

2004

KATHERYN CANNON, as surviving spouse,
LANE CANNON and ROLAND CANNON, as
surviving children and legal heirs of GARY R.
CANNON, deceased v. SALT LAKE REGIONAL
MEDICAL CENTER, INC., JOHN AND JANE
DOES 1 THROUGH X and DOE BUSINESS
ENTITIES 1 THROUGH V : Reply Brief

Utah Court of Appeals

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Douglas G. Mortensen; Matheson, Mortensen, Olsen and Jeppsen; Attorneys for Appellants.
David W. Slagle; Elizabeth L. Willey; Bradley R. Blackham; Snow, Christensen and Martineau;
Attorneys for Appellees.

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Douglas G. Mortensen, #2329
MATHESON, MORTENSEN, OLSEN & JEPPSON, P.C.
648 East 100 South
Salt Lake City, Utah 84102
Telephone: (801) 363-2244

Attorneys for Plaintiffs/Appellants

IN THE UTAH COURT OF APPEALS

KATHERYN CANNON, as surviving
spouse, LANE CANNON and ROLAND
CANNON, as surviving children and legal
heirs of GARY R. CANNON, deceased,

Plaintiffs/Appellants,

vs.

SALT LAKE REGIONAL MEDICAL
CENTER, INC., JOHN AND JANE DOES
1 THROUGH X and DOE BUSINESS
ENTITIES 1 THROUGH V,

Respondents/Appellees.

Case No. 2:0040486-CA

**UTAH COURT OF APPEALS
BRIEF**

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DOCKET NO. 2:0040486-CA

APPELLANTS' REPLY BRIEF

David W. Slagle, #2975
Elizabeth L. Willey, #5639
SNOW, CHRISTENSEN &
MARTINEAU
Attorneys for Salt Lake Regional
Medical Center Inc. (Appellee)
10 Exchange Place, 11th Floor
P.O. Box 45000
Salt Lake City, UT 84145
(801) 521-9000

Douglas G. Mortensen, #2329
MATHESON, MORTENSEN, OLSEN
& JEPPSON, P.C.
Attorneys for Plaintiffs/Appellants
648 East 100 South
Salt Lake City, Utah 84102
Telephone: (801) 363-2244

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UTAH APPELLATE COURTS**

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Douglas G. Mortensen, #2329
MATHESON, MORTENSEN, OLSEN & JEPPSON P.C.
648 East 100 South
Salt Lake City, Utah 84102
Telephone: (801) 363-2244

Attorneys for Plaintiffs/Appellants

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David W. Slagle, #2975
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SNOW, CHRISTENSEN &
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Medical Center Inc. (Appellee)
10 Exchange Place, 11th Floor
P.O. Box 45000
Salt Lake City, UT 84145
(801) 521-9000

Douglas G. Mortensen, #2329
MATHESON, MORTENSEN, OLSEN
& JEPPSON, P.C.
Attorneys for Plaintiffs/Appellants
648 East 100 South
Salt Lake City, Utah 84102
Telephone: (801) 363-2244

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45 CFR. §160.202 (2004)

45 CFR §164.501

45 CFR §164.524(a)(West 2004)

45 CFR §164.528

65 Fed Reg. 82462, 82677 (2000)

HIPAA §264(b) - (c), Stat at 2033-34

CASE AUTHORITIES

Benson v. IHC Hospitals, Inc., 866 P.2d 537 (Utah 1993)

Chevron USA, Inc., v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843 n.11 (1984)

STATEMENT OF FACTS

The Hospital's brief responding to Mrs. Cannon's appeal brief contains a five and a half page statement of facts. Some of the hospital's numbered facts are potentially misleading, particularly Fact Nos. 12, 13, 15, 19, 20, 21, 22, 26 and 27. (See pp. 5-8 of Brief of Appellees). In response, Mrs. Cannon provides the following clarifications:

1. On more than one occasion, apparent mailing irregularities prevented Cannon's counsel from timely receiving district court discovery rulings. For example, the district court's May 21 minute entry granting Mrs. Cannon's motion to compel the hospital to produce affiant Linda Wright for deposition was not received until July 7, 2004. (See Exhibit "A", attached). By that time, Mrs. Cannon had already filed her interlocutory appeal. Shortly after finally receiving word that the district court agreed with his interpretation of the Court's first discovery ruling (which did *not* preclude the deposing of Linda Wright as to the accuracy or inaccuracy of her affidavit assertions), Mrs. Cannon's counsel wrote the Hospital's counsel:

On July 7, I received in the mail for the first time a copy of the May 21 minute entry which grants my motion to compel discovery. Apparently, the district [court clerk] has a problem accurately sending out and receiving mail.

At the time my second motion to compel was granted, you had not yet served responses to my interrogatories and admission requests. Your objection and refusal to respond to that discovery has never been placed squarely before the court. I believe it is clear from Judge Atherton's most recent ruling that she would order you to supplement your answers to the two admission requests and two interrogatories I served on March 15, 2004. I therefore ask that you submit supplemental responses amending your earlier responses to that discovery within ten days of the date of this letter. If you

do not do so, I will file a motion to compel and request sanctions.

If you choose to take the position that the pendency of my interlocutory appeal relieves you of any duty to respond to the ongoing discovery, I will simply petition both the Court of Appeals and the District court for express leave to proceed with discovery. Under the circumstances, there appears little doubt the request will be granted. Please give me truthful responses to my two interrogatories and admission requests.

Please provide me with the earliest three alternative available dates for my deposing Linda Wright and whomever the hospital chooses to produce in response to my Rule 30(b) (6) deposition notice. Those dates may be provided to either me or my assistant, Ann. Please provide those dates at your earliest convenience.

(Exhibit "A", attached).

To Mrs. Cannon's disappointment, the Hospital and its counsel sought to use the pendency of the interlocutory appeal as a bar to any further factual discovery. The Hospital's motion to stay all discovery was filed with the district court one week after the above quoted letter was written. (R. 375-406). Thereafter, Mrs. Cannon filed her third motion to compel on August 9, 2004. The Hospital is correct in its assertion that the district court has made no ruling on that motion. What the hospital has not revealed, however, is that it has asked the district court not to rule on the motion because of the pendency of this appeal. (See the Hospital's August 26, 2004 Memorandum in Opposition to Plaintiffs' Motion to Compel Discovery and for Sanctions, pp. 1-4)¹

¹ The Hospital's actual argument heading reads unabashedly as follow: "I. PLAINTIFFS SHOULD NOT BE ALLOWED TO DEPOSE LINDA WRIGHT OR THE RULE 30(b)(6) DEPONENTS WHILE PLAINTIFFS' APPEAL IS PENDING". See Exhibit B, attached).

In short, the Hospital continues to use the pendency of the interlocutory appeal as a means of avoiding its obligation to cooperate in Mrs. Cannon's continuing efforts to discover pertinent facts concerning her husband's death and concerning the incident reports documenting the circumstances surrounding it.

2. In its initial disclosures, the Hospital disclosed the names of only two "employees" believed to have discoverable information concerning the facts of the case: Ed Gabiola, a CNA and Brad Wardle, a registered nurse. The Hospital did not disclose either the addresses or the telephone numbers of either of these persons. Ed Gabiola is not listed in any Salt Lake area telephone directory and apparently has left the area. It has been discovered that Brad Wardle is no longer employed by the Hospital. Believing he is precluded from doing so, he has conditionally refused to share information informally with Mrs. Cannon's counsel.

3. The Hospital's assertion that "plaintiffs have not taken any depositions in this case" (Fact No. 27, p.8) is true but misleading. Mrs. Cannon has attempted repeatedly to take Rule 30(b)(6) depositions of critical fact witnesses and to depose the Hospital's risk manager whose affidavit serves as the basis for the Hospital's refusal to produce factual reports concerning Gary Cannon's fall. (See Exhibit's A, B, H and J attached as Addenda to Mrs. Cannon's Appeal Brief in Chief).

It is Mrs. Cannon's prerogative to select the methods of discovery she believes will best enable her to obtain the critical facts. One of her concerns from the beginning has been her awareness that Hospital employees assigned to care for her husband could not speak English. That concern and the prohibitive cost of taking formal

depositions (particularly of well-coached staff members possessing convenient lapses of memory) may explain why she has proceeded in the manner she has. She should not be faulted for not yet having taken depositions in the case.

ARGUMENT

I

THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) AND ITS IMPLEMENTING REGULATIONS MANDATE PRODUCTION OF THE INCIDENT REPORTS.

In the Spring of 2003, federal legislation known as “HIPAA” effected a series of new rights for patients, including the right to access information about themselves. According to the portion of the Act granting patients a federal right of access, “an individual has the right of access to inspect and obtain a copy of protected health information about the individual in a designated records set. . . .” 45 CFR §164.524(a)(West 2004). (Exhibit C, attached).

“Protected health information” means “individually identifiable health information,” *Id.* §160.103, which Congress defined as

[A]ny information . . . collected from an individual, that -

- (A) Is created or received by a healthcare provider . . . and
- (B) **relates to the past**, present, or future physical health or condition of an individual, the **provision of health care to an individual**, or the past, present, or future

payment for the provision of health care to an individual and

- (i) identifies the individual; or
- (ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

42 USC §1320d (6)(West 2004). (Emphasis added). (Exhibit D, attached).

The incident reports sought in this case relate to the provision of health care to Gary Cannon. They are protected health information to which a patient, or the personal representative of a deceased patient, may have access, as long as they are part of the “designated records set.”

“Designated records set” includes a “group of records maintained by or for a covered entity” that are: “ (i) the medical records . . . about individuals maintained by or for a covered healthcare provider . . . or (iii) **used in whole or in part, by or for the covered entity to make decisions about individuals.**” *Id.* §164.501. (Emphasis added). (Exhibit E, attached).

Under HIPAA, Gary Cannon’s surviving legal representatives are entitled to see the incident reports in question.

II.

HIPAA PREEMPTS UTAH'S CARE REVIEW PRIVILEGE STATUTE

HIPAA guarantees patients throughout the United States the right to access their medical records. *Id.* §164.528. HIPAA addresses the possibility that state law may differ regarding these rights. It provides that the rights conferred by it or by implementing federal regulations

shall not supersede a contrary provision of state law, if the provision of state law imposes requirements, standards, or implementations specifications that are *more stringent than* [those of the federal regulation].

HIPAA, §264(b) - (c), 111 Stat at 2033-34 (codified in the note following 42 USC §1320d-2 (emphasis added). (Exhibit G, attached). Congress said, in effect, that whichever standard is better for the individual patient trumps the other.

The Department of Health and Human Services (HHS) promulgated a rule interpreting HIPAA's preemption provision.² The regulation applies the "more stringent"

² HIPAA's preemption language does not itself specifically address whether patients' federal right to access their own protected health information trumps a state law provision against access. It speaks generally, however, about rights relating to health information and the "exercise of such rights." *Id.* §264(b). This left a gap for the Department of Health and Human Services (HHS) to fill. One task of federal agencies is to interpret statutes which are ambiguous. If the agency conducts a formal rule making process and its interpretation is reasonable, courts must defer to the agency, even if they might reasonably interpret the statute differently. Only if a court finds that a regulation is arbitrary, capricious, or manifestly contrary to the statute may it substitute its own construction of a statutory provision. This is known as "Chevron deference," derived from the U.S. Supreme Court's ruling in Chevron USA, Inc., v. Natural

language to several contexts to determine whether one legal standard trumps the less stringent law. **“With respect to information to be provided to an individual who was the subject of the individually identifiable health information about use, disclosure, rights, and remedies,” a state law is more stringent than the federal regulation if it “provides the greater amount of information.”** 45 C.F.R. §160.202 (2004). (Exhibit H, attached). Any state law privilege authorizing the withholding of information from the patient would be less “stringent” than the federal law. Consequently, the federal rule requiring access trumps any state law restricting patient access.

Another portion of the same regulation, dealing with disclosure of information to others, reenforces this conclusion. Generally, patients have a right to keep their records private - a goal of HIPAA’s privacy rule. However, some laws permit disclosure. When deciding whether state or federal law controls disclosure, the rule that better maintains a patient’s privacy will predominate - “except if the disclosure is . . . to the individual who is the subject of the individually identifiable health information.” *Id.* Here again, HIPAA puts patients’ right to access their medical records first.

