

No. 04-2550

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

CITIZENS FOR HEALTH, et al.,

Plaintiff-Appellants,

v.

TOMMY G. THOMPSON, SECRETARY, UNITED STATES
DEPARTMENT OF HEALTH & HUMAN SERVICES,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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STATEMENT OF JURISDICTION

Plaintiffs invoked the jurisdiction of the district court under 28 U.S.C. § 1331. The court issued its decision and entered a final judgment on April 2, 2004. JA 1-15. Plaintiffs filed a timely notice of appeal on May 27, 2004. JA 16. This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

As required by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the Department of Health and Human Services (“HHS”) promulgated comprehensive standards for the privacy of individually identifiable health information, known collectively as the Privacy Rule. The present Privacy Rule, unlike an earlier

version, does not require certain health care providers to obtain patients' consent before disclosing protected health information for routine uses. The questions presented on this appeal are:

1. Whether HHS acted within its discretion under HIPAA and provided a reasoned explanation for its decision not to include a requirement that certain health care providers obtain patients' consent before using or disclosing protected health information for routine purposes.

2. Whether the agency's decision not to include a consent requirement violates plaintiffs' constitutional right to privacy or a First Amendment right to confidential physician-patient communications.

STATEMENT OF THE CASE

This case concerns a challenge to the final Privacy Rule promulgated by HHS to protect the privacy of individually identifiable health information under the new regulatory framework established under HIPAA. Plaintiffs contend that HHS violated both the Administrative Procedure Act and the Constitution by failing to require that certain health care providers obtain patients' consent before using or disclosing identifiable health information for certain "routine uses," i.e., treatment, payment, or health care operations. Because an earlier version of the Privacy Rule contained a consent requirement for such routine uses, plaintiffs assert that HHS lacked authority later to eliminate that requirement, even after the agency received thousands of comments demonstrating that the consent requirement would give rise to a host of unintended consequences that could substantially impair and delay the delivery of health care.

After an exhaustive review of the administrative record, the district court found no basis for concluding that the final regulation was arbitrary, capricious or contrary to law. The court held that HHS had provided a reasoned explanation for its decision not to impose a consent requirement for routine uses and had adequately examined and responded to the relevant data and public comments. The court further held that HIPAA gives HHS wide latitude in setting privacy standards and nowhere requires the agency to maximize privacy interests over efficiency in the health care system and other legitimate concerns. Finally, the court rejected plaintiffs' constitutional claims on the ground that the Privacy Rule does not compel anyone to use or disclose health information for routine uses without patients' consent and does not interfere with any existing rights under state law or other standards.

STATEMENT OF FACTS

A. Statutory Framework.

The provisions of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, at issue in this case, Subtitle F of Title II, seek to improve “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.” HIPAA § 261 (JA 27).¹ To accomplish this goal, Congress directed HHS, among other things, to adopt

¹ Subtitle F of Title II of HIPAA consists of sections 261 through 264. Section 262 amends Title XI of the Social Security Act, 42 U.S.C. § 1301 et seq., to add a Part C, “Administrative Simplification,” with sections 1171-1179. Section 261 is found in the United States Code as a note to 42 U.S.C. § 1320d. Section 264 is found as a note to 42 U.S.C. § 1320d-2. Section 263 amends the Public Health Service Act, 42 U.S.C. § 242k(k). For simplicity, the government will refer to HIPAA by the sections as enacted, which can be found at JA 27-40.

uniform standards “to enable health information to be exchanged electronically.” Id. § 262 (JA 31). Congress instructed HHS to adopt standards for unique identifiers to identify individuals, employers, health care plans, and health care providers across the nation, and to adopt standards for transactions and data elements relating to health information, the security of that information, and verification of electronic signatures. Id. (JA 31-32).

Congress recognized that the new regulatory scheme posed risks to the privacy of confidential patient information by eroding practical barriers that historically had acted as safeguards against improper access to that information. See H.R. Rep. No. 496, 104th Cong., 2d Sess. 1, 99-100, reprinted in 1996 U.S.C.C.A.N. 1865, 1900. Thus, Congress directed HHS to submit “detailed recommendations on standards with respect to the privacy of individually identifiable health information” within one year of the statute’s enactment. HIPAA § 264(a). Congress specified that those recommendations should address “at least” three areas: (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.” Id. § 264(b).

Congress also provided that, if it did not enact legislation covering these matters within three years, HHS would be required to “promulgate final regulations containing such standards” no later than 42 months after HIPAA’s enactment. HIPAA § 264(c)(1). Congress specified that the privacy regulations adopted by HHS

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.

Id. § 264(c)(2).² Congress directed HHS to consult with both the Attorney General, HIPAA § 264(d), and the National Committee on Vital and Health Statistics (“NCVHS”) – a federal advisory committee established under the Public Health Service Act, 42 U.S.C. § 242(k), that was charged with providing advice on HIPAA’s implementation, HIPAA § 263(4)(D).

B. The Evolution Of The Privacy Rule.

As mandated by Congress, HHS submitted recommendations for protecting the privacy of individually identifiable health information on September 11, 1997. Congress did not act by August 21, 1999, and, under Section 264(c)(1) of HIPAA, HHS thereby became obligated to promulgate privacy regulations.

1. The Proposed Original Privacy Rule.

² In Section 262 of HIPAA (amending Sections 1178(b) and 1178(c) of the Social Security Act), Congress also stated that nothing in the statute or the privacy regulations promulgated thereunder “shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention,” and also that nothing “shall limit the ability of a State to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.” HIPAA § 262(a) (JA 36).

In 1999, HHS issued a notice of proposed rulemaking, entitled “Standards for Privacy of Individually Identifiable Health Information,” 64 Fed. Reg. 59918 (Nov. 13, 1999). In that proposed rule, HHS explained that the purpose of the Privacy Rule was to “improve the efficiency and effectiveness” of health care services “by providing enhanced protections for individually identifiable health information.” Id. at 59918. At the same time, however, HHS emphasized that “[i]ndividuals’ right to privacy in information about themselves is not absolute.” Id. at 60008 (noting that privacy rights must, for example, be balanced against law enforcement needs and the reporting of public health information such as communicable diseases). Thus, HHS sought to achieve “a balance,” allowing important uses of such information while protecting the privacy of individuals. Id. at 59927.

To achieve the proper balance, the proposed rule prohibited covered health care providers from using or disclosing protected health information except as provided by the rule. See 64 Fed. Reg. at 59924 (text of proposed 45 C.F.R. § 164.502(a)).³ Among other things, the proposed rule allowed covered entities to use or disclose individual health information without patient authorization “to carry out treatment, payment, or health care operations,” JA 40A (proposed 45 C.F.R. § 164.506(a)(1)(i)), and also permitted uses and disclosures for certain public policy purposes, including research, health oversight, and law enforcement, 64 Fed. Reg. at 60056-59 (proposed 45 C.F.R. § 164.510). However, for any purposes not recognized by the rule, covered entities would have to obtain specific

³ Protected health information was generally defined as individually identifiable health information that is or has been electronically transmitted or electronically maintained, including such information in any other form. JA 40A (64 Fed. Reg. 60053).

authorizations before using or disclosing an individual's information. JA 41 (proposed 45 C.F.R. § 164.508).

