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Discoverability of De-Identified Patient Records

Lucy Tufts | Cunningham Bounds, LLC

There are a number of reasons plaintiffs seek discovery of medical records of patients other than themselves, and such other patients' records should be discoverable when relevant so long as personal identification information is redacted in conformance with Alabama and federal law. For example:

(1) In support of an argument that inadequate staffing in a nursing home led to a resident's neglect, a plaintiff may seek to examine other residents' acuity assessments to establish the type of care and amount of staffing needed at the nursing home during the relevant time period for the purpose of demonstrating that the facility was understaffed.

(2) In support of an argument that critical evidence was destroyed by a hospital as part of a coordinated effort to cover up its role in a patient's unanticipated death, a plaintiff may seek to examine other similar redacted records of patients undergoing the same tests at the same time by the same hospital personnel for the purpose of demonstrating that such tests were routinely placed in the permanent medical record of those patients and that the only such test that mysteriously disappeared was the one related to the patient who died unexpectedly.

(3) In support of a *qui tam* case against a healthcare facility for fraudulent billing practices, a plaintiff may seek to examine redacted non-parties' medical records in order to prove that the conditions for which the healthcare facility sought reimbursement from Medicare or Medicaid were not, in fact, the conditions from which the patients suffered.

This article describes arguments that can be made to obtain these records together with the authority that supports those arguments.

What Does HIPAA Protect?

In 1996, Congress enacted HIPAA, the Health Insurance Portability and Accountability Act, P.L. 104-191. Section 262 of that Act became 42 U.S.C. §§ 1320d through 1320d-8. These Code sections order the Secretary of Health and Human Services to adopt standards. They provide, in 42 U.S.C. § 1320d-5, a general penalty for failure to comply with the requirements and standards. They make it an offense for a person to, in violation of these Code sections, obtain or disclose "individually identifiable health information." 42 U.S.C. § 1320d-6(a). This offense carries a fine of "not more than $50,000" and imprisonment for "not more than one year, or both." 42 U.S.C. § 1320d-6(b)(1). "[I]f the offense is committed under false pretenses, [the offender shall] be fined not more than $100,000, imprisoned not more than five years, or both." 42 U.S.C. § 1320d-6(b)(3).

The regulation governing disclosure in connection with legal proceedings is found at 42 C.F.R. § 164.512(e). Section 164.512(e)(1)(i) specifies the following "permitted disclosures" in "judicial and administrative proceedings": "A covered entity may disclose protected health infor-

mation in the course of any judicial or administrative proceeding: (i) in response to an order of court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order." Section 164.512(e)(1)(ii) gives further permission for a health care entity to disclose protected health information "[i]n response to a subpoena, discovery request, or other lawful process" under carefully limited and specified circumstances.

HIPAA defines "individually identifiable health information" as:

"[I]nformation that is a subset of health information, including demographic information collected from an individual, and:

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

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

45 C.F.R. § 160.103. HIPAA protects most "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or medium, whether electronic, on paper, or oral. *Id.*

What Is De-Identification and What Is The Process for Accomplishing It?

Even before the passage of HIPAA, numerous state and federal courts permitted the disclosure of certain medical records after requiring that all identifying information be redacted. See, e.g., *Amente v. Newman*, 653 So. 2d 1030 (Fla. 1995); *Tanzi v. St. Joseph Hosp.*, 651 A.2d 1244 (R.I. 1994); *Terre Haute Regional Hosp., Inc. v. Trueblood*, 600 N.E.2d 1358 (Ind. 1992); *State ex rel. Lester E. Cox Med. Ctr. v. Keet*, 678 S.W.2d 813 (Mo.1984); *Ziegler v. Superior Court*, 656 P.2d 1251 (Ariz. 1982); *Community Hosp. Assn. v. Boulder Dist. Court*, 570 P.2d 243 (Colo. 1977).

HIPAA now expressly provides for the "de-identification" of medical records so that they will no longer be considered "protected health information" and therefore will no longer be subject to the Act. "Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information." 42 C.F.R. § 164.514(a).

