Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Drug Enforcement Administration Reporting to the National Practitioner Data Bank

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Inspector General

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OFFICE OF INSPECTOR GENERAL

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This report was prepared by Alan Levine, Senior Program Specialist, under the direction of Mary Beth Clarke, Staff Director, Planning and Coordination Staff.

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To review the Drug Enforcement Administration reporting of adverse actions to the National Practitioner Data Bank.

BACKGROUND

Hospitals and other health care organizations use the National Practitioner Data Bank (Data Bank) to help with employment background checks of health care practitioners. The Data Bank includes records of malpractice payments and adverse actions taken against health care practitioners. Under current policy the Drug Enforcement Administration is required to report to the Data Bank health care practitioners who have had their Controlled Substance Act registration number revoked or suspended because of violations of this law.

FINDING

This study found that the Drug Enforcement Administration was not reporting to the Data Bank practitioners who voluntarily gave up their registration number when confronted with a potential adverse action against them. According to Drug Enforcement Administration data, in 1994 and 1995 a total of 509 and 486 practitioners, respectively, voluntarily gave up their licenses rather than "show cause."

RECOMMENDATION

We recommend that the Drug Enforcement Administration and Data Bank officials work together to inlcude "voluntary withdrawals" as part of adverse action reporting to the Data Bank.

The Administrator of the Health Resources and Services Administration, who is responsible for the Data Bank, agreed.

PURPOSE

To review the Drug Enforcement Administration reporting of adverse actions to the National Practitioner Data Bank.

BACKGROUND

National Practitioner Data Bank

The National Practitioner Data Bank (Data Bank) was established by the Health Care Quality Improvement Act (Act) of 1986 as a result of congressional interest in improving the quality of medical peer review. The Data Bank would serve as a clearinghouse or resource to assist hospitals, State licensing boards, and other health care entities in conducting investigations of the qualifications of the health care practitioners they wish to hire, license, or to whom they wish to grant membership or clinical privileges.

The Act specified the types of information that had to be reported to the Data Bank. The Data Bank was to include medical malpractice payments, adverse actions taken against practitioners by hospitals and other health care entities, and sanctions taken against practitioners by professional societies and State medical boards. Although the statute required such reporting in the private sector, reporting by Federal agencies with health care programs, such as the Veterans Administration, Department of Defense, and Department of Health and Human Services (HHS) was optional. However, the law also provided that the Drug Enforcement Administration (DEA) should participate under a memorandum of agreement with HHS, which would operate the Data Bank.

The Data Bank, which became operational in September 1990, is operated by the Systems Research and Applications Corporation under contract to the Public Health Service (PHS). As of March 31, 1996, it contained 104,087 medical malpractice reports and 23,177 adverse action reports involving health care practitioners. A small number of these adverse action reports include DEA sanctions against doctors. Due to the fact that DEA had not submitted any reports since January 1995, PHS officials were concerned and informally asked the Office of Inspector General (OIG) to review the matter.

Reporting by the Drug Enforcement Administration

In order to practice medicine in a particular State, a doctor must be licensed by that State's medical board. Such licensure includes the authority to dispense regular prescription drugs. However, some drugs are seen as having potential for abuse apart from their use for bona fide medical purposes, and may not be prescribed without an

additional form of licensure. These drugs are called "controlled substances" and are regulated by the Controlled Substance Act of 1970, which classifies them into five categories (or "schedules"), according to their potential for abuse. In order to prescribe or dispense these drugs, a doctor, or other State licensed health care practitioners, must obtain (and periodically renew) a Federal Drug Enforcement Administration registration number, technically called a "Certificate of Registration." In addition, some States themselves require a license (i.e. "controlled substance registration") separate from the medical license for controlled substance authority; other States do not have this requirement. In these States, controlled substance authority is part of the medical license. Separate DEA registrations, and appropriate State authorizations, are required for each State in which a practitioner maintains a primary place of business.

As of October 1995, DEA had registrations for 825,000 health care practitioners (including physicians, dentists, podiatrists, veterinarians, optometrists, and mid-level practitioners). Registration costs practitioners $210 and is valid for 3 years. The DEA makes available the names of all registered practitioners to the public through the National Technical Information Service, which is part of the Department of Commerce.

Memorandum of Agreement

Under a memorandum of agreement between DEA and HHS, DEA is to routinely report sanctioned practitioners to the National Practitioner Data Bank. The agreement calls for reporting all actions involving the denial, suspension or revocation of a registration number. This memorandum of agreement is based on Section 432(c) of the Health Care Quality Improvement Act which states that the HHS Secretary and the Administrator of DEA shall enter into a memorandum of agreement to provide for:

> ...the reporting by the Administrator to the Secretary of information respecting physicians and other practitioners whose registration to dispense controlled substances has been suspended or revoked under section 304 of the Controlled Substances Act.

The DEA does not report such actions to other authorities, such as State medical licensing boards or the Federation of State Medical Boards[1]. However, suspensions or revocations are published in the Federal Register; consequently, medical boards, hospitals, and other health care entities can learn about such actions through the Federal Register.