In the proposed rule, HHS explained that the provision allowing uses and disclosures of protected information without prior consent for treatment, payment or health care operations – the “routine use” provision at issue in this case – was necessary for the efficient operation of the health care system. HHS observed that treatment and payment “are the core functions of the health care system” for which persons seeking medical care “expect their health information will be used.” 64 Fed. Reg. at 59940. Likewise, “health care operations” are routine activities directly related to the core functions of treatment and payment, such as quality assurance, performance reviews, underwriting, auditing, fraud detection, or legal proceedings. *Id.* at 59933. As a result, HHS noted, allowing disclosures for certain public policy purposes and for these routine purposes without patients’ prior consent was “necessary for the smooth operation of the health care system and for promoting key public goals such as research, public health, and law enforcement.” *Id.* at 59923.

Notably, the proposed rule did not merely allow covered entities to disclose protected health information for routine uses without obtaining patients’ consent; it prohibited providers from seeking consent to make disclosures for routine uses unless applicable law required such consent. *Id.* at 59940-41; see also JA 41 (text of proposed 45 C.F.R. § 164.508(a)(2)(iv)). HHS explained that consent for these purposes could not provide meaningful privacy protections because:

these authorizations provide individuals with little actual control over their health information. When an individual is required to sign a blanket

authorization at the point of receiving care or enrolling for coverage, that consent is often not voluntary because the individual must sign the form as a condition of treatment or payment for treatment.

64 Fed. Reg. at 59940. In lieu of consent for routine uses, the proposed rule gave individuals the right to receive notices of information practices from covered entities, detailing the permitted uses and disclosures they intended to make of protected health information. Id. at 59926, 5977-79. These notices were intended to advise patients of their rights to request that a covered entity restrict its uses or disclosures of their information, see 45 C.F.R. § 164.422(a), and to require covered entities to comply with disclosure practices stated in the notices. 64 Fed. Reg. at 59945, 59978.

Finally, the proposed rule was not intended to supersede more stringent state law or other privacy protections; it simply created “a federal floor of privacy protection.” Id. at 59926.

2. The Original Privacy Rule.

Over a year later, after receiving over 52,000 public comments on the proposed Privacy Rule, HHS promulgated a final version of the Privacy Rule. See 65 Fed. Reg. 82462 (Dec. 28, 2000) (JA 333-358). The “Original Rule” maintained the structure of the proposed rule, but made a significant change by adopting a requirement that direct treatment providers obtain prior consent for the use or disclosure of health information for routine uses. JA 42; 65 Fed. Reg. at 82810 (former 45 C.F.R. § 164.506(a)(1)).

In adopting a consent requirement, HHS reiterated concerns it had expressed in the proposed rule “about the coerced nature of consents currently obtained by providers and plans relating to the use and disclosures of health information.” JA 344 (65 Fed. Reg. at

82473). Despite the continuing validity of these concerns, however, HHS acknowledged that it had received many public comments indicating “that both patients and practitioners believe that patient consent is an important part of the current health care system and should be retained.” Ibid.

For example, HHS noted comments “that the approach proposed in the NPRM actually reduced patient protections by eliminating the opportunity for patients to agree to how their confidential information would be used and disclosed.” JA 344. Although HHS continued to “believe that the provisions in the NPRM that provided for detailed notice to the patient and the right to request restrictions would have provided an opportunity for patients and providers to discuss and negotiate over information,” it acknowledged “that many practitioners and patients believe the approach proposed in the NPRM is not an acceptable replacement for the patient providing consent.” Ibid. Thus, HHS believed at the time that the consent requirement “could accommodate both the covered entity’s need to use or disclose protected health information for treatment, payment and health care operations and also the individual’s interests in understanding and acquiescing to such uses and disclosures.” 65 Fed. Reg. at 82498. Accordingly, HHS altered the approach taken in the proposed rule, stating that its “goal” in so doing was “to provide an opportunity for and to encourage more informed discussions between patients and providers about how protected health information will be used and disclosed within the health care system.” JA 345 (65 Fed. Reg. at 82474).

The Original Rule required covered health care providers to obtain patients’ consent “prior to using or disclosing protected health information to carry out treatment payment, or health care operations,” JA 42; 65 Fed. Reg. at 82810 (text of former 45 C.F.R. §

164.506(a)(1)), although even this requirement was qualified by a number of important exceptions. The rule provided exceptions for any provider who has “an indirect treatment relationship” with a patient and for those offering treatment to prison inmates. 45 C.F.R. § 164.506(a)(2).⁴ And, the rule provided exceptions in three other limited sets of circumstances, including emergency treatment situations – so long as consent was sought as soon as reasonably practicable after emergency treatment was provided. Id. § 164.506(a)(3).

The rule also stated that the forms used to obtain patients’ consent must: (1) include a general statement that protected health information may be used to carry out treatment, payment or health care operations, (2) refer patients to the provider’s notice of privacy practices, (3) inform patients of their right to request restrictions on the use and disclosure of their protected health information, and (4) inform patients of their right to revoke consent at any time. JA 42 (65 Fed. Reg. at 82810). The Original Rule further provided that “covered health care providers may condition treatment on the provision by the individual of a consent under this section.” JA 42 (text of former 45 C.F.R. § 164.506(b)(1)).

⁴ In addition to indirect treatment providers, millions of other covered entities – health plans and health care clearinghouses – could disclose protected health information for routine purposes without patients’ consent. Thus, even under the version of the Privacy Rule preferred by plaintiffs, only a small subset of entities subject to the Privacy Rule would be required to obtain patient consent for routine uses.

Compliance with the Privacy Rule was not required until April 14, 2003.⁵ Thus, the rule conferred no immediate right on patients to stop uses or disclosures of protected health information without their consent. Moreover, the Original Rule allowed health care providers that provide direct treatment to use or disclose individual health information created or obtained prior to the compliance date based on patient consent obtained prior to that date, even if the pre-existing consent did not meet the formal requirements of the rule. 65 Fed. Reg. at 82828. Absent such consent, direct treatment providers were prohibited from using or disclosing protected health information obtained prior to April 14, 2003 for routine uses as of that date. ibid.

Finally, like the proposed rule, the Original Rule did not preempt state law or other provisions that provided more stringent privacy protections for individually identifiable health information. 65 Fed. Reg. at 82800-01.

3. The Proposed Amended Privacy Rule.

⁵ The initial compliance date was February 26, 2003, see 65 Fed. Reg. at 82462, but that date was later changed to April 14, 2003 based on HHS's determination that the report to Congress required by 5 U.S.C. § 801(a)(1) was not received until February 13, 2001. Because the effective date is 60 days after Congress receives the report, the Rule was not effective until April 14, 2001. Covered health care providers, health care clearinghouses and most health plans had two years – until April 14, 2003 – to come into compliance. Small health plans had three years – until April 14, 2004 – to come into compliance. See 66 Fed. Reg. 12434 (Feb. 26, 2001); 45 C.F.R. § 164.534.

After publication of the Original Rule, HHS received numerous inquiries and comments raising questions and concerns about the impact and operation of the rule on various sectors of the health care industry, focusing primarily on the rule's complexity and workability. As a result, in February 2001, HHS solicited additional public comments on the rule "to ensure that the provisions of the Privacy Rule would protect patients' privacy without creating unanticipated consequences that might harm patients' access to [quality] health care." 66 Fed. Reg. 12738, 12739 (Feb. 28, 2001). During the thirty-day comment period that followed, HHS received approximately 11,000 additional comments on the Original Rule. Many of these comments identified potential adverse effects that the consent requirement for routine uses would have on access to, and the delivery of, health care services. See generally JA 367-830 (selected comments raising concerns about consent requirement).