Sections 164.514(b) and (c) provide two methods that a covered entity must follow in order to meet the de-identification standard: the "Expert Determination" method and the "Safe Harbor" method, as illustrated below:

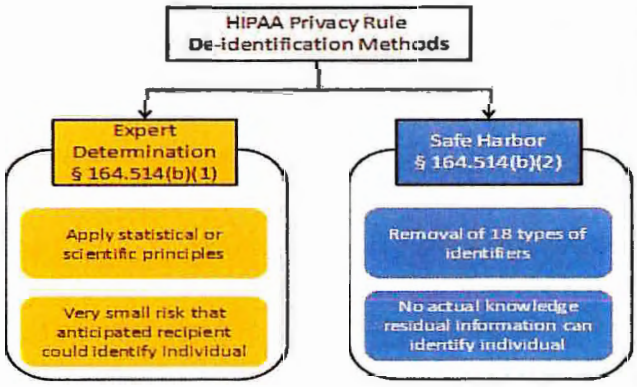

Illustration contained in Figure 1 of the Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability (HIPAA) Privacy Rule, Department of Health and Human Services: Understanding HIPAA, available at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.htm (last visited September 27, 2015).

Because the first method requires a qualified statistician to conclude that the risk of the information being used, alone or in combination with other information, to identify the individual to whom the information pertains is "very small," it is expensive and therefore not commonly used for purposes of de-identification.

Instead, the "Safe Harbor" method of de-identification, which is the method that will nearly always be used for purposes of discovery requests in litigation of the nature described in this article, permits the disclosure of information so long as 18 types of identifiers are removed and the covered entity has no actual knowledge that residual information can identify an individual. 45 CFR 164.514(b)(2). The regulation describes this method of de-identification as follows:

(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89

and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
(D) Telephone numbers;
(E) Fax numbers;
(F) Electronic mail addresses;
(G) Social security numbers;
(H) Medical record numbers;
(I) Health plan beneficiary numbers;
(J) Account numbers;
(K) Certificate/license numbers;
(L) Vehicle identifiers and serial numbers, including license plate numbers;
(M) Device identifiers and serial numbers;
(N) Web Universal Resource Locators (URLs);
(O) Internet Protocol (IP) address numbers;
(P) Biometric identifiers, including finger and voice prints;
(Q) Full face photographic images and any comparable images; and
(R Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and
(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

45 C.F.R. § 164.514(b)(i)-(ii).

The question of whether de-identified medical records of non-parties is discoverable has rarely been addressed in litigation in Alabama. There are no reported appellate opinions on this subject in this state.

In Jones v. Sava Senior Care, LLC, 03-CV-2009-900181, Montgomery County Circuit Court, the plaintiff filed a wrongful death case against a nursing home, alleging that its inadequate staffing led to abuse and neglect that caused the deceased's multiple pressure ulcers, septicemia, weight loss, and organ failure. The Montgomery County Circuit Court ordered the production of MDS assessments from the nursing home, which consist of a series of screening tools that allow a nursing home to conduct a comprehensive assessment on each resident. The MDS assessments provide an important tool for assessing the resource requirements for particular groups of residents because information about the acuity of the resident population provides a basis as to how to adequately staff the nursing home. They can be used to mathematically demonstrate the amount of care time required for the resident population and thus the staffing needs of the facility. In Jones, the Plaintiff specifically alleged in her complaint that the nursing home in which the plaintiff's decedent had died was inadequately staffed and that this understaffing was a proximate cause of the plaintiff's pressure ulcers and death. The Court ordered the production of the MDS with the identifying information of other residents redacted. The nursing home filed a petition for writ of mandamus in order to avoid the production of the MDS assessments on other patients, but the Alabama Supreme Court denied the nursing home's petition without opinion. Ex parte SSC Montgomery Woodley Manor Operating Co., 151 So. 3d 393 (2012) (denying mandamus petition).[1]

Thus, at least one trial court in Alabama has ordered the production of appropriately redacted non-party medical records when it was presented with arguments similar to those made in this article.

