



OCT 11 2005

TO: Betty James Duke
Administrator
Health Resources and Services Administration

Elias Zerhouni, M.D.
Director
National Institutes of Health

Charles Grim, D.D.S., M.H.S.A.
Director
Indian Health Service

FROM: Daniel R. Levinson *Daniel R. Levinson*
Inspector General

SUBJECT: HHS Agencies' Compliance With the National Practitioner Data Bank
Malpractice Reporting Policy, OEI-12-04-00310

Attached for your review is our final report examining Department of Health and Human Services (HHS) agencies' compliance with the medical malpractice reporting requirements of the National Practitioner Data Bank (NPDB). The NPDB, which is managed by the Health Resources and Services Administration (HRSA), receives and maintains records of medical malpractice payments and of adverse actions taken by hospitals, other health care entities, licensure boards, and professional societies against licensed health care practitioners. The NPDB makes these reports available to hospitals, other health care entities, and licensure boards to facilitate their background checks and credentialing.

According to an October 15, 1990, HHS policy directive, all settled or adjudicated HHS medical malpractice cases must be reported to the NPDB. This policy applies to all cases regardless of whether the standard of care has been met. The only exception is for those cases in which the adverse event was caused by system error.

We reviewed lists that HHS's Program Support Center (PSC) maintains of all HHS medical malpractice cases that have been settled or adjudicated. We focused on the period June 1997 through September 2004. We found that, as of October 2004, HHS agencies failed to report as many as 474 medical malpractice cases to the NPDB that should have been reported. Individual agency underreporting was as follows: Indian Health Service (IHS), 290 cases; HRSA, 179 cases; and National Institutes of Health (NIH), 5 cases.

This departmentwide underreporting was caused by a number of factors including: (1) lost medical malpractice files; (2) incomplete information in medical malpractice files; (3) a 1998 decision by the HHS peer review entity, the Medical Claims Review Panel, to not identify practitioners who met the standard of care (a decision that was inconsistent with longstanding HHS policy); and (4) the failure to replace a key PSC claims official or to reassign his NPDB reporting duties.

Failure to report medical malpractice cases to the NPDB has the effect of depriving health care organizations, such as hospitals and State licensure boards, of potentially useful information for their credentialing and regulatory activities, respectively.

We recommend that IHS, HRSA, and NIH each take steps to: (1) implement a corrective action process that would address the unreported cases, (2) improve internal controls involving case files management, and (3) assign staff to assume responsibility for addressing practitioner questions/complaints and data entry of reports to the NPDB.

In reply to the draft report, we received a response from the HRSA Administrator, who responded on behalf of the Secretary. This response, which is attached at Appendix A to this report, indicated that the Department is working to develop a final action plan that will include policy decisions relating to future reporting, including ensuring agency compliance. The response also included agency technical comments from HRSA, NIH, and IHS, which we have addressed as appropriate, in the attached report.

Since April 22, 2005, in response to the OIG review, IHS has reported 99 providers. However, contrary to current HHS policy, IHS is not reporting cases in which the standard of care was met.

Prior to the April 2005 IHS reporting, the last time HHS agency cases were entered into the NPDB was in July 2003 (two HRSA cases). NPDB staff have advised OIG that, as of June 30, 2005, neither HRSA nor NIH have reported any cases.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me or one of your staff may contact Elise Stein, Director, Public Health and Human Services Branch, at (202) 619-2686 or through e-mail (Elise.Stein@oig.hhs.gov). To facilitate identification, please refer to report number OEI-12-04-00310 in all correspondence.

cc:

Paula Stannard
Acting General Counsel
Department of Health and Human Services

Ann Agnew
Executive Secretary to the Department of Health and Human Services

HHS AGENCIES' COMPLIANCE WITH THE NATIONAL PRACTITIONER DATA BANK MALPRACTICE REPORTING POLICY, OEI-12-04-00310

BACKGROUND

National Practitioner Data Bank

The Health Care Quality Improvement Act of 1986 (the Act), as amended,¹ created the National Practitioner Data Bank (NPDB). Since it became operational in September 1990, the NPDB has received and maintained records of medical malpractice payments and of adverse actions taken by hospitals, other health care entities, licensure boards, and professional societies against licensed health care practitioners. The NPDB makes these reports available to hospitals, other health care entities, and licensure boards to facilitate their background checks and credentialing.