For example, many pharmacists explained that the consent requirement would prevent them from filling prescriptions, searching for potential drug interactions, or verifying coverage if an individual had not already provided consent before arriving to pick up a prescription and that this problem would be exacerbated in the case of patients too ill or elderly to pick up their own prescriptions. See, e.g., JA 371, 373, 377, 649, 820. Likewise, hospital representatives explained that the consent requirement would prevent them from using information from referring physicians to schedule and prepare for procedures before a patient arrives for treatment. See, e.g., JA 542, 670-71, 497, 520-21, 818, 866. Finally, emergency medical providers expressed concerns over what circumstances would qualify for the "emergency treatment" exception to the consent requirement, and explained that compliance with the requirement that they seek consent as soon as reasonably practicable

after an emergency would significantly increase their administrative burdens and divert their resources from responding to other emergencies. See, e.g., JA 408-12, 418-23, 719.

See also JA 930-31 (summarizing public comments in proposed rule).

As a result of these and numerous other comments – including a report by the General Accounting Office, JA 815-25, and an August 2001 hearing held by the NCVHS, JA 833-917 (the advisory committee Congress directed HHS to consult with in promulgating privacy standards, see HIPAA § 264(d)) – HHS proposed several modifications to the Original Privacy Rule, including elimination of the consent requirement for routine uses. See 67 Fed. Reg. 14776 (Mar. 27, 2002) (excerpts at JA 927-934).

HHS proposed to replace the consent requirement in the Original Rule with a new provision, 45 C.F.R. § 164.506(a),

that would provide regulatory permission for covered entities to use or disclose protected health information for treatment, payment, and health care operations, and a new provision at § 164.506(b) that would allow covered entities to obtain consent if they choose to, and make clear that such consent may not permit a use or disclosure of protected health information not otherwise permitted by the Privacy Rule.

67 Fed. Reg. at 14781. In addition, in order to enhance the opportunities for individuals to discuss privacy practices with their health care providers, HHS proposed to strengthen the requirements regarding notices of privacy practices, by requiring direct treatment providers to make good faith efforts to obtain patients' written acknowledgments that they have received the notices. Id. at 14780 (JA 931).

As HHS explained in the Proposed Amended Rule, these modifications were responsive to numerous public comments raising “issues and serious concerns that the consent requirements will impede access to, and the delivery of, quality health care.” Id. at 14779 (JA 930). Summarizing a few of the comments from pharmacists, hospitals, and emergency treaters outlined above, HHS stated that

many covered entities described an array of circumstances when they need to use or disclose protected health information for treatment, payment, or health care operations purposes prior to the initial face-to-face contact with the patient, and therefore prior to obtaining consent.

Ibid. In light of these and other comments, including a recommendation from the NCVHS that HHS should “consider circumstances in which protected health information could be used and disclosed without an individual’s prior written consent,” id. at 14790 (JA 931); see JA 918-23, HHS proposed to eliminate the consent requirement for routine uses. At the same time, HHS proposed to add a new provision to the Privacy Rule that would allow covered entities to obtain consent if they chose to, and would “make clear that such consent may not permit a use or disclosure of health information not otherwise permitted or required by the Privacy Rule.” JA 932 (67 Fed. Reg. at 14781).

4. The Final Amended Privacy Rule.

After considering over 11,400 comments received during the thirty-day period following publication of the proposed rule, HHS promulgated a Final Amended Privacy Rule eliminating the consent requirement contained in the Original Rule. See 67 Fed. Reg. 53182 (Aug. 14, 2002) (JA 1376-87). The Final Amended Rule allowed covered entities to seek consent to use or disclose information for routine uses if they chose to, and retained virtually all the other privacy protections contained in the Original Rule, including the requirement to obtain authorization for any uses or disclosures not permitted by the rule. JA 1381. Like earlier versions of the rule, the final rule also expressly provided that state law will not be preempted if it provides more stringent standards for protecting the privacy of individually identifiable health information. 45 C.F.R. § 160.203(b).

In explaining its rationale for eliminating the consent requirement for routine uses, HHS reiterated the primary concern expressed in the proposed rule: that the consent requirement would “result in unintended consequences that impede the provision of health care in many critical circumstances.” JA 1380 (67 Fed. Reg. at 53210). In addition, HHS noted that it was “also concerned that other such unintended consequences may exist which have yet to be brought to our attention.” Ibid. HHS then reviewed the voluminous public comments relating to the issue of consent and offered detailed responses. JA 1380-85.

HHS first noted that “almost all of the commenters that discussed consent acknowledged that there are unintended consequences of the consent requirement that would interfere with treatment.” JA 1380 (67 Fed. Reg. at 53210). HHS explained that the comments offered two potential approaches to fixing these problems: “adopting a single solution that would address most or all of the concerns,” or “adopting changes targeted to each specific problem.” Ibid. One goal in making modifications to the Privacy Rule was “to

simplify, rather than add complexity to, the Rule,” and another was “to assure that the Privacy Rule does not hamper necessary treatment.” For both of these reasons, HHS was concerned with adopting different changes for different issues related to consent, and thus explained that the options that it “most seriously considered were those that would provide a global fix to the consent problem.” Ibid. Nonetheless, after carefully considering the various global options proposed, HHS concluded that “each had some flaw or failed to address all of the treatment-related concerns brought to our attention.” JA 1382 (67 Fed. Reg. at 53212).

For example, HHS rejected comments suggesting “that the Rule be modified to require a good faith effort to obtain consent at first service delivery,” because they “failed to explain how that approach would provide additional protection than the approach we proposed.” JA 1382. Likewise, HHS

decided against eliminating the consent requirement only for uses and disclosures for treatment, or only for uses of protected health information but not for disclosures because these options fall short of addressing all of the problems raised. Scheduling appointments and surgeries, and conducting many pre-admission activities are health care operations activities, not treatment.

Ibid. Similarly, HHS explained that “[r]etaining the consent requirement for payment would be problematic because, in cases where a provider, such as a pharmacist or hospital, engages in a payment activity prior to face-to-face contact with the individual, it would prohibit the provider from contacting insurance companies to obtain pre-certification or to verify coverage.” Ibid. Given the flaws in these and other global approaches proposed, and the “substantial amount of support from commenters for the approach taken in the NPRM” (including support from the NCVHS, JA 1380), HHS concluded that eliminating the consent requirement “makes the most sense and meets the goals of not interfering with access to

quality health care and of providing a single standard that works for the entire industry.” JA 1382 (67 Fed. Reg. at 53212).

At the same time, however, HHS continued to recognize the importance of preserving patients’ opportunities “to discuss privacy practices” with their medical providers, and to be involved “in decisions related to the use and disclosure of protected health information.” JA 1380 Accordingly, the Final Amended Rule “strengthen[ed] the notice requirements to preserve the opportunity for individuals to discuss privacy practices and concerns with providers,” JA 1381 (67 Fed. Reg. at 53211), by requiring direct treatment providers to make good-faith efforts to obtain their patient’s written acknowledgment that they have received the provider’s notice of privacy practices, 67 Fed. Reg. at 53239-40 (45 C.F.R. § 164.520(c)(2)(ii)).⁶

Finally, HHS emphasized that the Final Amended Rule retained several other provisions critical to the protection of privacy, including the requirement that covered entities must obtain a patient’s authorization, under 45 C.F.R. § 164.508, for any uses or disclosures of protected health information not otherwise permitted under the rule, and the right of patients to request additional restrictions on the use or disclosure of their health information, pursuant to 45 C.F.R. § 164.522(a), which would then bind covered entities that agreed to such restrictions. See JA 1381 (67 Fed. Reg. at 53211).

