No. 13-14637-F

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

ADOLFO C. DULAY, M.D., AND ADOLFO C. DULAY, M.D., P.A.,

Defendants/Appellants,

and

STATE OF FLORIDA,

Intervenor,

vs.

GLEN MURPHY,

Plaintiff/Appellee.

On Appeal from the United States District Court
for the Northern District of Florida, Tallahassee Division,
Case No. 4:13-cv-00378-RH-CAS, before the Honorable Robert L. Hinkle

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BRIEF FOR AMICUS CURIAE FLORIDA JUSTICE REFORM INSTITUTE SUPPORTING REVERSAL

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No. 13-14637-F
Adolfo C. Dulay, et al. v. Glen Murphy

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to FRAP 26.1 and 11th Cir. R. 26.1-1, 26.1-2, and 26.1-3, Amicus Curiae Florida Justice Reform Institute hereby certifies that the following the following list of the trial judges, attorneys, persons, associations of persons, firms, partnerships, corporations, including subsidiaries, conglomerates, affiliates and parent corporations, or other identifiable legal entities related to a party that have an interest in the outcome of this appeal:

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Pursuant to Federal Rule of Appellate Procedure 26.1, Amicus Curiae Florida Justice Reform Institute certifies that it is a non-profit corporation exempt from taxation pursuant to Section 501(c)(4) of the Internal Revenue Code. It is not a publicly held corporation that issues stock.

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STATEMENT OF INTEREST OF AMICUS CURIAE PURSUANT TO FRAP 29(C)(4)

The Florida Justice Reform Institute (the "Institute") is Florida's leading organization of concerned citizens, small business owners, business leaders, doctors, and lawyers working toward the common goal of restoring predictability and personal responsibility to civil justice in Florida through the elimination of wasteful civil litigation and the promotion of fair and equitable legal practices. The Institute, which is the first independent organization focused solely on civil justice in Florida, works to restore faith in the Florida judicial system and protect Floridians from the social and economic toll incurred from rampant litigation.

The Institute has a strong interest in apprising the Court of the adverse consequences the District Court's decision would have for Florida's citizens, and particularly those which constitute a "covered entity" under HIPAA. A covered entity, such as a physician, has no idea why an authorization form it receives has been signed, including whether it has been signed as a requirement to secure a benefit. Requiring covered entities to look to the motivation behind a signature on an authorization form would create uncertainty as to the "validity" of every authorization form. The District Court's conclusion that any HIPAA-compliant authorization form that

contains a patient's signature because the patient had to sign it to secure some benefit is "involuntary" and, therefore, "invalid," would have a chilling effect on the necessary and efficient exchanges of protected health information that HIPAA is designed to permit.

Moreover, in a medical malpractice case like this one, the plaintiff's attorney already requires the client to sign a HIPAA-compliant authorization for the plaintiff's attorney to be able to prosecute the plaintiff's case. This is because, under HIPAA, such an authorization is required for the plaintiff's attorney to speak to his or her client's physician about the client's medical condition without the client being present. Section 766.1065, Florida Statutes, Florida's presuit authorization requirement, requires the same to be provided to the defendant's attorney, so that the defendant's attorney may have a similar conversation with that very same physician. A conclusion that an authorization required by the plaintiff's attorney to prosecute a plaintiff's case is valid as "voluntary," but an authorization required by state law to prosecute a plaintiff's case is not, is precisely the type of unworkable and one-sided legal standard the Institute was created to speak against.

STATEMENT OF AMICUS CURIAE PURSUANT TO FRAP 29(C)(5)

The Institute hereby certifies that no party's counsel authored the Institute's brief in whole or in part; that no party or party's counsel contributed money that

was intended to fund preparing or submitting the Institute's brief; and that no person, other than the Institute, its members or its counsel, contributed money that was intended to fund preparing or submitting the brief.

STATEMENT OF THE ISSUE

Whether the District Court misconstrued HIPAA's requirements for a "valid authorization" to conclude that Florida's presuit authorization requirement cannot be enforced in concert with HIPAA's permitted use and disclosure requirements.

