

STATE OF TENNESSEE

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Opinion No. 05-174

The Legal Duty of Pharmacies to Allow Inspection of Methamphetamine Precursor Registries

QUESTION

Does the Meth-Free Tennessee Act of 2005 require pharmacies to allow law enforcement officers to inspect their methamphetamine precursor registries maintained under Tenn. Code Ann. § 39-17-431(d) absent issuance of a court order, subpoena, authorized investigative demand, or other similar process as set forth under the Health Information Portability and Accountability Act of 1996 (HIPAA)?

OPINION

Yes. Under Tenn. Code Ann. § 39-17-431, pharmacies in Tennessee are required to limit the amount of methamphetamine precursors that may be sold to a single buyer during the same thirty-day period. Additionally, pharmacies are required to maintain a record of the sale and certain information concerning the buyer of the methamphetamine precursors. Under Tenn. Code Ann. § 53-11-406, the records maintained by the pharmacies are open for inspection by federal, state, county, and municipal law enforcement officers to enforce drug laws. The information security limitations imposed on health care providers under HIPAA do not apply here because information on non-prescription methamphetamine precursors does not constitute “individually identifiable health care information,” as defined under HIPAA.

ANALYSIS

By passage of the Meth-Free Tennessee Act of 2005, 2005 Tenn. Pub. Acts, ch. 18, the Tennessee General Assembly recognized “that the clandestine manufacture of the illegal drug methamphetamine is a clear and present danger to the health and well being of the State of Tennessee.” Under Section 2 of the Act, the General Assembly limited the sale of methamphetamine precursors to licensed pharmacies. *See* Tenn. Code Ann. § 39-17-431(a). Additionally, the Act now prohibits pharmacies from selling more than a specified amount of any product containing identified methamphetamine precursors to the same person during a single 30-day period and requires pharmacies to maintain a record of the sale of such products, including specific identification of the purchasers. *See* Tenn. Code Ann. § 39-17-431(c) and (d).

Although the Act itself imposes no obligation on the pharmacy to make such records available to law enforcement for inspection, such an obligation is specifically established under Tenn. Code Ann. § 53-11-406(a):

Prescriptions, orders and records, required by . . . title 39, chapter 17, part 4, and stocks of controlled substances, shall be open for inspection only to federal, state, county and municipal officers whose duty it is to enforce the laws or regulations of this state or of the United States relating to controlled substances or narcotic drugs.

Tennessee law, therefore, specifically provides for the inspection of the records maintained under title 39, chapter 17, part 4, which is the Tennessee Drug Control Act of 1989, of which certain provisions were modified by the Meth-Free Tennessee Act of 2005.

Having determined that law enforcement may inspect the records in question, the next issue is whether compliance with the Meth-Free Tennessee Act of 2005 conflicts with the requirements of the Health Insurance Portability & Accountability Act of 1996 (HIPAA), 42 U.S.C. § 1320d-1, *et seq.*, with respect to the security of individually identifiable health information. The purpose of HIPAA is

to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes.

Id., Preamble. HIPAA governs the standardization of electronic data interchange among health care organizations. HIPAA recognizes a patient's expectation of privacy in the information collected under this Act and provides for the imposition of both fines and imprisonment for the wrongful disclosure of individually identifiable health information. "Individually identifiable health information" is

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.

42 U.S.C.A. § 1320d(6). “Health care” includes the sale or dispensing of prescription drugs. 45 C.F.R. § 160.103. The term “health care provider” is defined under title XVIII of the Social Security Act, 42 U.S.C. § 1395x(u) and (s). Although the terms “pharmacy” and “pharmacist” do not appear among the terms enumerated as “providers,” the role of pharmacists and pharmacies in selling and dispensing prescription drugs supports the conclusion that they should be considered “health care providers” for purposes of HIPAA.¹

The next question is whether the information collected in the drug precursor registries constitutes “individually identifiable health information” subject to the security limitations of HIPAA. As noted above, HIPAA’s definition of “health care” includes the “sale or dispensing of a drug . . . in accordance with a prescription.” 45 C.F.R. § 160.103. The obvious implication is that a valid privacy interest arises from a patient’s relationship with a health care professional and does not reside with the drug itself. There is no provision to include the sale or dispensing of non-prescription medications sold over the counter or without a prescription in the category of “health care” as contemplated by HIPAA.

The purpose of monitoring and limiting the sale of methamphetamine precursors is clearly to discourage the clandestine manufacturing of methamphetamine. The precursors subject to the registry requirement are not prescription drugs and thus are not included under HIPAA’s definition of “health care.” Therefore, for purposes of HIPAA, information regarding the purchase of a non-prescription medication that would be sold over the counter but for the requirements of the Meth-Free Tennessee Act of 2005 should not be considered “individually identifiable health information.”

As an additional consideration, it should be noted that the provisions of HIPAA allow some exception for the release of individually identifiable health information for law enforcement purposes, although some style of legal process is required.² However, unlike information regarding medications prescribed by a doctor or other health care provider after a diagnosis of some condition

¹Although there appears to be no case law specifically addressing this issue, the United States District Court for the District of New Jersey appears to have accepted the proposition that pharmacists should be considered health care providers for purposes of HIPAA. See *In re Remeron End-Payor Antitrust Litigation States and Commonwealths of Texas v. Organon USA Inc.*, No. Civ. 02-2007 FSH, Civ. 04-5126 FSH, 2005 WL 2230314, *15 fn. 4 (D.N.J. 2005) (slip copy).

²45 C.F.R. § 164.512(f)(C) allows a covered entity to disclose protected health information for a law enforcement purpose to a law enforcement official upon receipt of:

An administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

- (1) The information sought is relevant and material to a legitimate law enforcement inquiry;
- (2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and
- (3) De-identified information could not reasonably be used.

justifying the prescription, there is no valid expectation of privacy in identifying information given by the buyer of a methamphetamine precursor absent some assurance on the part of the pharmacy that such information is to be kept confidential. In *Slim-Fast Foods Company v. Brockmeyer*, 627 S.2d 104 (Fla. Dist. Ct. App. 1993), consumers of a nonprescription diet aid sent letters of complaint to the product manufacturer and disclosed information about their medical conditions. Noting that the complainants did not request any confidentiality or anonymity in their letters, the District Court of Appeal of Florida determined that the consumers acted in a manner inconsistent with any reasonable expectation of privacy. *Id.* at 106. Similarly, when consumers provide identifying information as a prerequisite to their purchase of nonprescription medications that contain methamphetamine precursors, there is no assurance that the information is to be kept confidential. Nor are consumers disclosing information concerning any medical condition or treatment they might be receiving. There is no reasonable expectation of privacy in the information given.

Pharmacies are under a legal duty to make the records required to be kept by the Meth-Free Tennessee Act of 2005 available for inspection by “federal, state, county and municipal officers whose duty it is to enforce the laws or regulations of this state or of the United States relating to controlled substances or narcotic drugs.” Tenn. Code Ann. § 53-11-406(a)(1). Because the information collected does not constitute individually identifiable health information, it is the opinion of this office that such disclosure does not violate the provisions of the Health Insurance Portability and Accountability Act of 1996.

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