April 19, 2007

Alexander J. Brittin
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8000 Towers Crescent Drive, Suite 900
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Re: Formal Complaint 07-FC-75; Alleged Violation of the Access to Public Records Act by the Indiana Family and Social Services Administration

Dear Mr. Brittin:

This is in response to your formal complaint alleging that the Indiana Family and Social Services Administration ("FSSA") violated the Access to Public Records Act by refusing to disclose the prescription number and complete date of service from outpatient drug pharmacy claims data maintained by FSSA contractor Electronic Data Systems (EDS).

BACKGROUND

Your complaint was filed on behalf of Data Niche Associates ("DNA"). DNA is a specialized information services firm that acquires and standardizes prescription level data for Medicaid rebate validation purposes. You state that DNA receives data from over 40 state Medicaid agencies, 16 state pharmaceutical assistance programs and numerous drug manufacturers who participate in the Medicaid rebate program. You submitted material published by the Health Care Financing Administration [predecessor agency to CMS, the Centers for Medicare and Medicaid Services, the agency of U.S. Health and Human Services responsible for the Medicaid program] on the "Best Practices Under the Medicaid Drug Rebate Program." In that publication, DNA was specifically mentioned as a third party data vendor from which 30 major pharmaceutical manufacturers purchase Medicaid prescription claim level data.

You allege that from 1991 until the third quarter of 2005, DNA received from FSSA all the Medicaid rebate validation data requested by DNA. The data elements released to you included the National Drug Code (NDC) number, prescription number, date of service, paid date,

paid quantity, paid amount, billed amount, pharmacy identification and address, and prescriber identification and address, among other things. In early 2006, FSSA stopped providing all rebate validation data. This occurred at the same time that the state shifted from Affiliated Computer Services Corp. ("ACS") as the fiscal intermediary to EDS. Efforts to convince the state to resume sending all rebate validation data met with some success. However, by letter dated November 14, 2006 from Scott Linneweber, attorney for FSSA, the state continued to withhold the prescription number and complete date of service, citing the HIPAA Privacy Act and the Access to Public Records Act. In addition, the state contended that the disclosure of Medicaid recipient information was limited to disclosure directly connected with the administration of the state plan.

On December 7, DNA wrote to Mr. Linneweber explaining why the disclosure was permitted under Medicaid law and HIPAA. In addition, DNA wrote that the APRA does not prohibit disclosure. DNA reasserted its request for this information. On February 21, 2007, FSSA again denied the two data elements. This complaint, on behalf of DNA, followed.

I have sent your complaint and attachments to Mr. Linneweber. His April 4 response is enclosed. The arguments have been made by the parties in their various correspondences, and I do not set them forth in this section, but have included them in my analysis below.

ANALYSIS

Any person may inspect and copy the public records of any public agency, except as provided in section 4 of the Access to Public Records Act ("APRA"). Ind. Code 5-14-3-3(a). Hence, a public agency is required to disclose a record unless the record may be withheld, or must be withheld, under any one exception to disclosure set forth in Indiana Code 5-14-3-4. The public agency bears the burden of proof that the denial is proper under the APRA. IC 5-14-3-1; IC 5-14-3-9. The exceptions to disclosure are to be narrowly construed so as to effectuate the remedial purposes of the APRA. *Robinson v. Indiana University*, 659 N.E.2d 153, 156 (Ind. Ct. App. 1995) [Citations omitted.], quoting *Common Council of City of Peru v. Peru Daily Tribune, Inc.* 440 N.E. 2d 726, 729 (Ind. Ct. App., 1982) [Citations omitted].

Under IC 5-14-3-4(a), certain records may not be disclosed by a public agency, unless access to the records is specifically required by a state or federal statute or is ordered by a court under the rules of discovery. Two exceptions to disclosure under IC 5-14-3-4(a) are at issue in this complaint. The first is for records "required to be kept confidential by federal law." IC 5-14-3-4(a)(3). The FSSA has asserted that HIPAA, a federal law, makes the complete date of service confidential. In addition, the FSSA contends that federal Medicaid law limits disclosure of the dates of service and prescription number to only those purposes directly related to Medicaid state plan administration. FSSA argues that because these federal laws prohibit disclosure, the APRA applies to prohibit disclosure as well.

In addition, FSSA claims that the prescription number is a "patient medical record and chart created by a provider," and therefore must be denied unless DNA obtains patient consent, in accordance with IC 5-14-3-4(a)(9).

Hence, if FSSA can sustain its burden to show that the date of service or the prescription number fall within the HIPAA Privacy Rule, or federal Medicaid law, or a patient medical record or chart, then FSSA must deny the information. Any one of these laws, if applicable to the date of service or prescription number, would be sufficient for FSSA to deny the information.

