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Report to the Chairman, Subcommittee on National Economic Growth, Natural Resources and Regulatory Affairs, Committee on Government Reform, House of Representatives

November 2000

NATIONAL PRACTITIONER DATA BANK

Major Improvements Are Needed to Enhance Data Bank's Reliability



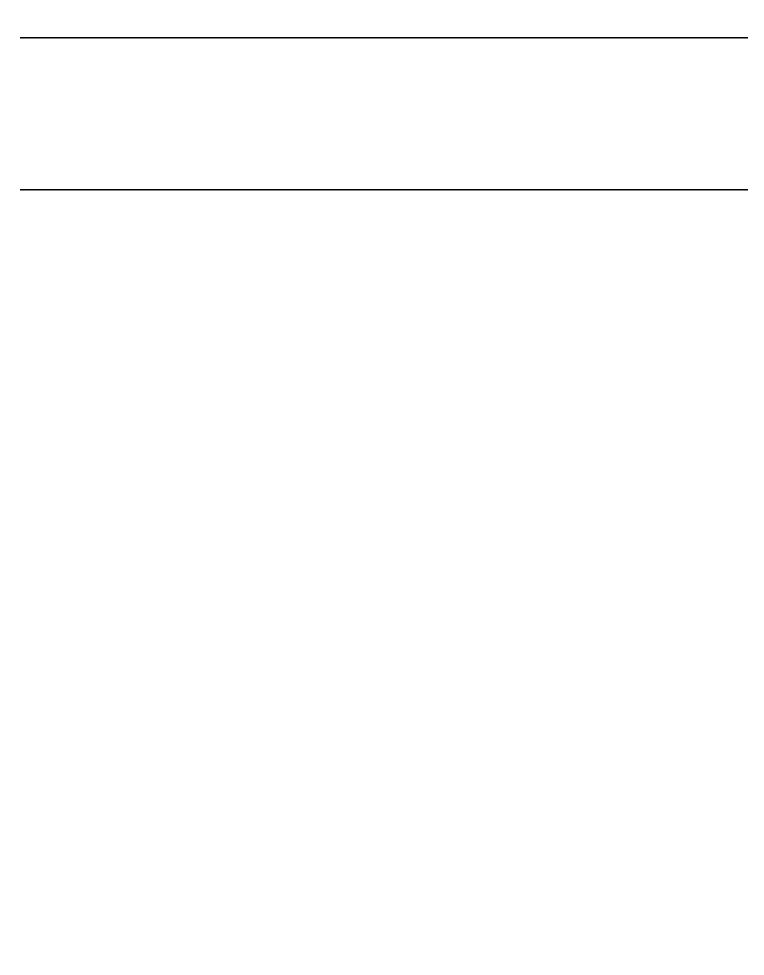


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Abbreviations

DEA	Drug Enforcement Administration
DFO	Division of Financial Operations
EFT	electronic funds transfer
HIPDB	Healthcare Integrity Protection Data Bank
HHS	Department of Health and Human Services
HHS/OIG	HHS/Office of Inspector General
HRSA	Health Resources and Services Administration
NAIC	National Association of Insurance Commissioners
NPDB	National Practitioner Data Bank





United States General Accounting Office Washington, D.C. 20548

November 17, 2000

The Honorable David M. McIntosh Chairman, Subcommittee on National Economic Growth, Natural Resources and Regulatory Affairs Committee on Government Reform House of Representatives

Dear Mr. Chairman:

To address concerns that states were hampered in their ability to protect the public from incompetent health care practitioners who cross state lines to continue the practice of medicine, the Health Care Quality Improvement Act of 1986 authorized the Secretary of Health and Human Services (HHS) to create the National Practitioner Data Bank (NPDB). Administered by HHS' Health Resources and Services Administration (HRSA), NPDB is the nation's only central source of information on physicians, dentists, and other health care practitioners who either have been disciplined by a state licensing board, professional society, or health care provider or have been named in a medical malpractice settlement or judgment. Hospitals and other health care providers periodically access NPDB, for a fee, to obtain information on practitioners who are currently on staff, under contract, or who have applied for clinical privileges. Because NPDB information can affect a practitioner's reputation and livelihood, the integrity of the data bank's information has been of great concern.

Since its beginning in 1990, questions have arisen about NPDB's operational efficiency and effectiveness. We studied NPDB's early development and recommended operational and security-related improvements. HRSA officials responsible for ensuring that the data bank has comprehensive information have questioned whether medical malpractice insurers and health care providers report all practitioners, as required. Officials from HHS' Office of Inspector General (HHS/OIG), who have studied and reported on the data bank, determined that a relatively

¹P. L. 99-660, title IV.

²Information System: National Health Practitioner Data Bank Has Not Been Well Managed (GAO/IMTEC-90-68, Aug. 21, 1990), Practitioner Data Bank: Information on Small Medical Malpractice Payments (GAO/IMTEC-92-56, July 7, 1992), and Health Information Systems: National Practitioner Data Bank Continues to Experience Problems (GAO/IMTEC-93-1, Jan. 29, 1993).

small number of disciplinary actions were reported by hospitals and other health care providers and recommended that HRSA do more to address potential underreporting. In addition, various organizations representing the health care industry have periodically questioned the accuracy of information submitted to NPDB. The industry has also questioned the appropriateness of fees charged to access data and HRSA's use of these fees. Accordingly, you asked that we (1) assess HRSA's efforts to address potential underreporting to the data bank, (2) evaluate the accuracy, completeness, and timeliness of NPDB data, and (3) assess the adequacy of internal controls over user fees and expenditures to determine whether these fees are set at the appropriate level.

To address issues related to underreporting, we reviewed HRSA's operational and research plans for NPDB, related studies and documentation, and interviewed officials from HRSA, HHS/OIG, and selected health care industry representatives. To assess the accuracy, completeness, and timeliness of reported data, we worked with HRSA officials and chose September 1999 as a typical reporting period. We analyzed the reports submitted to NPDB during that month. Additionally, we obtained and analyzed information from NPDB on 34 practitioners who were reported to NPDB during September 1999. Finally, to assess the adequacy of internal controls over user fees and expenditures, we interviewed HRSA officials to understand how NPDB's user fees are determined, collected, and disbursed. We also reviewed applicable laws, regulations, and other guidance concerning user fees, and tested a sample of the data bank's disbursements made between October 1994 and May 2000. We conducted our audit work between January 2000 and September 2000 in accordance with generally accepted government auditing standards. (See app. I for more detailed information on our scope and methodology.)

Results in Brief

Although HRSA has long been concerned that underreporting weakens NPDB's reliability, steps for addressing such issues are not part of the agency's strategic plan. As a result, HRSA's efforts to quantify or minimize underreporting have been unsuccessful. For example, the agency has focused on the underreporting of malpractice payments even though HHS/OIG and HRSA-sponsored studies conclude that underreporting of clinical privilege restrictions by hospitals and other health care providers is a more pressing issue. Industry experts also agree, pointing out that disciplinary actions taken by health care providers and states are better indicators of professional competence than medical malpractice. However,

HRSA has made little progress in addressing suspected underreporting by health care providers. HRSA officials said that additional resources and skills are needed to monitor and sanction nonreporters effectively. Also, HRSA has not implemented a 13-year-old law that expanded NPDB to include information on nurses and other health care practitioners. As a result, disciplinary actions taken against nurses and other practitioners are not reported to NPDB, despite these individuals' increasing importance in the delivery of health care.

Problems that we identified in the data submitted to NPDB during September 1999 raise concerns about the effectiveness of HRSA's management of the data bank and of the two mechanisms—practitioner notification and dispute resolution—that are intended to ensure the quality of reported information. We identified problems particular to each of the three types of reports we reviewed. The data in medical malpractice payment reports—representing about 80 percent of the information in NPDB—generally did not meet HRSA's criteria for completeness. For example, over 95 percent of the medical malpractice reports we reviewed did not note whether the standard of patient care had been considered when the claim was settled or adjudicated. Further, our analysis of 252 reports of state licensure actions revealed that about 30 percent were submitted late and 11 percent contained inaccurate or misleading information on the severity or number of times practitioners had been disciplined. We also found inaccurate information in about one-third of the 79 clinical privilege restriction reports we reviewed.

Finally, our review disclosed that HRSA has not adequately examined whether the level of user fees used to finance NPDB operations is appropriate. HRSA does not have a plan that projects cash flows such as revenue, disbursements, and capital investments. Such a plan is needed to determine if the level of fees is appropriate and if HRSA's long-standing policy of maintaining a cash balance of 4 to 6 months of operating expenses is still reasonable. HRSA has not reassessed the amount needed to cover operating expenses since 1994. As of the end of fiscal year 1999, it had a \$6.8 million cash balance. We also found that controls over NPDB transactions did not ensure that all collections were received and that disbursements were for authorized purposes. For example, HRSA and HHS' Division of Financial Operations (DFO), which performs the accounting functions, do not have adequate controls to ensure that all assessed user fees are collected and properly recorded in HRSA's general ledger. HRSA and DFO also could not ensure that user fees collected electronically presently about 30 percent of NPDB's receipts—were properly allocated

between NPDB and another data bank the agency also manages. Additionally, we found that controls over disbursements were not effective, as supporting documentation was sometimes missing or inadequate.

We are making several recommendations to the Secretary of HHS, the Administrator of HRSA, and the Director of HHS/DFO to improve both the operation and the financial management of the data bank. In its written comments on a draft of this report, HHS concurred with our recommendations to improve compliance monitoring and enforcement, allocate user fees appropriately, and develop criteria for the narrative section of disciplinary action reports. HHS also described actions it is taking or plans to take. HHS did not concur with our specific recommendations to improve the reliability of reported information and to strengthen its internal controls over NPDB user fee collections and disbursements. However, we believe that actions on these recommendations are necessary to enhance the accuracy, completeness, and timeliness of NPDB's information and to improve internal controls and financial operations.