In sum, HIPAA preempts any state law which restricts access to protected health information, including state care review or peer review privilege statutes.

Resources Defense Council, Inc., 467 U.S. 837, 843 n.11 (1984).

The foregoing conclusion is fortified by the following official portion of the preamble to HIPAA's privacy rule:

Comment: One commentor recommended that the final rule state that information developed as part of a quality improvement or medical error reduction program may not be disclosed under this provision. The commentor explained that peer-review information developed to identify and correct systemic problems in delivery of care must be protected from disclosure to allow a full discussion of the root causes of such events so they may be identified and addressed. According to the commentor, this is consistent with peer-review protections afforded this information by the states.

Response: . . . Under the final rule, ***no special protection against disclosure is provided for peer-review information*** of the type the commentor describes . . .

65 Fed Reg. 82462, 82677 (2000) (emphasis added). (Exhibit I, attached).

Every privilege in law has a purpose. Few privileges, however, are absolute. The care review privilege the hospital seeks to invoke must yield when a higher purpose is present. Such a higher purpose is present here. HIPAA preempts state laws and policies that shield care review records from disclosure to the patient or his representatives. HIPAA mandates the Hospital's disclosure of the incident reports Cannon seeks.

III.

THE “EVIDENCE” THAT THE INCIDENT REPORTS ARE PRIVILEGED IS *NOT* UNDISPUTED.

The affidavit of Linda Wright does not “establish” that the incident reports are privileged and non discoverable. Rather, it ~~merely~~ constitutes only a *prima facie* indication. It is terse and conclusory in the extreme. It is rebuttable. The Hospital has steadfastly stonewalled against all efforts to ascertain the accuracy of Ms. Wright’s assertions. It is by no means clear that the incident reports were “furnished by reason of this chapter.” It is also by no means clear that the incident reports were produced solely for the Hospital’s quality assurance department. The Hospital has refused to reveal whether the attorneys hired to defend it in this action have seen the incident reports. It has also refused to reveal the identity of all other persons who have seen the incident reports.

In short, the “evidence” of privilege is not undisputed.

IV.

ADDITIONAL CORROBORATING EVIDENCE *IS* NECESSARY.

The district court did not inalterably find the incident reports to be privileged. Rather, it found the reports privileged only “in the absence of any evidence to the contrary.” (R. 174). Its subsequent ruling makes clear that it did not intend to preclude

the discovery or presentation of contrary evidence. (R. 347-48). In its second discovery ruling, the district court stated: “The Court agrees with Plaintiff’s position concerning this Court’s prior ruling. . . . therefore, Plaintiff’s motion to compel is granted. . . .” (R. 347). Despite the district court’s express declaration that Mrs. Cannon could depose Linda Wright, the Hospital has not made her available and continues to fight against having to produce her.

Although Mrs. Cannon did not file a separate formal motion for the district court’s in-camera review of the incident reports or for production of the Hospital’s bylaws, rules and regulations, she did request the same in her memoranda. (See e.g., R. 113, 325).

V.

THE HOSPITAL’S REFERENCE TO AND RELIANCE UPON A HANDWRITTEN NOTE ON A LEGISLATIVE DOCUMENT OF DUBIOUS ORIGIN IS INAPPROPRIATE. EXHIBIT M TO THE HOSPITAL’S BRIEF SHOULD BE STRICKEN.

On pages 19-21 of its brief, the Hospital attempts to support its position by reliance on “legislative intent.” The legislative intent it seeks to invoke is a paragraph of handwriting at the bottom of a typed page which appears to be a proposed amendment to §26-25-3. The Hospital has not explained the origin of its Exhibit M. Exhibit M is not part of the record in this case. Although the Hospital quotes and even bolds and italicizes portions of the handwriting, it omits two portions of the handwriting. One is a

statement in the margin immediately to the left of the handwriting stating “data processing ignore this.” Another is a circled indication beneath the handwriting suggesting the handwritten language was not the legislature’s but was the work of Frank Carney, an attorney having some interest at the time in effecting a legislative “reversal” of Utah Supreme Court’s decision is Benson v. IHC. (See Exhibit M, attached to the Hospital’s brief).

Exhibit M should be stricken and this court should place no reliance on the argument advanced by the Hospital based on it.

VI.

PUBLIC POLICY *DOES NOT* SUPPORT PROTECTION OF THE INCIDENT REPORTS.

The Hospital’s reliance on Benson v. IHC Hospitals, Inc., 866 P.2d 537 (Utah 1993) is misplaced. Our Supreme Court there declared:

An obvious concern is whether §26-25-3 privileges only documents *prepared specifically* to be submitted for review purposes or whether the privilege also includes documents that *might or could* be used in the review process. The statutes’ rationale tends to favor only the former scenario. Otherwise, an argument could be advanced that all medical documents prepared by hospital personnel are created to improve health care rendered by a hospital, and therefore, the care review privilege would apply to all such documents.

866 P.2d at 540. In Benson, our Supreme Court dealt with the legitimate concern that

documents which should be a part of a patient's medical record are instead buried in an incident report which is then labeled as privileged:

[T]he Bensons express the concern that certain documents that should be in the medical record are missing. They allege that the hospital is labeling documents privileged that actually belong in the medical record. Therefore, it will also be necessary on remand for the trial court to determine what documents exist that should have been produced but were not. If indeed there are documents that should be in the medical record that are not found there, then the statutory privileges are being abused, and that information and those documents are discoverable. Because petitioners [IHC Hospitals, Inc. and Dr. Madsen] are asserting privileges, it is their burden to show that nothing is missing from the medical record.

866 P.2d at 540.

VII.

UNUSUAL CIRCUMSTANCES SURROUNDING THIS INTERLOCUTORY APPEAL MAKE IT HIGHLY APPROPRIATE FOR THIS COURT TO RULE ON ALL EXISTING DISCOVERY DISPUTES SURROUNDING THE INCIDENT REPORTS.

A filing deadline required Mrs. Cannon to request interlocutory review of the district court's first discovery ruling when she did. At the time she did so, the Hospital had not yet responded to some of her outstanding written discovery requests. In an effort to avoid discovery surrounding its incident reports, the Hospital has been

disingenuous. After the district court granted her second motion to compel, the Hospital refused to produce Linda Wright for deposition and took the position that other related discovery was inappropriate due to the pendency of this appeal. (See, e.g., R. 378-383).

Almost simultaneously, it has been telling this Court that the discovery issues are appropriately before the district court. See, e.g. p. 6 of the Hospital's August 26, 2004 submission herein, entitled Memorandum in Opposition to Plaintiffs' Motion for Extension . . . and to Allow Additional Discovery.) Again, however, it has told the district court that it should not take any action or grant any discovery whatsoever because of the pendency of this appeal proceeding before this Court. (R. 378-383). At least one court should see that Mrs. Cannon's legitimate discovery requests are honored. This Court appears to be in the best position to get the discovery issues resolved quickest. Mrs. Cannon respectfully asks it to do so.

CONCLUSION AND RELIEF REQUEST

This Court should declare the incident reports discoverable because the Hospital has failed to meet its burden to prove they are privileged. Benson, *supra*. Moreover, HIPAA preempts Utah's care review statute to the extent it shields the incident reports from discovery by the patient and his representatives.

This Court should compel the Hospital to honor Mrs. Cannon's requests to produce its risk manager, Linda Wright, for deposition and to honor Mrs. Cannon's Rule

30(b)(6) deposition notice by producing:

1. Each person who has knowledge and information as to the identity of each person who has seen or may have seen the incident reports which the hospital has refused to produce;
2. Each and every person who has at any time seen the incident reports the Hospital has refused to produce.

This Court should also compel the Hospital to answer Mrs. Cannon's First set of [two] Requests for Admissions and Second Set of [two] Interrogatories.

Finally, this Court should grant Mrs. Cannon's request for Rule 37 sanctions and award her the reasonable expenses incurred by her in obtaining the discovery she seeks and in prosecuting this appeal.

Respectfully submitted this 6th day of December, 2004.

A handwritten signature in black ink, appearing to read "Douglas G. Mortensen", with a large, sweeping flourish extending from the end of the name.

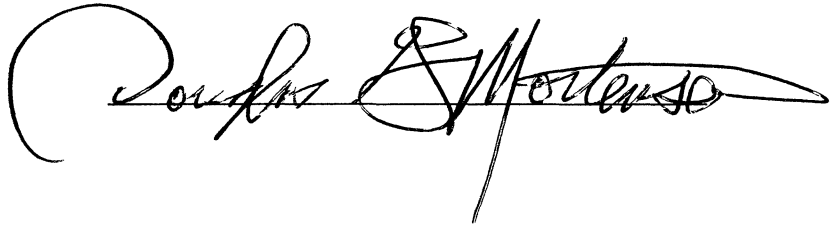
Douglas G. Mortensen
MATHESON, MORTENSEN, OLSEN & JEPPSON, P.C.
Attorneys for Plaintiffs/Appellants

CERTIFICATE OF SERVICE

I hereby certify that on the 6th day of December, 2004, I caused two true and correct copies of the foregoing to be delivered to the following via the means indicated:

David W. Slagle, #2975
Elizabeth L. Willey, #5639
SNOW, CHRISTENSEN &
MARTINEAU
Attorneys for Salt Lake Regional
Medical Center Inc. (Appellee)
10 Exchange Place, 11th Floor
P.O. Box 45000
Salt Lake City, UT 84145

☒ U.S. Mail
☐ Facsimile
☒ ~~Hand-Delivered~~
☐ Federal Express



ADDENDUM

- A. July 9, 2005 letter from Douglas G. Mortensen to Elizabeth L. Willey
- B. Hospital's August 26, 2004 Memorandum in Opposition to Plaintiffs' Motion to Compel Discovery and for Sanctions, *sans* exhibits
- C. 45 CFR §164.524(a)
- D. 45 CFR §160.103
- E. 45 CFR §164.501
- F. 42 USCS §1320d(3)
- G. 42 USCS §1230d-2
- H. 45 CFR §160.202
- I. 65 Federal Register 82462, 82677

Exhibit A

MATHESON, MORTENSEN, OLSEN & JEPPSON

a Professional Corporation

ATTORNEYS AT LAW

648 EAST FIRST SOUTH

SALT LAKE CITY, UTAH 84102

TELEPHONE (801) 363-2244

TELECOPIER (801) 363-2261

DOUGLAS G. MORTENSEN

WRITER'S VOICE MAIL

994-5601

WRITER'S E-MAIL

dmort@mnojlaw.com

July 9, 2004

Elizabeth L. Willey
Snow, Christiansen & Martineau
10 Exchange Place, 11th Floor
P.O. Box 45000
Salt Lake City, UT 84145

Re: Gary R. Cannon v. Salt Lake Regional Medical Center
Case No. 020914614

Dear Elizabeth:

On July 7 I received in the mail for the first time a copy of the May 21 minute entry which grants my motion to compel discovery. Apparently, the district has a problem accurately sending out and receiving mail.

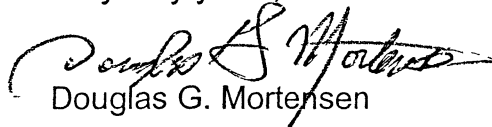
At the time my second motion to compel was granted, you had not yet served responses to my interrogatories and admission requests. Your objection and refusal to respond to that discovery has never been placed squarely before the court. I believe it is clear from Judge Atherton's most recent ruling that she would order you to supplement your answers to the two admission requests and two interrogatories I served on March 15, 2004. I therefore ask that you submit supplemental responses amending your earlier responses to that discovery within ten days of the date of this letter. If you do not do so, I will file a motion to compel and request sanctions.

If you choose to take the position that the pendency of my interlocutory appeal relieves you of any duty to respond to the ongoing discovery, I will simply petition both the Court of Appeals and the District court for express leave to proceed with discovery. Under the circumstances, there appears little doubt the request will be granted. Please give me truthful responses to my two interrogatories and admission requests.

Elizabeth Willey
July 9, 2004
Page 2

Please provide me with the earliest three alternative available dates for my deposing Linda Wright and whomever the hospital chooses to produce in response to my Rule 30(b) (6) deposition notice. Those dates may be provided to either me or my assistant, Ann. Please provide those dates at your earliest convenience.

