UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES, ex rel. SCOTT POGUE)))
Plaintiffs,) Civil No. 99-3298
V.) (related to 01-MS-50)
DIABETES TREATMENT CENTERS OF AMERICA, et al.) (MDL)) (RCL)
Defendants.)))

MEMORANDUM OPINION AND ORDER

Before the Court is the Relator's Motion to Compel DTCA to Produce Patient
Information Withheld from Its Production and For Sanctions [796]. Also, before the Court is the
Motion of Diabetes Treatment Centers of America, Inc. For Protective Order [813].

Upon review of the motion papers, the applicable law and the record in this case, the Court will deny Relator Pogue's motion to compel, and grant DTCA's motion for an amended protective order.

BACKGROUND

On December 18, 2002, this Court issued a Protective Order Governing Confidential Health Information ("2002 Protective Order"). In relevant part, that order provides that:

(1) Production of Health Information By The Parties That May Be Subject To 45 C.F.R. §§ 164.102-164.534, or Other Privacy Protections. West Paces, DTCA, and Atlanta Physicians (Defendants) may produce certain individually identifiable health information (defined as health information that is connected to a patient's name, address, Social Security

number or other identifying number, including HIC number) to Relator, pursuant to Relator's discovery requests. The information produced may be subject to the provisions of 45 C.F.R. §§ 164.102-164.534, O.C.G.A. § 24-9-40, or there may be no waiver by the patient to produce the records to any entity outside the United States. Defendants shall produce these documents unredacted to Relator. ...

- (2) Compliance with Federal and Georgia Law. The production of documents in the manner specified in this Order complies with federal law and Georgia state law governing the confidentiality of patient information...
- (8) **Modification Permitted.** Nothing in this Order shall prevent the Relator or Defendants from seeking modification of this Protective Order or from objecting to discovery that it believes to be otherwise improper.

Subsequent to the issuance of the 2002 Protective Order, the parties independently addressed several discovery disputes, and DTCA began producing patient records on or about February 12, 2003. On January 27, 2003, DTCA informed Relator Pogue that it would not produce ten pallets of boxes already reviewed and marked for copying because DTCA had not completed its confidentiality review. On January 28, 2003, DTCA also informed Relator Pogue that it would not produce patient information from states other than Georgia because DTCA did not read the 2002 Protective Order to authorize disclosure of information from states other than Georgia.

DTCA informed Relator Pogue that it needed to conduct state-by-state review of disclosure laws to determine whether the 2002 Protective Order authorized disclosure of patient records from states other than Georgia. In response to DTCA's refusal to release these documents, Relator Pogue filed the instant motion [796] on February 26, 2003 requesting that the Court order DTCA to immediately produce the withheld documents and award Relator Pogue expenses, including reasonable attorney's fees, incurred as a result of litigating this issue.

Relator Pogue maintains that DTCA is required to produce all patient information

pursuant to the 2002 Protective Order, irrespective of state disclosure laws, because state law privileges do not apply to the instant action which was brought solely under the federal False Claims Act, 31 U.S.C. §3729 et seq. Relator Pogue further maintains that an amendment to the Health Insurance Portability and Accountability Act ("HIPAA"), 42 U.S.C. §1320(d), which became effective on April 14, 2003, as construed by U.S. ex rel. Stewart v. Louisiana Clinic, 2002 WL 3181930, *2 (E.D. La. December 12, 2002), authorizes the disclosure of all patient information without a non-party patient hearing on the issue. Finally, Relator Pogue also contends that the Court should sanction DTCA for failing to produce the patient records without first seeking modification of the 2002 Protective Order.

On March 10, 2003, DTCA filed a motion [813] to modify the 2002 Protective Order to provide that all non-party patient records subject to restrictions on disclosure imposed by Florida state law shall be produced only after all individual-identifying information is redacted. In the alternative, DTCA requests the Court to modify the 2002 Protective Order to provide that prior to production of non-party patient records subject to restrictions on disclosure imposed by Florida state law, Relator Pogue shall provide reasonable notice to the respective patients that their records are being sought and that they are entitled to be heard on the matter of disclosure.