Background

In 1986, the Congress found that there was a need nationally to restrict the ability of incompetent practitioners to move between states without disclosure or discovery of their professional histories. Moreover, it was determined that states and individual organizations, acting independently, might not be able to do so. While there were several private and nonprofit organizations that collected data on state disciplinary actions, these groups did not have access to information either on the disciplinary actions taken by health care providers or on medical malpractice cases. As a result, the Congress created NPDB as the nation's central source of such information on health care practitioners.

HRSA has federal oversight responsibility for NPDB. As such, it has developed rules and regulations for reporting information and accessing NPDB. The instructions for reporting practitioner information to NPDB and for accessing the data bank, which is known as querying, are spelled out in the *NPDB Guidebook*, updated January 1999. HRSA is also responsible for ensuring health care industry compliance with reporting and querying requirements. A private contractor operates the data bank for HRSA.³

In 1988, HRSA commissioned a group of health care industry representatives and advocates to provide continual advice to its contractor on NPDB operational issues. This group, the NPDB Executive Committee, includes various health care industry representatives from organizations such as accrediting bodies and licensing boards, hospitals and other providers, malpractice insurers, professional societies, and others. With the advice of the NPDB Executive Committee, HRSA and its contractors developed and customized the software applications used to collect reports on practitioners and respond to user queries.

The Health Care Quality Improvement Act of 1986 also established criteria for reporting practitioners to NPDB. The requirements for reporters—malpractice insurers, health care providers, state licensing boards, and federal agencies—essentially parallel their areas of responsibility. Entities such as insurance companies must report practitioners on whose behalf medical malpractice payments are made. State licensing boards must report practitioners whom they have disciplined. Health care providers such as hospitals and health plans must report disciplinary actions restricting practitioners' clinical privileges for more than 30 days. In addition, professional societies such as the American Medical Association and the American Dental Association must report actions that adversely affect a practitioner's membership in the society. Finally, the law directed HRSA to negotiate Memorandums of Understanding with selected federal

³Several different private contractors have operated and maintained NPDB since it began operations Sept. 1, 1990. The current contractor has been operating NPDB since June 1995.

⁴According to the *NPDB Guidebook*, state licensing boards are required to report disciplinary actions such as revocations, suspensions, reprimands, and fines associated with license restrictions.

agencies, outlining the terms for reporting practitioners that they employ, insure, or regulate.⁵

Time frames for reporting the required information are set in the law, regulation, or *NPDB Guidebook*. Medical malpractice payments must be reported to NPDB within 30 days of the date of the initial payment. Health care providers that report electronically have up to 15 days to report simultaneously to NPDB and the applicable state licensing board. Providers submitting paper reports have up to 15 days to send reports to the applicable state licensing board. State boards have 15 days to forward paper reports to NPDB. State licensing actions against practitioners must be reported within 30 days. Professional societies must report actions taken against practitioners' memberships within 15 days. Some federal agencies, in their Memorandums of Understanding with HRSA, also agreed to report malpractice payments and disciplinary actions within 30 days of the payment or action.

Since 1986, NPDB has been expanded to include additional information and other categories of health care practitioners who must be reported. The Medicare and Medicaid Patient and Program Protection Act of 1987, as amended, requires that states have a system for reporting licensure actions taken against nurses and other state-licensed health care practitioners such as chiropractors, emergency medical technicians, and physical therapists to NPDB. Since 1997, under an agreement among the HHS/OIG, HRSA, and the Health Care Financing Administration, practitioners who are excluded from participation in the Medicare and Medicaid federal health care

⁵The law specifically directed HRSA to negotiate Memorandums of Understanding with the Department of Defense, the Department of Veterans Affairs, and the Drug Enforcement Administration (DEA). HRSA also has agreements with the Department of Transportation (U.S. Coast Guard), the Bureau of Prisons, and with the U.S. Public Health Service for reporting its physicians and dentists, including those working in community health centers or the Indian Health Service.

⁶P. L. 100-93.

programs due to fraudulent or abusive activities or who default on federal loan agreements are also reported to NPDB.⁷

The law also has provisions regarding access to and use of information contained in the data bank. Hospitals are required to query NPDB whenever a practitioner applies for clinical privileges and every 2 years for practitioners already on staff. State licensing boards, professional societies, and certain other types of health care providers are permitted to query but are not required to do so. Individual practitioners can query NPDB but only to obtain information on themselves. Under current law, malpractice insurers, advocacy groups, and the public cannot query NPDB; however, selected information that does not identify individual practitioners is available for purchase in a public use data file.

NPDB's operations are to be completely funded by the fees charged to users. Fees are imposed for each practitioner's name queried and must be sufficient to cover the cost of collecting reports and releasing query information. HRSA is responsible for setting these fees. In fiscal year 1999, HRSA collected about \$14 million in user fees, disbursed about \$12 million for NPDB expenses, and had a cash balance of \$6.8 million.

⁷The HHS/OIG's exclusion list provides information on individuals and organizations that are excluded from participation in Medicare, Medicaid, and other federal health care programs because of criminal convictions related to Medicare or state health programs, patient abuse or neglect, felony convictions related to controlled substances, health care fraud, and other criteria such as defaulting on federal loans and license revocations. As of January 1999, there were more than 15,000 individuals and entities excluded from program participation.

⁸Practitioners who query the data bank for information about themselves are charged \$10. They complete an Internet-based form that can be accessed from NPDB's home page. The completed form must be notarized and mailed to the NPDB contractor for processing.

⁹Plaintiffs' attorneys or plaintiffs acting on their own behalf may query NPDB only if they can independently prove that a hospital did not perform the query, as required by law, and a medical malpractice suit against that hospital, naming the specific practitioner among the defendants, has been filed in court. However, they may not query for information when suing practitioners.

¹⁰Users who submit queries via the Internet are charged \$4 per practitioner name, while those submitting queries on diskette are charged \$7 per practitioner.

¹¹The Secretary of Health and Human Services approves user fees for NPDB queries and publishes these fees periodically in the *Federal Register*.

Civil penalties can be assessed for nonreporting and for unauthorized use of NPDB information. Entities failing to report medical malpractice payments can be assessed up to \$11,000 for each unreported payment. HRSA can also impose penalties of up to \$11,000 for each instance of unauthorized access or improper distribution of NPDB information. There are no financial penalties for states, health care providers, or federal agencies that do not report practitioners to NPDB. HRSA officials said that several organizations have been fined for unauthorized access but none for not reporting to the data bank. HRSA cannot penalize organizations that do not report the required information on time.

Efforts to Address Underreporting Have Been Unsuccessful

Although HRSA has long suspected that some organizations do not report practitioners as required, the agency has not included steps for addressing underreporting in its strategic plan, nor has it taken a systematic approach to the problem. Most of HRSA's efforts to address underreporting have focused on medical malpractice insurers, while HHS/OIG and HRSAsponsored studies have concluded that underreporting of clinical privilege restrictions by hospitals and other health care providers is a larger and more pressing issue. Moreover, experts widely agree that disciplinary actions taken by state licensing boards and health care providers are better indicators of professional competence than malpractice settlements. Yet, very little has been done to address suspected underreporting among health care providers. Further, disciplinary actions taken against nurses and other health care practitioners are not being reported to NPDB because HRSA has not yet implemented the law. According to HRSA's management, additional staff and resources would be needed for the agency to identify and take effective action against organizations suspected of underreporting to the data bank.

Medical Malpractice Underreporting is a Long-Standing Problem

Although HRSA has been concerned that malpractice payments are underreported, it has not been able to determine the magnitude of the problem despite many years of effort. Medical malpractice payments can be underreported in two ways, neither of which has been successfully quantified. First, agency officials believe that some insurers may be using a technicality in NPDB's reporting requirements to avoid reporting some practitioners. Second, agency officials believe that some insurers and self-insured organizations such as HMOs and other health plans should report to NPDB but do not. However, HRSA has not yet identified or fined any organizations for failing to report the required information. Agency officials told us that they are reluctant to impose fines because they believe that the

cost of levying and collecting civil penalties often exceeds the \$11,000 maximum amount that can be assessed.

Soon after NPDB began operating in 1990, HRSA officials became aware that under the data bank's regulations, some practitioners, who may have committed malpractice, were not being reported because of what has become known as the "corporate shield." NPDB regulations require that only the practitioners named in final malpractice settlements be reported to the data bank. The corporate shield occurs when individuals filing malpractice claims remove the practitioner's name from the claim, leaving only the hospital or another corporate entity identified as the responsible party. When this happens, no report is submitted to NPDB. HRSA officials believe that practitioners who have committed malpractice use the corporate shield to avoid being reported. However, they have not been able to quantify the extent to which the corporate shield is used for such purposes. In addition, the agency has not found a means of successfully addressing this issue in a way that would also have the support of industry representatives on NPDB's Executive Committee, who could facilitate compliance by persuading member organizations to adopt this policy change.

In December 1998, HRSA proposed changing NPDB's malpractice payment reporting regulations. The proposal would have required that insurers report all practitioners for whose benefit a payment is made, including those practitioners who might not have been named in the final settlement or even in the initial malpractice claim. The health care industry—including those organizations on NPDB's Executive Committee—overwhelmingly opposed the proposal, arguing that it would interfere with settlement negotiations between the insurer and the claimant. The industry also argued that reporting all initially named practitioners would deny due process to those not found liable by the court. HRSA subsequently withdrew the proposal and initiated other strategies to solve this problem while working to gain NPDB Executive Committee support for a change in medical malpractice reporting requirements.

