IN THE UNITED STATE DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

PEDIATRIC SPECIALTY CARE, INC., ET AL — PLAINTIFFS

vs. NO. 4:01CV00830 WRW

ARKANSAS DEPARTMENT OF HUMAN SERVICES, ET AL — DEFENDANTS

ORDER

On May 28, 2004, an order was entered in this case addressing several pending motions, including a Motion by Plaintiff seeking an Order to compel or enjoin Defendants to reveal the names of peer reviewers responsible for determining when and whether services are medically necessary (Docket No. 150). Against my initial instinct that "secret doctors" should not be allowed to deny medical care when Medicaid beneficiaries could not effectively challenge the denial, I found that 42 U.S.C.§1320c-9 clothed the deliberations of peer review organizations (PRO) with a statutory privilege against the formal discovery process in any administrative or civil proceeding. On reflection, I tentatively changed my mind, but before entering this Order, I asked the parties to file letter briefs on the subject. After reviewing the Defendant's arguments, I am convinced that the original Order addressing this issue was wrong.

Background

Due to the complexity of the laws and regulations in this case, background information is necessary. In 1982, Congress amended the Social Security Act by enacting the "Peer Review Improvement Act," codified as 42 U.S.C. §1320c, et seq. The 1982 legislation allowed PROs to assume responsibility for the review of health care services funded under Medicare; to determine

if those services are medically necessary, efficient, effective; and if they meet professionally recognized standards of care. The amended statute also contained a number of confidentiality provisions that are in 42 U.S.C.§ 1320c-9. These generally prohibit the disclosure of information acquired or produced by a PRO in carrying out its functions under its contracts with the Department of Human Services (DHS). At the time the Act was amended, Congress also authorized the Secretary of Health and Human Services to create additional regulations addressing the confidentiality provision. The pertinent regulations were originally promulgated in 1985 and have not significantly changed since that time. *See* 42 CFR §§ 476.101-133 (1985) and 42 CFR §§ 480.101-133 (2002). Unfortunately, the names of these organizations change often, and what were referred to as peer review organizations (PROs) are now called quality improvement organizations (QIOs). To avoid any further confusion, I will continue to use the old moniker, PRO.

By amending the Act as codified in §1320c-9, and by limiting the formal discovery process in civil litigation, Congress created a statutory privilege with respect to certain information in the possession of, or produced by, PROs. In their letter brief, the Department of Human Services (DHS) claims that "nothing in Federal law authorizes the disclosure sought by plaintiffs." As stated above, I now disagree.

Plaintiffs do not have to prove that disclosure of evidence in a civil or administrative action is "authorized." The DHS must show that the disclosure is protected by a privilege. Privileges are not generally favored by federal courts and are narrowly construed so that access to truth will not be unnecessarily fettered. The general rule is that "the public has a right to every man's evidence." *Trammel v. United States,* 445 U.S. (1980) (quoting *United States v. Bryan,* 339 U.S. 323, 331 (1950)). Any infringements on the "predominant principle of utilizing

all rational means for ascertaining the truth," are to be strictly construed. *Jaffee v. Redmond,* 518 U.S. 1, 9 (1996); *University of Pa.,v. Equal Employment Opportunity Com'n* , 493 U.S. 182 at 189 (1990). Tensions arise in the law of privileges when the public benefit of keeping certain information confidential conflicts with the public benefit of ascertaining the truth of a matter through the disclosure of all relevant information. *See Trammel,* 445 U.S. at 50, 100 S.Ct. 906; *University of Pa,* 493 U.S. 182 at 189; *Jaffee,* 518 U.S. at 9. The United States Supreme Court summed up the guiding rule succinctly: "[A]n asserted privilege must serve the public ends." *Upjohn v. United States*, 449 U.S. 383, 389 (1981). Thus, to recognize a matter as privileged is to find that its concealment promotes an important public interest that outweighs the need for evidence. *See Trammel,* 445 U.S. at 51. These principles are manifested in 42 U.S.C. §1320c-9(d). The language of this subsection of the Act is unambiguous, and establishes what matters are and are not protected from formal discovery process. It is also clear that this section was promulgated by Congress to distinguish the formal discovery process -- together with the traditional subpoena power[1]-- from FOI requests and other discovery avenues provided to the general public. In other words, this section applies to individuals who are either parties to lawsuits or are pursuing administrative remedies.