Very truly yours,



Douglas G. Mortensen

DGM/ab

c: Jan Lindsay

Exhibit B

DAVID W. SLAGLE (2975)
ELIZABETH L. WILLEY (5639)
BRADLEY R. BLACKHAM (8703)
SNOW, CHRISTENSEN & MARTINEAU
Attorneys for Salt Lake Regional Medical Center, Inc.
10 Exchange Place, Eleventh Floor
Post Office Box 45000
Salt Lake City, Utah 84145
Telephone: (801) 521-9000

IN THE THIRD JUDICIAL DISTRICT COURT OF SALT LAKE COUNTY
STATE OF UTAH

KATHRYN CANNON, as surviving
spouse of GARY R. CANNON, deceased,
LANE CANNON and ROLAND
CANNON, as surviving children and legal
heirs of GARY R. CANNON, deceased,

Plaintiffs,

vs.

SALT LAKE REGIONAL MEDICAL
CENTER, INC., JOHN AND JANE DOES
1 THROUGH X AND DOE BUSINESS
ENTITIES 1 THROUGH V,

Defendants.

**DEFENDANT SALT LAKE
REGIONAL MEDICAL CENTER,
INC.'S MEMORANDUM IN
OPPOSITION TO PLAINTIFFS'
MOTION TO COMPEL DISCOVERY
AND FOR SANCTIONS**

Civil No. 020914614

Judge Judith S.H. Atherton

Defendant Salt Lake Regional Medical Center (“Salt Lake Regional”) submits the following memorandum in opposition to plaintiffs’ Motion to Compel Discovery and for Sanctions and Supporting Memorandum.

STATEMENT OF FACTS

1. This is a medical malpractice case arising from treatment and care rendered to decedent Gary Cannon while he was a patient at Salt Lake Regional from May 16, 2001 through May 21, 2001. (Compl.)

2. On January 6, 2003, plaintiffs served their first set of interrogatories and requests for production of documents on Salt Lake Regional. (Pls.’ First Set of Interrogs. and Req. for Prod. of Docs.)

3. Plaintiffs’ first set of requests for production of documents includes a request for each incident report that may exist regarding Mr. Cannon’s fall while he was a patient at Salt Lake Regional. (Id.)

4. On February 24, 2003, Salt Lake Regional responded to plaintiffs’ first set of interrogatories and requests for production of documents. Salt Lake Regional specifically objected to plaintiffs’ request for each incident report on the grounds of peer review and the provisions of Utah Code Ann. § 26-25-1 et seq. (1953 as amended). (Salt Lake Reg’l Answers to Pls. First Set of Interrogs. and Req. for Produc. of Docs.)

5. On October 24, 2003, plaintiffs served a motion to compel production of any incident report that may exist with respect to Mr. Cannon's fall at Salt Lake Regional. ("First Motion to Compel"). (Pls.' First Mot. to Compel.)

6. On November 16, 2003, Salt Lake Regional served its memorandum in opposition to plaintiffs' First Motion to Compel. Supporting Salt Lake Regional's memorandum is the affidavit of Linda Wright, who is the director of risk management at Salt Lake Regional. (Salt Lake Reg'l Mem. in Opp'n to Pls.' First Mot. to Compel.)

7. On December 5, 2003, plaintiffs served a reply memorandum in support of their First Motion to Compel and submitted the motion to the Court for decision. Plaintiffs did not request additional time to conduct discovery prior to submitting their First Motion to Compel for decision. (Reply Mem. in Supp. of Pls.' First Mot. to Compel; Pls.' Not. to Submit for Decision.)

8. On March 4, 2004, the Court issued an unsigned and undated minute entry ("Minute Entry 1") denying plaintiffs' First Motion to Compel. In Minute Entry 1, the Court acknowledged that the only evidence presented was the affidavit of Linda Wright. The Court ruled that in the absence of any evidence to the contrary, any existing incident reports are privileged. (Minute Entry 1.)

9. On March 15, 2004, plaintiffs served requests for admission on Salt Lake Regional. Plaintiffs specifically requested that Salt Lake Regional admit the following: (1) that any existing incident reports have been seen by Salt Lake Regional's counsel; and (2) that any existing incident

reports have been seen by individually named attorneys representing Salt Lake Regional. (Pls.' Req. for Admis. and Second Set of Interrogs.)

10. On March 15, 2004, plaintiffs served their second set of interrogatories on Salt Lake Regional. Plaintiffs specifically requested the following information: (1) the basis for any refusal to admit the statements specified in plaintiffs' requests for admission; (2) the names of every person having knowledge of the grounds for Salt Lake Regional's refusal to admit the statements specified in plaintiffs' request for admission; (3) the identity of each document supporting Salt Lake Regional's refusal to admit the statements specified in plaintiffs' request for admissions; and (4) the names of every person who has seen any existing incident report. (Id.)

11. On March 18, 2004, plaintiffs, pursuant to Rule 30(b)(6) of the Utah Rules of Civil Procedure, served a notice of deposition of the following individuals: (1) "[e]ach person who has knowledge or information as to the identity of each person who has seen or may have seen the incident report(s) which Salt Lake Regional Medical Center has refused to produce in this action;" and (2) "[e]ach and every person who has at any time seen the incident reports Salt Lake Regional Medical Center has refused to produce in this action pertaining to the fall on or about May 18, 2001 of patient Gary R. Cannon" ("Rule 30(b)(6) deponents"). (Pls.' Rule 30(b)(6) Notice of Dep.)

12. On March 18, 2004, plaintiffs also served a notice of deposition of Linda Wright. (Pls.' Notice of Dep. of Linda Wright.)

13. On March 19, 2004, counsel for Salt Lake Regional sent plaintiffs' counsel a letter regarding plaintiffs' March 18, 2004 notices of depositions. Based on the Court's ruling in Minute Entry 1, counsel for Salt Lake Regional refused to produce either Linda Wright or the Rule 30(b)(6) deponents without an order from the Court. (3/19/04 Willey Letter, attached as Exhibit A.)

14. On March 24, 2004, plaintiffs served a motion to compel the depositions of Linda Wright and the Rule 30(b)(6) deponents ("Second Motion to Compel"). Plaintiffs argued that Minute Entry 1 invites discovery into the accuracy of Linda Wright's affidavit testimony. (Pls.' Second Mot. to Compel.)

15. On March 24, 2004, plaintiffs also served an objection to Minute Entry 1. Plaintiffs specifically objected because Minute Entry 1 was not dated and signed. Plaintiffs requested that the Court not sign and enter Minute Entry 1 until it had resolved plaintiffs' Second Motion to Compel. (Pls' Objection to Minute Entry 1.)

16. On March 29, 2004, counsel for Salt Lake Regional received a signed copy of Minute Entry 1 ("Minute Entry 2") that is dated March 4, 2004. (Minute Entry 2.)

17. On March 31, 2004, Salt Lake Regional served its memorandum in opposition to plaintiffs' Second Motion to Compel. Salt Lake Regional argued that it reasonably relied on Minute Entry 1 and applicable statutory and case law in refusing to produce Linda Wright and the Rule 30(b)(6) deponents for depositions. (Salt Lake Reg'l Mem. in Opp'n to Pls.' Second Mot. to Compel.)

18. On April 16, 2004, Salt Lake Regional responded to plaintiffs' requests for admission. Salt Lake Regional objected to both requests for admission on the grounds of attorney client privilege; work product doctrine; Minute Entry 1; and the statutes and case law cited in Salt Lake Regional's memoranda in opposition to plaintiffs' First Motion to Compel and Second Motion to Compel. (Salt Lake Reg'l Answers to Pls.' First Set of Req. for Admis., attached as Exhibit B.)

19. On April 16, 2004, Salt Lake Regional responded to plaintiffs' second set of interrogatories. In response to plaintiffs' first interrogatory, Salt Lake Regional identified the grounds for its refusal to admit the statements specified in plaintiffs' request for admissions; identified counsel for both parties and Judge Atherton as individuals with knowledge supporting Salt Lake Regional's refusal to admit the statements specified in plaintiffs' request for admissions; and referred plaintiffs to Minute Entry 1 and the statutes and cases cited in Salt Lake Regional's memoranda in opposition to plaintiffs' First Motion to Compel and Second Motion to Compel as documents supporting Salt Lake Regional's refusal to admit the statements specified in plaintiffs' request for admissions. (Salt Lake Reg'l Answers to Pls.' Second Set of Interrogs., attached as Exhibit C.)

20. On May 21, 2004, the Court issued a minute entry ("Minute Entry 3") granting in part plaintiffs' Second Motion to Compel. Specifically, the Court ruled that plaintiffs "are entitled to depose Linda Wright." Minute Entry 3 is silent with respect to plaintiffs' request for an order compelling the depositions of the Rule 30(b)(6) deponents. (Minute Entry 3, attached as Exhibit D.)

21. On May 21, 2004, the Court issued a separate minute entry ("Minute Entry 4") clarifying Minute Entry 1. The Court explained that Minute Entry 1 had been signed and entered on March 4, 2004 but that the copies initially sent to counsel were undated and unsigned. To preserve plaintiffs' right to file an interlocutory appeal, the Court re-entered an order denying plaintiffs' First Motion to Compel on May 21, 2004. Minute Entry 4 did not alter the substance of Minute Entry 1 or otherwise change the Court's stated reasons for denying plaintiffs' First Motion to Compel. (Minute Entry 4.)

22. On June 4, 2004, plaintiffs' counsel sent a letter to the Court inquiring as to the status of plaintiffs' Second Motion to Compel. The letter reflects plaintiffs' counsel's belief that the Court had not yet ruled on plaintiffs' Second Motion to Compel. (6/4/04 Mortensen Letter.)

23. On June 10, 2004, plaintiffs filed a petition for interlocutory appeal of the Court's order denying plaintiffs' First Motion to Compel. (Pls.' Pet. for Permission to Appeal Interlocutory Order, attached as Exhibit E.)¹

24. On June 28, 2004, the Utah Court of Appeals granted plaintiffs' petition for interlocutory appeal of the Court's order denying plaintiffs' First Motion to Compel. (Order granting Pls.' Pet. for Interlocutory Appeal.)

¹Plaintiffs incorrectly alleged in their petition that the Court failed to rule on plaintiffs' Second Motion to Compel within the time allowed by Utah Code Ann. § 78-7-25(1). Exhibit E, p. 4 n. 1. In fact, the Court timely ruled on plaintiffs' Second Motion to Compel in Minute Entry 3 dated May 21, 2004.

25. On July 6, 2004, the Court issued a Minute Entry (“Minute Entry 5”) in response to the June 4, 2004 letter from plaintiffs’ counsel regarding the status of plaintiffs’ Second Motion to Compel. In Minute Entry 5, the Court explained that it had already ruled on plaintiffs’ Second Motion to Compel in Minute Entry 3. The Court attached a copy of Minute Entry 3 to Minute Entry 5. Minute Entry 5 did not alter the substance of Minute Entry 3. (Minute Entry 5, attached as Exhibit F.)

26. On July 9, 2004, plaintiffs’ counsel sent counsel for Salt Lake Regional at letter acknowledging recent receipt of the Court’s order granting in part plaintiffs’ Second Motion to Compel. In his letter, plaintiffs’ counsel requests a deposition date for Linda Wright and the Rule 30(b)(6) deponents. Plaintiffs’ counsel also threatened to file yet another motion to compel unless Salt Lake Regional provided supplemental responses to plaintiffs’ second set of interrogatories and requests for admission within ten days. (7/9/04 Mortensen Letter, attached as Exhibit G.)

27. On July 9, 2004, plaintiffs, pursuant to Rule 11 of the Utah Rules of Appellate Procedure, served their Certification of Absence of Transcript and Statement of Issues to be Presented on Appeal. (Pls.’ Cert. of Absence of Transcript and Statement of Issues to be Presented on Appeal, attached as Exhibit H.)

28. Plaintiffs identified the primary issue on appeal as whether any existing incident report is discoverable. (Id.)

29. Plaintiffs identified a secondary issue on appeal as whether Salt Lake Regional “should be compelled to respond to plaintiffs’ discovery requests (including interrogatories and admission requests) seeking to ascertain the identity and job description of all persons who have seen the incident reports and the purposes for which such reports were disseminated to such persons.” (Id.)

30. On July 16, 2004, Salt Lake Regional served its Motion for Protective Order and Stay of Discovery. Salt Lake Regional moved the Court for an order staying all discovery relating to the existence, substance, nature or dissemination of any existing incident report until the appeals process is complete. (Salt Lake Reg’l Mot. for Protective Order and Stay of Disc.)