HRSA officials have begun to work more closely with the NPDB Executive Committee to obtain its input and gain consensus before finalizing a new proposal. Two proposals have recently emerged from this collaboration and will be circulated within HRSA and the full Executive Committee for comment. The first proposal would require insurers to report to NPDB the names of corporations and individual practitioners named in malpractice settlements or judgments. HRSA officials told us that by collecting

information on corporations, they will have more complete data on the total number of claims settled or adjudicated, which will help them identify specific instances when the corporate shield has been used. However, they acknowledge that the proposal to report corporations does not fully solve the problem.

The second proposal would permit peer review organizations to determine which practitioners involved in malpractice settlements should be reported to NPDB. The Department of Defense and the Department of Veterans Affairs—two large federal health care providers—both have peer review processes for reporting practitioners to NPDB. As outlined in their Memorandums of Understanding with HRSA, only those identified by their agencies' peer review processes as responsible for injuring a patient or violating standards of patient care are reported. However, HRSA officials told us that they are presently concerned about the limited quantity and timeliness of reports that are submitted following the federal agencies' peer review processes. Further, this proposed alternative might require congressional action because NPDB's authorizing legislation does not provide for peer review of malpractice settlements or specify that HRSA can use the fees it collects for queries to fund this activity.

In addition to these efforts to alleviate the use of the corporate shield, HRSA officials told us that, since early 2000, they have been trying to identify insurers that have paid medical malpractice claims but have not reported the involved practitioners to NPDB. Using malpractice claims data that insurance companies voluntarily report to the National Association of Insurance Commissioners (NAIC), the agency identified 41 insurers that reported payments to NAIC but not to NPDB. HRSA contacted these companies seeking explanations regarding the differences in the reported payments. As of September 2000, 17 of the 41 companies have adequately explained the discrepancies to HRSA. For instance, NAIC data, for some companies, reflect total payments made by their corporations combining payments made on behalf of individual practitioners with payments made on behalf of organizations. NPDB data only represent payments made on behalf of individual practitioners. Of the remaining 24 companies, 18 recognized their omissions and agreed to file the delinquent reports. The other six companies have not responded to HRSA's inquiries and have been warned by the agency that they will be reported to HHS/OIG for possible enforcement action.

Although HRSA has had some success in identifying nonreporters using NAIC data, agency officials acknowledged that these data have some

significant limitations. NAIC's medical malpractice data are not comprehensive because companies report this information voluntarily. Moreover, they do not include payments made by self-insured organizations, such as health maintenance organizations and other health plans that do not report to NAIC. Also, as previously noted, NAIC data combine the payments made on behalf of practitioners with those made on behalf of institutions. Because HRSA could not independently reconcile NAIC and NPDB data, agency officials had to rely on insurers' explanations as to whether reports should have been submitted or not.

Underreporting of Clinical Privilege Restrictions Is Another Long-Standing Concern

HRSA and the HHS/OIG have been concerned about the relatively low number of reported clinical privilege restrictions since NPDB's early years of operation. While early estimates projected that as many as 10,000 clinical privilege restrictions would be reported annually, fewer than 9,000 reports were submitted from 1990 through 1999. Concerned with the contrast between the early estimates and the number of clinical privilege restrictions being reported, HRSA management asked HHS/OIG and others to study the issue. HHS/OIG concluded that providers are more likely to report if there are penalties for nonreporting and recommended that HRSA seek legislative authority to fine nonreporting providers, comparable to its authority to fine malpractice insurers. Although HRSA generally concurred with HHS/OIG's July 1999 recommendation, the agency did not act on it until late July 2000.

HRSA officials acknowledge that the agency has not been successful in encouraging provider compliance with clinical privilege reporting requirements. HRSA officials believe that to improve compliance significantly, the agency needs more than the ability to fine providers. They noted that the states report licensure actions, as required, but providers' reporting of clinical privilege restrictions have always fallen far short of the agency's projections. Before NPDB began operations, the Public Health Service projected that about 5,000 clinical privilege restrictions would be reported annually. The American Medical Association estimated there would be as many as 10,000 reports per year. As of the end of calendar year 1999—after 9 years of operation—NPDB had received fewer than 8,600 clinical privilege restriction reports.

HRSA officials told us that the original estimates may have been too high and that, over time, changes in industry practices may have resulted in different approaches to disciplining practitioners. Industry representatives told us that hospitals now provide more monitoring and training to address performance problems than at the time the Public Health Service and the American Medical Association estimates were made. This new approach to disciplining practitioners may reduce the number of restrictions that hospitals impose for more than 30 days and thus reduce the number of individuals who would be reported to NPDB. NPDB's authorizing legislation does not require that the data bank collect information on practitioners targeted for special monitoring or training.

In July 1999, an HHS/OIG study recommended that HRSA seek authority to fine nonreporting providers. HRSA officials told us that in late July 2000, they asked HHS to pursue legislation allowing the agency to fine health care providers up to \$25,000 when specific instances of noncompliance are identified. However, HRSA does not currently have the authority to access the confidential peer review records that hospitals and other health care providers maintain on practitioner performance. HRSA officials told us that the agency would need this additional authority and staff skilled in investigating specific instances of noncompliance to monitor and sanction nonreporters effectively. Recognizing that additional funding and skilled staff might not be forthcoming, agency officials have begun to develop a compliance monitoring plan that less specialized personnel could perform. Agency officials said they are hopeful that the plan would be implemented in fiscal year 2001.

13-Year-Old Law Awaits Implementation

HRSA has not implemented a law passed in 1987 that would have significantly increased the information reported to NPDB. The Medicare and Medicaid Patient and Program Protection Act of 1987 directed the states to have systems of reporting licensure actions taken against nurses and other licensed health care practitioners. Today, nurses and other licensed practitioners play an even more important role in the provision of health care. The law was amended in 1990 to include state reporting of adverse actions taken by peer review and accrediting organizations against nurses and other practitioners. HRSA officials told us that they did not implement this law when NPDB began operating in 1990 because the agency lacked the funding to include information on these additional practitioners in the data bank. According to HRSA officials, the HHS General Counsel initially advised the agency that it could not impose user fees to cover the cost of collecting and disseminating this additional information, but it has since reversed that opinion.

By July 1998, HRSA had drafted reporting regulations and had modified the data bank's software to accommodate additional categories of

practitioners. Nonetheless, implementation was postponed pending start-up of a new fraud and abuse data bank, the Healthcare Integrity Protection Data Bank (HIPDB), which HRSA manages for HHS/OIG. 12 HRSA officials told us that they made this decision because, in their opinion, expanding NPDB at the same time the agency initiated HIPDB might have confused the data banks' users. For instance, some state actions, such as denied licensure renewals, are reported to both data banks. Other actions, such as denied initial licenses, are only reported to HIPDB.

Recognizing the potential burden and confusion that users might face, the Congress directed that duplicative reporting requirements be avoided. As a result, HRSA developed a single system for users to access both data banks. This Internet-based system became operational in November 1999 and by October 2000 was the only way authorized organizations could report to or query the data banks. With this system, users only need to report information once. Information is automatically distributed to one or both data banks, as appropriate. For example, state licensure actions taken against physicians and dentists are routed to both data banks, while actions taken against nurses and other licensed practitioners are presently routed only to HIPDB.

Currently, hospitals are not authorized access to HIPDB. As a result, they cannot obtain information on licensure actions that states take against nurses and other licensed practitioners. For instance, while the state of Illinois reports at least 15 such actions each month, hospitals cannot obtain that information from HIPDB. HRSA officials told us that they have suggested a technical modification to HIPDB's authorizing legislation that would allow hospitals to access the data bank. While this would provide hospitals access to information on licensing actions, we believe that this is only a partial solution because the actions taken by peer review and accrediting organizations are not reported to HIPDB.

¹²As authorized by the Health Insurance Portability and Accountability Act of 1996, HIPDB is a central source of information on final actions that states and courts have taken against individuals and companies found guilty of health care fraud or abuse. It contains data on health-care-related criminal convictions and civil judgments, as well as the names of individuals and companies excluded from participation in federal health programs. NPDB, on the other hand, collects information on individuals whose professional competence may be at issue.

¹³Individual practitioners, who can only access information about themselves, must submit their queries on paper.

HRSA officials told us that they support HHS/OIG's suggestion that NPDB and HIPDB be combined into a single data bank and are working with members of HHS/OIG General Counsel's office to develop a legislative proposal. However, work on the legislative proposal has just begun and, if enacted, may take several years before a combined data bank would be available to users. In the interim, HHS/OIG officials have informed HRSA that they are concerned that the agency might again delay implementing the 1987 law. HRSA management officials told us that aside from seeking statutory changes—allowing hospital access to HIPDB and combining the two data banks—they do not have any other immediate plans for including actions taken against nurses and other practitioners in NPDB.

Weaknesses in NPDB Data Limit Their Usefulness

The quality of some of the reports we reviewed suggests weaknesses in the data bank's reliability. We found problems with each of three types of reports we analyzed—malpractice payments, state licensure actions, and clinical privilege restrictions. Medical malpractice payment reports, which comprise 80 percent of the data bank, generally did not meet HRSA's criteria for completeness. We also found that reports from state licensing boards and health care providers were, at times, untimely, inaccurate, or submitted in duplicate, which made it appear that twice the number of disciplinary actions against a practitioner had been taken. Moreover, when mistakes were made, practitioners had difficulty getting the reported information corrected.

HRSA officials acknowledged that there are problems with the accuracy and completeness of the data and that they have been working with consultants to revise the way information reported to the data bank is coded. Agency officials said they are considering revisions to the coding scheme to improve the accuracy and completeness of reports. They have also begun working with the NPDB contractor to remove duplicate reports from the data bank. They also acknowledged that some reports are submitted late, but they have not sought the additional authority to fine late reporters. Agency officials also realize that practitioners can face difficulties in correcting reported information. However, they said that NPDB's practitioner notification and dispute resolution processes adequately address individual concerns while maintaining the data bank's integrity.