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[1] The Compulsory Process Clause confers the right to compel witnesses to appear through use of subpoena power. The right to compel a witness's presence in the courtroom could not protect the integrity of the adversary process if it did not embrace the right to have the witness's testimony heard by the trier of fact. The right to offer testimony is thus grounded in the Sixth Amendment even though it is not described in so many words . *U.S. v. Janis* 2004 WL 2421999, 5 (8th Cir. 2004)

Section 1320c-9(d) reads:

(d) Subpoena and discovery proceedings regarding patient records

No patient record in the possession of an organization having a contract with the Secretary under this part shall be subject to subpoena or discovery proceedings in a civil action. No document or other information produced by such an organization in connection with its deliberations in making determinations under section *1320c-3(a)(1)(B) or 1320c-5(a)(2)* of this title shall be subject to subpoena or discovery in any administrative or civil proceeding; except that such an organization shall provide, upon request of a practitioner or other person adversely affected by such a determination, a summary of the organization's findings and conclusions in making the determination. 42 U.S.C. §1320c-9 (Emphasis added)

There are two types of documents protected under subsection (d) of §1320c-9: 1) patient records in possession of the PRO; 2) records produced by the PRO containing information about its deliberations that specifically deal with matters outlined in subsection 1320c-3(a)(1)(B) and subsection 1320c-5(a)(2). Patient records are addressed in the first sentence of subsection 1320c-9(d), while materials other than patient records are addressed in the second sentence. I will discuss these two types of information separately, starting first where subsection (d) begins -- *patient records*.

Discussion

The DHS argues that the term "patient records" means any patient information connected exclusively with medical necessity determinations. This is not what the sentence says, instead it refers to "patient records in possession of the PRO". 42 U.S.C. 1320c-9(d). Peer review organizations have custody and control of individual patient records for a variety of reasons, not just for medical necessity determinations.

Defendant DHS, also claims that the term *patient records* includes records that disclose the identity of any PRO physician who makes medical necessity decisions. In other words, Defendant has redefined patient records to include medical records of individuals under medical necessity review, and any documents revealing the name of the physicians responsible for medical necessity reviews. This interpretation is overly broad.

Statutory interpretation starts with the language of the statute itself; and a statute is read applying the "ordinary, contemporary and common meaning" of the words used. *Perrin v. United States,* 444 U.S. 37, 42 (1979). A patient record is a medical record generated by a treating physician for treatment and diagnosis. This is the common and ordinary usage of this term. In fact, Federal Regulations routinely interchange the terms "medical records" and "patient records" in rules designed to protect *patient* privacy.[2] In short, there is no indication that Congress meant to embellish the common sense definition of "patient records" in the manner suggested by Defendant.

Further, the first sentence of subsection 1320c-9(d) describes documents created by entities other than PROs, because it clearly refers to records in the *"possession of"* these organizations. By contrast, there is no reference to records *"created, produced or generated"* by the PRO. Applying common usage and common sense to the wording of the first sentence, I find that the term *patient records* includes medical records of treating physicians, not records created by reviewing physicians working for a PRO.

Medical or patient records generally contain private information and are owed protection. However, there is no specific federal privilege protecting the confidentiality of medical records

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[2]*See* 38 CFR §1.489; 38 CFR §17.81-82; 38 CFR §403.730 ;42 CFR §403.730; §416.47; 42 CFR §482.13; 42 CFR §482.24; 42 CFR §486.306; 42 CFR §489.24.

in federal cases. Federal Rule of Evidence 501 does not recognize a physician-patient (or hospital-patient) privilege. Rule 501 makes federal common law the source of any privileges in federal-question suits unless an Act of Congress provides otherwise. *Northwestern Memorial Hosp. v. Ashcroft,* 362 F.3d 923, (7th Cir. 2004). Congress would have no need to pass a law to protect a litigant's own medical records from discovery for the obvious reason that the patient-party could secure her own records simply by going to the source without resorting to serving costly subpoenas on PROs.

While a patient may secure her own records, she should not be allowed to gain access to the medical records of others because the records may be relevant to her pending lawsuit. This is the public policy rationale for the first sentence of subsection 1320c-9(d). It is designed to prevent parties to civil actions from getting non-party patient records in order to advance a theory of liability or to buttress a claim or defense to a civil action.

If, on the other hand, I were to adopt a more expansive interpretation of subsection 1320c-9(d) -- and find that the term *patient records* exempts from discovery all documents that are possessed by a PRO as well as produced by PRO physicians during a review process-- then there would have been no need for Congress to draft the second sentence carving out an additional privilege. Such an expansive reading would prohibit any litigant at any time, from determining what goes on during the review process of a PRO. In other words, Congress would have created a Star Chamber of the Medicare-Medicaid process.

