IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	Case No. 2:05-CR-00003
	)	Judge Campbell
YOUNG MOON	)	

BRIEF *AMICI CURIAE* OF AMERICAN MEDICAL ASSOCIATION
AND TENNESSEE MEDICAL ASSOCIATION
IN SUPPORT OF DEFENDANT'S MOTION TO SUPPRESS

The American Medical Association ("AMA") and the Tennessee Medical Association ("TMA") submit the following Brief *Amici Curiae* in support of the Motion to Suppress of Defendant, Young Moon, M.D., seeking to suppress evidence obtained from the search of her office on January 9, 2002. The search exceeded the scope of the government's authority under the Medicare and Medicaid regulations and Dr. Moon's own contractual consent. Equally, or perhaps more importantly, it violated the privacy rights of her patients, probably including patients who did not benefit from government funded health care programs.

Introduction

The right to personal privacy has long been protected as a fundamental right. The Fourth Amendment of the United States Constitution states: "The right of the people to be secure in their persons, houses, papers and effects, against unreasonable searches and seizures, shall not be violated." U.S. Const. amend. IV. Under the Fourth Amendment, a patient's health information may not be divulged to the government absent a warrant or the patient's consent. *Ferguson v. City of Charleston*, 532 U.S. 67, 76 (2001).

Patients have a reasonable expectation of privacy from government searches, even when such searches may otherwise be reasonable. *Id.* In *Ferguson*, a hospital performed warrantless, nonconsensual drug tests on pregnant patients and turned over the results to the police without the patients' consent or knowledge. The Court reversed the lower court's holding that such a search was reasonable, stating, "the reasonable expectation of privacy enjoyed by the typical patient undergoing diagnostic tests in a hospital is that the results of those tests will not be shared with nonmedical personnel without her consent." *Id.* at 78. Thus, even though the drug tests may serve a "special need" in decreasing the use of illicit drugs by patients receiving prenatal treatment, the interest in patient privacy was overriding. Specifically, an "intrusion on that expectation may have adverse consequences because it may deter patients from receiving needed medical care." *Id.* at n.14.

A patient's expectation of privacy is even more consequential in particularly sensitive areas of medicine, such as cancer treatment. Many cancer patients, fearing public exposure of their condition, trust their physicians to maintain the confidentiality of their treatment. Privacy violations will reduce that trust. Patients who do not trust their physicians may not make full disclosure of the information needed to provide accurate and reliable diagnosis and treatment. Any disruption of the bond between patient and physician can affect the course of treatment—possibly with life and death consequences. The mere perception of a physician's indiscretion, particularly an oncologist's, may sound the death knell to his or her practice. Thus, governmental searches should make all efforts to be discreet and avoid unnecessary spectacles. (*See* AMA Policies E-5.05, H-175.973, and H-175.977, attached as Exhibits 1-3.)

Amici do not dispute the government's interest in eliminating excessive billing for Medicare and Medicaid services. Nor do they dispute the government's authority under the Medicare and Medicaid regulations to audit patient records. However, as in *Ferguson*, such interests should be weighed against the potentially harmful effects of indiscriminantly violating patient privacy and the minimal effort needed by the government to obtain a search warrant. The need to monitor Medicare and Medicaid does not justify all incursions on well established privacy rights, especially when simple procedures can be followed to ensure their protection.

Statement of Facts

Dr. Moon is a board certified oncologist with a private practice in Crossville, Tennessee. As part of her practice, Dr. Moon treated cancer patients by administering chemotherapy and various injections of cancer medication. On average, she saw 15 to 20 patients a day in her office. [Ex. 4 of Corrected Opposition to Motion to Suppress at 2 (hereinafter "Opp")]

On January 9, 2002, agents of the Tennessee Bureau of Investigation ("TBI") and the Office of the Inspector General of the United States Department of Health and Human Services ("OIG-HHS") conducted a search of Dr. Moon's office. The search was conducted in response to a tip from a "front desk" employee at Dr. Moon's practice who suspected Dr. Moon of over-billing for certain medications. (Ex. 3 of Opp. at 1.) According to the TBI On-Site Review Operations Plan, the objective of the search was two-fold: "1) The primary objective will be to scan TennCare, Medicaid and Medicare patient records. 2) The second objective of the operation will be to interview Dr. Moon and all of her employees." (Ex. 4 of Opp. at 2.) The actual search that took place,

however, exceeded these objectives.