31. On August 9, 2004, plaintiffs responded to Salt Lake Regional’s Motion for Protective Order and Stay of Discovery by filing a motion with the Utah Court of Appeals to extend the time for filing an appeal brief and for an order compelling Salt Lake Regional to (a) allow plaintiffs to depose Linda Wright and the Rule 30(b)(6) deponents; and (b) respond to plaintiffs’ two outstanding requests for admission and second set of interrogatories. (Pls.’ Mot. for Extension of Time Within Which to File Appeal Brief and to Allow Additional Discovery and Supp. Mem., attached as Exhibit I.)

32. On August 9, 2004, plaintiffs further responded to Salt Lake Regional’s Motion for Protective Order and Stay of Discovery by filing a motion with this Court to compel supplemental responses to plaintiffs’ request for admissions and interrogatories and the depositions of Linda

Wright and the Rule 30(b)(6) deponents (“Third Motion to Compel”).² (Pls.’ Third Motion to Compel.)

ARGUMENT

I. PLAINTIFFS SHOULD NOT BE ALLOWED TO DEPOSE LINDA WRIGHT OR THE RULE 30(b)(6) DEONENTS WHILE PLAINTIFFS’ APPEAL IS PENDING

On May 21, 2004, the Court granted plaintiffs’ motion to compel the deposition of Linda Wright in Minute Entry 3. Following the Court’s issuance of Minute Entry 3, plaintiff did not seek a date for the deposition of Linda Wright until after the Utah Court of Appeals had granted plaintiffs’ petition for interlocutory appeal. *See* Exhibit G. On the same day that plaintiffs sought dates for the deposition of Linda Wright in a letter dated July 9, 2004, they filed a statement of issues to be presented on appeal. *See* Exhibit H. Plaintiffs specifically identified the primary issue on appeal as whether any existing incident report is discoverable. *Id.* Plaintiffs also identified the following secondary issue on appeal: Whether Salt Lake Regional “should be compelled to respond to plaintiffs’ discovery requests (including interrogatories and admission requests) seeking to ascertain the identity and job description of all persons who have seen the incident reports and the purposes for which such reports were disseminated to such persons.” *Id.*

²Although plaintiffs assert that their Third Motion to Compel serves as a memorandum in opposition to Salt Lake Regional’s Motion for Protective Order and Stay of Discovery, the caption of plaintiffs’ Third Motion to Compel indicates that it is a separate pleading and not a memorandum in opposition to Salt Lake Regional’s motion.

The deposition of Linda Wright is solely for the purpose of eliciting information regarding the use, content and dispersion of incident reports. Salt Lake Regional has previously argued that this information is privileged based on the scope of Utah's care-review privilege. Plaintiffs' appeal goes to the scope of Utah's care-review privilege. Given the issues on appeal that have been identified by plaintiffs, Utah's appellate courts will likely provide trial courts with additional guidance on the scope of the care-review privilege in general and the permissible scope of discovery pertaining to incident reports.

For these reasons, Salt Lake Regional has moved the Court for an order staying all discovery related to incident reports, including the deposition of Linda Wright, until the appeals process is complete. While the Court has ruled that plaintiffs are allowed to depose Linda Wright, that ruling came before plaintiffs' petition for interlocutory appeal was granted. Now that the issues pertaining to the scope of the care-review privilege and the scope of discovery related to incident reports is before the Utah Court of Appeals, all discovery pertaining to incident reports should be stayed until Utah's appellate courts have had an opportunity to examine the care-review statute and provide additional guidance. An order compelling immediate discovery runs the risk of improperly intruding on the Utah Court of Appeals' review of the case and making any orders or guidance issued by that court moot. Furthermore, an order compelling immediate discovery runs the risk of prejudicing Salt Lake Regional's interest in protecting privileged materials.

Plaintiffs assert that they requested that the Court of Appeals deal with various discovery issues based on plaintiffs' incorrect understanding that this Court had failed to deal with those issues. Pls.' Third Mot. to Compel, p. 8. The facts do not support plaintiffs' assertion. First, this Court has never ruled on the issue of whether Salt Lake Regional should be compelled to provide supplemental responses to plaintiffs' second interrogatories and requests for admission. Second, plaintiffs identified the issues to be presented on appeal on July 9, 2004, two days after plaintiffs' counsel acknowledged receipt of this Court's order regarding the deposition of Linda Wright. Exhibit G. Finally, plaintiffs recently moved the Utah Court of Appeals to "direct the district court to compel the Hospital to comply promptly with the district court's order allowing the Plaintiffs to depose the Hospital's risk manager and Rule 30 (b)(6) designees and to compel the Hospital to respond to the Plaintiffs' two outstanding admission requests and interrogatories." Exhibit I, p. 7. Thus, plaintiffs have repeatedly placed the issue of whether discovery related to incident reports should be allowed, before the Utah Court of Appeals.

Plaintiffs acknowledge that the Court has never expressly granted plaintiffs' Second Motion to Compel as it pertains to the Rule 30(b)(6) deponents.³ See Pls.' Third Mot. to Compel, p. 5.

³It should be noted that plaintiffs incorrectly represent and imply to the Utah Court of Appeals that this Court ordered the depositions of the Rule 30(b)(6) deponents. While plaintiffs have distinguished between the Court's actual orders and plaintiffs' interpretation of those orders in their Third Motion to Compel filed with this Court, plaintiffs did not make a similar distinction in the memorandum filed with the Utah Court of Appeals for an extension of time to file an appeal brief and for an order allowing additional discovery. See Exhibit I, pp. 3, 7.

While Minute Entry 5 does mention in passing that plaintiffs moved to compel depositions of the Rule 30(b)(6) deponents, the Court ultimately re-affirmed its ruling in Minute Entry 3 and attached a copy of that minute entry to Minute Entry 5. Exhibit F. Thus, Minute Entry 3 is the governing order. Minute Entry 3 merely granted plaintiffs' motion as it pertains to Linda Wright. Minute Entry 3 is silent with respect to plaintiffs' motion to compel depositions of the Rule 30(b)(6) deponents. Thus, plaintiffs are incorrect in arguing that the issue has been decided by the Court as it pertains to the depositions of the Rule 30(b)(6) deponents. *See* Pls.' Third Motion to Compel, p. 6. Even if the Court had granted plaintiffs' motion to compel the depositions of the Rule 30(b)(6) deponents, those depositions should be stayed for the same reasons that the deposition of Linda Wright should be stayed.

II. PLAINTIFFS HAVE FAILED TO ADDRESS THE UNDERLYING OBJECTIONS RAISED BY SALT LAKE REGIONAL IN ITS RESPONSES TO PLAINTIFFS' SECOND SET OF INTERROGATORIES AND REQUESTS FOR ADMISSION

In conclusory fashion, plaintiffs argue that because the Court has granted plaintiffs' Second Motion to Compel as it applies to Linda Wright, the Court should order Salt Lake Regional to "respond" to plaintiffs' second set of interrogatories and requests for admission. Pls.' Third Mot. to Compel, p. 7. Plaintiffs' argument fails for at least two reasons. First, plaintiffs incorrectly allege and imply that Salt Lake Regional has not responded to the discovery requests at issue. As a matter of fact, Salt Lake Regional timely responded to the discovery requests at issue on April 16, 2004. *See* Exhibits B & C.

Second, plaintiff have failed to put forth any argument as to the merits of Salt Lake Regional's objections to the discovery requests at issue. Salt Lake Regional raised numerous legal objections to plaintiffs' interrogatories and requests for admission, including the attorney-client privilege, attorney work product doctrine, and the care-review privilege. *See id.* Plaintiffs have wholly failed to present any argument as to whether the privileges and objections asserted by Salt Lake Regional apply and preclude discovery of the information requested. In the absence of any argument on the underlying merits of plaintiffs' request for an order to compel discovery, the request should be denied. *See State v. Thomas*, 1999 UT 2, ¶ 11, 974 P.2d 269 (“[A] reviewing court is entitled to have the issues clearly defined with pertinent authority cited and is not simply a depository in which the appealing party may dump the burden of argument and research.” (Quotations and citations omitted)).

In any event, the procedural status of this case demonstrates that an order compelling supplemental responses to plaintiffs' second set of interrogatories and requests for admission would not be appropriate at this time. The issues on appeal include the permissible scope of discovery related to incident reports and whether Salt Lake Regional reasonably relied on the attorney-client privilege, attorney work product doctrine, the care-review privilege and other objections in responding to plaintiffs' discovery requests. *See Exhibit H.* Until the appellate process is complete, the prudent course of action is to stay further discovery in any way related to incident reports.

III. AN ORDER STAYING DISCOVERY RELATED TO INCIDENT REPORTS WILL NOT PREJUDICE PLAINTIFFS ON APPEAL

An order staying incident report discovery will not prejudice plaintiffs on appeal. Plaintiffs' petition for an interlocutory appeal of the Court's denial of plaintiffs' First Motion to Compel is currently pending before the Utah Court of Appeals. The only evidence offered and considered by this Court in connection with plaintiffs' First Motion to Compel is the affidavit of Linda Wright. *See* Minute Entry 1. As a matter of law, appellate court review of the order denying plaintiffs' First Motion to Compel is limited in scope to a review of the evidence that was presented and considered by this Court.⁴ *See, e.g., Bailey v. Bayles*, 2002 UT 58, ¶ 19, 52 P.3d 1158 (concluding that the Utah Court of Appeals "exceeded its proper role" by finding facts beyond those found by the trial court); *Brigham City v. Stuart*, 2002 UT App 317, ¶ 10, 57 P.3d 1111 (refusing appellant's request to supplement the trial court's factual findings); *Lyons v. Booker*, 1999 UT App 172, ¶ 2, 982 P.2d 1142 (stating that the Utah Court of Appeals does not consider new evidence on appeal). Thus, additional or supplemental evidence beyond the affidavit testimony of Linda Wright may not be considered on appeal.

⁴Salt Lake Regional has fully briefed this argument in its memorandum in opposition to plaintiffs' motion to the Utah Court of Appeals for an extension of time to file an appeal brief and for an order allowing additional discovery. In their motion for an extension of time and for an order allowing additional discovery, plaintiffs argue that the Utah Court of Appeals should consider supplemental evidence not presented to or considered by this Court. Pls.' Mot. for Extension of Time, p. 6 ("Unquestionably, this Court will be better able fairly to decide the issue on appeal if it has before it all the relevant facts.").

Because supplemental incident-report evidence may not be considered on appeal, an order staying all discovery related to incident reports will not prejudice plaintiffs on appeal. To the contrary, an order compelling further and immediate discovery regarding incident reports runs the risk of (1) improperly intruding on the Utah Court of Appeals' review of the case; (2) making any direction from Utah's appellate courts on the issue moot; and (3) prejudicing Salt Lake Regional's interest in protecting privileged care-review materials and processes.

Furthermore, an order staying all discovery related to incident reports would not foreclose other avenues of discovery. Salt Lake Regional does not oppose continued fact or expert discovery unrelated to incident reports. Thus far, plaintiffs have not taken any depositions in this case. Even if plaintiff believe any existing incident reports are necessary to take the depositions of the nurses and other health care providers involved in this case, discovery related to causation and damages remains to be conducted and does not involve any incident reports that may exist. Thus, an order staying discovery related to incident reports would preserve the status quo while issues related to incident reports are on appeal but still leave the parties with discovery to pursue during the appeals process.

CONCLUSION

The scope of Utah's care-review privilege and the permissible scope of discovery related to material protected under the care review privilege are currently on appeal to the Utah Court of Appeals. To preserve the status quo until Utah's appellate court have had an opportunity to provide

further direction, an order staying all discovery related to incident reports should be issued. Accordingly, plaintiffs' request for an order compelling the deposition of Linda Wright and the Rule 30(b)(6) deponents and for an order compelling supplemental responses to plaintiffs' second set of interrogatories and requests for admission should be denied.

Furthermore, plaintiffs' request for an order compelling supplemental responses to written discovery should be denied because plaintiffs have wholly failed to address the merits of Salt Lake Regional's objections to those discovery requests. Because new evidence relating to incident reports may not be considered on appeal, an order staying discovery would not prejudice plaintiffs on appeal. For these reasons, plaintiffs' Third Motion to Compel should be denied in its entirety, and Salt Lake Regional's motion for an order staying all discovery related to incident reports should be granted

DATED this 26 day of August, 2004.