SUMMARY OF THE ARGUMENT

The District Court's decision issued in an action for declaratory and injunction relief in a potential medical negligence suit against one of Mr. Murphy's treating physicians, Dr. Dulay. Under Florida law, Mr. Murphy was required, as a condition precedent to pursuing his medical-negligence claim, to comply with presuit requirements. See §§ 766.106, 766.1065, Fla. Stat. Those presuit requirements include, inter alia, submitting with his presuit notice a signed authorization. Id. That authorization provides the defendant's attorney with the same access the plaintiff's attorney would have—the ability to conduct an ex parte interview with Mr. Murphy's healthcare providers solely regarding matters pertinent to the potential medical negligence claim. § 766.1065(3)(e), Fla. Stat.

HIPAA permits use or disclosure of personal health information upon a covered entity "obtaining or receiving" a "valid authorization." See 45 C.F.R. §

164.508(a). Nothing in HIPAA requires that authorization to be "voluntarily" given to be "valid." Indeed, HIPAA expressly contemplates circumstances in which authorization may be required. See 45 C.F.R. § 164.508(b)(4). HIPAA preempts state law only to the extent that state law is "contrary" to HIPAA. See 45 C.F.R. § 160.203. Because HIPAA does not invalidate an authorization form simply because it is required to obtain a benefit, Florida's presuit authorization requirement is not contrary to or preempted by HIPAA.

ARGUMENT

I. THE DISTRICT COURT MISCONSTRUED HIPAA'S REQUIREMENTS FOR A "VALID AUTHORIZATION" TO CONCLUDE THAT FLORIDA'S PRESUIT AUTHORIZATION REQUIREMENT CANNOT BE ENFORCED IN CONCERT WITH HIPAA'S PERMITTED USE AND DISCLOSURE REQUIREMENTS.

A. HIPAA expressly permits use or disclosure of PHI upon a covered entity obtaining or receiving a "valid authorization" like the one Florida's presuit authorization requirement requires.

Congress passed the Health Insurance Portability and Accountability Act ("HIPAA") in 1996. Pub.L. 104-191, 110 Stat. 1936. Title II of HIPAA, the focus here, is the "Administrative Simplification" provision. The Administrative Simplification provision contains national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers. The Administrative Simplification provision also includes a national set of standards for the privacy ("Privacy Rule") and security ("Security Rule") of

certain health information. See 45 C.F.R. Part 160 and 164, Subparts A and C (Security Rule); 45 C.F.R. Part 160 and 164, Subparts A and E (Privacy Rule).

Title II of HIPAA is not a blanket protection to prevent all disclosures for all persons in all circumstances. Rather, the HIPAA Privacy Rule and Security Rule outline the standards under which individually identifiable, personal health information ("PHI") can be used and disclosed, as well as the administrative, technical and physical safeguards that covered entities must implement to secure individuals' electronic protected health information ("ePHI") when that information is either held or transferred. Id. HIPAA permits many uses or disclosures of PHI, and many more if the individual executes a written authorization. 45 C.F.R. § 164.502(a); see also 45 C.F.R. § 164.508.

The Privacy Rule, specifically, permits a covered entity to use or disclose PHI for purposes of treatment, payment, and health care operations without an individual's written authorization. 45 C.F.R. § 164.502(a). The Privacy Rule also permits certain other uses and disclosure of information without an individual's written authorization. For example, a covered entity may disclose PHI for certain public health activities, for health oversight activities, for organ donation purposes, for certain law enforcement purposes, and as required by law. 45 C.F.R. § 164.512. If the disclosure is not otherwise authorized or permitted by HIPAA, however, a covered entity will need the individual's written authorization prior to

making the disclosure. OCR Privacy Brief, Summary of HIPAA Privacy Rule, at 3, available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html (last visited Dec. 20, 2013); 45 C.F.R. § 164.508(a).

The purpose of HIPAA, then, is not to erect an impenetrable wall around patient privacy absent purely voluntary authorization. As stated by the Department of Health and Human Services' Office for Civil Rights, which enforces the HIPAA Privacy and Security Rules, the standards for PHI use and disclosure are aimed at ensuring that an individual's information is protected, while allowing the free flow of such information needed to provide and promote adequate and quality health care, and to protect the public's health. Id. at 1. Thus, to achieve its purpose of balancing patient privacy with the need for disclosures in the course of providing health care, HIPAA expressly permits a covered entity to use or disclose PHI upon obtaining or receiving a valid authorization, so long as the covered entity's use or disclosure is consistent with that authorization. 45 C.F.R. § 164.508(a)(1).