The TBI and OIG-HHS agents arrived unannounced at Dr. Moon's office at approximately 9:30 a.m. Upon Dr. Moon's arrival, TBI Special Agent William A. Corbitt explained that the agents "were there to scan Medicare and Medicaid/TennCare patient medical records due to some issues that [were] brought to [their] attention." (Ex. 5 of Opp. at 1.) Nothing was said about going beyond the record scanning. Dr. Moon was also not advised of her right to an attorney, and at no time during her search was an attorney present. The agents, however, had two attorneys available on call. In total, TBI and OIG-HHS employed a team of nine agents to search an office with approximately the same number of rooms. (Ex. 4 of Opp. at 3.)

TBI and OIG-HHS agents searched and videotaped every room of the office complex, including the break room, a private bathroom with a shower, a patient bathroom, and patient examination and treatment rooms. (Exs. 5 and 7 of Opp.) The agents also searched the billing room, the receptionist area, the medical records room, the chemotherapy lab, and multiple storage and supply facilities. *Id.* Various photographs were also taken. *Id.*

The mere presence of the investigators disrupted patient examinations. The agents entered and videotaped Dr. Moon's patient examination and treatment rooms. The investigation notes of TBI Nurse Investigator Marsha M. Neuenschwander, RN, indicate that she and another agent intruded on Dr. Moon's examination of a patient in the "Treatment Room." (Ex. 7 of Opp. at 1.) Investigator Neuenschwander's record of this examination stated that Dr. Moon asked if the patient was "experiencing any diarrhea or vomiting." *Id.* The other agent observing the examination was an employee of Blue

Cross Blue Shield, Sue McKesson, RN, who accompanied the TBI and OIG-HHS team in order to review Blue Cross Blue Shield files. *Id.*

Agents rummaged through storage and supply facilities. Nurse Investigator Neuenschwander's investigation notes describe her search of the "Wig Room," in which she entered a room with numerous wigs and took note of the sign out sheet. *Id.* at 2. Her notes of the "Medicine Room" indicate that she looked inside two refrigeration units and a medicine closet and cataloged their contents in detail. *Id.* She did not suggest that these items were related to the treatment of Medicare or Medicaid patients or were pertinent to Dr. Moon's billing statements. *Id.*

Nurse Investigator Neuenschwander's notes also indicate that the office manager was asked to provide: "names of all employees, titles, job duties and license, usual and customary charges, incident/accident reports, patient appointment books, sheets or logs, X-rays, lab books, invoices, CLIA certification if lab tests are performed, EKG reports, a listing of all meds and narcotics… [and all] other logs, books or invoices which have any of the patient billing or procedures to determine if performed and documented." *Id.* at 3. The requested items did not distinguish between information pertaining to Medicare and Medicaid patients and those pertaining to other patients. *Id.*

Agents interviewed Dr. Moon and her staff members, including the billing clerk, receptionist, and office manager, while patients were present in the office. (Exs. 5 and 7 of Opp.) During the interview of Dr. Moon, Special Agent Corbitt obtained a notebook containing information pertaining to private paying patients in addition to Medicare and Medicaid/TennCare patients. This notebook contained lists of patient names, dates of service, and specific information regarding the administration of medication. (Ex. 5 of

Opp. at 2.)

Special Agent Corbitt videotaped each room of the office while Investigator Neuenschwander narrated. *Id.* at 3. Dr. Moon refused to consent to the videotaping. In fact, she demanded that the recording be stopped and the tape be destroyed. *Id.* Dr. Moon's demands were refused. The government agents set up a high-speed scanner to duplicate patient files. *Id.* at 1. Their scanning was done from the time the search team arrived until approximately 5:45 p.m. *Id.* at 3.

The search concluded at approximately 6:15 p.m. *Id.* at 4.

Argument

I. DR. MOON'S PURPORTED CONSENT DID NOT AUTHORIZE THE TYPE OF SEARCH DESCRIBED IN THE GOVERNMENT'S INVESTIGATION NOTES.

The government contends that the warrantless search of Dr. Moon's office was permissible under Medicaid regulations, the TennCare managed care contractor agreement, and Dr. Moon's provider agreement with BlueCare.[1] None of these bases, however, would justify the search of information other than specific Medicare and Medicaid patient records and payment information pertaining to billing. This Court should not allow the government to abuse its limited right to audit such material by permitting more invasive searches of a physician's practice.