At the end of September 2004, the NPDB contained 358,590 reports on individuals, of which 263,742 were medical malpractice payment reports. During the first 9 months of 2004, the NPDB received 2,652,153 requests for information from hospitals, other health care entities, and licensure boards. Of those requests, 371,565 matched information contained in the NPDB, for a match rate of 14 percent. The NPDB also received 37,879 self-queries from practitioners. Of these self-query requests, 2,300 matched reports in the NPDB, for a self-query match rate of 11 percent. A HRSA-funded survey of NPDB users in 2000 by the University of Illinois and Northwestern University found that 9 percent of the time an NPDB report caused the hospital, other health care entity, or licensure board to change a privileging, membership, or licensing decision. Based on the survey results, HRSA has estimated that, for a 1-year period, 40,100 licensure, credentialing, or membership decisions were affected by new information provided in NPDB responses.

Section 421 of the Act² requires that private insurers and self-insured health care entities report medical malpractice settlements or court judgments to the NPDB. However, the statute does not explicitly require HHS or other Federal departments to report medical malpractice settlements or court judgments. Instead, section 432³ requires that HHS enter into Memorandums of Agreement with the Department of Defense (DOD) and Department of Veterans Affairs (VA) regarding their reporting policies. These agreements, dated November 1990 and September 1997, respectively, outline DOD and

¹ Title IV of P.L. 99-660, 100 Stat. 3784 (codified at 42 U.S.C. §§ 11101-11152).

² 42 U.S.C. § 11131.

³ 42 U.S.C. § 11152.

VA reporting practices. In May 2004 DOD issued Instruction 6025.13, which updated and modified its reporting procedures. VA's updated reporting procedures are found at 38 CFR Part 46.

HHS set forth its own policy on agency medical malpractice reporting in an October 15, 1990, directive from the Assistant Secretary for Health to Public Health Service (PHS) agency heads. This policy statement is entitled "Policies for PHS Reporting and Querying the National Practitioner Data Bank." The policy memorandum states that reports are to be made whenever payment is made as a result of a claim or suit filed against the U.S. Government alleging substandard practice by a physician, dentist, or other health care practitioner providing services under the auspices of PHS or one of its programs. The policy provides that if a payment results from a claim in which it was determined that the standard of care was met, the payment ". . . shall be reported under the name of the physician(s), dentist(s), or other licensed health care practitioner(s) found through the procedures to be primarily responsible for the episode" The policy also states that "the finding that the standard was met will be clearly indicated under any names so reported." An exception to this reporting requirement is for payments for claims determined to be the result of a system breakdown, rather than the fault of the provider.

The October 15, 1990, directive also requires that HHS, at the time a report is made to the NPDB, ". . . send a copy to the State Board of Medical or Dental Examiners in the State in which the claim arose and to the State(s) of known licensure of the responsible practitioner within 30 days from the date . . . payment was made" This HHS policy reflects a similar requirement set forth in section 424 of the Act,⁴ which mandates private-sector medical malpractice reporting to State licensing boards at the time such reports are made to the NPDB.

In October 1995, PHS was reorganized. The November 9, 1995, Federal Register Notice (60 FR 56605) announced the elimination of the Office of the Assistant Secretary of Health and the designation of PHS agencies, which had been organizationally part of the Office of the Assistant Secretary of Health, as Operating Divisions reporting directly to the Secretary. Although the Office of the Assistant Secretary of Health no longer existed as an organizational entity, the PHS policy on medical malpractice reporting to the NPDB remained in effect. The Federal Register announcement noted as follows: ". . . all statements of policy and interpretations with respect to the Office of the Secretary, and the Public Health Service heretofore issued and in effect prior to the date of the reorganization are continued in full force and effect"

⁴ 42 U.S.C. § 11134.

The Federal Tort Claims Act and the Processing of Medical Malpractice Claims Within HHS

The Federal Tort Claims Act (FTCA)⁵ is a limited waiver of Federal sovereign immunity under which, with certain exceptions, the United States may be liable for the negligent conduct of its employees acting within the scope of their employment to the same extent a private party would be liable under the governing State law. Claims under the FTCA may include medical malpractice claims. Under the FTCA, claimants must first present an administrative claim for agency consideration and possible administrative settlement. If the agency denies the claim or more than 6 months elapse after presentation without agency disposition, the claimant may deem the claim denied and file suit against the United States in Federal district court.