However, Congress drafted a second sentence that is more specific in the creation of an additional privilege. In other words, the second sentence in §1320c-9(d) sets out what materials in addition to patient records are privileged. An overly broad construction of the terminology in the first sentence would render the second sentence superfluous. In statutory construction,

where specific expressions conflict with general ones, the rule is to give greater effect to the specific expression. *See Reeder-Simco GMC, Inc. v. Volvo GM Heavy Truck Corp.* 374 F.3d 701, 716 (8th Cir. 2004); Sutherland Statutory Construction § 51.05, at 499-500 (N. Singer ed.1984). At the very least, specific expressions should inform an interpretation of general expressions. An expansive construction of the first sentence of §1320c-9(d) would create a privilege protecting from disclosure all documents as well as the identity of all physicians connected to PROs. I have reviewed federal case law and have discovered that when faced with similar questions, federal courts are reluctant to recognize a broad privilege applicable to peer review organizations.[3] Because I decline to accept the interpretation of the first sentence suggested by DHS, an examination of the more specific second sentence of subsection 1320c-9(d) is now in order.

The second sentence precludes discovery of information described in two other subsections of the Amended Act. These are §1320c-3(a)(1)(B) and §1320c-5(a)(2). In order to better understand the intent of Congress, it is important to review both subsections in context. I will begin with the §1320c-3(a):

> (a)Review of professional activities, determinations of review authority; consultation with professional health care practitioners, standards of health care; other duties....
>
> **(1)** The organization shall review some or all of the professional activities in the area, subject to the

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[3] *University of Pa.*, 493 U.S. at 195; *Virmani v. Novant Health, Inc.*, 259 F.3d 284 (4th Cir. 2001); *Memorial Hosp. For McHenry County*, 664 F.2d 1058 (7th Cir. 1981); *Leon v. County of San Diego*, 202 F.R.D. 631 (S.D. Cal, 2001); *Nilavar, M.D. v. Mercy Health System-Western Ohio*, 210 F.R.D. 597 (S.D. Ohio, 2002); *Public Citizen, Inc. V. U.S. Dept. Of Health and Human Services*, 332 F.3d 654 (D.C. Cir., 2003); *Atteberry v. Longmont United Hospital*, 221 F.R.D. 644 (D. Col. 2004).

> terms of the contract and subject to the requirements of subsection (d) of this section, of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made... for the purpose of determining whether–
>
> > **(A)** such services and items are or were reasonable and medically necessary and whether such services and items are not allowable under subsection (a)(1) or (a)(9) of section 1395y of this title;
> >
> > **(B)** *the quality of such services meets professionally recognized standards of health care; and*
> >
> > **(C)** in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.
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> 42U.S.C § 1320c-3(a) (Emphasis added).

Clearly, placing §1320c-3(a)(1)(B) in context shows that there are two other categories listed in subsection (A) and (C) which have been *excluded* from the privilege created in §1320c-9(d). These excluded materials are: (1) documents gathered for the purpose of making a medical necessity determination; and (2) information gathered to determine feasibility of outpatient versus inpatient care. On the other hand, Congress specifically included information gathered by a PRO to determine whether medical providers meet recognized "standards of care." 42 U.S.C.§1320c-3(a)(1)(B).

This brings me to a consideration of §1320c-5(a) and a review of the entire subsection:

> (a) Assurances regarding services and items ordered or provided by practitioner or provider

> It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) ... to assure, to the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this chapter--
>
> **(1)** will be provided economically and only when, and to the extent, medically necessary;
>
> **(2)** *will be of a quality which meets professionally recognized standards of health care; and*
>
> **(3)** will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities. 42 U.S.C.A. § 1320c-5(a) (Emphasis added).

Again, there are two additional categories of information outlined in this subsection that are *not* privileged. These two categories are set out in subsections (1) and (3) and address information gathered to determine medical necessity and the efficacy of the evidence supporting medical necessity. The privileged information set out in subsection (2) is information gathered to determine if medical providers meet recognized "standards of care." 42 U.S.C.§1320c-5(a)(2).

Both §1320c-3(a) and §1320c-5(a) list three categories of information that a PRO may gather. Only *one* of these categories of information is designated as privileged by §1320c-9(d). The category involves *standard of care* inquiries. The pertinent language of §1320 (a)(1)(B) refers to information that the care provided by the physician is "of a quality which meets professionally recognized standards of health care." Likewise, the pertinent language of §1320c-5(a)(2) refers to information that the care provided by the physician is "of a quality which meets professionally recognized standards of health care." When a physician fails to

provide care that meets recognized standards, he or she has committed malpractice.[4] The use of the phrase *standard of care* makes it clear that this category of information concerns negligence inquiries.