⁶ HHS rejected arguments “that the signed notice of a provider’s privacy policy would be meaningless if the individual has no right to withhold consent.” JA 1383 (67 Fed. Reg. at 53213). Because providers had a right under the Original Rule to withhold treatment absent consent by patients to their disclosure practices, HHS explained that the notice provisions in the Final Amended Rule provided essentially the same privacy protections as the “right to withhold consent” in the Original Rule – by allowing a patient “who disagrees with the covered entity’s information practices” to “choose not to receive treatment from that provider.” Ibid.

C. Proceedings In This Case.

Plaintiffs, a group of health care providers, individuals, and health care organizations, filed suit in district court challenging HHS's decision not to require consent for routine uses in the Final Amended Privacy Rule. Plaintiffs argued: (1) that HHS violated the APA by failing to provide a reasoned explanation for its decision to eliminate the consent requirement for routine uses, (2) that HHS exceeded its authority under the HIPAA by eliminating that requirement, and (3) that HHS's decision not to require consent for routine uses in the Final Amended Privacy Rule violated plaintiffs' constitutional rights, including their right to privacy and a First Amendment right to confidential physician-patient communications.

On cross-motions for summary judgment, the district court upheld the Final Amended Privacy Rule in all respects. JA 1-15. After describing the applicable regulatory framework and the evolution of the Privacy Rule, the court first held that at least one of the plaintiffs, Dr. Deborah Peel, had standing to challenge the rule. The court concluded that Dr. Peel had demonstrated "injury in fact" because the Final Amended Rule "changed the legal landscape established by the Original Rule for the disclosure of health information for routine purposes," JA 9, and also held that there was sufficient causation for standing purposes "because the Amended Rule has a sufficiently determinative or coercive effect on the action of the providers," JA 10. Moreover, the court held that Dr. Peel had demonstrated redressability because "it is not 'merely speculative' that vacating the Amended Rule and reinstating the Original Rule would redress Dr. Peel's alleged injury."⁷ Ibid.

⁷ Although HHS did not cross-appeal the district court's

decision with respect to standing, it is well-settled that “[s]tanding represents a jurisdictional requirement which remains open to review at all stages of the litigation.” National Organization for Women, Inc. v. Scheidler, 510 U.S. 249, 255 (1994). At a minimum, the district court’s conclusion “that vacating the Amended Rule and reinstating the Original Rule would redress Dr. Peel’s alleged injury,” JA 9, is highly questionable because, if the Final Amended Privacy Rule is held unlawful in some respect, the proper remedy would not be to reinstate the Original Rule but rather to remand to the agency for appropriate action in light of the court’s decision.

Turning to plaintiffs' APA claim, the district court held that HHS had provided a reasoned explanation for its decision to eliminate the consent requirement and had adequately examined and responded to the relevant data and public comments. JA 11-13. Among other things, the court noted that HHS had properly relied on numerous public comments which "indicated that the consent requirement represented a significant change in practice and could substantially impair delivery of health care," and stated that HHS had adequately "explained that rescinding the consent requirement solved the identified health care delivery problems caused by the requirement in the most efficient manner." JA 11. The court also emphasized HHS's findings that "incorporating targeted fixes as suggested by some commenters would make the rule even more complex, without solving all of the problems." JA 11 (citing 67 Fed. Reg. at 53212).

Likewise, the court held that HHS had examined the relevant data and had not taken any action inconsistent with its previous findings. Among other things, the court found that HHS "never stated that the right to privacy was absolute when it implemented the Original Rule," and emphasized that "[p]rivacy concerns were always to be balanced against the goal of improving efficiency of the health care system." JA 12. "Indeed," the court noted, "the very findings that supported the Original Rule had supported the initial proposal to prohibit consent." Ibid. The court stated that "[c]onsent in the Original rule was required to provide patients with the opportunity to discuss privacy practices and request further restrictions," and noted HHS's explanation that "the Amended Rule achieves the same goal through its more stringent notice requirements." Ibid. As a result, the court held that "the Secretary examined the relevant data and the Secretary's explanation shows more than a

mere rational connection between the facts and the choice to rescind the consent requirement.” Ibid.

In addition, the court held that HHS had adequately responded to public comments because it “considered the relevant factors Congress intended the agency to consider,” such as the efficiency and effectiveness of the health care system and the privacy of health information. JA 12-13. In the end, the court concluded, the Secretary “just balanced the factors in a way with which the plaintiffs disagree.” JA 13.

With respect to plaintiffs’ claim that HHS had exceeded the scope of its authority under the HIPAA, the district court first noted that “[a] regulation falls within the scope of statutory authority as long as it is reasonably related to the purposes of the enabling legislation.” JA 13 (citing Mourning v. Family Publications Serv., Inc., 411 U.S. 356, 369 (1973)). The court found that the regulation easily satisfied this standard because the agency’s “mandate is to balance privacy protection and the efficiency of the health care system – not simply to enhance privacy.” JA 13.

In addition, the court held that the Final Amended Privacy Rule was not impermissibly retroactive in any respect. Although the Original Rule became effective on April 14, 2001, covered entities were not required to comply with that rule – including the consent requirement – for two years. Because “[c]overed entities were never under a legal obligation to comply with the Original Rule’s consent requirement,” the court held that “the Original Rule did not create rights that were subsequently eliminated by the Amended Rule.” JA 14. Likewise, relying on the non-preemption provisions in both HIPAA and the Privacy Rule itself, the court also held that “the Amended rule does not impair any stricter privacy rights created by state law, ethical codes or standards of practice.” JA 13.

Finally, the court rejected plaintiffs' argument that HHS's decision to eliminate the consent requirement for routine uses in the Final Amended Privacy Rule violates their constitutional rights. Assuming, without deciding, "that the plaintiffs have a constitutional right to privacy over their medical records and to patient-health care provider communications," the court held that the final Privacy Rule does not violate those rights because it "is wholly permissive with respect to whether a covered entity should seek consent from a patient before using his or her information for routine purposes." JA 14. Because the rule does not "place obstacles in the paths of patients seeking to have confidential communications with their health care providers," and "does not require doctors to do anything with respect to routine uses of health care information," the court concluded that "it does not affirmatively interfere with any right." Ibid. Indeed, the court noted, "[t]o the extent the Amended Rule mandates any actions, it protects plaintiffs' putative rights" by, for example, prohibiting "covered entities from disclosing and using health information for reasons unrelated to health care without proper authorization." JA 15. Thus, characterizing plaintiffs' claim as a challenge to HHS's decision "not to compel covered entities to obtain prior consent," the court concluded that the Constitution "does not command the Secretary to act affirmatively to protect such rights." Ibid.

SUMMARY OF ARGUMENT

In enacting HIPAA, Congress sought to improve the efficiency of the nation's health care system by promoting standards for the electronic transmission of health information. Recognizing that increased transmission of medical information could increase the risk that

confidential information might be improperly disclosed, Congress also directed HHS to promulgate standards to protect patient privacy.

The final Privacy Rule issued by HHS reflects a balance between HIPAA's two primary goals: promoting efficiency and cost-savings in the delivery of health care services, and protecting the privacy of individual medical information. The Privacy Rule prohibits the use or disclosure of individually identifiable health information except as specifically permitted under the rule, and it does not displace any state law or other provisions that provide more stringent privacy protections.