For that written authorization to be "valid" under HIPAA so as to permit a covered entity's use or disclosure of PHI, HIPAA provides only that three requirements must be met: (1) HIPAA's content requirement, (2) HIPAA's notice requirement, and (3) HIPAA's form requirement.

HIPAA's first requirement, the content requirement, provides that the following must be included in the authorization: (1) a description of the

information to be used or disclosed that identifies the information in a specific and meaningful fashion; (2) the name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure; (3) the name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure; (4) a description of each purpose of the requested use or disclosure, or the statement "at the request of the individual"; (5) an expiration date or description of an expiration event that relates to the individual or the purpose of the use or disclosure, including but not limited to the statement that there is no temporal limitation on the disclosure; and (6) the signature of the individual and date signed. 45 C.F.R. § 164.508(c)(1).

HIPAA's second requirement, the "notice" requirement, provides that the authorization must include statements regarding: (1) the individual's right to revoke the authorization, a description of how to revoke, and any exceptions (or a reference to the HIPAA Notice of Privacy Practices describing the revocation procedure); (2) the ability or inability to condition treatment, payment, or eligibility for benefits on the authorization; and (3) the potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and, if this occurs, would no longer be protected by HIPAA. Id. at (c)(2).

HIPAA's third requirement, the form requirement, requires the authorization to be in plain language, and it must be signed and dated. Id. at (c)(1)(vi) & (c)(3).

Where an authorization meets these three HIPAA requirements, it is "valid" and covered entities are prohibited from rejecting it as "invalid." See Final Rule, HHS, Office of the Assistant Secretary for Planning and Evaluation, "Standards for Privacy of Individually Identifiable Health Information," 65 Fed. Reg. 82462, 82657 (Dec. 28, 2000) (prohibiting covered entities from "reject[ing] as invalid an authorization containing such elements"). As the District Court recognizes in the decision on appeal, there is no dispute in the instant case that Florida's presuit authorization requirement contemplates an authorization meeting HIPAA's three "validity" requirements. (Doc. 44, Op. at 14 of 19 ("To be valid, an authorization must contain specific elements. The authorization mandated by the Florida statute includes those elements.").) This conclusion should have resulted in the District Court's upholding Florida's presuit authorization requirement.

In addition to HIPAA, the confidentiality of health information is governed by state law. Federal law does not preempt state privacy and disclosure laws where compliance with both HIPAA and state law is possible. Rather, only "State laws that are contrary to the HIPAA regulations are preempted by the federal requirements, which means that the federal requirements will apply." OCR Privacy Brief, Summary of HIPAA Security Rule, available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html (last visited Dec. 20, 2013). A state law is "contrary" only if an entity subject to HIPAA

"would find it impossible to comply with both State and Federal requirements," or if "State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives" of HIPAA's Administrative Simplification provisions. 45 C.F.R. § 160.203; 45 C.F.R. § 160.202. Here, Florida's presuit authorization requirement and HIPAA can govern in concert. As detailed below, Florida's presuit authorization requirement does not interfere with HIPAA's express requirements for making a "valid authorization," and nothing in Florida's presuit authorization requirement stands as an obstacle to effecting a "valid authorization."

B. Concluding that a required authorization is "invalid," even where it meets HIPAA's express content, notice and form requirements that otherwise make it "valid," would run contrary to HIPAA and be wholly unworkable for covered entities to implement.

The circumstances in which HIPAA expressly limits the ability to require an authorization to be signed are straightforward and few. See Office for Civil Rights, HHS Proposed Rule, "Standards for Privacy of Individually Identifiable Health Information," 67 Fed. Reg. 14776, 14797 (Mar. 27, 2002) (prohibiting only covered entities from conditioning treatment, payment, or eligibility for benefits or enrollment in a health plan on an authorization); see also HHS Final Rule, 67 Fed. Reg. 53182, 53219 (Aug. 14, 2002) (same).