DTCA maintains that in the process of reviewing the production documents, it discovered that Relator Pogue requested medical records for patients in the District of Columbia and twenty-seven of the thirty-four states in which DTCA operated centers. DTCA maintains that prior to the 2002 Protective Order, the parties were under no obligation to produce any patient information other than that related to the West Paces Medical Center in Atlanta, Georgia. Therefore, DTCA maintains that the 2002 Protective Order did not apply to document production from any state or

jurisdiction other than Georgia. In the alternative, DTCA contends that although the 2002 Protective Order mandates that disclosure comply with HIPAA, and HIPAA generally preempts contrary state disclosure laws, the 2003 amendment to HIPAA also provides that disclosure of patient information remains subject to state law requirements that are more "stringent" than HIPAA. As such, DTCA maintains, if the 2002 Protective Order does authorize the disclosure of patient records from states other than Georgia, DTCA was correct to conduct state-by-state analysis of disclosure laws to determine whether the requested disclosures were permissible, and to shield itself from civil liability to non-party patients for improper disclosure of confidential medical information. In the process of this discovery dispute, DTCA initially determined that while it could release un-redacted patient information from twenty-two states, it could not release un-redacted patient information from Colorado, Florida, Illinois, Louisiana, or Texas. Upon further research, DTCA amended its position after determining that it could also release unredacted patient information from Colorado, Illinois, Louisiana and Texas. However, DTCA maintains that it still cannot release un-redacted patient records from Florida because Florida law governing patients' rights to medical privacy are more stringent than HIPAA, thus prohibiting the release of un-reacted records by operation of law that would otherwise be available under HIPAA.

The United States has filed a Statement of Interest [851], in which it maintains that because the HIPAA amendment did not become effective until April 14, 2003, it does not apply to DTCA's obligation to produce the patient records at issue, because it arose prior to the effective date.

ANALYSIS

Whether the 2003 amendment to HIPAA applies retroactively is an issue of first

impression in this jurisdiction, and is yet to be addressed in any other. As noted by the United States in their Statement of Interests [851], §1320d, and respective regulations, did not become affective until April 14, 2003, after the instant dispute arose and was briefed. Although, the amendment and regulations were not in effect at the time this dispute arose, DTCA acted in anticipation of the looming effective date, presumably realizing that even if the discovery issue was litigated and resolved before April 14, 2003, the disclosure would probably not have begun until after the effective date and continued thereon. As discussed below in the section regarding sanctions, DTCA was wise to tread so lightly given the civil liability to which it would be subject for improper disclosure. Contrary to the United States plea that the Court refrain from bearing the burden of hearing an issue of first impression, this Court would be foolish to allow partial disclosure to take place, knowing full and well that, at the least, a later set of the same disclosure would be subject to new regulations in a matter of months. The United States is correct that issues of retroactivity have yet to be vetted, but this Court will not permit disclosures that may violate federal or state law upon the mere hope that the amendment will not apply retroactively. The instant discovery dispute is contemporary not prospective, and the Court will not risk violation of patient privacy rights while issues of retroactivity languish in the various branches and levels of government. As such, the Court will apply §1320(d) and address the instant issue.

While generally preempting contrary state law, HIPAA does not preempt state law that is "more stringent" than the requirements that it mandates. <u>See</u> 42. U.S.C. §§1320d-2, 1320(d)(7). Specifically, state law is not preempted where: (1) state law is contrary to HIPAA; (2) relates to matters of individually identifiable health information; and (3) is more stringent than the HIPAA requirements. See 45 C.F.R. §160.202. For the following reasons, the Court finds that Florida

law is not preempted by HIPAA, and, therefore, any discovery of the medical records of Florida patients must comply with Florida law governing such disclosures.

First, Florida laws governing patients' privacy rights in medical information are contrary to HIPAA. A state regulation is contrary to HIPAA when: (1) it would be impossible for a covered entity to comply with both state and federal law; or (2) compliance with state law would preclude full execution of the purpose and objectives of HIPAA. See 45 C.F.R. §160.203. Here, whereas HIPAA permits a covered entity to disclose patient information subject to an appropriate protective order, Florida law only permits disclosure pursuant to court order after reasonable notice to non-party patients, thus imposing additional requirements upon the party seeking the disclosure and the covered entity attempting to comply with the disclosure requirements. See Fla. Stat. Ann. 395.3025(4)(d). As such it would be impossible for DTCA to comply with Florida law, which requires the additional step of notification, and HIPAA simultaneously.