A. The Medicaid Act and its regulations, which require physicians to consent to the furnishing of certain records and payment information, do not authorize disruptive and invasive searches of physician offices.

[1] In its Corrected Opposition to Motion to Suppress, the government does not argue that its search of Dr. Moon's office was authorized by her oral consent. Consequently, this brief is directed to Dr. Moon's contractual obligation and how the government's search infringed her constitutional rights, as well as the constitutional and statutory rights of her patients.

Title XIX of the Social Security Act, entitled "Grants to States for Medical Assistance Programs" (the "Medicaid Act"), provides that states participating in Medicaid are required to establish certain agreements with those managed care contractors and physicians participating in their programs. 42 U.S.C. § 1396a(a)(27). The purpose of this provision, as well as the federal regulations implementing it, is to allow governmental access to records and payment information of Medicaid patients in order to ensure compliance with the programs' standards. *Id.* The Medicaid Act requires participating state governments to:

> "provide for agreements with every person or institution providing services under the State plan under which such person or institution agrees (A) ***to keep such records as are necessary fully to disclose the extent of the services provided*** to individuals receiving assistance under the State plan, and (B) ***to furnish the State agency or the Secretary with such information***, regarding any payments claimed**,** by such person or institution for providing services under the State plan, as the State agency or the Secretary may from time to time request."

(Emphasis added.) *Id*. Thus, physicians who participate in state Medicaid programs are only required to: (1) maintain certain "records" and (2) furnish those records that pertain to "any payments claimed." *Id.*

The federal Medicare and Medicaid regulations essentially mirror the Medicaid Act's language. The regulations state:

> "A state plan must provide for an agreement between the Medicaid agency and each provider or organization furnishing services under the plan in which the provider or organization agrees to:
> (1) Keep any records necessary to disclose the extent of services the provider furnishes to recipients.
> (2) On request, furnish…any information maintained under paragraph (b)(1) of this section and any information regarding payments claimed by the provider."

42 C.F.R. 431.107(b). Like the Medicaid Act, these regulations are limited to records

and payment information.

Neither the Medicaid Act nor the federal regulations implementing it contain any language suggesting that participating physicians are required to allow government agents to enter their offices unannounced, interview employees, disrupt patient examinations, videotape the entire premises while patients are present for treatment, or obtain information pertaining to non-Medicare and Medicaid patients. *Supra*, at 4-5. Certainly they were not meant to authorize invasive searches like the one described in the government's own investigation notes or the furnishing of any information pertaining to non-Medicare or Medicaid patients. An overt search, visible to patients, necessarily endangers the trust required as part of the medical process.

In fact, the regulations were intended only to facilitate "routine surveys." Medicare and Medicaid Programs; Advance Directives, 57 Fed. Reg. 8194 (Mar. 6, 1992). The search of Dr. Moon's office, however, was not close to what the Medicaid Act and its regulations would indicate to be "routine." The government did not limit the search to the mere review and audit of Medicare or Medicaid records and payment information. Before it even determined whether it had a case worthy of prosecution, the government created an unnecessary spectacle, thereby causing immense harm to Dr. Moon's practice and injury to her patients.

B. TennCare's participating provider agreements should not be interpreted in a manner that exceeds the mandate of the Medicaid Act and its regulations.

The government argues that the search of Dr. Moon's office was contractually authorized under TennCare's Contractor Risk Agreement ("CRA") as well as the participating physician agreements with BlueCare. Under the Medicaid Act and its

regulations, the State of Tennessee requires managed care contractors in its TennCare program to enter into the CRA. According to the government, the CRA requires managed care contractors to have their physicians "preserve a wide range of medical and billing data," allow the government "access to their records," and "cooperate" and "assist" in any request for records. (Opp. at 3.) These terms are supposed to be reflected in the physicians' agreements with BlueCare. Thus, like the Medicaid Act and its regulations, the purpose of the CRA and the physician agreements is to facilitate access to patient "records."

In the present case, however, more was involved than the mere review of patient "records" and Dr. Moon's files. Agents intruded on a patient examination, videotaped and scrutinized every room of the office, rummaged through storage and supply closets, and requested information pertaining to patients who were not enrolled in either Medicare or Medicaid. *Supra*, at 4-5. A contract requiring physicians to preserve records and cooperate in the audit of such records should not be construed to authorize an invasive search of a physician's entire office and the inevitable exposure of information concerning non-Medicare and Medicaid patients.