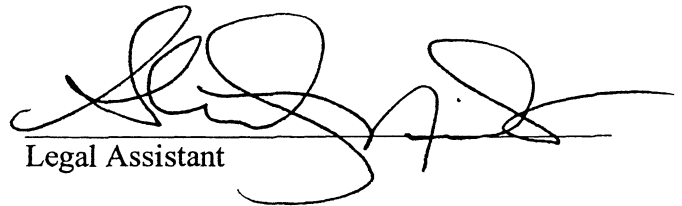
SNOW, CHRISTENSEN & MARTINEAU

By Bradley R. Blackham
David W. Slagle
Elizabeth L. Willey
Bradley R. Blackham
Attorneys for Salt Lake Regional Medical Center,
Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 26th day of August, 2004, I caused a true and correct copy of the foregoing **DEFENDANT SALT LAKE REGIONAL MEDICAL CENTER, INC.'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL DISCOVERY AND FOR SANCTIONS** to be mailed to the following:

Douglas G. Mortensen
Matheson, Mortensen, Olsen & Jeppson
648 East 100 South
Salt Lake City, UT 84102
Attorneys for Plaintiffs Kathryn Cannon, Lane Cannon and Roland Cannon



Legal Assistant

020440-0051\brb\54907.wpd

Exhibit C

or part of that information could endanger the individual.

(2) *Implementation specifications: Conditions on providing confidential communications.*

(i) A covered entity may require the individual to make a request for a confidential communication described in paragraph (b)(1) of this section in writing.

(ii) A covered entity may condition the provision of a reasonable accommodation on:

(A) When appropriate, information as to how payment, if any, will be handled; and

(B) Specification of an alternative address or other method of contact.

(iii) A covered health care provider may not require an explanation from the individual as to the basis for the request as a condition of providing communications on a confidential basis.

(iv) A health plan may require that a request contain a statement that disclosure of all or part of the information to which the request pertains could endanger the individual.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002]

§ 164.524 Access of individuals to protected health information.

(a) *Standard: Access to protected health information.* (1) *Right of access.* Except as otherwise provided in paragraph (a)(2) or (a)(3) of this section, an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:

(i) Psychotherapy notes;

(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and

(iii) Protected health information maintained by a covered entity that is:

(A) Subject to the Clinical Laboratory Improvements Amendments of 1988, 42 U.S.C. 263a, to the extent the provision of access to the individual would be prohibited by law; or

(B) Exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR 493.3(a)(2).

(2) *Unreviewable grounds for denial.* A covered entity may deny an individual access without providing the individual an opportunity for review, in the following circumstances:

(i) The protected health information is excepted from the right of access by paragraph (a)(1) of this section.

(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of protected health information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.

(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.

(iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law.

(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

(3) *Reviewable grounds for denial.* A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed, as required by paragraph (a)(4)

of this section, in the following circumstances:

(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;

(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or

(iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

(4) *Review of a denial of access.* If access is denied on a ground permitted under paragraph (a)(3) of this section, the individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny. The covered entity must provide or deny access in accordance with the determination of the reviewing official under paragraph (d)(4) of this section.

(b) *Implementation specifications: requests for access and timely action.* (1) *Individual's request for access.* The covered entity must permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.

(2) *Timely action by the covered entity.* (i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access no later than 30 days after receipt of the request as follows.

(A) If the covered entity grants the request, in whole or in part, it must in-

form the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (c) of this section.

(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d) of this section.

(ii) If the request for access is for protected health information that is not maintained or accessible to the covered entity on-site, the covered entity must take an action required by paragraph (b)(2)(i) of this section by no later than 60 days from the receipt of such a request.

(iii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) or (ii) of this section, as applicable, the covered entity may extend the time for such actions by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) or (ii) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for access.

(c) *Implementation specifications: Provision of access.* If the covered entity provides an individual with access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Providing the access requested.* The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the protected health information about them in designated record sets. If the same protected health information that is the subject of a request for access is maintained in more than one designated record set or at more than one location, the covered entity need only produce the protected health information once in response to a request for access.

(2) *Form of access requested.* (i) The covered entity must provide the individual with access to the protected health information in the form or format requested by the individual, if it is readily producible in such form or format; or, if not, in a readable hard copy form or such other form or format as agreed to by the covered entity and the individual.

(ii) The covered entity may provide the individual with a summary of the protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:

(A) The individual agrees in advance to such a summary or explanation; and

(B) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.

(3) *Time and manner of access.* The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.

(4) *Fees.* If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

(i) Copying, including the cost of supplies for and labor of copying, the protected health information requested by the individual;

(ii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and

(iii) Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(ii) of this section.

(d) *Implementation specifications: Denial of access.* If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Making other information accessible.* The covered entity must, to the extent possible, give the individual access to any other protected health information requested, after excluding the protected health information as to which the covered entity has a ground to deny access.

(2) *Denial.* The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain:

(i) The basis for the denial;

(ii) If applicable, a statement of the individual's review rights under paragraph (a)(4) of this section, including a description of how the individual may exercise such review rights; and

(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in § 164.530(d) or to the Secretary pursuant to the procedures in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii).

(3) *Other responsibility.* If the covered entity does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.

(4) *Review of denial requested.* If the individual has requested a review of a denial under paragraph (a)(4) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in paragraph (a)(3) of this section. The covered entity must promptly provide

written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.

(e) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by § 164.530(j):

(1) The designated record sets that are subject to access by individuals; and

(2) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

§ 164.526 Amendment of protected health information.

(a) *Standard: Right to amend.* (1) *Right to amend.* An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in the designated record set.

(2) *Denial of amendment.* A covered entity may deny an individual's request for amendment, if it determines that the protected health information or record that is the subject of the request:

(i) Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of protected health information is no longer available to act on the requested amendment;

(ii) Is not part of the designated record set;

(iii) Would not be available for inspection under § 164.524; or

(iv) Is accurate and complete.

(b) *Implementation specifications: requests for amendment and timely action.*

(1) *Individual's request for amendment.* The covered entity must permit an individual to request that the covered entity amend the protected health information maintained in the designated record set. The covered entity may require individuals to make requests for amendment in writing and to provide a reason to support a requested amendment, provided that it informs individuals in advance of such requirements.

(2) *Timely action by the covered entity.* (i) The covered entity must act on the individual's request for an amendment no later than 60 days after receipt of such a request, as follows.

(A) If the covered entity grants the requested amendment, in whole or in part, it must take the actions required by paragraphs (c)(1) and (2) of this section.

(B) If the covered entity denies the requested amendment, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d)(1) of this section.

(ii) If the covered entity is unable to act on the amendment within the time required by paragraph (b)(2)(i) of this section, the covered entity may extend the time for such action by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for an amendment.

(c) *Implementation specifications: Accepting the amendment.* If the covered entity accepts the requested amendment, in whole or in part, the covered entity must comply with the following requirements.

(1) *Making the amendment.* The covered entity must make the appropriate amendment to the protected health information or record that is the subject of the request for amendment by, at a minimum, identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment.

(2) *Informing the individual.* In accordance with paragraph (b) of this section, the covered entity must timely inform the individual that the amendment is accepted and obtain the individual's identification of and agreement to have the covered entity notify the relevant persons with which the amendment needs to be shared in accordance with paragraph (c)(3) of this section.

Exhibit D

SUBCHAPTER C—ADMINISTRATIVE DATA STANDARDS AND RELATED REQUIREMENTS

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

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AUTHORITY 42 U S C 1302(a) 42 U S C 1320d—1320d-8 and sec 264 of Pub L 104-191 110 Stat 2033-2034 (42 U S C 1320d-2(note))

SOURCE 65 FR 82798 Dec 28 2000 unless otherwise noted

Subpart A—General Provisions

§ 160.101 Statutory basis and purpose.

The requirements of this subchapter implement sections 1171 through 1179 of the Social Security Act (the Act), as added by section 262 of Public Law 104-191, and section 264 of Public Law 104-191

§ 160.102 Applicability.

(a) Except as otherwise provided the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities

(1) A health plan

(2) A health care clearinghouse

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter

(b) To the extent required under the Social Security Act, 42 U S C 1320a-7c(a)(5), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U S C App)

[65 FR 82798, Dec 28, 2000 as amended at 67 FR 53266, Aug 14, 2002]

§ 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter

Act means the Social Security Act

ANSI stands for the American National Standards Institute

Business associate (1) Except as provided in paragraph (2) of this definition, *business associate* means, with respect to a covered entity, a person who

(1) On behalf of such covered entity or of an organized health care arrangement (as defined in § 164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and pricing, or

(B) Any other function or activity regulated by this subchapter, or

(1) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity

ity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement

(3) A covered entity may be a business associate of another covered entity

CMS stands for Centers for Medicare & Medicaid Services within the Department of Health and Human Services

Compliance date means the date by which a covered entity must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter

Covered entity means

(1) A health plan

(2) A health care clearinghouse

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter

Disclosure means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information

EIN stands for the employer identification number assigned by the Internal Revenue Service, U S Department of the Treasury The EIN is the taxpayer identifying number of an individual or other entity (whether or not an employer) assigned under one of the following

(1) 26 U S C 6011(b), which is the portion of the Internal Revenue Code dealing with identifying the taxpayer in tax returns and statements, or corresponding provisions of prior law

(2) 26 U S C 6109, which is the portion of the Internal Revenue Code dealing with identifying numbers in tax returns, statements, and other required documents

Electronic media means

(1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card, or

(2) Transmission media used to exchange information already in electronic storage media Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with

information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.

Electronic protected health information means information that comes within paragraphs (1)(i) or (1)(ii) of the definition of *protected health information* as specified in this section.

Employer is defined as it is in 26 U.S.C. 3401(d).

Group health plan (also see definition of *health plan* in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg-91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies related to the health of an individual. *Health care* includes, but is not limited to, the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Health care clearinghouse means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information means any information, whether oral or recorded in any form or medium, that:

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

(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.

Health insurance issuer (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300gg-91(b)(2) and used in the definition of *health plan* in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791(b)(3) of the PHS Act, 42 U.S.C. 300gg-91(b)(3) and used in the definition of *health plan*

in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(1) *Health plan* includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section.

(iv) Part A or Part B of the Medicare program under title XVIII of the Act.

(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, *et seq.*

(vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(ix) The health care program for active military personnel under title 10 of the United States Code.

(x) The veterans health care program under 38 U.S.C. chapter 17.

(xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in 10 U.S.C. 1072(4)).

(xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, *et seq.*

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, *et seq.*

(xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, *et seq.*

(xv) The Medicare+Choice program under Part C of title XVIII of the Act, 42 U.S.C. 1395w-21 through 1395w-28.

(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(2) *Health plan* excludes:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of, health care; or

(B) Whose principal activity is:

(1) The direct provision of health care to persons; or

(2) The making of grants to fund the direct provision of health care to persons.

Implementation specification means specific requirements or instructions for implementing a standard.

Individual means the person who is the subject of protected health information.

Individually identifiable health information is information 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.