The Program Support Center's (PSC) Claims Office is responsible for the administrative processing of all Federal tort claims involving medical malpractice against practitioners employed by HRSA, IHS, and NIH.⁶ PSC's Claims Office staff collect medical records and other information related to the plaintiff's claim and then forward the file to peer reviewers at the agency where the practitioner works. Agency peer review staff, or a medical review contractor working for the agency, evaluate the merits of the claim and make an initial determination as to whether the standard of care was met or not met. The case file then goes to the Office of the General Counsel (OGC) for a determination of whether to deny the claim or settle. Once a claim has been paid pursuant to a settlement or court judgment, OGC sends the cases to the HHS Medical Claims Review Panel, Office of the Secretary. The Medical Claims Review Panel is a peer review group that includes medical staff from the Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and other HHS agencies. The Medical Claims Review Panel is responsible for: (1) making a final determination as to whether the standard of care was met or not met, and (2) identifying the clinician(s) who provided the treatment giving rise to the claim. The named practitioner(s) will then be reported to the NPDB.⁷

Once the Medical Claims Review Panel completes its review, the case is sent back to PSC for reporting to the NPDB. All medical malpractice reports to the NPDB must contain the

⁵ P. L. 109-41

⁶ The PSC Claims Office staff handling this responsibility were transferred to OGC in October 2004, after the period covered by this study. For purposes of describing the step-by-step process of the handling of medical malpractice cases, we are using the organizational framework that existed at the time of the study.

⁷ Prior to 2004, almost all claims were reviewed by the Medical Claims Review Panel prior to settlement or litigation to provide additional peer review input to OGC attorneys handling the claims. Starting in 2004, the reviews have been done after the claim was settled or adjudicated. The change was made to expedite the processing of cases within HHS.

name and signature of an agency official who certifies that the report is accurate. In addition, all reports to the NPDB must contain the name of the reporting entity and the name of a contact person a practitioner named in a report could call to discuss the report. All practitioners who are reported to the NPDB automatically receive a copy of the report. At the time PSC submits a report to the NPDB, a copy of the report is also forwarded to the appropriate State licensure board.

According to PHS policy, once a case is settled or adjudicated, a report is supposed to be made to the NPDB within 30 days.

METHODOLOGY

Our work took place from November 2003 through March 2005.

We reviewed lists of all HHS medical malpractice cases that have been settled or adjudicated that the PSC Claims Office maintained; we focused on the period June 1997 through September 2004. These listings provide historical information, by HHS agency, for the following data elements: case number, claimant, dollar amount of settlement or judgment, provider name, standard of care met/not met, date PSC requested verification of information to be reported to the NPDB, and date reported to the NPDB. To obtain a better understanding of the processes HHS agencies use for reporting to the NPDB, we held discussions with knowledgeable staff from HRSA, IHS, NIH, PSC, and OGC. We also talked with a representative of the Federation of State Medical Licensing Boards (FSMB). When necessary, we used e-mail to obtain additional or clarifying information from individuals.

We conducted this study in accordance with the Quality Standards for Inspections issued by the President's Council on Integrity and Efficiency.

FINDINGS

Numerous HHS Cases Are Not Being Reported to the NPDB and State Licensure Boards

Since the NPDB became operational in September 1990, HHS agencies have reported 257 medical malpractice cases to the NPDB, according to HRSA's Practitioner Data Bank Branch, Bureau of Health Professions. However, as a result of our review of the PSC listing of medical malpractice cases, the Office of Inspector General (OIG) has determined that as many as 474 additional cases should have been reported to the NPDB but were not. These unreported cases cover the period June 1997 through September 2004. Our review of the PSC listing revealed the following:

- 290 IHS cases have not been reported,
- 179 HRSA cases have not been reported, and
- 5 NIH cases have not been reported.

As noted earlier, PHS policy requires that all medical malpractice settlements/judgments be reported, except when HHS peer review determines that there was a system breakdown. Of the 474 unreported cases, HHS's own peer review determined that the standard of care was not met in 226 IHS cases, 100 HRSA cases, and 1 NIH case. Furthermore, in accordance with PHS policy, even those agency cases involving determinations that the standard of care was met should have been reported. While we did not review individual cases to identify any claims that fell into the category of system breakdown and, therefore, would not have to be reported, PSC has advised us that none of the cases included in our computations for this report involved a peer review determination of system breakdown. Furthermore, we specifically excluded from our computations 28 HRSA cases and 10 IHS cases on the PSC listing that did not have a final Medical Claims Review Panel determination as to whether the standard of care was met or not met. Six of these cases dated as far back as 1998/1999.