Conversely, HIPAA recognizes that there are situations in which a covered entity may require an individual to authorize the release of PHI as a condition of

receiving a benefit, or for a necessary type of use or disclosure. For instance, a provider may require an authorization to be signed as a condition of receiving research-related treatment, so that the information may be used and disclosed for research purposes. A covered entity may also require an authorization to provide health care that is solely for the purpose of creating PHI for disclosure to a third party, e.g., an employer, for a fitness-for-duty exam. Likewise, a health plan may condition enrollment on the provision of an authorization for nearly any health records on grounds that such information is needed for eligibility or enrollment determinations, underwriting, or risk rating. 45 C.F.R. § 164.508(b).

There are many other situations, too, in which an individual may be required to sign an authorization to gain a benefit or exercise a right. This includes to obtain life insurance, allow his or her attorney to receive PHI directly from a physician, or obtain medical certifications (e.g., for drivers and pilots). An authorization may also be required to disclose drug test results to an employer, to be entitled to disability or workers' compensation benefits, to participate in travel opportunities or camps, or to disclose the results of physical exams to establish fitness for duty, or to participate in sports. Likewise, an individual may be required to provide a written authorization to allow the patient's photograph to be used in provider advertising or marketing, to enable the individual to receive marketing solicitations, to permit a physician to disclose health information to a

third party, such as an online fitness database, or to enable a physician or hospital to speak to the media about an individual's medical condition.

These scenarios make it clear that the District Court's decision was incorrect in deciding that to be an effective, "valid authorization" under HIPAA, it must be a no-strings-attached, purely voluntary consent. (Doc. 44, Op. at 15 of 19.) To the contrary, HIPAA does not attempt to regulate authorizations to ensure only the purest of authorization is actionable, and for good reason. Were HIPAA to require every authorization signed for reasons other than a purely voluntary one (for instance, one signed to gain certain benefits, or to proceed with a lawsuit), a covered entity receiving a signed authorization would have to look behind every signature to figure out why it was signed before it could act on it.

Such an interpretation of HIPAA's requirements would put covered entities in an impossible situation. Covered entities acting on what amounts to an invalid authorization could be subject to civil money penalties. See 45 C.F.R. § 160.402(a). Such penalties can reach as high as $50,000 per violation, if the covered entity knew or, by exercising reasonable diligence, would have known, that the disclosure violated HIPAA. See 45 C.F.R. § 160.404(b)(2)(i). State Attorneys General are also authorized to impose a civil money penalty equal to $100 per violation, with an annual maximum cap of $25,000 for multiple violations, of a single HIPAA standard. See 42 U.S.C. § 1320d-5(d). Failing to

act on what turns out to be a valid authorization, however, would run afoul of the federal Department of Health and Human Services' ("HHS") directive that a covered entity cannot "reject as invalid" an authorization that contains HIPAA's enumerated requirements. See 65 Fed. Reg. at 82657.

And how would a covered entity be expected to attempt to determine whether an authorization was executed purely voluntarily, begrudgingly, or something else? The Institute submits that HIPAA's intended balance between privacy and disclosure can only be achieved if the District Court's view is rejected. Validity plainly depends on HIPAA's clear and objectively verifiable content, notice and form requirements, and not on a signatory's subjective intent. Such an added requirement would impose a burden on covered entities receiving a signed authorization that is too difficult and expensive to meet.

Rather than regulating the reasons behind a signed authorization, HIPAA instead "attempt[s] to create authorization requirements that make the individual's decision as clear and voluntary as possible." 65 Fed. Reg. at 82659. In the preamble to the Privacy Rule promulgated in 2000, HHS recognized that there are even acceptable circumstances in which individuals are "coerced" into signing authorization forms. See 65 Fed. Reg. at 82658 (acknowledging that a health plan or Medicaid agency may condition payment of a claim for specified benefits on obtaining an individual's authorization, and that an employer may require an

employee to sign an authorization as a condition of employment). Thus, even "coercion," alone, does not render an otherwise valid authorization invalid. Id.