Modify or *modification* refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification

Organized health care arrangement means

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider,

(2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities

(i) Hold themselves out to the public as participating in a joint arrangement, and

(ii) Participate in joint activities that include at least one of the following

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf,

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf, or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan,

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor, or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but

only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans

Protected health information means individually identifiable health information

(1) Except as provided in paragraph (2) of this definition, that is

(i) Transmitted by electronic media, or

(ii) Maintained in electronic media, or

(iii) Transmitted or maintained in any other form or medium

(2) *Protected health information* excludes individually identifiable health information in

(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U S C 1232g,

(ii) Records described at 20 U S C 1232g(a)(4)(B)(iv), and

(iii) Employment records held by a covered entity in its role as employer

Secretary means the Secretary of Health and Human Services or any other officer or employee of HHS to whom the authority involved has been delegated

Small health plan means a health plan with annual receipts of \$5 million or less

Standard means a rule, condition, or requirement

(1) Describing the following information for products, systems, services or practices

(i) Classification of components

(ii) Specification of materials, performance, or operations, or

(iii) Delineation of procedures, or

(2) With respect to the privacy of individually identifiable health information

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part

State refers to one of the following

(1) For a health plan established or regulated by Federal law, State has the

meaning set forth in the applicable section of the United States Code for such health plan

(2) For all other purposes, *State* means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction)

Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions

(1) Health care claims or equivalent encounter information

(2) Health care payment and remittance advice

(3) Coordination of benefits

(4) Health care claim status

(5) Enrollment and disenrollment in a health plan

(6) Eligibility for a health plan

(7) Health plan premium payments

(8) Referral certification and authorization

(9) First report of injury

(10) Health claims attachments

(11) Other transactions that the Secretary may prescribe by regulation

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity

[65 FR 82798, Dec 28, 2000, as amended at 67 FR 38019, May 31, 2002; 67 FR 53266, Aug 14, 2002; 68 FR 8374, Feb 20, 2003]

§ 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months

(b) The Secretary may adopt a modification at any time during the first year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard or implementation specification

(c) The Secretary will establish the compliance date for any standard or implementation specification modified under this section

(1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification

(2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification

(3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate

[65 FR 82798, Dec 28, 2000, as amended at 67 FR 38019, May 31, 2002]

Subpart B—Preemption of State Law

§ 160.201 Applicability.

The provisions of this subpart implement section 1178 of the Act, as added by section 262 of Public Law 104-191

§ 160.202 Definitions.

For purposes of this subpart, the following terms have the following meanings

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means

(1) A covered entity would find it impossible to comply with both the State and federal requirements, or

(2) The provision of State law stands as an obstacle to the accomplishment

Exhibit E

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable
Technical Safeguards (see § 164.312)		
Access Control	164.312(a)(1)	Unique User Identification (R) Emergency Access Procedure (R) Automatic Logoff (A) Encryption and Decryption (A)
Audit Controls	164.312(b)	(R)
Integrity	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information (A)
Person or Entity Authentication	164.312(d)	(R)
Transmission Security	164.312(e)(1)	Integrity Controls (A) Encryption (A)

Subpart D [Reserved]

Subpart E—Privacy of Individually Identifiable Health Information

AUTHORITY: 42 U.S.C. 1320d-2 and 1320d-4, sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(note)).

§ 164.500 Applicability.

(a) Except as otherwise provided herein, the standards, requirements, and implementation specifications of this subpart apply to covered entities with respect to protected health information.

(b) Health care clearinghouses must comply with the standards, requirements, and implementation specifications as follows:

(1) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, the clearinghouse must comply with:

(i) Section 164.500 relating to applicability;

(ii) Section 164.501 relating to definitions;

(iii) Section 164.502 relating to uses and disclosures of protected health information, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(iv) Section 164.504 relating to the organizational requirements for covered entities;

(v) Section 164.512 relating to uses and disclosures for which individual authorization or an opportunity to

agree or object is not required, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(vi) Section 164.532 relating to transition requirements; and

(vii) Section 164.534 relating to compliance dates for initial implementation of the privacy standards.

(2) When a health care clearinghouse creates or receives protected health information other than as a business associate of a covered entity, the clearinghouse must comply with all of the standards, requirements, and implementation specifications of this subpart.

(c) The standards, requirements, and implementation specifications of this subpart do not apply to the Department of Defense or to any other federal agency, or non-governmental organization acting on its behalf, when providing health care to overseas foreign national beneficiaries.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003]

§ 164.501 Definitions.

As used in this subpart, the following terms have the following meanings:

Correctional institution means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with

or convicted of a criminal offense or other persons held in lawful custody. *Other persons* held in lawful custody includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.

Data aggregation means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a covered entity, the combining of such protected health information by the business associate with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

Designated record set means:

(1) A group of records maintained by or for a covered entity that is:

(i) The medical records and billing records about individuals maintained by or for a covered health care provider;

(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or

(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

Direct treatment relationship means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies

resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;

(3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances,

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity, and

(v) Consistent with the applicable requirements of § 164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity

Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant

Indirect treatment relationship means a relationship between an individual and a health care provider in which

(1) The health care provider delivers health care to the individual based on the orders of another health care provider, and

(2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual

Inmate means a person incarcerated in or otherwise confined to a correctional institution

Law enforcement official means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to

(1) Investigate or conduct an official inquiry into a potential violation of law, or

(2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law

Marketing means

(1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made

(i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about the entities participating in a health care provider network or health plan network, replacement of, or enhancements to, a health plan, and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits

(ii) For treatment of the individual, or

(iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual

(2) An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service

Payment means

(1) The activities undertaken by

(i) A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan, or

(ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care, and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to

(i) Determinations of eligibility or coverage (including coordination of

benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims,

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics,

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing,

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges,

(v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services, and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement

(A) Name and address,

(B) Date of birth,

(C) Social security number,

(D) Payment history,

(E) Account number, and

(F) Name and address of the health care provider and/or health plan

Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record *Psychotherapy notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date

Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of

such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party, consultation between health care providers relating to a patient, or the referral of a patient for health care from one health care provider to another

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266 Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003]

§ 164.502 Uses and disclosures of protected health information: general rules.

(a) **Standard** A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter

(1) **Permitted uses and disclosures** A covered entity is permitted to use or disclose protected health information as follows

(i) To the individual,

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506,

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of § 164.502(b), § 164.514(d), and § 164.530(c) with respect to such otherwise permitted or required use or disclosure,

(iv) Pursuant to and in compliance with a valid authorization under § 164.508,

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510, and

(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(e), (f), or (g)

Exhibit F

as added Oct. 30, 1972, P. L. 92-603, Title II, § 249F(b), 86 Stat. 1442-1445; Dec. 31, 1975, P. L. 94-182, Title I, § 112(c), 89 Stat. 1055; Oct. 25, 1977, P. L. 95-142, §§ 5(h)-(j), (n), 91 Stat. 1189-1191; Aug. 13, 1981, P. L. 97-35, Title XXI, Subtitle A, Ch 3, § 2113(j), 95 Stat. 795) were omitted in the general revision of this Part by Act Sept. 3, 1982, P. L. 97-248, Title I, Subtitle C, § 143, 96 Stat. 382. Section 1320c-14 provided for a correlation of functions between the Professional Standards Review Organizations and administrative instrumentalities; § 1320c-15 prohibited the disclosure of information (similar provisions are now contained in 42 USCS § 1320c-9); § 1320c-16 related to the limitation on liability for persons providing information, for members and employees of Professional Standards Review Organizations, and for Health Care practitioners and providers (similar provisions are now contained in 42 USCS § 1320c-6); § 1320c-17 authorized the use of certain funds for administration (similar provisions are now contained in 42 USCS § 1320c-8); § 1320c-18 provided for technical assistance to organizations desiring to be designated as Professional Standards Review Organizations; and § 1320c-19 provided for exemptions of Christian Science sanatoriums (similar provisions are now contained in 42 USCS § 1320c-11).

§ 1320c-20. [Repealed]

HISTORY; ANCILLARY LAWS AND DIRECTIVES

This section (Act Aug. 14, 1935, ch 531, Title XI, Part B, § 1171, as added Oct. 25, 1977, P. L. 95-142, § 5(d)(2)(D), 91 Stat. 1186) was repealed by Act Aug. 13, 1981, P. L. 97-35, Title XXI, Subtitle A, ch 3, § 2113(k), 95 Stat. 795. Such section provided for memorandums of understanding and Federal-State relations, generally.

Other provisions:

Application of repeal. Act Aug. 13, 1981, P. L. 97-35, Title XXI, Subtitle A, Ch 3, § 2113(o), 95 Stat. 796, which appears as 42 USCS § 1396a note, provided that the repeal of this section is applicable to agreements with Professional Standards Review Organizations entered into on or after Oct. 1, 1981.

§§ 1320c-21, 1320c-22. [Omitted]

HISTORY; ANCILLARY LAWS AND DIRECTIVES

These sections (Act Aug. 14, 1935, ch 531, Title XI, Part B, §§ 1172, 1173, as added Oct. 25, 1977, P. L. 95-142, § 5(k), (l)(1), 91 Stat. 1190, 1191; Dec. 5, 1980, P. L. 95-499, Title IX, Part A, Subpart III, § 923(e), 94 Stat. 2628; Aug. 13, 1981, P. L. 97-35, Title XXI, Subtitle A, Ch 3, Subtitle D, §§ 2113(l), 2193(c)(7), 95 Stat. 795, 827) were omitted in the general revision of this Part by Act Sept. 3, 1982, P. L. 97-248, Title I, Subtitle C, § 143, 96 Stat. 382. Section 1320c-21 provided for annual reports; and § 1320c-22 provided that Medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands were included in the Professional Standards Review Program; similar provisions to these sections are now contained in 42 USCS §§ 1320c-10, 1320c-12.

PART C. Administrative Simplification

§ 1320d. Definitions

For purposes of this part [42 USCS §§ 1320d et seq.]:

(1) Code set. The term “code set” means any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes.

(2) Health care clearinghouse. The term “health care clearinghouse” means a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements.

(3) Health care provider. The term “health care provider” includes a provider of services (as defined in section 1861(u) [42 USCS § 1395x(u)]), a provider of medical or other health services (as defined in section 1861(s) [42 USCS § 1395x(s)]), and any other person furnishing health care services or supplies. *

(4) Health information. The term “health information” means any information, whether oral or recorded in any form or medium, that—

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

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

(5) Health plan. The term “health plan” means an individual or group plan that provides, or pays the cost of, medical care (as such term is defined in section 2791 of the Public Health Service Act [42 USCS § 300gg-91]). Such term includes the following, and any combination thereof:

(A) A group health plan (as defined in section 2791(a) of the Public Health Service Act [42 USCS § 300gg-91(a)]), but only if the plan—

(i) has 50 or more participants (as defined in section 3(7) of the Employee Retirement Income Security Act of 1974 [29 USCS § 1002(7)]); or

(ii) is administered by an entity other than the employer who established and maintains the plan.

(B) A health insurance issuer (as defined in section 2791(b) of the Public Health Service Act [42 USCS § 300gg-91(b)]).

(C) A health maintenance organization (as defined in section 2791(b) of the Public Health Service Act [42 USCS § 300gg-91(b)]).

(D) Part A or part B of the Medicare program under title XVIII [42 USCS §§ 1395c et seq. or 1395j et seq.].

(E) The medicaid program under title XIX [42 USCS §§ 1396 et seq.].

(F) A Medicare supplemental policy (as defined in section 1882(g)(1) [42 USCS § 1395ss(g)(1)]).

(G) A long-term care policy, including a nursing home fixed indemnity

policy (unless the Secretary determines that such a policy does not provide sufficiently comprehensive coverage of a benefit so that the policy should be treated as a health plan).

(H) An employee welfare benefit plan or any other arrangement which is established or maintained for the purpose of offering or providing health benefits to the employees of 2 or more employers.

(I) The health care program for active military personnel under title 10, United States Code.

(J) The veterans health care program under chapter 17 of title 38, United States Code [38 USCS §§ 1701 et seq.].

(K) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in section 1072(4) of title 10, United States Code.

(L) The Indian health service program under the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

(M) The Federal Employees Health Benefit Plan under chapter 89 of title 5, United States Code [5 USCS §§ 8901 et seq.].

(6) Individually identifiable health information. The term “individually identifiable health information” means any information, including demographic information collected from an individual, that—

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

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

(i) identifies the individual; or

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

(7) Standard. The term “standard”, when used with reference to a data element of health information or a transaction referred to in section 1173(a)(1) [42 USCS § 1320d-2(a)(1)], means any such data element or transaction that meets each of the standards and implementation specifications adopted or established by the Secretary with respect to the data element or transaction under sections 1172 through 1174 [42 USCS §§ 1320d-1 through 1320d-3].

(8) Standard setting organization. The term “standard setting organization” means a standard setting organization accredited by the American National Standards Institute, including the National Council for Prescription Drug Programs, that develops standards for information transactions, data elements, or any other standard that is necessary to, or will facilitate, the implementation of this part [42 USCS §§ 1320d et seq.].

(Aug. 14, 1935, ch 531, Title XI, Part C, § 1171, as added Aug. 21, 1996, P. L. 104-191, Title II, Subtitle F, § 262(a), 110 Stat. 2021.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Explanatory notes:

A prior § 1171 of Act Aug. 14, 1935, ch 531, as added Oct. 25, 1977, P.