HIPAA

Effective in April 2003, the Standards for Privacy of Individually Identifiable Health Information (commonly called "HIPAA" or "the Privacy Rule") provides that protected health information may not be used or disclosed except as permitted or required by the Privacy Rule. 45 CFR §164.502(a). In its April 4 letter, FSSA argues that the complete date of service is protected health information because the date of service is directly related to an individual, and must be removed before the health information can be deemed to be "de-identified." Since the complete date of service and prescription number is helpful but not necessary for rebate validation, FSSA considers that disclosure of the date of service does not meet the "minimum necessary" standard set forth in HIPAA.

DNA counters that even if the date of service and prescription number is protected health information because the information is not "de-identified" information, HHS has sanctioned a Medicaid agency's disclosure of the information to third party data vendors such as DNA, citing the guidance at the HHS website. HHS mentions prescription numbers specifically when referring to rebate validation services performed by third party data vendors in its guidance. Accordingly, since the disclosure to DNA is permitted under the Privacy Rule, then disclosure to DNA is required under the APRA, since *per force*, the information is not "*required* to be kept confidential by federal law." With respect to the "minimum necessary" standard, DNA disputes that the date of service and prescription number are not necessary for DNA to perform rebate validation services. Although not specifically mentioned by HHS in its guidance, the date of service would distinguish duplicate payments, a critical element of the rebate validation process.

HHS has issued guidance that says the Privacy Rule permits State Medicaid agencies to disclose protected health information, such as prescription numbers, to pharmaceutical manufacturers and third party data vendors that assist the pharmaceutical manufacturers, for purposes of validating claims submitted under the Medicaid Drug Rebate program. Such disclosure is permitted as part of a State Medicaid agency's payment activities. Further, if the disclosure is required by law to drug manufacturers as part of the drug rebate program, the minimum necessary standard does not apply. To the extent that protected health information is disclosed for payment purposes but not pursuant to a legal requirement, the State Medicaid agency must make reasonable efforts to limit that information to that which is the minimum necessary to adjudicate the rebate claims. *See* www.hhs.gov/hipaafaq/providers/treatment/456.html.

From my reading of the HHS guidance, the disclosure to DNA would be permitted under the Privacy Rule if DNA assists pharmaceutical manufacturers for purposes of validating claims submitted under the Medicaid Drug Rebate program. Further, this permissive disclosure is not required by law. Therefore, the minimum necessary standard applies.

A covered entity is required to make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. 45 CFR §164.502(b)(1). However, it is not clear to me that FSSA has applied the minimum necessary standard correctly. Mr. Linneweber applies the minimum necessary standard in this argument:

> "DNA has tried to argue that their services are rendered useless without the complete date. DNA claims that the date of service is useful when identifying identical claims. "Useful" is not "necessary" and if the disclosure is not necessary, then the complete date is not actually required…The state should not provide protected health information to a private corporation merely because it is in the corporation's best economic interest to have such data."

It is not clear why disclosing the date of service with the rest of the claim level data that FSSA currently discloses for purposes of DNA's claims validation process exceeds the minimum necessary to accomplish the purpose of validation of claims. Receiving complete service dates (month, day and year) is an obvious method by which duplicate payments would be detected, and FSSA does not set forth an alternate means by which such validation would occur in the absence of this disclosure. Having said this, I hasten to point out that FSSA has the expertise to determine this, and deserves some deference on this point from this office. Nevertheless, Mr. Linneweber's argument as counsel to FSSA may not adequately sustain FSSA's burden for denying the date of service on the basis of the Privacy Rule. Moreover, DNA has asserted that many other states' Medicaid programs disclose to DNA dates of service and prescription numbers, under the same standards for privacy of protected health information as Indiana is subject to. Whether this claim has been validated by FSSA by talking to other states, as DNA had suggested to FSSA, is not in evidence. I believe that FSSA must buttress its argument that the minimum necessary standard would prevent disclosure to DNA in order to sustain its burden to deny the date of service, if the denial is challenged in a court action brought under IC 5-14-3-9(e).