Where not superseded by provisions of state law providing "more stringent" privacy protections, the Privacy Rule also permits the limited use and disclosure of individually identifiable health information for certain "routine uses" (i.e., treatment, payment, or health care operations) without patients' prior consent. That is because such uses and disclosures are critical to the timely and efficient delivery of health care and because numerous public comments received by HHS during the extensive rulemaking proceedings for the Privacy Rule demonstrated that imposing a consent requirement in this context would give rise to a host of unintended consequences that could substantially impair and delay the delivery of health care.

In promulgating the final Privacy Rule, HHS explained that the difficulties created by a consent requirement in the routine use context would not be offset by a significant gain in privacy protections. As the agency consistently recognized throughout the rulemaking process, consent, which is frequently involuntary, would not provide significant additional privacy protections in the context of routine uses, because medical providers could always refuse treatment absent consent to their disclosure practices. Thus, although a consent

requirement could provide an opportunity for patients to discuss disclosure practices with their providers, HHS reasonably concluded that functionally equivalent benefits could be realized by strengthening the provisions governing notice of privacy practices.

Plaintiffs contend that HHS's decision to eliminate the consent requirement for routine uses in the final version of the Privacy Rule violated the Administrative Procedure Act, exceeded the scope of HHS's authority under HIPAA, and violated their constitutional right to privacy in their medical records and their First Amendment rights to confidential physician-patient communications. As the district court correctly held, each of these arguments is without merit.

I. As noted, HIPAA does not mandate the imposition of a consent requirement in the context of routine uses. To the contrary, the statute expressly recognizes the need to balance efficiency in the delivery of health care with privacy interests and delegates to HHS the task of promulgating a Privacy Rule reflecting a proper balance between these competing considerations. As the district court correctly observed, nothing in the statute's broad delegation of authority to HHS requires the agency "to maximize privacy interests over efficiency interests." JA 13.

Throughout the extensive rulemaking proceedings, HHS at no time believed that a consent requirement for routine uses was statutorily compelled. To the contrary, at every stage in the process, the agency recognized the need to strike a balance between gains in efficiency and gains in privacy. And, at every stage, HHS provided a reasoned explanation for the balance it struck. The agency consistently recognized that the consent requirement would provide only marginal added privacy protections in the routine use context. Thus, when numerous public comments underscored the adverse consequences that would likely

flow from imposing a consent requirement, HHS modified the Privacy Rule to make consent for routine uses optional, while simultaneously strengthening the notice provisions of the rule to ensure that patients would have an adequate opportunity to discuss disclosure practices with their providers.

Plaintiffs do not seriously contend that HHS acted unreasonably in assessing the adverse impact that would result from a consent requirement. Instead, plaintiffs argue primarily that HHS failed to draw the proper conclusions from the public comments and failed adequately to consider “more targeted” alternative approaches to eliminating the consent requirement. At bottom, however, these arguments do not demonstrate that HHS acted unreasonably; they reflect plaintiffs’ preference for a different approach than the one HHS adopted. But neither plaintiffs nor the courts may substitute their judgment for that of the agency charged by Congress to evaluate competing policy considerations and strike the proper balance between privacy concerns and efficiency in the delivery of health care. Because HHS examined the relevant evidence and provided a rational explanation for the facts found and the choices made, its decision to eliminate the consent requirement in the final Privacy Rule must be sustained.

II. Plaintiffs’ constitutional claims do not advance their argument. Even assuming (as the district court did) that plaintiffs have a constitutional right to privacy regarding their health information and medical records, the Privacy Rule promulgated by HHS to enhance the protection of that right does not violate the Constitution. The Privacy Rule does not diminish otherwise existing privacy protections, and the Constitution clearly does not require the agency to enact new protections meeting plaintiffs’ preferred standards. As the district court recognized, “[b]ecause the Amended Rule does not compel anyone to use or disclose the

plaintiffs' health information for routine purposes without the plaintiffs' consent," JA 14-15, it does not even implicate, much less violate, their constitutional rights.

STATEMENT OF RELATED CASES AND PROCEEDINGS

This case has not previously been before this Court, and we are unaware of any related proceeding before this Court or any other court of appeals.

STANDARD OF REVIEW

An agency's decision to rescind or modify a regulation is reviewed under the same "arbitrary or capricious" standard that the APA applies to the initial promulgation of a rule. See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co., 463 U.S. 29, 41 (1983). Under this deferential standard, a court may not "substitute its judgment for that of the agency." Id. at 43. Judicial review is instead limited to determining whether the agency has articulated a "rational connection between the facts found and the choice made . . . whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Ibid. (internal quotations and citations omitted). So long as the agency provides a reasoned explanation for its action, it must be upheld. See Fertilizer Institute v. Browner, 163 F.3d 774, 778 (3d Cir. 1998); CK v. New Jersey Dep't of Health and Human Servs., 92 F.3d 171, 182 (3d Cir. 1996); Frisby v. HUD, 755 F.2d 1052, 1055 (3d Cir. 1985).

Questions of law, such as the scope of HHS's authority under the HIPAA and the constitutionality of the agency's actions, are subject to de novo review.

ARGUMENT

I. HHS ACTED WELL WITHIN ITS DISCRETION UNDER HIPAA AND PROVIDED A REASONED EXPLANATION FOR ITS DECISION NOT TO INCLUDE A CONSENT REQUIREMENT FOR ROUTINE USES IN THE FINAL PRIVACY RULE.

In enacting HIPAA, Congress sought to improve “the efficiency and effectiveness of the health care system,” by developing “standards and requirements for the electronic transmission of certain health information.” HIPAA § 261 (JA 27). To accomplish this goal, Congress directed HHS, among other things, to adopt uniform standards “to enable health information to be exchanged electronically.” *Id.* § 262 (JA 31). Congress also instructed HHS to submit “detailed recommendations on standards with respect to the privacy of individually identifiable health information” within one year of the statute’s enactment. HIPAA § 264(a). Congress specified that those recommendations should address “at least” three areas: (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.” *Id.* § 264(b) (JA 39).

The final Privacy Rule adopted by HHS provides a panoply of protections for the privacy of individually identifiable health information. See generally JA 1381 (67 Fed. Reg. at 53211). It prohibits the use or disclosure of protected health information except as expressly permitted by the rule, and it requires covered entities to obtain a patient’s authorization for uses or disclosures not otherwise permitted. See 45 C.F.R. § 164.508. It

permits, but does not require, covered entities to obtain patients' consent for routine uses of their protected health information, and it also makes clear that such consent does not constitute authorization for uses or disclosures other than routine uses. Id. § 164.506(b). It allows individuals to request restrictions on the use and disclosure of their protected health information, id. § 164.522(a), and allows individuals and covered entities to enter agreements reflecting such restrictions. It requires covered entities to make good-faith efforts to obtain their patients' written acknowledgment that they have received the provider's notice of privacy practices, id. § 164.520(c)(2)(ii). And, it does not displace "more stringent" privacy protections under state law or other provisions. HIPAA § 264(c)(2); 45 C.F.R. § 160.203.

Plaintiffs here challenge that aspect of the final Privacy Rule that deals with disclosures of medical information for treatment, payment, or health care operations. In promulgating that rule, HHS concluded that very real threats to efficiency created by the imposition of a consent requirement would not be offset by meaningful gains in privacy protection. Accordingly, the agency did not require advance consent in these circumstances and, instead, strengthened the requirement for covered health care providers who provide direct treatment to distribute notices of privacy practices "to preserve the opportunity for individuals to discuss privacy practices and concerns with their providers." JA 1381 (67 Fed. Reg. at 53211). Moreover, the final Privacy Rule expressly allows such providers to seek consent in this context if they choose to do so. 45 C.F.R. § 164.506(b).