L. 95-142, § 5(d)(2)(D), 91 Stat. 1186, appeared as 42 USCS § 1320c-20 prior to repeal by Act Aug. 13, 1981, P. L. 97-35, Title XXI, Subtitle A, Ch 3, 2113(k), 95 Stat. 795.

Other provisions:

Purpose of Subtitle F of Title II of Act Aug. 21, 1996. Act Aug. 21, 1996, P. L. 104-191, Title II, Subtitle F, § 261, 110 Stat. 2021, provides: “It is the purpose of this subtitle [enacting 42 USCS §§ 1320d et seq., among other things; for full classification, consult USCS Tables volumes] to improve the Medicare program under title XVIII of the Social Security Act [42 USCS §§ 1395 et seq.], the medicaid program under title XIX of such Act [42 USCS §§ 1396 et seq.], and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.

§ 1320d-1. General requirements for adoption of standards

(a) **Applicability.** Any standard adopted under this part [42 USCS §§ 1320d et seq.] shall apply, in whole or in part, to the following persons:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction referred to in section 1173(a)(1) [42 USCS § 1320d-2(a)(1)].

(b) **Reduction of costs.** Any standard adopted under this part [42 USCS §§ 1320d et seq.] shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.

(c) **Role of standard setting organizations.** (1) In general. Except as provided in paragraph (2), any standard adopted under this part [42 USCS §§ 1320d et seq.] shall be a standard that has been developed, adopted, or modified by a standard setting organization.

(2) Special rules. (A) Different standards. The Secretary may adopt a standard that is different from any standard developed, adopted, or modified by a standard setting organization, if—

(i) the different standard will substantially reduce administrative costs to health care providers and health plans compared to the alternatives; and

(ii) the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, United States Code [5 USCS §§ 561 et seq.].

(B) No standard by standard setting organization. If no standard setting organization has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under this part [42 USCS §§ 1320d et seq.]—

(i) paragraph (1) shall not apply; and

(ii) subsection (f) shall apply.

RESEARCH GUIDE

Federal Procedure:

17 Fed Proc L Ed, Health, Education and Welfare §§ 42 493, 496, 498, 504, 505
30 Fed Proc L Ed, Social Security and Medicare §§ 71 729, 730

Am Jur

70C Am Jur 2d, Social Security and Medicare § 2506

Law Review Articles:

Stanger A HIPAA Primer Simplifying "Administrative Simplification" 45 Advoc (Boise) 11, May 2002
McKenzie Handling medical data? Think HIPAA now 17 Computer Internet Law 15, November 2000
Antognini The Law of Unintended Consequences HIPAA and Liability Insurers 69 Def Couns J 296, July 2002
Lovitky The Privacy of Health Information Consents and Authorization under HIPAA 76 Fla BJ 10, May 2002
Roach HIPAA privacy "individual rights" and the "minimum necessary" requirements 33 J Health L 549, Fall 2000
Rosati HIPAA privacy the compliance challenges ahead 35 J Health L 45, Winter 2002
Tatelbaum Practice Resource Checklist of Federal and State Privacy Issues 35 J Health L 283, Spring 2002
Stein What Litigators Need to Know about HIPAA 36 J Health L 433, Summer 2003
Remus, L'Huillier HIPAA and lawyers yes, lawyers! 44 NH BJ 14, March 2003
Woody Health Information Privacy the Rules Get Tougher 37 Tort & Ins LJ 1051, Summer 2002
Hartin New federal privacy rules for health care providers 75 Wis Law 14, April 2002

INTERPRETIVE NOTES AND DECISIONS

1. Generally

42 USCS § 1320c-5(a) establishes conditions of participation, rather than prerequisites to receiving reimbursement, thus, since statute does not expressly condition payment on compliance with its terms,

provider's certification on Medicare reimbursement form is not legally false for purposes of liability under False Claims Act (31 USCS §§ 3729 et seq.) United States ex rel Mikes v Straus (2001, CA2 NY) 274 F3d 687

§ 1320c-9. Prohibition against disclosure of information

INTERPRETIVE NOTES AND DECISIONS

1. Generally

42 USCS § 1320c-9(d) bar against discovery runs with documents or information, not with organization or individuals who happen to possess documents or information at any given time thus, absolute prohibition against discovery is not destroyed simply because materials or copies of materials, are in hands of physician who is subject of peer review organization (PRO) quality review inquiry and part of PRO review system Armstrong v Dwyer (1998, CA3 NJ) 155 F3d 211

or individuals who happen to possess documents or information at any given time, thus, absolute prohibition against discovery is not destroyed simply because materials, or copies of materials, are in hands of physician who is subject of peer review organization (PRO) quality review inquiry and part of PRO review system Armstrong v Dwyer (1998, CA3 NJ) 155 F3d 211

Absolute prohibition against discovery of material generated by peer review organization includes all documents received by defendant from organization's inquiry Armstrong v Dwyer (1998, CA3 NJ) 155 F3d 211

3. Discovery

42 USCS § 1320c-9(d) bar against discovery runs with documents or information, not with organization

§ 1320c-11. Exemptions for religious nonmedical health care institutions

INTERPRETIVE NOTES AND DECISIONS

Section 4454 of Balanced Budget Act of 1997 (Act Aug 5 1997, P L 105 33 § 4454, 111 Stat 426), which creates exceptions to Medicare Act (42 USCS §§ 1395 et seq.) and Medicaid Act (42 USCS §§ 1396 et seq.) for persons who have religious objections to receipt of medical care, does not violate Establishment Clause of First Amendment Children's Healthcare Is a Legal Duty, Inc v De Parle (2000, CA8 Minn) 212 F3d 1084

Amendment to Medical and Medicare Acts, exempting "religious" nonmedical health care institutions from medical oversight requirements of 42 USCS § 1320c-11 did not violate First Amendment Children's Healthcare Is a Legal Duty, Inc v De Parle (2000, CA8 Minn) 212 F3d 1084, 69 Soc Sec Rep Serv 543

PART C. Administrative Simplification

§ 1320d. Definitions

For purposes of this part [42 USCS §§ 1320d et seq.]

(1)-(4) [Unchanged]

(5) Health plan The term "health plan" means an individual or group plan that provides, or pays the cost of, medical care (as such term is defined in section 2791 of the Public Health Service Act [42 USCS § 300gg-91]) Such term includes the following, and any combination thereof

(A)-(C) [Unchanged]

(D) Parts A, B, or C of the Medicare program under title XVIII [42 USCS §§ 1395c et seq., 1395j et seq. or 1395w-21 et seq.]

(E)-(M) [Unchanged]

(6)-(8) [Unchanged]

(As amended Dec 27, 2001, P L 107-105, § 4, 115 Stat 1007)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Amendments:

2001. Act Dec 27, 2001, in para (5)(D), substituted "Parts A, B, or C" for "Part A or part B"

CODE OF FEDERAL REGULATIONS

Department of Health and Human Services—General administrative requirements, 45 CFR Part 160
Department of Health and Human Services—Administrative requirements, 45 CFR Part 162

RESEARCH GUIDE

Am Ju

43 Am Jur 2d, Insurance § 552
44 Am Jur 2d, Insurance § 1059

Law Review Articles:

Stanger A HIPAA Primer Simplifying "Administrative Simplification" 45 Advoc (Boise) 11, May 2002
McKenzie Handling medical data? Think HIPAA now 17 Computer Internet Law 15, November 2000
Antognini The Law of Unintended Consequences HIPAA and Liability Insurers 69 Def Couns J 296, July 2002
Lovitky The Privacy of Health Information Consents and Authorization under HIPAA 76 Fla BJ 10, May 2002
Roach HIPAA privacy "individual rights" and the "minimum necessary" requirements 33 J Health L 549, Fall 2000
Tatelbaum Practice Resource Checklist of Federal and State Privacy Issues 35 J Health L 283, Spring 2002
Stein What Litigators Need to Know about HIPAA 36 J Health L 433, Summer 2003
Remus, L'Huillier HIPAA and lawyers yes, lawyers! 44 NH BJ 14, March 2003
Woody Health Information Privacy the Rules Get Tougher 37 Tort & Ins LJ 1051, Summer 2002
Hartin New federal privacy rules for health care providers 75 Wis Law 14, April 2002

§ 1320d-1. General requirements for adoption of standards

RESEARCH GUIDE

Am Jur:

43 Am Jur 2d, Insurance § 552
44 Am Jur 2d, Insurance § 1059

Law Review Articles:

McKenzie Handling medical data? Think HIPAA now 17 Computer Internet Law 15, November 2000
Roach HIPAA privacy "individual rights" and the "minimum necessary" requirements 33 J Health L 549, Fall 2000
Stein What Litigators Need to Know about HIPAA 36 J Health L 433, Summer 2003
Remus, L'Huillier HIPAA and lawyers yes, lawyers! 44 NH BJ 14, March 2003
Hartin New federal privacy rules for health care providers 75 Wis Law 14, April 2002

§ 1320d-2. Standards for information transactions and data elements

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Other provisions:

To protect the privacy of protected health information in oversight investigations. Ex Or No 13181 of December 20, 2000, 65 Fed Reg 81321, provides

Exhibit G

EXHIBIT G

**REGRETTABLY, COUNSEL'S
RESEARCHER/COPIER FAILED TO INCLUDE
USC §1320d-2 IN THE PAGES COPIED.
FORGIVENESS IS SOUGHT.**

Exhibit H

Modify or *modification* refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

Organized health care arrangement means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but

only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium.

(2) *Protected health information* excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and

(iii) Employment records held by a covered entity in its role as employer.

Secretary means the Secretary of Health and Human Services or any other officer or employee of HHS to whom the authority involved has been delegated.

Small health plan means a health plan with annual receipts of \$5 million or less.

Standard means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services or practices:

(i) Classification of components.

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of individually identifiable health information.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the

meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, *State* means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

(1) Health care claims or equivalent encounter information.

(2) Health care payment and remittance advice.

(3) Coordination of benefits.

(4) Health care claim status.

(5) Enrollment and disenrollment in a health plan.

(6) Eligibility for a health plan.

(7) Health plan premium payments.

(8) Referral certification and authorization.

(9) First report of injury.

(10) Health claims attachments.

(11) Other transactions that the Secretary may prescribe by regulation.

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, May 31, 2002, 67 FR 53266, Aug. 14, 2002; 68 FR 8374, Feb. 20, 2003]

§ 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.

(b) The Secretary may adopt a modification at any time during the first year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard or implementation specification.

(c) The Secretary will establish the compliance date for any standard or implementation specification modified under this section.

(1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification.

(2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.

(3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, May 31, 2002]

Subpart B—Preemption of State Law

§ 160.201 Applicability.

The provisions of this subpart implement section 1178 of the Act, as added by section 262 of Public Law 104-191.

§ 160.202 Definitions.

For purposes of this subpart, the following terms have the following meanings:

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

(1) A covered entity would find it impossible to comply with both the State and federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment

and execution of the full purposes and objectives of part C of title XI of the Act or section 264 of Pub L 104-191, as applicable

• *More stringent* means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria

(1) With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is

(i) Required by the Secretary in connection with determining whether a covered entity is in compliance with this subchapter, or

(ii) To the individual who is the subject of the individually identifiable health information

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable

(3) With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information

(4) With respect to the form substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

(5) With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration

(6) With respect to any other matter, provides greater privacy protection for the individual who is the subject of the

individually identifiable health information

Relates to the privacy of individually identifiable health information means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way

State law means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law

[65 FR 82798 Dec 28 2000 as amended at 67 FR 53266 Aug 14, 2002]

§ 160.203 General rule and exceptions.

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met

(a) A determination is made by the Secretary under § 160.204 that the provision of State law

(1) Is necessary

(i) To prevent fraud and abuse related to the provision of or payment for health care,

(ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation,

(iii) For State reporting on health care delivery or costs, or

(iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served, or

(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law

(b) The 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 under subpart E of part 164 of this subchapter

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals

[65 FR 82798 Dec 28, 2000, as amended at 67 FR 53266 Aug 14, 2002]

§ 160.204 Process for requesting exception determinations.