Medicaid Law

Under 42 CFR §431.301, a state is required to have a Medicaid plan that restricts the disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan. Purposes directly related to the plan include determining eligibility and the amount of medical service, providing service, and investigating fraud, according to FSSA. FSSA has determined that disclosure to DNA of the dates of service and prescription numbers of prescriptions paid for Medicaid recipients is not a purpose directly connected with the administration of the state plan. I interpret FSSA's argument to be that even if the broad function of making payment is a purpose directly connected to the plan, the activities of the third party rebate vendors is not a necessary function of the Medicaid program; therefore, CMS does not require states to give the dates of service and prescription number (or any claims level data, for that matter) to third party rebate vendors. The very guidance cited by DNA sustains FSSA's argument that a disclosure to a third party rebate vendor is not required under federal law, says FSSA. Hence, FSSA can determine in its discretion that DNA's activities do not rise to the level of "purposes connected to administration of the plan" because DNA merely

provides information on line to subscribing drug manufacturers. This function is not an agency relationship with the drug manufacturers. It is only if DNA could provide proof that it is receiving the information as an agent of a drug manufacturer would FSSA provide it. Without that, FSSA is within its authority to deny the information as confidential under 42 CFR §431.301.

This argument has some merit. Again, FSSA's expertise in administering the Medicaid program and determining the extent to which it can disclose information about Medicaid applicants and recipients cannot be doubted. DNA's assertion, however, that other state Medicaid programs give DNA this very information somewhat diminishes FSSA's position. Although some discretion may be inherent in the determination made by FSSA, if states do make available prescription number and date of service to third party rebate data vendors without violating 42 CFR §431.301, FSSA must disclose the information under Indiana's sunshine law even if nondisclosure would not offend the federal Medicaid statute.

Accordingly, it is my opinion that FSSA may rely upon 42 CFR §431.301 to deny the date of service or prescription number only if CMS would consider a disclosure by FSSA to DNA to be in violation of the approved Indiana state plan. If CMS would not consider the disclosure to violate the state plan, then the information is not required to be kept confidential by federal law, and IC 5-14-3-4(a)(3) would not apply.

Patient Medical Records and Charts

A public agency may not disclose a "patient medical record and chart created by a provider, unless the patient gives written consent under Indiana Code 16-39." IC 5-14-3-4(a)(9). "Provider" has the meaning set forth in IC 16-18-2-295(a). IC 5-14-3-2(k). "Patient" has the meaning set out in IC 16-18-2-272(d). IC 5-14-3-2(i).

A pharmacist is among the health care professionals described as a provider in IC 16-18-2-295. "Patient" means an individual who has received health care services from a provider for the examination, treatment, diagnosis, or prevention of a physical or mental condition. IC 16-18-2-272(d). "Medical record" is defined along with "health record" and "hospital record" as "written or printed information possessed by a provider (as defined in IC 16-18-2-295) concerning any diagnosis, treatment, or prognosis of the patient, unless otherwise defined." IC 1-1-4-5.

FSSA contends that the prescription number is a patient medical record or chart created by a provider, and on this basis denies the prescription number without patient consent. The fact that the prescription number is used in payment does not diminish its tendency to identify the treatment of a patient, and perhaps allow inference of a medical condition or diagnosis. A prescription number is unique to the pharmacy and works to identify the prescription for purposes of refilling the prescription. FSSA has asserted that with respect to a patient medical record, APRA is more protective of patient privacy than is federal law.

DNA cites to IC 16-39-5-3(c)(1), which allows a provider to disclose information from a patient's health record for payment purposes, to argue that FSSA is not precluded from

disclosing the prescription number to DNA for the same purpose. I agree with FSSA that IC 16-39-5-3(c)(1) applies only to the provider who creates or incorporates medical information into her own patient's record. It does not apply to a state agency that receives the medical record from the provider. I also agree with FSSA that the mere fact that a prescription number is related to payment for a service does not preclude that information from being deemed a medical record or chart. Surely the number and type of services rendered to a patient during a medical visit is supplied on a claim and is for payment purposes, but no one would argue it is not confidential under section 4(a)(9).

However, FSSA's argument that state law is more protective of patient privacy than federal law may prove too much. If state law prohibits disclosing the prescription number and date of service (if FSSA asserts this latter information is also protected), FSSA would not be able to disclose any information contained on a claim except for disclosures *required* by state or federal law. If FSSA discloses claim level data when the disclosure is *permitted* rather than required, such disclosure would be prohibited under state law, if I understand FSSA's stance correctly. Moreover, disclosing the NDC number (which tells what drug was prescribed) to DNA, for example, seems inconsistent with FSSA's position that the prescription number and date of service is confidential under state law as a patient medical record or chart.

In any case, no reported Indiana case has determined the extent to which information from a claim that is separated from identifying information about the patient, is a medical record or chart under IC 5-14-3-4(a)(9). As stated earlier, FSSA bears the burden to show that the prescription number or date of service are confidential under IC 5-14-3-4(a)(9).

Sincerely,

Karen Davis
Public Access Counselor

cc: Scott Linneweber