As the district court recognized, the final Privacy Rule in no sense contravenes any specific statutory command. To the contrary, as the language quoted above demonstrates,

HIPAA confers broad rulemaking authority on HHS to promulgate privacy standards.⁸ As the district court observed, HHS’s modifications to the final Privacy Rule fall well within that grant of authority because they “are reasonably related to the legislative purpose of Subtitle F.” JA 13.

⁸ Although HIPAA’s grant of authority to HHS is quite broad, the Fourth Circuit recently held that the statute does not violate the non-delegation doctrine. See South Carolina Medical Ass’n v. Thompson, 327 F.3d 346 (4th Cir. 2003). While the Association of American Physicians and Surgeons has filed an amicus brief in this case advancing a non-delegation argument, it would be inappropriate for this Court to address that argument given plaintiffs’ failure to raise it either in this Court or in the district court. See In re: Paoli Railroad Yard PCB Litigation, 221 F.3d 449, 465 (3d Cir. 2000) (noting that Court need not reach arguments presented only by amici).

Relying on snippets of legislative history from HIPAA, plaintiffs contend that “[t]here is no evidence of Congressional intent to sacrifice the public’s medical privacy to the interests of covered entities in efficiency and ‘flexibility’ as the Secretary as done in the Amended Rule.” Pl. Br. 39. This rhetorical declaration mischaracterizes both the content of the Privacy Rule and the requirements of HIPAA. As explained above, the final Privacy Rule establishes comprehensive protections for the privacy of individually identifiable health information. See JA 1381 (67 Fed. Reg. at 53211). The agency’s decision not to impose a consent requirement for routine uses thus by no means “eliminates medical privacy.”⁹ It is simply a modification to one component of the many provisions of the Privacy Rule that provide new federal protections for the overall privacy of medical records and information.

At no point in the extensive rulemaking history did HHS believe that the particular requirement sought by plaintiffs was statutorily compelled. From the time of its first proposed rule, HHS recognized that the task before it was to create privacy protections that would not undermine the enhanced efficiency that is an express goal of the HIPAA. See JA 27 (HIPAA § 261) (noting that purpose of administrative simplification provisions is to

⁹ Plaintiffs repeatedly level the accusation that the final Privacy Rule “eliminates medical privacy” in routine use situations. See, e.g., Pl. Br. 60. It does no such thing. As HHS has consistently explained, even when it promulgated the Original Rule, a consent requirement would provide little meaningful added privacy protection, because providers could refuse treatment absent consent to their disclosure practices. JA 351 (65 Fed. Reg. at 82648). Thus, consent has never been the equivalent of privacy, and plaintiffs’ continued efforts to conflate these two concepts are both misguided and misleading.

improve “the efficiency and effectiveness of the health care system”). Indeed, the initial version of the Privacy Rule HHS proposed would have prohibited covered entities from seeking consent to make disclosures for routine uses. See JA 41 (text of proposed 45 C.F.R. § 164.508(a)(2)(iv)).

The agency’s reluctance to impose a consent requirement in the context of routine uses reflects a consistent recognition that such a requirement would likely provide little meaningful privacy protection or offer patients any real control over the use of their health care information. Because physicians could simply refuse to provide treatment absent consent, the consent process would inevitably include a strong element of coercion. See 64 Fed. Reg. at 59940; JA 351 (65 Fed. Reg. at 82648).¹⁰ The primary virtue of a consent requirement would be “to provide an opportunity for and to encourage more informed discussions between patients and providers about how protected health information will be used and disclosed within the health care system,” JA 345 (65 Fed. Reg. 82474).

Ultimately, HHS concluded, consistent with its original proposed rule, that the benefits of a consent requirement could be achieved in other ways, such as by strengthening the requirement to distribute notices of privacy practices and thus enhancing opportunities for patients to discuss those practices with their providers. In reaching this conclusion, HHS

¹⁰ Plaintiffs incorrectly contend that the Original Rule would have avoided this problem because “[t]he plain language of the Original Rule does not prohibit a patient from receiving health care if he does not sign a consent form.” Pl. Br. 49. But the plain language of the Original Rule clearly does allow covered entities to condition treatment on consent by a patient. See JA 42 (text of former 45 C.F.R. § 164.506(b)(1)). Thus, the record supports HHS’s view that the options available to patients under the Original Rule (withholding consent and being refused treatment) are functionally equivalent to the options available under the Amended Rule (choosing not to receive treatment based on a provider’s description of his disclosure practices). See JA 1383 (67 Fed. Reg. at 53213).

analyzed public comments, testimony, and the expert recommendations of the NCVHS (the advisory committee Congress directed HHS to consult with in promulgating the Privacy Rule) demonstrating that the consent requirement would substantially impede the delivery of health care services, resulting in delay and inconvenience for patients and, in certain critical situations, threatening the health or well-being of persons in need of medical treatment. See JA 1379-80 (67 Fed. Reg. at 53209-10) (summarizing public comments).

For example, the consent requirement would likely have interfered with patients' timely access to prescription drugs, see JA 371, 373, 377, 649, 820, delayed or interfered with treatment by specialists and hospitals receiving referrals from other physicians, see JA 542, 670-71, 497, 520-21, 818, 866, and interfered with treatment by emergency medical providers, see JA 408-12, 418-23, 719. As HHS summarized,

The most troubling, pervasive problem was that health care providers would not have been able to use or disclose protected health information for treatment, payment, or health care operations purposes prior to their initial face-to-face contact with the patient, something which is routinely done today to provide patients with timely access to quality health care.

JA 1379 (67 Fed. Reg. 53209).

Plaintiffs do not seriously dispute that the public comments identified significant adverse impacts on patients' access to health care. JA 1380 (67 Fed. Reg. at 53210) (noting that "almost all of the commenters that discussed consent acknowledged that there are unintended consequences of the consent requirement that would interfere with treatment"). Nor could they, as a wide range of individuals and institutions – including the NCVHS, JA 919-21, and the GAO, JA 822-24 – expressed serious concerns about the likely negative impact of that requirement. Indeed, the NCVHS supported eliminating the consent requirement in the context of routine uses, noting that HHS's revision "strikes the proper

balance between the benefits of informing and empowering patients and the burdens of requiring covered entities to have patients complete additional paperwork.” JA 935.

Instead, plaintiffs argue that HHS failed to address various comments and alternatives with sufficient specificity. As the district court recognized, however, these arguments reveal not a flaw in the rulemaking but a disagreement with HHS’s conclusion.

Plaintiffs assert that 5,000 comments urged HHS to retain the consent requirement while 4,000 comments urged HHS to revoke that requirement, and that 3,000 of the “anti-consent” comments “were submitted by hospitals, health facilities and insurers, and many were form letters generated by a few large insurance companies and health system.” Pl. Br. 56. However, the issue is not the sheer volume of comments on side or another of a specific question, but whether the agency considered the relevant factors as revealed by “the policy, purpose, and goals set forth in the applicable statute.” Frisby, 755 F.2d at 1057. See also City of Waukesha v. EPA, 320 F.3d 228, 257 (D.C. Cir. 2003).