(a) A request to except a provision of State law from preemption under § 160.203(a) may be submitted to the Secretary. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information

(1) The State law for which the exception is requested,

(2) The particular standard, requirement, or implementation specification for which the exception is requested,

(3) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate,

(4) How health care providers, health plans, and other entities would be affected by the exception,

(5) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at § 160.203(a); and

(6) Any other information the Secretary may request in order to make the determination

(b) Requests for exception under this section must be submitted to the Secretary at an address that will be published in the FEDERAL REGISTER. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect

(c) The Secretary's determination under this section will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at § 160.203(a) has been met

§ 160.205 Duration of effectiveness of exception determinations.

An exception granted under this subpart remains in effect until

(a) Either the State law or the federal standard, requirement, or implementation specification that provided the basis for the exception is materially changed such that the ground for the exception no longer exists, or

(b) The Secretary revokes the exception, based on a determination that the ground supporting the need for the exception no longer exists

Subpart C—Compliance and Enforcement

§ 160.300 Applicability.

This subpart applies to actions by the Secretary, covered entities, and others with respect to ascertaining the compliance by covered entities with and the enforcement of the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter

§ 160.302 Definitions.

As used in this subpart, terms defined in § 164.501 of this subchapter have the same meanings given to them in that section

§ 160.304 Principles for achieving compliance.

(a) *Cooperation* The Secretary will, to the extent practicable, seek the cooperation of covered entities in obtaining compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter

(b) *Assistance* The Secretary may provide technical assistance to covered entities to help them comply voluntarily with the applicable requirements

Exhibit I

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 164

Rin: 0991-AB08

Standards for Privacy of Individually Identifiable Health Information

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, DHHS.

ACTION: Final rule.

SUMMARY: This rule includes standards to protect the privacy of individually identifiable health information. The rules below, which apply to health plans, health care clearinghouses, and certain health care providers, present standards with respect to the rights of individuals who are the subjects of this information, procedures for the exercise of those rights, and the authorized and required uses and disclosures of this information.

The use of these standards will improve the efficiency and effectiveness of public and private health programs and health care services by providing enhanced protections for individually identifiable health information. These protections will begin to address growing public concerns that advances in electronic technology and evolution in the health care industry are resulting, or may result, in a substantial erosion of the privacy surrounding individually identifiable health information maintained by health care providers, health plans and their administrative contractors. This rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996.

DATES: The final rule is effective on February 26, 2001.

FOR FURTHER INFORMATION CONTACT: Kimberly Coleman, 1-866-OCR-PRIV (1-866-627-7748) or TTY 1-866-788-4989.

SUPPLEMENTARY INFORMATION: Availability of copies, and electronic access.

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I. Background

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used to make decisions about them. We list certain records that are always part of the designated record set. For covered providers these are the medical record and billing record. For health plans these are the enrollment, payment, claims adjudication, and case or medical management records. The purpose of these specified records is management of the accounts and health care of individuals. In addition, we include in the designated record set to which individuals have access any record used, in whole or in part, by or for the covered entity to make decisions about individuals. Only protected health information that is in a designated record set is covered. Therefore, if a covered provider has a phone conversation, information obtained during that conversation is subject to access only to the extent that it is recorded in the designated record set.

We do not require a covered entity to provide access to all individually identifiable health information, because the benefits of access to information not used to make decisions about individuals is limited and is outweighed by the burdens on covered entities of locating, retrieving, and providing access to such information. Such information may be found in many types of records that include significant information not relevant to the individual as well as information about other persons. For example, a hospital's peer review files that include protected health information about many patients but are used only to improve patient care at the hospital, and not to make decisions about individuals, are not part of that hospital's designated record sets.

We encourage but do not require covered entities to provide interpretive assistance to individuals accessing their information, because such a requirement could impose administrative burdens that outweigh the benefits likely to accrue.

The importance to individuals of having the right to inspect and copy information about them is supported by a variety of industry groups and is recognized in current state and federal law. The July 1977 Report of the Privacy Protection Study Commission recommended that individuals have access to medical records and medical record information.² The Privacy Act (5 U.S.C. 552a) requires government agencies to permit individuals to review records and have a copy made in a form comprehensible to the individual. In its

report "Best Principles for Health Privacy," the Health Privacy Working Group recommended that individuals should have the right to access information about them.³ The National Association of Insurance Commissioners' Health Information Privacy Model Act establishes the right of an individual to examine or receive a copy of protected health information in the possession of the carrier or a person acting on behalf of the carrier.

Many states also establish a right for individuals to access health information about them. For example, Alaska law (AK Code 18.23.005) entitles patients "to inspect and copy any records developed or maintained by a health care provider or other person pertaining to the health care rendered to the patient." Hawaii law (HRS section 323C-11) requires health care providers and health plans, among others, to permit individuals to inspect and copy protected health information about them. Many other states have similar provisions.

Industry and standard-setting organizations also have developed policies to enable individual access to health information. The National Committee for Quality Assurance and the Joint Commission on Accreditation of Healthcare Organizations issued recommendations stating, "Patients' confidence in the protection of their information requires that they have the means to know what is contained in their records. The opportunity for patients to review their records will enable them to correct any errors and may provide them with a better understanding of their health status and treatment."⁴ Standards of the American Society for Testing and Materials state, "The patient or his or her designated personal representative has access rights to the data and information in his or her health record and other health information databases except as restricted by law. An individual should be able to inspect or see his or her health information or request a copy of all or part of the health information, or both."⁵ We build on this well-established principle in this final rule.

³ Health Privacy Working Group, "Best Principles for Health Privacy," Health Privacy Project, Institute for Health Care Research and Policy, Georgetown University, July 1999

⁴ National Committee on Quality Assurance and the Joint Commission on Accreditation of Healthcare Organizations, "Protecting Personal Health Information: A Framework for Meeting the Challenges in a Managed Care Environment," 1998, p. 25

⁵ ASTM, "Standard Guide for Confidentiality, Privacy, Access and Data Security, Principles for Health Information Including Computer-Based Patient Records," E 1869-97, § 11.1.1

Comment: Several commenters advocated for access to not only information that has already been used to make decisions, but also information that may be used to make decisions. Other commenters believed accessible information should be more limited. For example, some commenters argued accessible information should be restricted to only information used to make health care decisions.

Response: We agree that it is desirable that individuals have access to information reasonably likely to be used to make decisions about them. On the other hand, it is desirable that the category of records covered be readily ascertainable by the covered entity, and therefore define "designated records" to include certain categories of records (a provider's medical record and billing record, the enrollment records, and certain other records maintained by a health plan) that are normally used, and are reasonably likely to be used, to make decisions about individuals. We also add a category of other records that are, in fact, used, in whole or in part, to make decisions about individuals. This category includes records that are used to make decisions about any individuals, whether or not the records have been used to make a decision about the particular individual requesting access.

We disagree that accessible information should be restricted to information used to make health care decisions, because other decisions by covered entities can also affect individuals' interests. For example, covered entities make financial decisions about individuals, such as whether an individual's deductible has been met. Because such decisions can significantly affect individuals' interests, we believe they should have access to any protected health information included in such records.

Comment: Some commenters believe the rule should use the term "retrievable" instead of "retrieved" to describe information accessible to individuals. Other commenters suggested that the rule follow the Privacy Act's principle of allowing access only when entities retrieve records by individual identifiers. Some commenters requested clarification that covered entities are not required to maintain information by name or other patient identifier.

Response: We have modified the proposed definition of the designated record set to focus on how information is used, not how it is retrieved. Information may be retrieved or retrievable by name, but if it is never used to make decisions about any

² Privacy Protection Study Commission, "Personal Privacy in an Information Society," July 1977, p. 298-299

issue prior to the request for disclosure being presented to the covered entity. We are reluctant to put the covered entity in the position of having to solve disputes concerning the type of information that may be disclosed when that dispute should more appropriately be settled through the judicial or administrative procedure itself.

Comment: One commenter asked that the final regulation clarify that a court order is not required when disclosure would otherwise be permitted under the rule. This commenter noted that the preamble states that the requirement for a court order would not apply if the disclosure would otherwise be permitted under the rule. For example, disclosures of protected health information pursuant to administrative, civil, and criminal proceedings relating to "health oversight" are permitted, even if no court or administrative orders have been issued. However, the commenter was concerned that this principle only appeared in the preamble and not in the rule itself.

Response: Section 164.512(e)(4) of the final regulation contains this clarification.

Comment: One commenter was concerned that the rule is unclear as to whether governmental entities are given a special right to "use" protected health information that private parties do not have under the proposed regulation or whether governmental entities that seek to use protected health information are treated the same as private parties in their use of such information. This commenter urged that we clarify our intent regarding the use of protected health information by governmental entities.

Response: Generally governmental entities are treated the same as private entities under the rule. In a few clearly defined cases, a special rule applies. For instance, under § 164.504(e)(3), when a covered entity and its business associate are both governmental entities, they may enter into a memorandum of understanding or adopt a regulation with the force and effect of law that incorporates the requirements of a business associate contract, rather than having to negotiate a business associate contract itself.

Comment: One commenter recommended that final rule state that information developed as part of a quality improvement or medical error reduction program may not be disclosed under this provision. The commenter explained that peer review information developed to identify and correct systemic problems in delivery of care must be protected from disclosure to allow a full discussion of the root causes

of such events so they may be identified and addressed. According to the commenter, this is consistent with peer review protections afforded this information by the states.

Response: The question of whether or not such information should be protected is currently the subject of debate in Congress and in the states. It would be premature for us to adopt a position on this issue until a clear consensus emerges. Under the final rule, no special protection against disclosure is provided for peer review information of the type the commenter describes. However, unless the request for disclosure fits within one of the categories of permitted or required disclosures under the regulation, it may not be disclosed. For instance, if disclosure of peer review information is required by another law (such as Medicare or a state law), covered entities subject to that law may disclose protected health information consistent with the law.

Comment: One commenter stated that the requirements of this section are in conflict with Medicare contractor current practices, as defined by the HCFA Office of General Counsel and suggested that the final rule include more specific guidelines.

Response: Because the commenter failed to indicate the nature of these conflicts, we are unable to respond.

Comment: One commenter stated that the rule should require rather than permit disclosure pursuant to court orders.

Response: Under the statutory framework adopted by Congress in HIPAA, a presumption is established that the data contained in an individual's medical record belongs to the individual and must be protected from disclosure to third parties. The only instance in which covered entities holding that information must disclose it is if the individual requests access to the information himself or herself. In the final rule (as in the proposed rule), covered entities may use or disclose protected health information under certain enumerated circumstances, but are not required to do so. We do not believe that this basic principle should be compromised merely because a court order has been issued. Consistent with this principle, we provide covered entities with the flexibility to deal with circumstances in which the covered entity may have valid reasons for declining to release the protected health information without violating this regulation.

Comment: One commenter noted that in some states, public health records are not subject to discovery, and that the

proposed rule would not permit disclosure of protected health information pursuant to court order or subpoena if the disclosure is not allowed by state law. The commenter requested clarification as to whether a subpoena in a federal civil action would require disclosure if a state law prohibiting the release of public health records existed.

Response: As explained above, the final rule permits, but does not require, disclosure of protected health information pursuant to a court order. Under the applicable preemption provisions of HIPAA, state laws relating to the privacy of medical information that are more stringent than the federal rules are not preempted. To the extent that an applicable state law precludes disclosure of protected health information that would otherwise be permitted under the final rule, state law governs.

Comment: A number of commenters expressed concern that the proposed rule would negatively impact state and federal benefits programs, particularly social security and workers' compensation. One commenter requested that the final rule remove any possible ambiguity about application of the rule to the Social Security Administration's (SSA) evidence requests by permitting disclosure to all administrative level of benefit programs. In addition, several commenters stated that requiring SSA or states to provide the covered entity holding the protected health information with an individual's consent before it could disclose the information would create a huge administrative and paperwork burden with no added value to the individual. In addition, several other commenters indicated that states that make disability determinations for SSA also support special accommodation for SSA's determination process. They expressed concern that providers will narrowly interpret the HIPAA requirements, resulting in significant increases in processing time and program costs for obtaining medical evidence (especially purchased consultative examinations when evidence of record cannot be obtained). A few commenters were especially concerned about the impact on states and SSA if the final rule were to eliminate the NPRM's provision for a broad consent for "all evidence from all sources."

Some commenters also note that it would be inappropriate for a provider to make a minimum necessary determination in response to a request from SSA because the provider usually will not know the legal parameters of SSA's programs, or have access to the