question of whether federal law has preempted state law. The definition of "more stringent"

is supported by six clarifying criteria. These criteria minimize the risk of misapplication of the standards and the risk of conflicting judicial opinions. This Court concludes that this law can be applied in a manner that is not sufficiently arbitrary or discriminatory. Should conflicting opinions in fact occur, Congress can act to correct any confusion or ambiguity in the language of the regulations.

IV. Conclusion

Based on the analysis set forth above, this Court hereby grants the Motion to Dismiss on all claims.

IT IS SO ORDERED.

Terry L. Wooten
United States District Court Judge

August 14, 2002
Florence, South Carolina