Even a cursory examination of the final Privacy Rule demonstrates that HHS “balanced the privacy implications of uses and disclosures for treatment, payment, and health care operations and the need for these core activities to continue.” JA 1378 (67 Fed. Reg. at 53208). Among other things, HHS took privacy interests into account by allowing health care providers to obtain consent for routine uses of protected medical information (in contrast with the Proposed Rule’s prohibition on consent), and by strengthening the notice provisions requiring providers to obtain a written acknowledgment of receipt of the notice – thereby enhancing opportunities for patients to discuss disclosure practices with their providers. Thus, as the district court recognized, plaintiffs’ claim was not that HHS ignored

the relevant factors but that it “balanced the factors in a way with which the plaintiffs disagree.” JA 13.

Contrary to plaintiffs’ assumption, HHS was not required to specifically address all comments and proposed alternatives. Although plaintiffs identify a variety of specific comments HHS allegedly “failed to address,” PI. Br. 57, plaintiffs’ own description of HHS’s responses in many cases demonstrates not that HHS ignored comments but that the agency responded in a way that plaintiffs believe was insufficiently attuned to their views of the best ways to protect privacy.

For example, plaintiffs contend that HHS “summarily dismissed” concerns raised by the American Medical Association that optional consent, combined with a broad definition of “health care operations,” would compel patients to permit a broad range of uses and disclosures. PI. Br. 57. However, plaintiffs acknowledge (as they must) that HHS specifically responded to the AMA’s comments by stating “that narrowing the definition of ‘health care operations’ would place serious burdens on covered entities and impair their ability to conduct legitimate business and management functions.” JA 1382 (67 Fed. Reg. at 53212). Plaintiffs’ stated belief that “[t]his response ignored the thrust of the comment that the loss of medical privacy would compel patients to allow their health information to be used against their will,” PI. Br. 57, does not demonstrate that HHS ignored the AMA’s comments; it shows only that plaintiffs disagree with how HHS chose to address these comments.

Likewise, plaintiffs criticize HHS for not citing “a single example where access to quality health care actually had been delayed due to obtaining patient permission for the use and disclosure of health information.” PI. Br. 47. But this charge is highly misleading because, as noted, HHS eliminated the consent requirement long before health care

providers ever had to comply with it. And, although plaintiffs suggest that examples of negative impacts from a consent requirement for routine uses should have been available because “consent has been required throughout the nation’s history by federal and state statutory and common law and standards of medical practice,” Pl. Br. 48, the administrative record demonstrates that it is not standard practice among health care providers to obtain prior written consent before using or disclosing protection health information for many routine uses. See e.g., JA 344 (65 Fed. Reg. at 82473) (examining state laws and noting that, “[u]nder these exceptions, providers can disclose health information without any consent or authorization from the patient”).

HHS also provided a reasoned explanation for its decision not to rely on piecemeal solutions to specific problems. Because the treatment-related obstacles and other problems identified by commenters were numerous and varied – and even more problems could reasonably be anticipated after compliance with the Privacy Rule was required – HHS was concerned that individual fixes would simply add complexity to an already-complex rule, while still overlooking important problems. JA 1379-82 (67 Fed. Reg. at 53209-12). HHS thus explored the “global approaches” proposed by various commenters, but explained that “each had some flaw or failed to address all of the treatment-related concerns brought to our attention.” JA 1382.¹¹

¹¹ For example, HHS explained that “[t]he suggestion to allow certain uses and disclosures prior to first patient encounter would not address concerns [about] tracking consents, use of historical data for quality [assurance] purposes, or the concerns of emergency treatment providers.” JA 1382.

In the end, plaintiffs largely ignore the explanations HHS provided for its actions while faulting the agency for not providing more complete responses to other comments. But the focus and extent of HHS's responses to comments and proposed alternatives reflect the agency's expert judgment concerning the relative importance of different issues. Although plaintiffs clearly disagree with the manner in which HHS chose to address the voluminous administrative record before it, their belief that the explanations HHS gave for rejecting various alternatives were inadequate – no matter how strongly held – does not demonstrate that the agency failed to respond adequately to public comments. Because HHS adequately considered the most significant concerns raised by public comments and responded in detail to those it concluded were the most important, the agency fully satisfied the “reasoned decision-making” requirement under the APA.

In a different vein, plaintiffs also argue that HHS did not adequately address comments suggesting that the Privacy Rule would effectively supersede more stringent state law and ethical standards, Pl. Br. 51-53. But both the Privacy Rule and HIPAA expressly state that “more stringent” state privacy protections will not be preempted. See 45 C.F.R. § 160.203(b); HIPAA § 264(c)(2) (JA 39-40). HHS thus responded to these comments by noting that the “Privacy Rule provides a floor of privacy protection” and does not displace any more stringent state laws or ethical standards. JA 1382 (67 Fed. Reg. at 53212).

Plaintiffs contend that this response is “misleading” because the government has “successfully argued that state statutes and common laws which require consent or afford a physician-patient privilege are overridden by the Amended Rule in federal question cases.” Pl. Br. 52 (citing Northwestern Memorial Hosp. v. Ashcroft, 362 F.3d 923 (7th Cir. 2004)).

As a careful reading of the Seventh Circuit's decision in Northwestern Memorial demonstrates, however, the government argued solely that the evidentiary privileges established under Fed. R. Evid. 501 are not displaced by HIPAA. 362 F.3d at 925 ("we agree with the government that the HIPAA regulations do not impose state evidentiary privileges on suits to enforce federal law"). The government has never taken the position that the Privacy Rule overrides more stringent state or ethical privacy standards. Under the plain terms of both HIPAA and the Privacy Rule itself, state laws providing more stringent privacy standards remain applicable. In addition, "professional standards that are more protective of privacy retain their vitality." JA 1382.

Plaintiffs also seek to minimize the deference accorded to HHS's regulation by arguing that it "reverses a 'settled course of action.'" Pl. Br. 43 (citing cases). But an agency is entitled to deference so long as it provides a reasoned explanation for its actions and articulates "a rational connection between the facts found and the choices made." State Farm, 463 U.S. at 41-42; Frisby, 755 F.2d at 1055.

In any event, the consent requirement adopted in an earlier version of the Privacy Rule was far from settled. The inclusion of a consent requirement in the Original Rule was a departure from the Proposed Original Rule, see JA 1379 (noting that consent requirement "was a significant change" from the proposed rule), and within two months of its adoption in December 2000, HHS reopened the rulemaking process to reconsider that requirement, after receiving numerous unsolicited comments raising concerns about the adverse consequences that it would likely have on the delivery of health care. See 66 Fed. Reg. 12738 (Feb. 28, 2001). Because the consent requirement was thus called into question almost immediately upon its promulgation – and long before covered entities were ever

required to comply with it – the inclusion of that requirement in the Original Rule cannot reasonably be deemed a settled course of action triggering a presumption that subsequent changes are unreasonable.¹²

Finally, plaintiffs' contention that HHS exceeded its rulemaking authority by engaging in retroactive rulemaking, Pl. Br. 40-41, is wholly without merit. As the district court explained, the final Privacy Rule did not eliminate any vested rights. JA 14. Compliance with the Original Privacy Rule (which contained the consent requirement for routine uses) was not required until April 14, 2003, but the final Privacy Rule (eliminating the consent requirement) was promulgated well before that date, on August 14, 2002. JA 1376. Thus, because “[c]overed entities were never under a legal obligation to comply with the Original Rule’s consent requirement . . . the Original Rule did not create rights that were subsequently eliminated by the Amended Rule.” JA 14.