Underreporting of the Department's own medical malpractice cases lessens the usefulness of the NPDB and undermines departmental efforts to regulate private- and public-sector compliance with NPDB requirements.

Furthermore, since HHS policy and procedures require that PSC report to State licensure boards at the time a report is submitted to the NPDB, failure to report to the NPDB deprives State licensure boards of potentially useful information for their regulatory activities. According to the Federation of State Medical Licensing Boards, the majority of State medical boards require that medical malpractice claims, judgments, and/or settlements be reported to them. Nineteen of these boards provide malpractice history as part of their publicly available physician profiling information. In a September 14, 2004, e-mail, FSMB advised OIG that compliance with reporting requirements ". . . is essential in assuring that state medical boards receive sufficient information to evaluate the performance of licensees in fulfilling their responsibilities of public protection."

Several Factors Influence Reporting to the NPDB

Lost Files

Before PSC files a report with the NPDB, it sends the case file to agencies for final verification that information is accurate and complete. According to HRSA, eight cases that PSC sent to HRSA during 1997 and 1998 have been lost. According to NIH, five cases PSC sent to NIH during the period 1997 through 2002 have been lost. Both agencies indicated that they would work with PSC to recreate the files.

Incomplete Records

According to PSC documents, as noted earlier, PSC is missing peer review determinations for 28 HRSA cases and 10 IHS cases. PSC is also missing practitioner identification information for 73 HRSA cases, 33 IHS cases, and 2 NIH cases. PSC would need this information to complete the reporting process to the NPDB.

Medical Claims Review Panel Decision

One cause of the missing practitioner identification information is a 1998 decision by the Medical Claims Review Panel (then called the Quality Review Panel) to forgo naming a practitioner when the standard of care was met. Practitioners' names are a required data element for NPDB reporting; therefore the decision, which was inconsistent with the October 1990 PHS policy directive, effectively makes it impossible to report these cases to the NPDB.

According to HRSA, in addition to the 1998 Medical Claims Review Panel decision, the decision to forgo naming a provider was sometimes caused by the necessity of obtaining “. . . feedback from the PSC Claims Office or OGC in certain situations as to the rationale for the payment in settlement or litigation.”

HRSA also advised OIG that “There are other practical reasons for missing practitioner identification information” HRSA indicated that these reasons include the following:

- Many cases were filed years after the alleged incidents, and, since they took so long to reach settlement or go through litigation, in many instances relevant data or records were misplaced or lost. HRSA is attempting to retrieve or regenerate this information.
- Many HRSA-funded health centers that have been sued under the FTCA may have been unaware of the importance of keeping for years certain files containing information necessary for NPDB reporting.
- In some cases, HHS peer reviewers were advised that payments were made “for the convenience of the government” in settling certain claims to avoid the costs of litigation. According to HRSA, it is difficult in these situations to assign responsibility to a particular practitioner.

Failure to Replace Key Official

Finally, in addition to the above problems, we identified an additional impediment to reporting. In June 2003, the PSC Claims Officer retired. Prior to his retirement, he was the official whose name and telephone number had appeared on the report sent to

practitioners and therefore he was the individual they would call. When he retired, his name was removed from HHS medical malpractice reports; in lieu of his name, PSC inserted "PSC Claims Officer." Because there is no longer a Claims Officer, and because HHS components have yet to agree on new reporting procedures, practitioners have no identifiable HHS contact.

In addition to the unresolved issue of an HHS contact for practitioners, the actual responsibility for entering reports into the NPDB remains a problem. The PSC Claims Officer was responsible for actual data entry of reports. Because of his retirement, the fact that he was not replaced, and organizational changes involving the planned relocation of the PSC Claims Office to OGC, the responsibility for data entry of reports to the NPDB has not been resolved.

Last HHS Report

For the period of our review, June 1997 through September 2004, we determined that the last HHS data entry to the NPDB was made on July 30, 2003, when two HRSA cases were reported by one of the paralegal staff in the PSC Claims Office. According to PSC, an additional 23 HRSA cases were ready for reporting in July 2003. However, after PSC had reported these two cases, it became concerned that because there was no official Claims Officer to assume legal responsibility for data entry, the 23 HRSA cases, as well as subsequent reports, should not be entered into the NPDB.