Moreover, Alabama public policy appears to be moving in the direction of requiring de-identification in pleadings and discovery responses. In fact, as a general matter, the redaction of sensitive information in documents filed with the court is becoming so commonplace that it is now required in most instances. The Alabama Rules of Civil Procedure were recently amended to require redaction of all but the last four digits of any social security number, taxpayer-identification number, or financial account number in any court filings (with a few exceptions) unless a court orders otherwise. Ala. R. Civ. P. 5.1.

What Is The Effect of State Privilege and Privacy Laws?

As a preliminary matter, the HIPAA regulations promulgated by the Secretary of Health and Human Services "shall supersede any contrary provision of State law." 42 U.S.C. § 1320d-7(a)(1) (sometimes referred to as the "supersession clause"). The regulations promulgated by the Secretary of HHS include a general rule that a federal standard preempts a contrary state law unless "[t]he provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted" in the relevant parts of the regulations adopted by the Secretary. 42 C.F.R. § 160.203(b) (emphasis added). HIPAA provides that a state regulation more stringent than the HIPAA privacy regulations is not superseded. See P.L. 104-191, § 1320d-2.

State Privilege Laws

Defendants and non-parties objecting to the disclosure of de-identified information have argued that state privilege laws – i.e., those laws that provide privilege protection to communications by a patient to a physician for purposes of healthcare treatment – are not preempted by HIPAA and therefore prohibit the disclosure even of de-identified information.

While this issue has not been

addressed by many courts, those that have generally hold that de-identified information does not fall within the scope of most privilege laws because those laws only protect information that identifies a patient. *See In re Zyprexa Products Liability Litigation*, 254 F.R.D. 50, 55 (E.D.N.Y. 2008) (finding that the state privilege laws of Montana, New Mexico, Connecticut, Louisiana, and Mississippi only provided protection to communications that identified a patient and therefore did not protect or prevent the disclosure of de-identified records). *See also Northwestern Memorial Hospital v. Ashcroft*, 362 F.3d 923 (7th Cir. 2004) ("Provided that medical records are redacted in accordance with the redaction requirements (themselves quite stringent) of § 164.514(a), they would not contain "individually identifiable health information" and the "more stringent" clause would fall away."). [2]

Alabama does not recognize a general physician-patient privilege. *See, e.g., Romine v. Medicenters of America, Inc.*, 476 So. 2d 51, 54 fn.2 (Ala. 1985) ("There is no testimonial privilege in Alabama covering communications between a physician and his patient or the physician's knowledge of the patient's condition acquired by reason of the relationship."). However, Alabama courts do recognize a "general rule that confidential health information of nonparties is protected from discovery." *Ex parte St. Vincent's Hospital,* 991 So. 2d 200 (Ala. 2008).

The argument in favor of disclosure is simply that Alabama's general rule regarding the privacy of non-party health information is not implicated because de-identified records are, by their very nature, not identifiable. Thus, no privacy interest is being infringed or impaired. Second, a court must enter a protective order that requires that the records in question be redacted in accordance with HIPAA's de-identification procedures and that prohibits disclosure of those redacted records outside of the litigation.

In *Ex parte St. Vincent's Hospital,* the Alabama Supreme Court grappled with the extent of the general rule that confidential health information of nonparties is protected from discovery and addressed the issue of whether, in a fraud case, certain identifiable non-party medical records must be produced. In that case, the plaintiffs' fetus died at around 15 weeks' gestation. After delivery of the deceased fetus, the plaintiffs instructed that no autopsy and no pathological testing were to be performed on the fetus. Nevertheless, pathological testing was performed on the fetus "per hospital policy." Plaintiffs were also assured that the fetus would be cremated within a few days, but records later revealed that it was not cremated for one and a half years.

Plaintiffs filed suit against St. Vincent's Hospital and other defendants claiming, among other things, a "pattern and practice" of holding fetuses in morgue freezers for extended periods of time despite promising to timely cremate them. Plaintiffs sought copies of all "pathology or morgue log books or sign-in records (however designated) for the month of December 2000," and while St. Vincent's initially objected to the request, it later voluntarily produced a morgue report with the names of patients redacted and a cremation record showing that 19 other fetuses had been cremated on the same date as the plaintiffs' fetus. In many cases, the redacted records would be sufficient and, although not at issue in *Ex Parte St. Vincent's*, the fact that the hospital voluntarily produced the records demonstrates that such a process is not unprecedented and can be done in compliance with HIPAA.