Though given the opportunity, HHS has never concluded that an authorization form is invalid simply because it was required to be signed. When HHS was asked to consider prohibiting "the provision of anything of value, including employment, from being conditioned on receipt of an authorization," 65 Fed. Reg. at 82658, HHS responded that it desired only "to minimize the potential for covered entities to coerce individuals into signing authorizations for the use or disclosure of [PHI] when such information is not essential to carrying out the relationship between the individual and the covered entity." Id. In so stating, HHS recognized there are circumstances when required authorization forms are acceptable; for instance, even the government Job Corps program "may make such an authorization a condition of enrollment." Id. HHS has also recognized that it lacks authority to prohibit an employer from requiring an authorization as a condition of employment, or to prevent individuals from signing an authorization form. Id. HHS did not find that this jeopardizes HIPAA's protections because, as HHS has emphasized, what "is essential to ensuring that the authorization is voluntary" is the right to revoke it if an individual decides that a particular use or disclosure is no longer in his or her best interest. Id. Section 766.1065, Florida Statutes, recognizes the right to revoke. See § 766.1065(3)(g), Fla. Stat.

Such an interpretation of HIPAA's requirements poses a significant practical challenge for covered entities attempting to act on what facially appear to be valid, signed authorizations. Acting on a signed authorization that turns out to be invalid could subject covered entities receiving such authorizations to civil money penalties. See 45 C.F.R. § 160.402(a). Those civil money penalties can reach as high as $50,000 per violation, even where the covered entity did not know but, had "reasonable diligence" been exercised, the covered entity would have known that the disclosure violated HIPAA. See 45 C.F.R. § 160.404(b)(2)(i). In addition, State Attorneys General are authorized to impose a civil money penalty equal to $100 per violation, with an annual maximum cap of $25,000, for multiple violations of a single HIPAA standard. See 42 U.S.C. § 1320d-5(d).

The District Court's decision cites no HIPAA provision in support of its analysis that certain signatures (e.g., one penned by an incompetent person or a hostage, or a signature secured by fraud) may be deemed insufficient to constitute a valid, authorized signature for purposes of HIPAA. (Doc. 44, Op. at 15 of 19.) Even if it were arguable that a signature on a contract, made solely to comply with Florida law, is insufficient to bind the signatory, there is nothing in HIPAA to prohibit it. To the contrary, the only HIPAA signature requirement is that there must be one, made either by the patient or the patient's personal representative. 45 C.F.R. § 164.508(c)(1)(vi). Instead, the notion of an "invalid" signature is rooted

in principles of state law, not HIPAA. See, e.g., Hindman v. Bischoff, 534 So. 2d 743, 744 (Fla. 2d DCA 1988) (applying "fraud or duress" exception in section 63.082(5), Fla. Stat., to whether an executed consent to adoption form could be set aside, and declining to do so without the necessary evidence that fraud or duress occurred, despite the harsh result, because "[w]e are without choice in the matter of this kind, . . . and must follow the law as it is ordained by the legislature"); see also 65 Fed. Reg. at 82530 (recognizing that HIPAA does not interfere with production of PHI by a party to litigation who put his or her medical condition at issue).

Nor is there any conflict of purpose. Florida's presuit authorization requirement simply levels the playing field in a specific type of lawsuit in which the plaintiff is already authorizing the disclosure of PHI, at least to his attorney for purposes of advancing his suit. All Florida's presuit authorization requirement does is require the plaintiff to authorize the same to the other side at the same stage in the litigation in which those disclosures are being made. It cannot be said that such a state law conflicts with HIPAA, so that HIPAA must preempt that state law.

CONCLUSION

For these reasons, the Institute respectfully requests that the Court reverse the judgment issued below.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to FRAP 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitations of FRAP 29(d) and FRAP 32(a)(7)(B).

1. Exclusive of the exempted portions of the brief, as provided in FRAP 32(a)(7)(B), the brief contains 3,683 words.

2. The brief has been prepared in proportionally-spaced typeface using 14-point Times New Roman font. As permitted by FRAP 32(a)(7)(B), the undersigned has relied upon the word count feature of the word processing system in preparing this Certificate.

/s/ Gigi Rollini
Attorney

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 23rd day of December, 2013, I electronically filed the foregoing document with the Clerk of the Court by using the CM/ECF system, which generates a Notice of Electronic Filing to all attorneys of record.

/s/ Gigi Rollini
Attorney

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