Test Results Revealed Lags and Gaps in NPDB Submissions

To evaluate the reliability of NPDB information, we obtained electronic copies of the 1,645 reports submitted to the data bank during September 1999. In general, we analyzed the timeliness of reports by comparing the dates they were submitted with NPDB's reporting time frames. We assessed the completeness of reports by comparing information in them with NPDB's criteria for the items of information that should be reported. Because NPDB is the only central source for much of the information it contains, we assessed accuracy by determining the internal consistency of the narrative and coded information in individual reports. (See app. I for a more detailed description of the types of reports submitted in September 1999.)

As figure 1 indicates, nearly 80 percent of the reports submitted to NPDB during September 1999 were related to medical malpractice payments. This percentage is somewhat comparable to the data bank's cumulative totals. Since 1990, almost 173,000 out of approximately 228,000 NPDB reports—or 76 percent—involved malpractice.

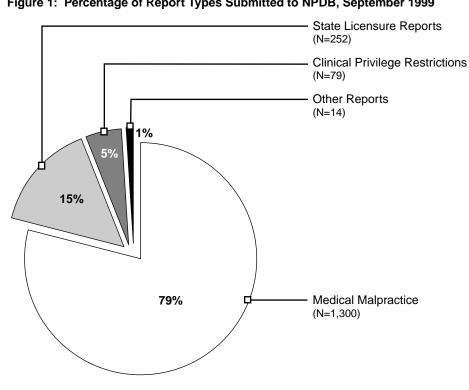


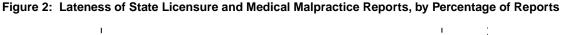
Figure 1: Percentage of Report Types Submitted to NPDB, September 1999

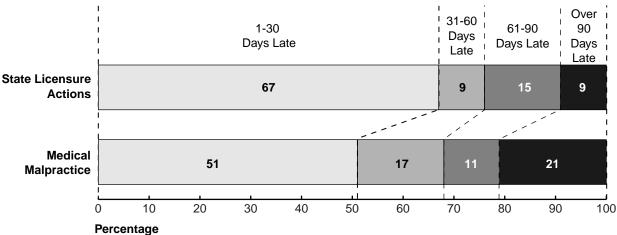
Source: GAO analysis of September 1999 NPDB reports.

Clinical privilege restrictions comprise 5 percent of the September 1999 reports and less than 4 percent of NPDB's cumulative totals. On average, fewer than 1,000 such reports are submitted annually. HRSA officials estimate that about 60 percent of the nation's hospitals had never reported a practitioner to NPDB. Officials arrived at this figure by comparing the list of authorized reporters with those entities that have submitted at least one report to NPDB since it began operating in 1990. While the estimate may include entities that may no longer exist or that may have more than one authorization number, it appears that many of the nation's hospitals have never reported to NPDB.

Our analysis revealed weaknesses in the timeliness and currency of medical malpractice payment reports. About 25 percent (331) of the 1,300 malpractice reports received in September 1999 were not submitted to NPDB within 30 days of the initial payment, as required. On average, these reports were about 85 days late. About 30 percent (76) of the state

licensure reports submitted during September 1999 were late by an average of 61 days. As noted in figure 2, our analysis of these late submissions showed that one-third of state licensure reports and almost one-half of medical malpractice reports were 31 or more days late. We did not measure the timeliness of reports submitted by hospitals and other health care providers.¹⁴





Source: GAO analysis of 331 medical malpractice and 76 state licensure reports submitted to NPDB in September 1999.

HRSA does not track the timeliness of reports submitted and does not have the authority to sanction late reporters. Agency officials told us that penalizing late reporters may have a chilling effect on submissions.

The timely submission of information does not necessarily ensure that information about practitioners is quickly available. The malpractice payments reported in September 1999 involved incidents that occurred, on average, 4-1/2 years earlier. The median time was 4 years, which is not an

¹⁴Health care providers have two options for submitting reports to NPDB, with different reporting deadlines for each. Electronic submissions have a 15-day deadline, while paper submissions pass through the state licensing board and are allowed up to 30 days to reach NPDB. From the information we obtained from NPDB, we could not determine which reporting option was used. As a result, we could not measure the timeliness of clinical privilege restrictions.

unusual length of time to resolve malpractice claims. During the time it takes to resolve claims and report malpractice payment information, practitioners could move between states or change health care providers.

In addition to the lateness and dated nature of reported information, our analysis also revealed some delays in getting reports into NPDB. For 512 reports, or more than 30 percent of the September reports, we noted delays between the date the report was submitted to NPDB and the date that the information was incorporated into the data bank. These delays ranged from 5 days to more than 1 year. The median processing delay was about 13 days. HRSA officials were unaware of the lengthier delays. They explained the shorter delays by noting that, at times, organizations do not submit reports on the dates indicated. However, we could not determine how frequently reports had the wrong submission date and could not adjust our analysis to take this into consideration. Nonetheless, late and delayed reports can weaken NPDB's reliability as a mechanism for alerting others of potential problems with a practitioner's past performance.

HRSA officials told us that NPDB's new Internet-based reporting and querying system would alleviate processing delays by instantaneously incorporating submitted information into the data bank. As of October 1, 2000, the new Internet-based system became the primary means of reporting information to NPDB. However, instantaneous processing, without other improvements in the data bank's software controls, may exacerbate the problems of incomplete and inaccurate reporting that we found.

Malpractice Payment Reports Were Incomplete and Included Inappropriate Information We found that the usefulness of NPDB's medical malpractice data was further compromised by the data bank's acceptance of incomplete report submissions. We selected 250 of the 1,300 malpractice reports submitted in September 1999 for a more detailed review and found that only 1 met NPDB requirements for disclosing the circumstances associated with payments. The *NPDB Guidebook* recommends that narrative descriptions include at least seven items of information describing the events leading up to the medical malpractice claim. Such information can help users identify potential weaknesses or problems in a practitioner's past performance. Some items are descriptive, such as patient age, gender, and inpatient or outpatient status. However, others, such as the initial event or diagnosis and standard of patient care, relate more to the quality of practitioner performance. As table 1 shows, more than 95 percent of the malpractice reports in our sample did not mention whether the standard of patient care

had been considered when the claim was settled or adjudicated. Moreover, of those reports whose narrative mentioned that the standard of patient care had been considered, only one noted the actual determination.¹⁵

Table 1: Malpractice Reports Submitted to NPDB, by Items of Information Missing

Items of information	Number of reports missing information	Percentage of GAO sample	
Patient age	134	53.6	
Patient gender	108	43.2	
Patient type	199	79.6	
Initial event (procedure/diagnosis)	68	27.2	
Subsequent event	37	14.8	
Damages (medical or legal)	61	24.4	
Standard of patient care determination	239	95.6	

Source: GAO analysis of 250 reports.

HRSA officials acknowledged that medical malpractice reports are often incomplete and explained that reports are submitted electronically and are not manually screened before acceptance into the data bank. They explained that NPDB's software only checks for the presence of text in the narrative section of malpractice reports. It does not verify that all seven items of information are present. They also told us that NPDB contract staff do not routinely review the narratives and thus would not request additional narrative information, even if the narrative was incomplete or uninformative. NPDB contract staff only examine reports when there is a need to verify that a query has resulted in identifying the correct practitioner. If staff note obvious errors or questionable information, the reporting institution is contacted and, if necessary, asked to submit a corrected report. Contract staff are not authorized to change any of the information reported to NPDB.

¹⁵Our analysis did not reveal any substantive difference in the completeness of reports involving settlements compared with those involving court judgments.

¹⁶NPDB uses a matching algorithm that compares queries with information in the data bank. Before NPDB determines that it has matched a query with the correct practitioner, a certain level of information must be identical. If NPDB identifies a potential but not definite match, an NPDB contract staff member compares information to verify the match.

In addition to the problems of untimely and incomplete submissions, we also found that 71 of the 250 medical malpractice reports included patient and practitioner names in the narrative sections of the reports, in violation of NPDB reporting instructions. HRSA officials said that they were aware of the problem but had not found a cost-effective method for removing names. At one point, the NPDB contractor tested a "name-filtering" program that could be added to NPDB's software to detect and remove names inappropriately included in the narrative sections. However, the test was not successful because the program could not distinguish between individuals' names that should be removed and other names that could be included, such as those of institutions or street names. HRSA officials said they do not ask entities reporting information to NPDB to revise their submissions when names are included in the narrative.

Licensure Reports Were Inaccurate, Inconsistent, and Submitted in Duplicate

Our analysis of 266 licensure action reports, which includes 14 actions reported by the U.S. Drug Enforcement Administration (DEA) and professional societies, indicated additional weaknesses in NPDB's reliability. As table 2 shows, 24 of the 252 reports submitted by state licensing boards contained errors that could confuse or mislead querying organizations about the severity of sanctions imposed. These errors were related to the way sanctions were coded in the reports submitted by state licensing boards. For example, several reports indicated that practitioners' licenses had been restored or reinstated when, in fact, they had been placed on probation. Other reports indicated that practitioners had been reprimanded when, instead, restrictions had been placed on their licenses. Other reports did not contain sufficient detail in the narrative section for us to determine whether they had been coded accurately.

¹⁷NPDB classifies reports submitted by DEA and professional societies as licensure actions.

Table 2: Disciplinary Action Reports Submitted to NPDB

Source of reports submitted to NPDB	Miscoded	Detail insufficient to verify coding	Number in sample
State licensing boards	24	57	252
Health care providers (clinical privilege restrictions)	23	3	79
Professional societies	0	4	7
DEA	0	7	7
Total	47	71	345

Source: GAO analysis.