The discovery dispute in *Ex parte St. Vincent's Hospital* arose later when the Plaintiffs served St. Vincent's with additional discovery requests that asked for identifying information of the fetuses and their parents for the purpose of learning whether they, too, had been told that the fetuses would be cremated within a matter of days but were, in fact, not cremated for more than a year. The Alabama Supreme Court ordered the production of the records, holding:

> "We conclude that the information contained in the logbooks of the morgue and pathology department and records of the 19 other fetuses and their parents and guardians regarding the disposition of the fetuses after delivery falls within an exception to a patient's right to confidentiality because of the supervening societal interest, recognized in *[Ex parte] Mack* [461 So. 2d 799 (Ala. 1984)], in knowledge of a hospital's practices regarding the disposition of fetuses after delivery and the availability of avenues of discovery in a fraud case based on such activities." Thus, at least in the context of a fraud case in which the Alabama Medical Liability Act is not applicable, and in which a clear supervening societal interest was recognized, the Alabama Supreme Court was willing to order the production of individually identifiable (and particularly sensitive) health information under the facts of the case despite the general rule that confidential health information of nonparties is protected from discovery.

Given that, under the right circumstances, the Alabama Supreme Court has shown a willingness to order the production of even extremely sensitive and identifiable non-party medical records, this case lends some support to the argument that redacted records should and will be discoverable.

State Constitutional Right of Privacy

Ten states recognize a constitutional protection for health information privacy. Catherine Louisa Glenn, Protecting Health Information Privacy: The Case for Self–Regulation of Electronically Held Medical Records, 53 Vand. L. Rev. 1605, 1609 n. 25 (2000) (identifying the constitutions of Alaska, Arizona, California, Florida, Hawai'i, Illinois, Louisiana, Montana, South Carolina, and Washington as protecting health information privacy). Most of these states have not yet addressed the

issue of whether their state constitutional right of privacy prohibits the disclosure of de-identified health information of non-parties in spite of HIPAA's de-identification procedures.

The Hawai'i Supreme Court very recently grappled with this issue, but in the context of a defendant desiring to disclose the plaintiff's medical information outside of the litigation rather than in the context contemplated in this article – i.e., a party who desires redacted non-party medical information that is directly relevant to the claims at issue in the litigation. *Cohan v. Ayabe*, 132 Hawai'i 408 (Haw. 2014). While the holding in the case is clearly distinguishable with respect to the purposes for which this article contemplates the discoverability and use of the medical information of non-parties, the Hawai'i Supreme Court's analysis of the underlying principles and competing interests is nonetheless instructive.

In *Cohan,* an arbitrator entered an order that required a plaintiff in a personal injury case to sign a medical authorization insisted upon by the defendants that contained, among other things, the following provision: "I understand that the health information released under this authorization may be re-disclosed by the recipient, in relation to the case/matter for which this authorization is provided, and may no longer be protected under the federal privacy regulations." The protective order proposed by the defendants and to which the medical records would be subject contained a de-identification provision in the event the medical records were re-disclosed by defendants. The arbitrator's order requiring plaintiff to sign the authorization was affirmed by a trial court. The plaintiff filed a petition for writ of mandamus to the Hawai'i Supreme Court, which granted the Petition and directed the trial court to vacate its order affirming the arbitrator's decision and to enter a qualified protective order governing the release of the relevant medical records pursuant to an authorization without this and other offending provisions.

The Hawai'i Supreme Court recognized that because HIPAA's supersession clause provides that federal law will not preempt "more stringent" state laws only when those state laws relate to the privacy of "individually identifiable health information," 45 C.F.R. § 160.203(b), it "leads to the conclusion that state law also does not protect de-identified information." *Id.* at 417. However, relying on an earlier case that held that the state's constitutionally recognized right of privacy "protects the disclosure outside of underlying litigation of....health information produced in discovery," the Court nevertheless held that "[t]o allow this information to be used outside the litigation, regardless of whether it is de-identified or not, would reach beyond what the Hawai'i Constitution permits in the absence of a showing of a compelling state interest." *Id.* at 416-18.