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[1]*An organization representing all State medical licensing boards. It maintains its own data base on adverse actions taken by State medical licensing boards.*

FINDING

The Drug Enforcement Administration Does Not Report Practitioners Who Voluntarily Surrender Their Certificate Of Registration

The DEA takes action to revoke or suspend a DEA registration number when a practitioner violates the Controlled Substance Act of 1970 (e.g., improperly selling controlled drugs). The DEA also takes such action when a practitioner is sanctioned by a State licensing authority or law enforcement agency (e.g., State medical board revoking a license for a physician who sexually abused patients).

When DEA takes action against a registrant for violation of the Controlled Substance Act, several courses of action are available. The DEA may issue an Order to Show Cause why DEA should not revoke, suspend, or deny a practitioner's registration. In this case, if a hearing is requested the matter is heard by an Administrative Law Judge whose recommendation is forwarded to the Deputy Administrator. The Deputy Administrator renders all final determinations whether a hearing is requested or not. The Final Order, which may or may not be revocation or denial, is then published in the Federal Register. The registrant may appeal the final ruling to the U.S. Circuit Court of Appeals. As an alternative to the Show Cause Order, DEA may ask the registrant to voluntarily surrender his or her controlled substance registration. In these instances, the registrant is advised that he/she has a right to a hearing and that the surrender is voluntary. When health care practitioners voluntarily give up their registration number, they complete Form Number 104.

According to both PHS and DEA officials, since September 1990, when the Data Bank opened, DEA has reported a total of about 150 actions to the Data Bank. However, according to DEA, it annually sanctions about three times the number of providers reported to the Data Bank. These sanctions are not reported because they involve health care providers who "voluntarily" gave up their DEA registration number, i.e., they signed Form Number 104. According to DEA data, in 1994 and 1995 a total of 509 and 486 practitioners, respectively, voluntarily gave up their license rather than "show cause."

Voluntary Surrender and Reporting by Medical Boards and Others

Although the memorandum of agreement between DEA and HHS, as well as Section 432 of the Health Care Quality Improvement Act, indicate that only DEA revocations and suspensions must be reported, other sections of the Act deal differently with the "voluntary surrender" issue. Section 422 of the Act requires medical boards to report:

> ...a description of the acts or omissions or other reasons (if known) for the revocation, suspension, or surrender of license, and such other information respecting the circumstances of the action or surrender as the Secretary deems appropriate...

Section 423 states that health care entities (i.e., hospitals, health maintenance organizations) must report each professional review action that adversely affects the clinical privileges of a physician for a period of longer than 30 days including the surrender of clinical privileges under the following circumstances:

> ...while the physician is under an investigation...or in return for not conducting such an investigation...

According to the House report on this legislation, Congress intended that:

> The purpose of requiring reports even for circumstances in which physicians surrender their privileges is to ensure that health care entities will not resort to "plea bargains" in which a physician agrees to such a surrender in return for the health care entity's promise not to inform other health care entities about the circumstances of the physician's surrender of privileges. While such agreements may serve the immediate self-interests of the two parties involved, they may jeopardize the health and safety of future patients...

Clearly, congressional intent seems to warrant DEA reporting of "voluntary withdrawals."

DEA Position on Increased Reporting

In discussions about the reporting of "voluntary withdrawals," DEA officials have indicated a willingness to report such actions, provided the reporting could be accomplished by electronic tape or hard copy printout. The DEA also agreed to revise the memorandum of agreement to include the reporting of "voluntarily withdrawals" provided the increased reporting can be accomplished by either of these methods.

RECOMMENDATION

Data Bank Officials Should Work With The Drug Enforcement Administration To Expand Reporting To Include Voluntary Withdrawals.

In order to assure that the Data Bank maintains as comprehensive a data base as possible, Data Bank officials should work with DEA to expand DEA reporting. Such reporting would include only those voluntary withdrawals that are the result of misconduct. For example, it should exclude those health care providers who voluntarily give up their DEA registration when they retire in order to avoid registration costs.

Expansion of DEA reporting will provide credentialling and hiring officials with additional information with which to evaluate prospective employees.

Since the memorandum of agreement between HHS and DEA does not now require the reporting of voluntary withdrawals, the agreement should be modified accordingly. The agreement should specify which voluntary withdrawals are reportable and those that are not.

COMMENTS

The HRSA concurred with the recommendation in the draft report and indicated that HRSA and DEA will work together on reporting issues.

A copy of the HRSA response is included as Appendix A to this report.

APPENDIX A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and
Services Administration
Rockville MD 20857

DEC 18 1996

TO: Inspector General, DHHS

FROM: Deputy Administrator

SUBJECT: OIG Draft Report: "Drug Enforcement Administration Reporting to the National Practitioner Data Bank," OEI-12-96-00160

In accordance with your September 6 request, HRSA has reviewed the subject draft report and has the following comments.

OIG Recommendation

Data Bank Officials should work with the Drug Enforcement Administration to expand reporting to include voluntary withdrawals.

HRSA Comments

HRSA agrees that Data Bank officials should work with staff from DEA to determine the best way to provide the Data Bank's querying entities with access to DEA reports. Data Bank officials will meet periodically with DEA staff to ensure that current reporting requirements, as outlined in the current memorandum of agreement (MOE), are fully met. In addition, at these periodic meetings, Data Bank and DEA staff will discuss other reporting possibilities and ascertain whether the current MOA should be expanded. I have asked for a status report, from the Division of Quality Assurance, BHPr, concerning current implementation of the MOA and the need to revise or amend it.

John D. Mahoney