HRSA has not established criteria for the information that should be included in the narrative sections of state licensure reports. Our analysis of the reports submitted in September 1999 revealed considerable variation in the amount and quality of narrative information. Some reports included sufficient detail to indicate why practitioners were disciplined. Others, however, contained insufficient explanations of disciplinary actions. For example, 26 of the state licensure reports we reviewed were based on actions taken by another state. The narrative sections of more than one-half of these reports did not note which state initially took action or why. In theory, organizations querying NPDB should receive information from all the states that have sanctioned practitioners. However, if the initial action was reported late—as 30 percent of the state reports we reviewed were—or not at all, organizations querying NPDB might not be able to identify the appropriate state to contact to obtain additional information on the initial licensure action.

We also found reports that may have been inadvertently submitted twice to NPDB, making it appear as though practitioners had been disciplined more than once for the same offense in a relatively short time. We queried NPDB for information on four practitioners who were reported at least twice during September 1999 and found that the narrative sections of state licensure reports, in particular, lacked sufficient detail to determine whether they were duplicates or reports of separate actions taken against practitioners. For example, a state reported that a practitioner's license was surrendered twice within 1 week. The response we obtained to our query indicated that the second report had been erroneously submitted.

In another instance, a state reported issuing a public letter of reprimand because of the poor condition of a practitioner's medical records. Approximately 1 week later, the state submitted an identical report to

NPDB. The information we received in response to our query did not provide sufficient detail to determine if the practitioner had been reprimanded once or twice for poor recordkeeping. Although NPDB software routinely generates notices to practitioners who have been reported to NPDB, practitioners may not realize that a second report notification may indicate that a duplicate report had been submitted. HRSA officials informed us that they have directed the NPDB contractor to begin identifying and removing duplicate reports from the data bank during the next contract year.

Clinical Privilege Restriction Reports Were Miscoded and Included Inappropriate Information

As with state licensure action reports, the reports that hospitals and other health care providers submitted on clinical privilege restrictions also contained errors affecting the accuracy of NPDB information. We found coding errors in about one-third of the 79 clinical privilege restriction reports we reviewed. Several health care providers used codes that indicated licensure actions had been taken when, in fact, the practitioners' clinical privileges had been restricted. In another instance, a provider coded a report as though the practitioner's privileges had been restricted, while the narrative section stated that the application for privileges had been denied. While the narrative sections of clinical privilege reports generally contained sufficient information to discern which actions were taken, those purchasing copies of NPDB's public use file do not receive the narratives and thus might be misled about the severity of disciplinary actions taken against practitioners.

HRSA has not set criteria for the narrative sections of clinical privilege restriction reports but has been working with consultants to identify ways to improve the level of detail and consistency of reported information. A recently completed study recommended that HRSA revise NPDB's new Internet-based reporting format so that guidance specific to each type of disciplinary action is displayed as the reporter keys in the narrative information. For example, health care providers submitting reports on clinical privilege restrictions imposed due to alcohol or substance abuse would be instructed to include information in the narrative about the specific circumstances under which the practitioner displayed a substance abuse problem. Similarly, providers reporting practitioners whose privileges were restricted because of incompetence would be instructed to state specifically what the practitioner did or did not do.

HRSA officials told us that some of the study's recommended changes might be too detailed to implement. They said that, in the past, reporters

have tended to select the top few choices for coding actions and might not review an even longer list before selecting the most appropriate code. Furthermore, HRSA officials' analysis of the extensive use of the "not otherwise classified" category has led them to believe that some reporters prefer to be less specific when reporting practitioners to the data bank. As of December 31, 1998, 49 percent of the reports concerning disciplinary actions were coded as not otherwise classified, while 34 percent of the malpractice reports were so coded. HRSA officials said that they are reviewing the study's recommendations to determine which ones are feasible for implementation.

Controls Do Not Ensure Reporting Accuracy

HRSA officials cited practitioner notifications and the dispute resolution process as two control mechanisms that ensure the accuracy of information reported to NPDB. However, our analysis of reports submitted to the data bank and the results of our queries for information on particular practitioners suggest that these controls have not prevented erroneous information from remaining in the data bank once it is reported. As previously noted, there are instances—such as duplicate reports—when practitioners are notified but may not realize that the same information has been erroneously reported twice.

One NPDB Executive Committee member we spoke with told us that it is very difficult to get information in the data bank corrected—and costly, if practitioners get legal assistance. We found several examples of this. For instance, on September 1, 1999, a hospital reported restricting a practitioner's privileges because of poor recordkeeping. The practitioner disputed the report, noting that the hospital planned to monitor his medical records and not restrict clinical privileges. About 1 week later, the hospital attempted to correct the information, requesting that NPDB cancel the initial report. However, in doing so, the hospital incorrectly coded the action as a state license revocation. As of July 2000, when we queried NPDB, the incorrect information on the initial restriction and the erroneously reported licensure revocation were still in the data bank.

Our July 2000 query also yielded information on a practitioner that, based on our analysis, should no longer be available to organizations querying the data bank. In this instance, a state reported revoking a license because the practitioner did not meet its continuing medical education requirements. The practitioner disputed the report and supplied evidence to the state of its error. Although the state reported the mistake to NPDB in February 2000, we received both reports in response to our query, indicating that the

information had not been expunged. These reports would likely be of particular concern to the practitioner because this was the only information that NPDB had on this individual. HRSA officials said that while there may be instances when practitioners have difficulty getting reported information corrected, the practitioner notification and dispute resolution processes are generally adequate to address most problems.

User Fee Structure Not Validated and Controls Over Collections and Disbursements are Inadequate

As stated earlier, NPDB operations are funded by the fees that users pay to query the data bank for information on practitioners. HRSA does not receive a separate appropriation for these purposes. In fiscal year 1999, HRSA collected \$14 million in user fees, disbursed about \$12 million, and had a \$6.8 million cash balance at the end of fiscal year 1999. In recent years, HRSA has not adequately examined whether the level of the user fees to finance NPDB operations is appropriate. In reviewing the collection and disbursement activities, we also found that controls over NPDB transactions did not ensure that all collections were received and that disbursements were for authorized purposes.

At the end of fiscal year 1994, NPDB had a cash balance of \$3.3 million. As table 3 shows, this balance has fluctuated over the last 5 years. Officials told us these fluctuations occurred because some of these funds were used for software and hardware enhancements to NPDB.

¹⁸Section 427(b) of the Health Care Quality Improvement Act of 1986, as amended in 1987, states that user fees may not exceed the costs of "processing the requests for disclosure and providing such information." However, beginning with the HHS appropriation act for fiscal year 1993 and each year through fiscal year 2000, an additional provision has been included regarding user fees. The provision states that, in addition to user fees authorized by section 427(b) of the 1986 act, fees shall be collected for the full disclosure of information and be "sufficient to recover the full costs of operating" the data bank.

Table 3: 5-Year Trend in Accumulated NPDB Fees (in Millions of Dollars)

	FY 95	FY 96	FY 97	FY 98	FY 99
Beginning user fee balance	\$3.3	\$4.6	\$2.6	\$2.4	\$3.1
Collections	10.8	7.6	9.3	12.0	14.0
Recoveries ^a	0	0.2	0.3	0	1.6
Total available	14.1	12.4	12.2	14.4	18.7
Disbursements	(9.5)	(9.8)	(9.8)	(11.3)	(11.9)
Ending user fee balance	\$4.6	\$2.6	\$2.4	\$3.1	\$6.8

^aAt the beginning of the year an estimated amount of NPDB funds are set aside for NPDB's portion of HRSA's overhead. At the end of the year, funds that are not used are reported as recoveries.

HRSA officials told us that the agency does not have a plan for its financial operations that would project cash flows such as revenue, disbursements, and capital investments. Neither has it reassessed the amount it needs to cover NPDB operating expenses. While the accumulated fee balance in fiscal year 1999 is consistent with HRSA's long-standing policy of retaining about 4 to 6 months of operating expenses, HRSA has not confirmed that this is an appropriate time frame. Performing an analysis could also help HRSA determine whether the balance could be used to adjust the rates charged for NPDB queries.

HRSA's management is responsible for establishing internal controls to account for and manage user fees properly. The Comptroller General's *Standards for Internal Control in the Federal Government* contain the criteria that federal agencies should follow in establishing and maintaining internal controls. ¹⁹ As such, HRSA management is responsible for developing the detailed policies, procedures, and practices that fit its agency's operations. Specifically, this includes implementing procedures to (1) assess user fees properly, (2) collect and record user fees, and (3) reconcile user fees assessed with those collected and recorded.

HRSA and the Division of Financial Operations (DFO) did not have controls to ensure that all assessed user fees were collected and properly recorded in the general ledger. For example, unique identifying numbers that NPDB assigns to each batch of queries for credit card transactions do not remain with the transactions once they are entered into the commercial

¹⁹The Comptroller General's *Standards*, as updated in November 1999, were issued pursuant to the Federal Managers' Financial Integrity Act of 1982.

bank for processing. When the batch is electronically submitted to the commercial bank for collection, the bank assigns a new identifying number, deposits the funds in HRSA's Department of Treasury account, and sends a daily deposit ticket to DFO, which records the funds in HRSA's general ledger.

However, because the commercial bank assigned the batch of queries a different identifier than the one originally assigned by NPDB, HRSA cannot track the amounts of assessed user fees for credit card transactions to the related collection amounts in the general ledger. Officials at the commercial bank told us that they did not know that HRSA needed a unique identifier for credit card transactions and that HRSA officials had not contacted them about this issue. Without a common identifier, HRSA cannot be assured that all assessed fees have been collected and may be foregoing income that it is due. DFO and bank officials told us that, as a result of our review, they have begun discussions about ways to correct this problem.

DFO officials realized that there were discrepancies between the amount of user fees assessed and the amount collected and had conveyed this information to the division within HRSA that oversees NPDB operations. However, the discrepancies between amounts assessed and actual collections were not reconciled because HRSA and DFO officials have not agreed on which organization is responsible for performing these reconciliations. HRSA officials acknowledged that reconciliations should be performed but stated that DFO maintains the necessary documents and that HRSA does not have access to them.