There are two other categories of information that are excluded from the privilege conferred by §1320c-9(d), and include information gathered for medical necessity and feasibility. See above §1320c-3(a)(1) (A) and (C); §1320c-5(a) (1) and (3). I can only conclude that Congress did not intend to protect these categories of information from disclosure, else Congress would have listed them. It follows that Congress intended for information within these two categories to be non-privileged. It is sound statutory construction that the express designation of one thing may properly be construed to mean the exclusion of another. Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion. *INS v. Cardoza-Fonseca,* 480 U.S. 421, 432, (1987). *See also Singh-Kaur v. Ashcroft* 385 F.3d 293, 299 (3rd Cir. 2004)

Subsections (A) and (C) of §1320c-3 and (1) and(3) of §1320c-5 refer to information gathered by PROs for the purpose of determining that care is medically necessary, is economically effective, and is supported by evidence of medical necessity and quality. In sum, the second sentence in 1320c-9(d) protects from disclosure any investigative material associated with findings of possible medical negligence. Such a protection from disclosure would conform with numerous state laws which protect peer review evaluations made for the purpose of

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[4]ARKANSAS MODEL JURY INSTRUCTIONS, Instruction 1501 (1999); *Dewitt v. Brown,* 669 F.2d 516 (8th Cir. Ark. 1982)

investigating possible malpractice.[5] The public interest at play here is the need to encourage peer review committees to evaluate candidly a provider's competence or lack thereof, so safety issues may be addressed and corrected for the public good. Congress determined that such public interest is important enough to outweigh the need for evidence, and therefore, justified the creation of a privilege. *Trammel,* 455 U.S. at 51.

The case repeatedly cited by Defendants in this matter is *Armstrong v. Dwyer,* 155 F.3d 211 (3rd Cir. 1998). The *Armstrong* case involved a medical malpractice investigation made by a PRO on behalf of the DHS. The plaintiff in *Armstrong* was seeking material from the PRO that investigated the defendant physician's care of the plaintiff. The court applied the specific language of §1320c-9 and held that such materials were privileged.

However, the facts presented in *Armstrong* are clearly distinguishable from a Medicare-Medicaid beneficiary pursing a civil action requesting material from the PRO which denied benefits based on medical necessity. As I have explained above, Congress specifically allows disclosure of such material by excluding it from the list of material protected in the second sentence of §1320c-9(d). The first sentence is not applicable in this situation because the patient records belong to the beneficiary challenging the denial, and the plaintiffs would not have to obtain their own medical records from the PRO, since plaintiffs have a right to those records.

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[5]*See* Ark. Code. Ann. § 25-19- 105(a) *et seq.* (Supp.1995); Ark.Code Ann. § 16-46-105 (Repl.1994)(provides that peer review and quality assurance records shall not be subject to discovery or admissible in any legal proceeding and shall be absolutely privileged communications.); *Berry v. Saline Memorial Hosp.*, 322 Ark. 182 (Ark.,1995)

Defendant, Arkansas Foundation for Medical Care (AFMC) bases its argument on regulations enacted by the Secretary of Health and Human Services. AFMC begins its argument by quoting 42 U.S.C.§1320c-3(a)(9)(A), which authorizes the Secretary to permit access to any information "*subject to the provisions of 1320c-9 of this title*." I agree. Any regulations must be consistent with the intent of Congress as set forth in the statute itself.

In two cogent opinions from the District of Columbia Circuit, the District Court and Circuit Court refused to accept the Defendant's broad interpretation of the Peer Review Improvement Act as evidenced in the PRO manual created by the Department of Human Services. *Public Citizen, Inc. v. Department of Health and Human Service, et al.* 151 F.Supp.2d 64 (D.C.D.C.2001) *aff'd* 332 F.3d 654 (D.C. Cir. 2003). Instead the District Court ordered the Department to provide a litigant with substantive information contained in a peer review investigation. The District Court pointed out-- and the Circuit Court agreed-- that when a statute is clear and unambiguous, consideration of administrative interpretation contrary to such language is inappropriate. *Id.* at 151 F. Supp. 70; 332 F.3d 659 (citing *Chevron U.S.A. Inc. v. Natural Resources Defense Council,* 467 U.S. 837, 104 S.Ct. 2778 (1984)).