Moreover, not every term of the CRA is incorporated in the physicians' agreement with BlueCare. The government cites sections "l" through "n" of the CRA to support its contention that Dr. Moon contractually consented to the right of "TENNCARE, U.S. Department of Health and Human Services, and Office of Inspector General Comptroller" to conduct unannounced on-site inspections. (Opp. at 4.) These provisions, however, are not fully incorporated into the BlueCare agreements signed by Dr. Moon. (*Id.* at 5; *see also* Ex. C of Mot. to Suppress.) In fact, Dr. Moon's contract

does not grant TBI and OIG-HHS the right to conduct unannounced on-site inspections. *Id.*

II. THE GOVERNMENT'S "SEARCH" OF DR. MOON'S OFFICE VIOLATED HIPAA AS WELL AS TENNESSEE'S PATIENT PRIVACY STATUTES.

The importance of patient privacy is not a mere construct of the medical profession. It is also well recognized under federal and state statutory law. The government's search of Dr. Moon's office violated the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and various Tennessee patient privacy laws.

A. Patient health information is protected under HIPAA.

Congress enacted HIPAA to "protect the privacy and confidentiality of personal health information." 65 Fed. Reg. 82464, 82463 (Dec. 28, 2000). HIPAA prohibits the disclosure of "protected health information" to the government without the explicit authorization or consent of the patient to whom the information pertains. 45 C.F.R. §§ 164.508 and 164.510 (2005). Disclosure of such information may be allowable, however, for the purpose of "health oversight activities authorized by law." 45 C.F.R. § 164.512(d) (2005).

A valid "authorization" under HIPAA requires the following elements:

(1) a "specific and meaningful" description of the information to be disclosed;
(2) the name of the individual authorized to make the disclosure;
(3) the name of the individual to whom the disclosure is to be made;
(4) a description of the purpose of the disclosure;
(5) an expiration date or an expiration event that relates to the individual or the purpose of the disclosure; and
(6) the patient's signature.

45 C.F.R. § 164.508(c). In addition, the patient must be given written notice, in plain language, of: (1) his or her right to revoke the authorization, (2) the situations in which

"treatment, payment, enrollment or eligibility for benefits" may be conditioned on authorization, and (3) the situations in which redisclosure of information is permitted. *Id.*

A valid "consent" requires that a physician inform the patient of the "protected health information" that may be disclosed as well as the individuals to whom the disclosure is to be made. The patient must also have an opportunity to restrict or prohibit some or all of the permitted disclosures. 45 C.F.R. 164.510(a)(2). In the present case, none of these conditions were met, so there was no valid authorization or consent.

The government contends that patient records may be disclosed without a warrant to "a health oversight agency for oversight activities authorized by law." (Opp. at 26, *citing* 45 C.F.R. § 164.512(d).) In support of its argument, it cites *Ohio Legal Rights Serv. v. Buckeye Ranch, Inc.*, 365 F. Supp.2d 877 (S.D. Ohio 2005). However, the "search" in *Ohio Legal* was merely a routine document production, made during discovery in a civil suit. Unlike the present case, it was hardly a search at all.

United States v. Louisiana Clinic, 2002 U.S. Dist. LEXIS 24062, *1 (E.D. La. Dec. 12, 2002), is also inapplicable because the patient information in that case was procured by a court order and only after all patient identifying information had been redacted. Moreover, the information sought was limited to just the medical records of Medicare and Medicaid patients. There was no physical search of the physician's premises or a procurement of information pertaining to non-Medicare and Medicaid patients.

Moreover, Section 164.512(d)'s exception to HIPAA's general prohibition was not intended to allow government investigators to circumvent existing procedural protections of patient information. In response to comments to HIPAA's final rule that

health oversight agencies could "use their relatively unencumbered access to protected health information to circumvent the more stringent process requirements that otherwise would apply to disclosures for law enforcement purposes," the HHS stated that the exception was not intended "to serve as a 'back door' for law enforcement access to protected health information." Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462, 82674 (Dec. 28, 2000). In the present case, this is precisely what the government seeks to do, as it failed to procure a search warrant for its search of Dr. Moon's office.

Therefore, any "protected health information" the government may have accessed or acquired during its search of Dr. Moon's office was not "authorized by law" and was in violation of HIPAA.