Second, the parties do not dispute that this matter involves state law that relates to the privacy of individual identifiable health information, which HIPAA defines as information that has the purpose of protecting the privacy of health information, or affects the privacy of health information in a direct, clear, and substantial way. See 45 C.F.R. §160.202. Here, the requested disclosures reveal specific and explicit information about patients identified by name, birth date, social security number and the like and are, in important part, for the purpose of attempting to establish a pattern of improper medical treatment and billing practices, clearly satisfying definition provided for in §160.202 by invading patient privacy rights in a direct, clear and substantial way.

Third, Florida law is also more stringent than HIPAA. Contrary to Relator Pogue's

assertion, only one of the criteria in §160.202 need be met in order to find that a state law is more stringent than the requirements of HIPAA. See 45 C.F.R. §160.202 (stating that "[m]ore stringent means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria: ..."). As relevant to the instant case, a state law is deemed more stringent than HIPAA when it "prohibits or restricts a use or disclosure otherwise permitted" under HIPAA. See 45 C.F.R. §160.202. Here, whereas HIPAA would allow disclosure without non-party patient notice, Florida law requires such notice, and thus prohibits or restricts a use or disclosure that would be permissible under HIPAA.

Therefore, because Florida law is contrary to HIPAA, relates to matters of individually identifiable health information, and is more stringent than HIPAA, it is not preempted by HIPAA and DTCA must comply with the law governing Florida patient privacy. Florida law requires, in relevant part, that:

- (4) Patient records are confidential and must not be disclosed *without the* consent of the person to whom they pertain, but appropriate disclosure may be made without such consent to:
- (d) In any civil or criminal action, unless otherwise prohibited by law, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice by the party seeking such records to the patient or his or her legal representative.

Therefore, pursuant to Florida law, medical records originating from this state may only be disclosed if: (1) redactions are sufficient to prevent disclosure of private patient health information or protect the privacy of health information in a direct, clear, or substantial way; (2) with patient consent; or (3) upon proper notice to the non-patient party so that he/she may obtain

legal representation on be heard on the issue of disclosure. Therefore, Relator Pogue's motion to compel the un-redacted disclosure of Florida medical patient information is denied, and the 2002 Protective Order, is hereby amended accordingly.

Having denied Relator Pogue's motion to compel, the Court also denies Relator Pogue's request for sanctions. Sanctions are intended to deter the abuse implicit in litigation-forcing actions that squander valuable court and party resources. See Cobell v. Norton, 213 F.R.D. 16, 29 (D.D.C. 2003). As such, the imposition of sanctions is only appropriate when a party forces a discovery dispute to court when no genuine dispute exists. See Cobell, 213 F.R.D. at 29. Where there is a genuine dispute or circumstance in which reasonable people could differ as to the appropriateness of the contested action, sanctions are not appropriate. Pierce v. Underwood, 487 U.S. 552, 565 (1988); Cobell v. Norton, 213 F.R.D. 48, 61 (D.D.C. 2003). Such is the case here. DTCA was correct to tread lightly in the arena of patient privacy rights and medical record disclosure in anticipation of and after the 2003 amendment to HIPAA. The principal purpose of HIPAA and the 2003 amendment is to safeguard individually identifiable health information, such as that sought in the instant matter, and while patients enjoy heightened privacy protection, covered entities, such as DTCA, must adhere to the significant, time-consuming, often convoluted, and administratively and precedentially undeveloped compliance requirements. See Guthrie, Jennifer, Time is Running Out - - The Burdens and Challenges of HIPAA Compliance: A Look at Preemption Analysis, The "Minimum Necessary" Standard, and the Notice of Privacy Practices, 12 Annals Health L. 143, 146-47 (2003) (arguing that covered entities should not be forced to vet compliance requirements in the absences of congressional, administrative and judicial guidance). As such, the Court finds that DTCA's actions were substantially justified, and, therefore, denies Relator Pogue's request for sanctions and the award of expense and fees.

CONCLUSION

For the aforementioned reasons, Court will DENY the Relator's Motion to Compel DTCA

to Produce Patient Information Withheld from Its Production and For Sanctions [796], and

GRANT the Motion of Diabetes Treatment Centers of America, Inc. For Protective Order [813],

amending the 2002 Protective Order so as to mandate compliance with Florida law governing

patient privacy in medical records as noted above.

SO ORDERED.

/signed/

The Honorable Royce C. Lamberth United States District Court Judge

Date: May 17, 2004

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