However, a stated above, in *Cohan,* the dispute involved whether the plaintiff's medical information could be used outside of the litigation. Requesting the types of records that this article addresses involves medical information (typically of non-parties) that is directly relevant to the claims in the underlying action. The Hawai'i Supreme Court has not yet addressed the question of whether a non-party's right to privacy under article I, section 6 of the Hawai'i state constitution trumps a party's right to those non-parties' medical records – even after de-identification – that are directly relevant to the claims at issue in the case in which those medical records are sought. In fact, that precise question was recently certified to the Hawai'i Supreme Court by the federal district court in Hawai'i and the issue remains pending at the time this article went to print. *Pacific Radiation Oncology, LLC v. The Queen's Medical Center,* 2015 WL 419654 (D. Hawai'i Jan. 30, 2015).

Do Non-Parties Have to Be Notified of the Production?

It is important to recognize that HIPAA permits the disclosure even of individually identifiable health information through the subpoena process without notice to the party who is the subject of that information so long as "[t]he covered entity receives satisfactory assurance...from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements [of HIPAA]." 45 C.F.R. 164.512(e)(1)(ii)(B).

Moreover, courts have held that the de-identification of records "obviates the need for a mechanism to address the individual privacy objections of patients and health care providers." *In re Zyprexa Products Liability Litigation,* 254 F.R.D. 50, 56 (E.D.N.Y. 2008).

Even in *Ex parte St. Vincent's*, described at length above, the Alabama Supreme Court did not require notice to be given to the parents of fetuses whose records were ordered disclosed. Instead, the Court merely suggested it as a courtesy to those families:

> We invite the trial court to consider using a neutral intermediary, such as the trial court itself, a court official, or other appropriate person, to notify, to the extent practicable, the persons named in the records of the pendency of this action, of the order of the trial court compelling disclosure, and of the action of this Court, preliminary to producing these records for the [plaintiffs]. The Court makes this suggestion solely for the humane purpose of giving the persons named in the records an opportunity to be apprised of the extremely sensitive facts underlying the litigation and the fact of the impending production of the records before those persons are contacted by the [plaintiffs]

in pursue of further discovery.
991 So. 2d at 212. Thus, so long as the de-identified records are produced pursuant to a qualified protective order, notice need not be given to the individual non-parties whose records are sought.

However, while there is no such statute in Alabama, other states have statutes that require notice to a non-party under the circumstances described herein. See, *e.g. Crowley v. Lamming*, 66 So.3d 355 (Fla. App. 2011) (holding that a trial court could not compel the disclosure of redacted medical records of non-parties without notice to the patients as required by F.S.A. § 456.057(7)(a) unless there is a showing that prior notice is impossible.).

In a Medical Malpractice Action, Does Ala. Code § 6-5-551 Prohibit The Disclosure Of De-Identified Records?

As is evidenced by some of the examples at the beginning of this article, there are many situations in which redacted non-parties' health information may be relevant to claims made in a case that is not governed by the Alabama Medical Liability Act.

However, there may also be reasons why these types of records would be important in a medical malpractice case, in which case defendants will likely invoke Ala. Code § 6-5-551. That code provision states:

> In any action for injury, damages, or wrongful death, whether in contract or in tort, against a health care provider for breach of the standard of care, whether resulting from acts or omissions in providing health care, or the hiring, training, supervision, retention, or termination of care givers, the [AMLA] shall govern the parameters of discovery and all aspects of the action. The plaintiff shall include in the complaint filed in the action a detailed specification and factual description of each act and omission alleged by plaintiff to render the health care provider liable to plaintiff and shall include when feasible and ascertainable the date, time, and place of the act or acts.... Any party shall be prohibited from conducting discovery with regard to any other act or omission or from introducing at trial evidence of any other act or omission.

Ala. Code § 6-5-551 (emphasis added).