¹² In light of this history, plaintiffs' reliance on the principle that “agency interpretations that are more contemporaneous with the authorizing statute are entitled to greater deference,” Pl. Br. 43, actually undermines their arguments because HHS’s position in the 1999 Proposed Original Rule – and thus the position closest in time to the enactment of HIPAA – was that consent for routine uses should be prohibited.

Ignoring the timing of the modifications to the Privacy Rule outlined above, plaintiffs contend that they “have ‘settled expectations’ that information placed in their medical records prior to the compliance date of the Amended Rule would not be used or disclosed in routine situations without their consent.” Pl. Br. 40-41. On its face, this assertion makes no sense; information placed in medical records prior to the compliance date of the Original Rule could, by definition, be disclosed without consent until the compliance date for the new rule. Thus, HHS’s decision to eliminate the consent requirement clearly did not attach any new consequences to plaintiffs’ conduct.¹³

II. HHS’S DECISION NOT TO INCLUDE A CONSENT REQUIREMENT FOR ROUTINE USES IN THE FINAL PRIVACY RULE DID NOT VIOLATE PLAINTIFFS’ CONSTITUTIONAL RIGHTS.

When HHS eliminated the consent requirement under the Privacy Rule, it did not deprive anyone of any fundamental constitutional rights. To the contrary, the sole effect of the agency’s action was to refrain from exercising the regulatory authority of the federal government to prevent certain covered health care providers from using or disclosing protected health information for treatment, payment, or health care operations without first obtaining their consent. As the district court recognized, “[b]ecause the Amended Rule does

¹³ Nor is there any merit to plaintiffs’ contention that “they had no notice or reasonable expectation” that HHS would eliminate the consent requirement. Pl. Br. 41. As outlined above, HHS reopened the rulemaking process to reconsider that requirement within two months after it was adopted, see 66 Fed. Reg. 12738 (Feb. 28, 2001), and the agency proposed to eliminate the consent requirement just over a year later, see 67 Fed.

not compel anyone to use or disclose the plaintiffs' health information for routine purposes without the plaintiffs' consent," it does not violate their constitutional rights. JA 14-15.

Plaintiffs devote a significant portion of their brief to arguing that individuals have a fundamental right to privacy in their medical records and that laws affecting such a right are subject to heightened scrutiny. See Pl. Br. 10-26. Plaintiffs also spend considerable energy arguing that the First Amendment protects confidential physician-patient communications and that the exercise of this right can be chilled by inadequate protections for the privacy of medical records and health information. See Pl. Br. 26-32. However, even assuming plaintiffs have constitutionally protected rights in the privacy of their medical records and in confidential physician-patient communications (as the district court assumed), the final Privacy Rule does not impair those rights.

As explained in detail above, the Privacy Rule provides enhanced federal protections for the privacy of protected health information by prohibiting health care providers from using or disclosing such information except as authorized and by requiring that providers obtain a patient's authorization for uses and disclosures not otherwise permitted. See 45 C.F.R. § 164.508. Moreover, the Privacy Rule does not supersede or displace "more stringent" privacy protections provided under state law or any ethical or other standards. As such, the Privacy Rule does not interfere in any way with patients' exercise of their privacy rights. Whatever rights patients had to prevent the use and disclosure of their protected medical information before the promulgation of the Privacy Rule are either retained or enhanced under that rule. The Privacy Rule simply adds an additional panoply of federal protections for the privacy of medical records, creating a federal "floor" of privacy in recognition of potential risks to privacy in the new regulatory scheme governing medical records established under the HIPAA.¹⁴

On appeal, plaintiffs persist in arguing that the final Privacy Rule violates the Constitution because HHS did not go far enough in protecting privacy – specifically, by not including a consent requirement for routine uses in the final rule. As the district court

¹⁴ In light of the many provisions of the Privacy Rule designed to protect patient privacy, plaintiffs' allegation that the government had "unconstitutional intent" in issuing the Privacy Rule, Pl. Br. 37, is difficult to fathom. Moreover, their attempt to draw an analogy between the Privacy Rule and a "rule authorizing hospitals to refuse to serve minorities," ibid., is wholly inappropriate. Comparing the careful balance struck in the Privacy Rule between privacy rights and the efficient delivery of health care with a hypothetical rule sanctioning racial discrimination in hospitals only demonstrates the extremity of plaintiffs' position and their fundamental refusal to recognize that the Privacy Rule does not "authorize" a covered entity to use or disclose protected health information for routine uses where that covered entity was not already permitted to do so before the rule's promulgation.

correctly held, however, the Constitution “does not command the Secretary to act affirmatively to protect such rights.” JA 15 (citing DeShaney v. Winnebago County Soc. Servs. Dep’t, 489 U.S. 189, 195 (1989)).

Recognizing (as they must) that the Constitution imposes no affirmative duty on the government to protect privacy rights, plaintiffs contend that the Privacy Rule nonetheless interferes with their rights because it has a “determinative or coercive effect” on the actions of health care providers. Pl. Br. 34. As noted above, however, the Privacy Rule does not displace “more stringent” privacy protections, and, unlike the 1999 Proposed Rule, it does not prohibit providers from seeking patient consent for routine uses or disclosures. See 45 C.F.R. § 164.506(b)(1) (allowing covered entities to seek consent). As such, the Privacy Rule has no “coercive effect” whatsoever; it simply provides express authority for health care providers to do what they have always been free to do, absent independent prohibitions under state law (which the Privacy Rule expressly preserves). Thus, despite plaintiffs’ efforts to distinguish DeShaney on the ground that the government would have had a duty to protect the child in that case “if the state had rendered the child more vulnerable to the damage or had played a part in creating it,” Pl. Br. 35, the fact remains that the Privacy Rule has not rendered patients “more vulnerable” to privacy violations because that rule has not eliminated any pre-existing rights patients may have had to protect their privacy.

In the end, plaintiffs’ insistence that “the Amended Rule has eliminated [their] ability to protect their medical privacy by withholding consent,” Pl. Br. 38, boils down to their argument that the final version of the Privacy Rule did not go far enough in protecting their constitutional rights because it did not include a consent requirement for routine uses. The

irony of this argument is that, if the government's failure to "do more" to protect a constitutional right can itself give rise to a constitutional claim, the government will be significantly less likely to attempt to enact legislation or promulgate regulations to enhance the protections of constitutional rights – as the Privacy Rule undoubtedly enhanced patients' privacy protections here – for fear that the new statutes or regulations will be subject to constitutional challenges on the ground that they did not go far enough. Thus, allowing plaintiffs to challenge HHS's alleged failure to provide what they believe were adequate protections for the privacy of medical information would have the perverse effect of deterring the government from ever attempting to provide enhanced protections for other constitutional rights.

In sum, because it was plainly constitutional for the government to have taken no action to impose a federal requirement that health care providers obtain patients' consent before releasing individually identifiable medical information for routine uses prior to promulgation of the Privacy Rule, HHS's decision not to impose such a requirement in the final version of the Privacy Rule likewise violates no constitutional rights.

CONCLUSION

For the foregoing reasons, the district court's decision should be affirmed.

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CERTIFICATE OF COMPLIANCE

In accordance with Fed. R. App. P. 32(a)(7)(C), I hereby certify that the foregoing Brief for the Appellee is monospaced in courier font of 10 characters per inch. Exclusive of the portions exempted by Fed. R. App. P. 32(a)(7)(B)(iii), this brief contains 11,401 words, according to Corel WordPerfect 9, the word-processing program used to prepare this brief.

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