DFO reported that about \$8.3 million in user fees were collected during the first 8 months of fiscal year 2000, while HRSA's contractor reported \$8.7 million in fees assessed in the same period. At the time of our review, an analysis had not been performed to determine the reasons for this difference. However, DFO officials speculated that the difference could be due to denied credit card transactions, electronic funds transfer (EFT) charges, or differences in when the commercial bank and HRSA post transactions.

HRSA officials told us that DFO compares the collections recorded in the general ledger to Treasury's records; however, this procedure is not sufficient because the collections that are recorded in the general ledger may not be accurate. As noted above, HRSA does not reconcile assessments with actual collections. Reconciliation procedures are a

control necessary to ensure accurate reporting of user fee receipts. Until a reconciliation is performed between the user fees assessed in NPDB and the user fees collected and recorded in HRSA's general ledger, HRSA cannot be assured that the general ledger is accurate. The Comptroller General's *Standards for Internal Control in the Federal Government* states that internal control activities help ensure that management directives are carried out. These activities include reconciliations and maintenance of related records that provide evidence that these activities were executed and appropriately documented.

HRSA and DFO also cannot ensure that the user fees collected electronically—about 30 percent of NPDB's receipts—are properly allocated between NPDB and HIPDB. HRSA's contractor operates NPDB and HIPDB and assigns unique identifying numbers to each query processed by the data banks. However, the bank commingles EFT transactions for the two data banks and sends deposit information to DFO without differentiating between NPDB and HIPDB transactions. Because DFO cannot independently determine how much should be allocated to each data bank, it subtracts total HIPDB assessments—as shown in the contractor's report—from the total deposits to arrive at the amount credited to NPDB. This allocation process assumes that all assessed user fees are collected.

Given the current allocation process, neither HRSA nor DFO can ensure that the amounts that either data bank allocates in EFT-related collections are accurate and that the collections posted to the general ledger for each data bank are accurate. Without this knowledge, HRSA cannot be assured that it is receiving all fees it is due nor can it ascertain whether these collections stem from NPDB or HIPDB queries. Although EFT transactions accounted for only about 30 percent of HRSA's total user fee receipts for fiscal years 1998 and 1999, these transactions are expected to increase. According to HRSA officials, the agency plans to request that all users of NPDB pay for queries electronically to reduce processing costs. When this procedure is fully implemented, EFT transactions will become an even larger part of NPDB's transactions. HRSA and DFO officials also told us that as a result of our review, they are revising the allocation process so that it more accurately reflects collections for each data bank.

Based on our review of NPDB disbursements, we determined that controls were not effective. After reviewing and testing 118 statistically selected disbursements from a population of 102,393, we estimate that HRSA and DFO could not provide adequate documentation for 7,810 transactions.²⁰

We also estimate that HRSA and DFO could not provide any documentation for 6,942 disbursement transactions. ²¹ The Comptroller General's *Standards for Internal Control in the Federal Government* states that all transactions and significant events need to be clearly documented and that documentation should be readily available for examination.

Conclusions

Quantifying and reducing underreporting to NPDB are admittedly difficult, but without a coherent strategy for systematically addressing the areas of greatest significance, agency efforts may continue to be ineffective. While NPDB is presently the nation's only central source of medical malpractice payment information, it is not clear that all such data are being properly reported. Underreporting of clinical privilege restrictions is another area of particular concern because these reports are seen as better indicators of professional competence and involve events far more recent than medical malpractice settlements and judgments. However, HRSA only recently requested that HHS seek the additional legislative authority that the HHS/OIG recommended as necessary for addressing noncompliance by hospitals and other health care providers. Even more troubling is HRSA's failure to implement the law regarding nurses and other practitioners, despite their increasing importance in the delivery of health care services.

While we only sampled 1 month's submissions, our review suggests that NPDB information may not be as accurate, complete, or timely as it should be. Nearly one-third of the reports involving disciplinary actions were either miscoded or did not have sufficient detail to determine what action was taken and why. Inaccuracies in the way reported information was coded could confuse or mislead querying organizations about the severity of actions taken against practitioners. Additionally, duplicate reports overstate the amount of information that NPDB has on a particular practitioner. Some reporters may have purposely submitted vaguely coded and uninformative reports; however, HRSA bears part of that responsibility. The agency has not established criteria for the descriptive information that must be reported by states and other entities when notifying the data bank of the disciplinary actions taken. Moreover, the agency does not have

 $^{^{\}overline{20}}$ We are 95 percent confident that the actual total lies between 3,973 and 13,563 disbursement transactions.

²¹We are 95 percent confident that the actual total lies between 3,325 and 12,533 disbursement transactions.

procedures for ensuring that reporters adhere to the criteria it has established for medical malpractice reports, including inappropriate references to patients' names. Furthermore, the practitioner notification and dispute resolution processes have not ensured that inaccurate and erroneously reported information is removed from the data bank and not released to entities seeking information on specific practitioners.

Finally, without an examination of its financial operations, HRSA has little assurance that its NPDB user fees are appropriate. An analysis of its cash balances and cash flows—user fee collections and disbursements—would be the best way for HRSA to determine the appropriateness of fees. Moreover, HRSA needs to improve controls over its collection and disbursement activities. For example, HRSA and DFO did not have adequate controls to ensure that all assessed user fees were collected and properly recorded in its general ledger. As a result, HRSA could be foregoing income that it is due. Until monthly reconciliations of user fee information are performed, HRSA cannot be assured that its assessments and collections are accurate and complete. In addition, neither HRSA nor DFO have procedures to ensure proper allocation of EFT user fee receipts between NPDB and HIPDB. Without these procedures, HRSA cannot ascertain whether its collections stem from NPDB or HIPDB. Also, controls over NPDB disbursements were not effective because supporting documentation that would provide confidence that disbursements were for authorized purposes was too often missing or inadequate.

Recommendations for Executive Action

To address underreporting, we recommend that the Secretary of Health and Human Services determine what resources and authorities are required to monitor and enforce compliance with NPDB's reporting requirements efficiently and effectively, and then seek the necessary legislative remedies to carry out these responsibilities. Additionally, the Secretary should require the Administrator of HRSA and the Director of DFO to work together to accomplish the following:

 Develop an annual financial plan for projecting cash flows—including revenue, operating expenses, and capital investments—as a basis for assessing operating cash needs. This includes assessing the adequacy of the human capital and technical resources needed for NPDB operations. Further, taking into consideration existing cash balances and projected cash flows, they should evaluate whether current user fees are appropriate.

- Develop procedures to ensure that all assessed user fees are collected, including (1) establishing an audit trail of user fees from the NPDB system to the general ledger and (2) periodically reconciling user fees.
- Develop procedures to ensure that user fees are properly allocated between NPDB and HIPDB.
- Ensure that NPDB disbursements are adequately documented. This could be done by establishing internal controls that require original support and a clear audit trail for all disbursements.

We also recommend that the Administrator of HRSA

- Take immediate action to incorporate information on the disciplinary actions taken against nurses and other health care practitioners into NPDB.
- Incorporate NPDB into the agency's strategic plan, including the measures needed to improve the reliability of reported information.
- Develop criteria for the information that should be included in the narrative sections of reports concerning disciplinary actions taken against practitioners.
- Develop procedures for routinely checking the accuracy and completeness of information reported to NPDB and for obtaining corrections from reporters, when necessary.
- Revise NPDB user and practitioner notifications to include disclosures on the limitations of the data and warnings regarding duplicate submissions as an interim measure until procedures to monitor data quality are implemented.

Agency Comments and Our Evaluation

In written comments (reprinted in app. II) on a draft of this report, HHS said that it generally agreed with the report's findings. HHS concurred with three of our recommendations and described actions it is taking. It disagreed with the rest of our recommendations.

HHS concurred with our recommendation concerning compliance monitoring and enforcement. The Department agreed that it needs to assess the additional resources and authorities needed to address noncompliance proactively. However, HHS noted that, to improve compliance with reporting requirements, HRSA needs to coordinate its efforts with OIG and the health care community. HHS also concurred with our recommendation to properly allocate user fees between NPDB and HIPDB. The Department noted that HRSA has directed its commercial bank to implement procedures separating collections between NPDB and

HIPDB. Finally, HHS concurred with our recommendation to develop criteria for the narrative section of disciplinary action reports and indicated that HRSA has begun taking steps to do so.

HHS did not concur with our recommendation to develop an annual financial plan. HHS indicated that this is unnecessary because HRSA projects its revenue, disbursements, and capital investments annually, and monitors income and expenditures on a monthly basis. We acknowledge that, although HRSA may make projections to adjust user fees, it could not provide us with a written plan during our study indicating how, and how often, these projections are made.

Similarly, HHS did not agree with our recommendation that it develop procedures over the collection process, including establishing an audit trail of user fees from NPDB to the general ledger and periodically reconciling these fees. It indicated that NPBD user fees are collected promptly and properly. Despite its disagreement with our recommendation, HHS stated that HRSA's contractor and bank will implement procedures to create an audit trail and DFO will routinely reconcile amounts processed with amounts deposited and recorded in HRSA's general ledger.

HHS also did not concur with our recommendation regarding disbursements. It acknowledged that it could not provide documentation for some transactions, but explained that these disbursements occurred before HHS adopted its new accounting system. HHS said that its new system ensures effective internal controls over disbursements and a clear audit trail. Further, HHS noted that the organization managing the NPDB accounting system for HRSA—HHS' Program Support Center—had received clean opinions from its independent auditor on its internal controls for fiscal years 1998 and 1999. However, our test results showed that HRSA's controls over disbursements are not effective. Several of the disbursements for which HRSA could not provide documentation occurred after the new system was implemented. In addition, we believe that HHS' statement that the Program Support Center has received clean opinions on its internal controls is misleading. Our review of these internal control reports showed that the audits involved computer system controls and not the detailed testing of disbursements that was covered by our audit.