This provision of the Alabama Medical Liability Act should not be a bar to the discoverability of non-parties' redacted medical information so long as a strong argument can be made that those records have information that is "with regard to" the acts and omissions described in the Plaintiff's Complaint. *Ex Parte Mendel*, 942 So. 2d 829, 837 (Ala. 2006) ("Therefore, the issue for this Court to resolve in applying the discovery exemption of § 6-5-551 to the acts and omissions pleaded in the complaint is whether the discovery ordered by the trial court is 'with regard to' those acts and omissions."). The redacted medical records of non-parties may be "with regard to" the acts or omissions described in the complaint if, for example, they would evidence a profound understaffing issue that is directly related to the plaintiff's injuries, or if they would evidence the routine placement of certain tests in a patient's permanent medical record (the absence of which in the plaintiff's decedent's record indicates a cover-up, which is relevant to punitive damages), or another patient's medical record may evidence what a defendant nurse was actually doing at a critical moment when the plaintiff's decedent needed attention that he or she did not receive.

The key to overcoming an objection pursuant to Ala. Code § 6-5-551 is to request only those de-identified records that clearly contain evidence that pertains directly to allegations made in the complaint that would render a healthcare provider liable.

Conclusion

While there is relatively little case law on the issue of the discoverability of the redacted medical records of non-parties, if such evidence may be helpful (or even crucial) to your client's case, these arguments may help you to obtain an order from the court that requires a defendant to produce them.

1 "An order of affirmance issued by the Supreme Court or the Court of Civil Appeals by which a judgment or order is affirmed without an opinion, pursuant to section (a), shall have no precedential value and shall not be cited in arguments or briefs and shall not be used by any court within this state, except for the purpose of establishing the application of the doctrine of law of the case, res judicata, collateral estoppel, double jeopardy, or procedural bar." Ala. R. App. P. 53(d).

2 Note that, while the Seventh Circuit Court of Appeals recognized that the supersession clause does not apply to de-identified records because it requires that a provision of state law must be more stringent and related to the privacy "of individually identifiable health information" in order to avoid preemption, the Court went on to hold that a privacy interest exists in redacted medical documents because compliance with a subpoena would impose an "undue burden" under Fed. R. Civ. P. 45(c)(3)(A)(iv) on patients whose redacted records were subpoenaed. "The only issue for us is whether, given that there is a potential psychological cost to the hospital's patients, and a potential cost in lost goodwill to the hospital itself, from the involuntary production of the medical records even as redacted, the cost is offset by the probative value of the records.". 362 F.3d at 930. The Court held that the potential loss of privacy (via "skillful Googlers" who could potentially sift through the information and "put two and two together") outweighed the probative value of those records, which the court, in this particular case, determined to be "meager." Id. at 929-30. This case involved the government seeking redacted records of patients who had received partial birth abortions in litigation related to the constitutionality of the Partial-Birth Abortion Ban Act. Thus, the incredibly controversial and sensitive nature of the records at issue likely make this case an outlier. In addition, because the Court engaged in a balancing of the costs of production and the probative value of the de-identified records, it left room for future litigants to argue that when the probative value of the records was high, the records should be produced. Indeed, this argument has since been made with success, albeit in a case that involved the production of identifiable (rather than redacted) health information. U.S. ex rel. Block v. Del Campo, 2010 WL 2698295 (N.D. Ill. 2010) ("Unlike Northwestern Memorial Hospital, Plaintiffs have identified what they hope to gain from patient interviews and how that information is highly relevant to their claims. Plaintiffs' case centers on whether Defendants sought reimbursement for services allegedly provided to Medicare and Medicaid patients which were based on false claims. Plaintiffs need not accept at face value the facts presented by Defendants. Plaintiffs' counsel is entitled to ask patients whether they recall having the surgical procedures or the application of photosensitizing agents during light treatments which are recorded in Del Campo's files. The Court is sensitive to Defendants' concern for the privacy rights of Del Campo's nonparty patients. It may well be distressing and even embarrassing for patients to participate in this bitterly contested lawsuit, but Defendants have not shown that such concerns outweigh Plaintiffs' need for the requested patient information.").