Defendant, AFMC cites 42 CFR §480.139 (b) (1) which forbids the disclosure of QIO (PRO) deliberations and the identity of the physicians, advisors and consultants involved in deliberations. However, the preceding regulation, 42 CFR §480.138 (b) (1), sets forth the application of the regulation. First, confidential material in medical necessity determinations are only mentioned in relation to investigations by state and federal licensing agencies who are studying the patterns of certain practitioners. Again, this is applicable to professional standards inquiries.

Second, 42 CFR §430.138(b) (1) states that restrictions on disclosures are not *applicable "in the course of administrative hearings held under the Social Security Act."* Finally, 42 CFR §480.138(b)(2) states in pertinent part that "[A] QIO must disclose information regarding QIO deliberations and *quality* review study information only as specified in 42 CFR §480.139" (Emphasis added). Once again, the words medical necessity are absent. This, I believe, is an eloquent silence. It follows that this exclusion means that 42 CFR §480.139 applies to *quality* reviews, not *medical* necessity reviews, except to the extent that medical necessity materials reveal patterns of professional conduct or misconduct.

AFMC strenuously argues that the identity of physicians and others who take part in PRO deliberations are absolutely protected from a formal discovery process by the above cited regulation. As stated, the regulations must be consistent with the intent expressed by Congress as unambiguously set out in §1320c-9. I have read this section of the Peer Review Improvement Act carefully. There is nothing in the language of §1320c-9 that demonstrates an intent to protect the confidentiality of PRO physicians and advisors. In fact, §1320c-9(a)(2) declares its general purpose is to insure the confidentiality of the following PRO material: "[A]ny data or information acquired by any such organization in the exercise of its duties and functions shall be held in confidence and shall not be disclosed to any person." Again, I point out that the use of the term "acquired" and the absence of the term "produced" is significant. The word produced only appears in subsection 1320c-9(d), addressing *standard of care* investigations, which I have already discussed.

Most importantly, Congress gives the Secretary the right to create exceptions to any limitations imposed by §1320c-9, but Congress does not give the Secretary the power to expand

the Act. The Act requires the Secretary to formulate regulations so that exceptions to the confidentiality rule may be created for the following reasons:

> **(1)** to the extent that may be necessary to carry out the purposes of this part,
>
> **(2)** in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of *patients, health care practitioners, or providers of health care.* (emphasis added)

A close reading of subsection (a)(2), quoted above, indicates that Congress was interested in protecting the privacy and interests of patients, health care practitioners, and other health care providers—not members of PRO organizations. The court in the *Public Citizen* case agrees that the Secretary's role with regard to non-disclosure is not expansive:

> [But] §1320c-9(a)(2) does not permit the Secretary to impose his own non-disclosure requirements; rather, it authorizes the Secretary to promulgate regulatory *exceptions* to the general non-disclosure requirement. *Public Citizen, Inc.*, 332 F.3d at 664.

Although the level of deference afforded an agency interpretation is high, courts remain the final authority in matters of statutory interpretation and must reject administrative constructions which are contrary to clear congressional intent. *Ragsdale v. Wolverine Worldwide Inc.,* 218 F.3d 933, 936 (8th 2000). In the instant case, I do not find that the regulation relied on by the AFMC to be necessarily in conflict with §1320c-9. The conflict arises only if I accept AFMC's interpretation of the regulation, and I do not. Instead, I find that 42 C.F.R. §480.138, limits the application of 42 CFR §480.139 to quality investigations that are concerned with possible safety issues involving departures from standard of care, and licensing of practitioners.

Conclusion

In view of the above, I find that Plaintiffs may utilize all formal discovery tools provided by the Federal Rules of Civil Procedure. Consequently, Plaintiffs may discover the name, qualifications, and identity of each peer review physician and advisor who participated in the denial of medical benefits, based on the premise that the care did not meet medical necessity requirements.

Further, the Plaintiffs may discover any other relevant material produced by the PRO in making medical necessity determination in their case. On the other hand, consistent with the intent of §1320c-9 (d),Plaintiffs may not discover any patient records of non-parties, nor may Plaintiffs discover any material produced by the PRO that evaluated the failure of a particular medical provider to follow professional standards of care.

IT IS SO ORDERED this 29th day of November, 2004

UNITED STATES DISTRICT JUDGE
WM. R. WILSON, JR.

THIS DOCUMENT ENTERED ON DOCKET SHEET IN COMPLIANCE WITH RULE 58 AND/OR 79(a) FRCP
ON 11/30/04 BY

bm

UNITED STATES DISTRICT COURT
Eastern District of Arkansas
U.S. Court House
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November 30, 2004

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