B. Tennessee patient privacy laws provide patients with an expectation of privacy to their medical records.

Tennessee statutes provide patients with an expectation of privacy in their medical records. Section 68-11-1502 of the Tennessee Code states, "[e]very patient entering and receiving care at a health care facility licensed by the board for licensing health care facilities has the expectation of and right to privacy for care received at such facility." Tenn. Code Ann. § 68-11-1502 (2005).

The Tennessee Medical Records Act also provides, "[e]xcept for any statutorily required reporting to health or government authorities…the name and address and other identifying information of a patient shall not be divulged." Tenn. Code Ann. § 63-2-101(b)(2) (2005). Similarly, the Health Facilities and Resources Act allows for the disclosure of "the name, address, and other identifying information" of a patient under any "statutorily required reporting to health or government authorities." Tenn. Code

Ann. § 68-11-1503 (2005). The limited scope of information to be provided under these statutes is far narrower than the information the government obtained in the present case.

HIPAA explicitly preserves these state law protections [42 U.S.C.S. § 1320d-7(a)(2) (2005) and *Louisiana Clinic*, 2002 U.S. Dist. LEXIS 24062 at *3], and nothing within any other federal law suggests that they should be abrogated.

Conclusion

Amici believe that law enforcement agencies seeking to obtain patient health information beyond that which is expressly authorized under the Medicare and Medicaid regulations should be given access to such information only through a court order. The investigation in the present case was forbidden under the Fourth Amendment as well as the federal and state statutes that protect patient privacy. It not only invaded the general privacy rights of Dr. Moon and her patients, it also disrupted the relationship between physician and patient which is critical to effective medical care.

WHEREFORE, *Amici Curiae* request that this Court grant Defendant's Motion to Suppress.

Date: June 16, 2005

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true copy of the foregoing document was served by U. S. Mail this 16th day of June, 2005, upon the following counsel of record:

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E-5.05 Confidentiality

The information disclosed to a physician during the course of the relationship between physician and patient is confidential to the greatest possible degree. The patient should feel free to make a full disclosure of information to the physician in order that the physician may most effectively provide needed services. The patient should be able to make this disclosure with the knowledge that the physician will respect the confidential nature of the communication. The physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by law. The obligation to safeguard patient confidences is subject to certain exceptions which are ethically and legally justified because of overriding social considerations. Where a patient threatens to inflict serious bodily harm to another person or to him or herself and there is a reasonable probability that the patient may carry out the threat, the physician should take reasonable precautions for the protection of the intended victim, including notification of law enforcement authorities. Also, communicable diseases and gun shot and knife wounds should be reported as required by applicable statutes or ordinances.

H-175.973 Medicare Investigation Search and Seizure Process

(1) It is the policy of our AMA that: (1) no duly authorized law enforcement or legal agency conduct any unannounced search of physicians' offices or seizure of records without observance of appropriate legal procedures;

(2) should unannounced search and seizure procedures be warranted in emergency situations based on clear and immediate threats to the lives or physical well-being of patients or the general public, such searches/seizures be conducted within the following parameters: (a) the search and/or seizure shall be conducted in a non-threatening and thoroughly professional manner; (b) the search and/or seizure shall not disrupt patient care; (c) the search and/or seizure shall be conducted in a manner to avoid publicity injurious to a physician's practice and professional reputation until all facts are known and culpability, if any, can be proven;

(3) When an episode occurs whereby a governmental agency disrupts the daily activities of a physician's office in the process of investigating alleged fraud and abuse activities, that such episodes be reported to the Division of Private Sector Advocacy for tracking purposes and to assist the involved/affected physician(s); and.

(4) If abusive practices of the investigative agency are noted, the AMA will inform the Department of Justice of those tactics.

H-175.977 Disruptive Visits to Medical Offices by Government Investigators and Agents

Our AMA: (1) supports legislation and/or other appropriate means to ensure that State and Federal investigators, and/or agents, give a physician written notice prior to a visit to a medical office, so that such visit may be scheduled upon mutual agreement at a time when patients are not present in the medical office; (2) in any circumstances which lawfully permit a visit to a medical office without notice, such as a search warrant, arrest warrant or subpoena, investigators and/or agents should be required to initially identify themselves to appropriate medical staff in a quiet and confidential way that allows the physician an opportunity to comply in a manner that is least disruptive and threatening to the patients in the medical office; and (3) encourages physicians to report incidents of inappropriate intrusions into their medical offices to the AMA's Office of the General Counsel and consider development of a hotline for implementation.