HHS disagreed with our recommendation to immediately incorporate into NPDB disciplinary action information against nurses and other health care practitioners. Instead, it indicated that it needs to review the Medicare and Medicaid Patient and Program Protection Act of 1987—in light of more

recent legislation that established HIPDB—before it can take any action. We believe that HHS has had ample time to study this issue because the original Act became effective more than 13 years ago and HIPDB was established in legislation that was passed more than 4 years ago.

HHS did not concur with our recommendations to improve the reliability of information contained in NPDB. In regard to our recommendation to include NPDB operations into HRSA's strategic plan, HHS stated that it does not include individual programs in a plan that covers broad programmatic areas. Instead, it indicated that HRSA's 2001 Annual Performance Plan contains information about NPDB operations. While HRSA believes that its Performance Plan may be an appropriate place to address NPDB operations, there is no mention in this plan of NPDB or measures associated with improving the reliability of its information. We continue to believe that this information should be incorporated into the agency's strategic plan.

Finally, HHS also disagreed that it should develop procedures to ensure the accuracy and completeness of NPDB information and that it should revise its notification to users regarding limitations in the data. HHS responded that HRSA already has adequate procedures in place to ensure the integrity of NPDB information. It also said that users are properly informed about the contents and limitations of NPDB data. However, we believe that the results of our detailed tests raise serious concerns about the integrity of NPDB information. For example, over 95 percent of the medical malpractice reports we reviewed were missing information on standard of patient care determinations. Accordingly, we continue to believe that our warnings about the data's limitations are warranted.

HHS also suggested several technical comments, which we incorporated where appropriate.

As agreed with your offices, unless you announce its contents earlier, we plan no further distribution of this report until 30 days after its issuance date. At that time, we will send copies to the Honorable Donna E. Shalala, Secretary of Health and Human Services; the Honorable Claude E. Fox, Administrator of HRSA; and interested congressional committees. Copies of this report will also be made available to others upon request.

If you have any questions about HRSA's operation of NPDB as described in this report, please contact Leslie G. Aronovitz at (312) 220-7600. If you have

questions about HRSA's financial operations relative to NPDB, please call Gloria Jarmon at (202) 512-4476. Other GAO contacts and staff acknowledgments are listed in appendix III.

Leslie G. Aronovitz

Director, Health Care

Program Administration and Integrity Issues

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Gloria L. Jarmon Managing Director

External Liaison

Scope and Methodology

To address issues related to underreporting, we reviewed NPDB's authorizing legislation and regulations and the NPDB Guidebook to identify the reporting requirements and instructions given to those accessing the data bank. We interviewed HRSA officials and reviewed the agency's fiscal year 2000 and 2001 performance plans and the fiscal year 1999 performance report to determine how NPDB fits into HRSA's overall strategic plan. 1 Additionally, we reviewed NPDB's annual reports for calendar years 1993² through 1999 and internal research proposals prepared by HRSA's Division of Quality Assurance, the unit overseeing NPDB operations. We interviewed HHS/OIG officials and reviewed their reports on the data bank to obtain information on NPDB's weaknesses and open recommendations. We also reviewed HRSA-sponsored studies on issues related to underreporting, including Hospital Peer Review and the National Practitioner Data Bank (July 1999), The Roundtable on Hospital Reporting to the NPDB (1996), HRSA's Report to the Congress on Small Malpractice Payment Issues (1996), and the data bank's user satisfaction surveys.

We reviewed HRSA's December 24, 1998, notice of proposed rulemaking, comments the agency received on the proposal, and the Federal Register notice that subsequently withdrew the proposal. We reviewed the minutes of meetings held since late 1998 and interviewed 17 of the 24 health care industry representatives and advocacy groups on NPDB's Executive Committee. This included interviewing officials from medical and dental professional societies such as the American Medical Association, the American Dental Association, American Association of Dental Examiners. the Federation of State Medical Boards, and the National Council of State Boards of Nursing. In addition, we interviewed officials of the Physicians Insurers Association of America and Harvard Risk Management Foundation, which represent the medical malpractice industry. We also interviewed representatives of the American Hospital Association, the National Committee for Quality Assurance, the Joint Commission on Accreditation of Healthcare Organizations, and representatives of advocacy groups such as Public Citizen and the American Association of Retired Persons. Finally, we reviewed the federal Memorandums of Understanding that HRSA negotiated with the Departments of Defense,

¹The Government Performance and Results Act of 1993 (P.L.103–62) specifically requires that federal agencies develop multiyear strategic plans, annual performance plans, and annual performance reports.

²The 1993 annual report covered the period Sept. 1, 1992, to Aug. 31, 1993.

Appendix I Scope and Methodology

Transportation, and Veterans Affairs; the Drug Enforcement Administration; the Indian Health Service; and the Public Health Service.

To evaluate the accuracy, completeness, and timeliness of NPDB data, we obtained electronic copies of the 1,645 reports submitted to NPDB during September 1999 and electronic copies of the 447 reports that were submitted as corrections, changes, or in dispute of the September reports, as of June 2000.³ We categorized these reports by type of information reported—medical malpractice payment, state licensure action, and clinical privilege restrictions.⁴ Because these three types of reports have different requirements for coding and descriptive information, we analyzed each type separately.

We used NPDB's reporting time frames to gauge the timeliness of reports. We compared the dates malpractice payments were made or disciplinary actions were taken (date of action) with the dates that the reports were submitted (the certification date) to NPDB. In total, we analyzed 1,552 reports for timeliness, including 1,300 medical malpractice payment reports and 252 state licensure actions. We did not analyze the timeliness of clinical privilege restrictions because their submission deadlines vary by the method used to transmit the information to NPDB, and we could not determine which method had been used. Reports submitted electronically have a 15-day deadline, while those submitted on paper pass through state licensing boards and are allowed up to 30 days to reach NPDB.

We also analyzed the currency of information included in the 1,300 medical malpractice reports submitted to NPDB during September 1999. We compared the dates of the events initiating the claims (date of act or omission) with the dates that the payments were reported to NPDB. We could not analyze the currency of state and health care provider reports because they do not contain comparable information.

We assessed only medical malpractice payment reports for completeness because this was the one type of report that had NPDB-prescribed criteria

³We omitted reports concerning 298 practitioners that HHS/OIG submitted to NPDB as being excluded from participation in the Medicare and Medicaid health care programs. This present study was focused on the accuracy, completeness, and timeliness of reports involving malpractice payments and disciplinary actions taken against practitioners.

⁴We grouped the Drug Enforcement Administration and professional society reports together with state licensure actions because NPDB classified all three as licensure actions.

Appendix I Scope and Methodology

on the data that should be included in narrative descriptions. We selected 250 of the 1,300 medical malpractice payment reports to determine the frequency with which seven of the items of information were present. We randomly selected 125 reports, then added to that number 101 reports involving practitioners who had been reported more than once during September 1999 and 24 reports that were disputed.

We assessed the accuracy of state licensure actions and clinical privilege restriction reports by determining the internal consistency of the narrative and coded information contained in individual reports. As part of this analysis, we also identified the frequency with which reporters identified why a particular action was taken against a practitioner. In total, we analyzed 345 reports for accuracy, including those involving 252 state licensure actions, 79 clinical privilege restrictions, 7 actions limiting professional society memberships, and 7 DEA actions curtailing practitioners' authorization to prescribe controlled substances.

We also queried NPDB for information on 34 practitioners reported during September 1999. We selected these 34 practitioners due to the nature of the reported information, such as apparently erroneous or duplicate report submissions. We did this to determine what information NPDB would provide on these practitioners and to gauge the impact of potentially erroneous reports.

Two limitations affect our analysis of information reported to NPDB. First, we had to rely on NPDB's own criteria and the internal consistency of reports to gauge timeliness, accuracy, and completeness. There was no independent, single source for much of the information contained in NPDB. Second, we only had a snapshot of the information in the data bank. Working with HRSA officials, we selected 1 month's submissions to NPDB for our analysis. We did not find any evidence that would lead us to believe that September 1999 was an atypical month for NPDB. Besides the 34 practitioners for which we obtained query results, we do not know what other information has been reported on the practitioners included in our September 1999 sample.

⁵As specified in the *NPDB Guidebook*, medical malpractice reports should include information on the patients' age, gender, inpatient or outpatient status, the events (initial and subsequent) precipitating the claim, and the medical or legal damages incurred. The reports are also to include information on whether a standard of patient care determination had been made in connection with the settlement or judgment.

Appendix I Scope and Methodology

To review the adequacy of HRSA's internal controls to ensure proper accountability and management of user fees, we interviewed officials from DFO and HRSA to understand how user fees are determined, assessed, collected, recorded, and disbursed. We also interviewed and reviewed the workpapers of independent public accountants who in fiscal year 1999 performed work technically known as "agreed-upon procedures" for userfee-related issues. The accountants told us they could not develop an audit trail for user fee transactions. To independently verify the accountants' work, we selected one credit card and one electronic funds transfer (EFT) to trace pertinent data from the point at which a user fee was assessed to its posting to HRSA's general ledger.

In addition, we selected and tested a statistical sample of the disbursement transactions from HRSA's general ledger that occurred between October 1, 1994, and May 31, 2000. We traced the sampled disbursements from the general ledger to supporting documentation. We also reviewed the supporting documentation to determine whether the disbursements had been properly approved and reviewed pertinent laws, regulations, and guidance related to NPDB user fees to determine whether the disbursements were used for authorized purposes. Finally, we discussed with HRSA officials their reasons for maintaining excess user fees and reviewed documentation supporting management's decision to maintain these additional funds.

We performed our work between January 2000 and September 2000 in accordance with generally accepted government auditing standards.

⁶The term "agreed-upon procedures" means that the client and accountant have agreed that specific work will be performed in areas involving certain items of the financial statement. The final report is limited to the results (findings) of the work performed.

⁷We statistically selected a probability sample of 118 disbursements from HRSA's population of 102,392. With this statistically valid probability sample, each disbursement had a nonzero chance of being included in the sample. Each sample element was subsequently weighted in the analysis to account statistically for all disbursements in the population, including those that were not selected.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

NOV 9 2000

Ms. Leslie G. Aronovitz
Director, Health Care-Program Administration
and Integrity Issues
United States General
Accounting Office
Washington, D.C. 20548

Dear Ms. Aronovitz:

Enclosed are the Department's comments on your draft report entitled, "National Practitioner Data Bank: Improvements Are Needed to Enhance the Data Bank's Reliability." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department also provided some technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

June Gibbs Brown Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GENERAL ACCOUNTING OFFICE'S DRAFT REPORT, "NATIONAL PRACTITIONER DATA BANK: IMPROVEMENTS ARE NEEDED TO ENHANCE THE DATA BANK'S RELIABILITY"

General Comments

The Department of Health and Human Services (Department) thanks the General Accounting Office (GAO) for the opportunity to review and comment on GAO's draft report, "National Practitioner Data Bank: Improvements Are Needed to Enhance the Data Bank's Reliability." The Department believes that GAO's draft report accurately describes the regulatory evolution of the Department's National Practitioner Data Bank (NPDB). In general, we agree with the report's findings, though with some qualifications. The report describes the efforts of the NPDB to identify and improve the accuracy of data collected and the underlying significant factor that the Department does not have meaningful cost-effective authority to penalize nonreporters.

GAO Recommendation

To address underreporting, we recommend that the Secretary of HHS determine what resources and authorities are required to efficiently and effectively monitor and enforce compliance with NPDB's reporting requirements, then seek the necessary legislative remedies to effectively carry out these responsibilities.

Department Comment

We concur with GAO's recommendation, though we believe the Department's Office of Inspector General (OIG) would have to be involved in any enforcement activity. The GAO report states that, "Most of HRSA's efforts to address underreporting have focused on medical malpractice insurers, while HHS/OIG and HRSA-sponsored studies have concluded that underreporting of clinical privilege restrictions by hospitals and other healthcare providers is a larger and more pressing issue. Moreover, experts widely agree that disciplinary actions, taken by state licensing boards and healthcare providers, are better indicators of professional competence than malpractice settlements."

The Department does not entirely concur with GAO's assessment. We must address underreporting on malpractice because it is required by statute; we will continue to broaden our view of underreporting to include privilege restrictions and other disciplinary actions.

The issue of nonreporting or underreporting is complicated and contentious because proactively addressing the issue may require increased legislative authority to allow access to internal medical facility records, peer review findings, and possibly an investigative capability that exceeds the current capacity and capability of NPDB staff. Such changes would require careful

consideration and coordination with the health care community in order to have any chance of success.

The NPDB staff currently and actively investigate and pursue all specific allegations of violations of the Health Care Quality Improvement Act of 1986, including failure to report clinical privilege actions, medical malpractice payments and violations of confidentiality; and, where appropriate, refer allegations to the Department's OIG for further action.

GAO Recommendation

Additionally the Secretary should require the Administrator of HRSA and the Director of DFO work together to develop an annual financial plan for projecting cash flows - including revenue, operating expenses, and capital investments--as a basis for assessing operating cash needs. This includes assessing the adequacy of human capital and technical resources needed for NPDB operations. Further, taking into consideration the existing cash balances and projected cash flows, evaluate whether current user fees are appropriate.

Department Comment

We do not concur with GAO's recommendation. The Health Resources and Services Administration (HRSA) appropriately examines the level of user fees and conducts appropriate planning. HRSA annually projects budgets that take into account revenue, disbursements, and capital investments. The fee charged to users of the system reflects the projections and historic trends of the financial health of the NPDB. The income and expenditures are monitored on a monthly basis and adjustments are made periodically. This has allowed the NPDB to adjust the user fees several times to achieve a balance of income versus expenditures while minimizing the financial planning and internal budget impact to users within the medical community.

The monitoring and planning done by HRSA has also allowed the NPDB to be periodically upgraded and enhanced in a timely and cost-effective manner with minimal impact to the medical community. Planning is also necessary to replace the contract to operate and maintain the NPDB. This is a costly process that may double the operating cost of the NPDB during the transition to a new contractor. The reserve that GAO questions resulted from this planning process and will be used to replace the expiring contract in the coming fiscal year. The HRSA would be remiss in its fiduciary responsibility if no planning were done to forecast the additional financial burden imposed by these necessary actions.

GAO Recommendation

develop procedures to ensure that all assessed user fees are collected, including (1) establishing an audit trail of user fees from the NPDB system to the general ledger and (2) periodically reconciling user fees.

Department Comment

We do not concur. Overall, user fees are collected promptly and properly, and HRSA will make continued efforts to improve their efficiency and documentation.

The Division of Financial Operations (DFO) in the Department's Program Support Center (PSC) has taken the lead in this endeavor. Currently, the DFO reconciles amounts deposited by Mellon Bank and transferred to Treasury. The amount is then deposited and recorded in the core accounting system. Therefore, the amount reflected in the general ledger is accurate. The HRSA contractor has revised their weekly reports to more accurately reflect amounts successfully processed. Also, the contractor and Mellon Bank will commence capturing sequence identifying numbers from each other's systems which will create an audit trail from credit card and electronic funds transfer transactions. The DFO will routinely reconcile amounts successfully processed with amounts deposited and recorded in the general ledger.

The \$400,000 difference reflected in paragraph 2 on page 30 of GAO's draft report is primarily due to inaccurate reporting by the contractor. Revised reports reflect a \$16,845 difference over a 12-month period from what DFO (\$13.4 million in user fees collected) and the contractor reported. This minimal difference primarily relates to the timing of recording transactions.

GAO Recommendation

develop procedures to ensure that user fees are properly allocated between NPDB and HIPDB.

Department Comment

We concur with GAO's recommendation. We have requested Mellon Bank to separate collections for each program based on the two header records being transmitted by the contractor for electronic funds transfer transactions. Mellon Bank is currently reviewing the feasibility of meeting this request and separating the amounts collected on their weekly reports to DFO.

GAO Recommendation

ensure that NPDB disbursements are adequately documented. This could be done through establishing internal controls that require original support, and a clear audit trail, for all disbursements.

Department Comment

We do not concur with GAO's recommendation, as there are already effective internal controls in place. It is our opinion that GAO's estimates reflected on pages 31 and 32 of the report relating to inadequate documentation are overstated. Documentation was provided for the majority of the transactions; items not provided for were primarily from transactions incurred in Fiscal Year (FY) 1996 when PSC utilized the Legacy Health Accounting System and the items were not

available or identifiable at program offices. The PSC has since implemented internal controls to ensure obligations are authorized and disbursements are supported. The core accounting system does create a clear audit trail. In addition, PSC has received clean opinions from an independent audit firm for their FY 1998 and FY 1999 Statement on Auditing Standards 70 reviews relating to internal controls.

GAO Recommendation

We also recommend that the Administrator of HRSA take immediate action to incorporate information on the disciplinary actions taken against nurses and other healthcare practitioners into NPDB.

Department Comment

We do not concur with the recommendation to take immediate action. We will first review the issues associated with the implementation of the *Medicare and Medicaid Patient and Program Protection Act of 1987 (Act)*, including its duplicative information with the Healthcare Integrity and Protection Data Bank and the necessity of providing hospitals' access to this information as required by the Act.

GAO Recommendation

incorporate NPDB into the agency's strategic plan, including the measures needed to improve the reliability of reported information.

Department Comment

We do not concur that the NPDB should be incorporated into the HRSA strategic plan, but we believe that the NPDB should be included in the overall HRSA performance plan. The HRSA stategic plan covers broad programmatic areas, and it would not be consistent to include specifics concerning individual programs such as the NPDB. The HRSA 2001 Annual Performance Plan does address the NPDB. While the reliability of data requires continued effort, we do not agree with the recommendation's implication that the data are essentially flawed.

GAO Recommendation

develop criteria for the information that should be included in the narrative sections of reports concerning disciplinary actions taken against practitioners.

Department Comment

We concur with GAO's recommendation. Criteria have been developed for information that should be included in the narrative sections of reports concerning medical malpractice payments. Efforts presently are underway to develop criteria for reports concerning disciplinary actions taken against practitioners.

GAO Recommendation

develop procedures for routinely checking the accuracy and completeness of information reported to NPDB and for obtaining corrections from reporters, when necessary.

Department Comment

We do not concur with GAO's recommendation because HRSA already has procedures for verifying and correcting the information contained in a report. A copy of each report submitted to the NPDB is sent to the reporter and the subject of the report. Each report can and often does identify corrections, omissions and discrepancies which the reporter is obliged to revise when appropriate. In addition, HRSA often identifies potentially erroneous information and asks the reporter to review and revise the information as necessary. Therefore, we believe this procedure of checks and balances is appropriate, has worked well, and therefore no additional corrective action is necessary.

GAO Recommendation

revise NPDB user and practitioner notifications to include disclosures on the limitations of the data, as well as warnings regarding duplicate submissions, as an interim measure until procedures to monitor data quality are implemented.

Department Comment

We do not concur with GAO's recommendation. The expectations of users are important, and currently the public perception of the NPDBdatabase is that of a "flagging system." We do not include user and practitioner notifications because the literature describing the database already carries a full description of the database and its limitations.

GAO Contacts and Staff Acknowledgments

GAO Contacts	Geraldine Redican-Bigott, (312) 220-7678 Rosa Ricks Harris, (202) 512-9492
Staff Acknowledgments	Enchelle Bolden, Marian Cebula, Tiffani Clark, Lynn Filla-Clark, Tarunkant Mithani, and Barbara Mulliken also made key contributions to this report.

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