AGENCY COMPLIANCE ACTIONS

Staff-Level Discussions

After we identified the underreporting problem in October 2003, we provided each agency with the PSC listing of unreported cases. We then met with HRSA and IHS representatives, as well as PSC and OGC staff, on December 4, 2003, to discuss compliance. While agency staff generally agreed to start working more closely with PSC to provide the information required for reporting, it was not clear whether they would fully comply with the current PHS policy. For example, IHS staff advised OIG in a December 22, 2003, e-mail that "The IHS will continue to work within the framework of the current HHS policy and report those cases in which a provider was found to be negligent" However, IHS did not indicate that it would report cases where the standard of care was met, which is a requirement of current PHS policy (except when there has been a determination of a system breakdown). At the December 4, 2003, meeting, HRSA and IHS staff expressed their personal opinions that the current PHS reporting policy should be revised so that the only cases reported by HHS would involve claims in which the standard of care was not met. It should be noted that the private sector is required to report all medical malpractice settlements and judgments to the

NPDB, regardless of the standard of care determination. The standard of care is not a consideration in the regulatory reporting requirements for the private sector.⁸

IHS Corrective Action Activities

An October 19, 2004, memorandum from the IHS Director to the Inspector General updated the IHS position, as follows:

- Depending on the outcome of due process notification to providers, IHS will report up to 103 providers.
- A detailed administrative process for reviewing and reporting medical malpractice claims has been developed; IHS has assigned a senior physician and one administrative employee to work on this process.
- IHS believes that its reporting of providers who are not negligent in their care to the NPDB in accordance with current HHS policy could compromise the recruiting and retention of high-quality health care providers.
- There are circumstances in which IHS contract providers are not covered by the FTCA. IHS has identified 21 such providers.
- IHS, NIH, and HRSA are pursuing a revision to the 1990 PHS policy on malpractice reporting to the NPDB.

RECENT DEVELOPMENTS

Relocation of Claims Office Staff to OGC

On October 4, 2004, PSC Claims Office staff who had been processing medical malpractice cases were organizationally relocated to OGC; these former Claims Office staff now follow the same process for handling medical malpractice claims as they did when they were part of PSC. Also as a result of this reorganization, OGC, instead of PSC, currently maintains the list of reported and unreported medical malpractice cases.

RECOMMENDATIONS

We recommend that IHS, HRSA, and NIH each take steps to: (1) implement a corrective action process that would address unreported cases, (2) improve internal controls involving case file management, and (3) assign staff to assume responsibility for addressing practitioner questions/complaints and data entry of reports to the NPDB.

⁸ 42 U.S.C. § 11131

With respect to individual agency corrective action activities, we offer the following details.

IHS

As noted earlier, IHS has taken steps to address reporting to the NPDB. In addition to planning to report 103 providers, IHS also indicated in its memorandum that it is planning to review the reporting status of the remaining cases. We would appreciate receiving an update on IHS's efforts to address all unreported cases.

HRSA and NIH

As soon as possible, HRSA and NIH should implement a corrective action process for reporting cases. This should include "reconstructing" lost cases and, in instances for which OGC's listing of HRSA and NIH cases is missing information on the standard of care (met/not met) or practitioner's name, provide such information for NPDB reporting purposes. In view of the large number of HRSA cases, HRSA may want to consider prioritizing cases so that practitioners with significant peer review findings involving deficient care can be reported at the earliest possible time. Additionally, in accordance with current policy, reports to the NPDB should also be sent to the appropriate State licensing board(s).

Both HRSA and NIH should review and improve internal controls, including the possible development of an agency tracking and case management file system, to ensure that: (1) cases are reported timely, (2) case files are not lost, and (3) information in files is maintained in accordance with record retention policies. As part of this activity, HRSA should inform health centers of record retention requirements so that information required to be reported to the NPDB is maintained, notwithstanding the length of time between the onset of a medical malpractice case and reporting to the NPDB and State licensure boards.

IHS, HRSA, and NIH

In view of the retirement of the PSC Claims Officer, the relocation of the PSC Claims Office to OGC, and the fact that each agency has the most knowledge about its own practitioners' peer review findings, OIG believes that the most effective management practice for implementing HHS medical practice reporting policy would be for each agency to designate an individual to handle practitioner inquiries. This can be accomplished by each agency registering independently with the NPDB. The NPDB online registration form allows for a point of contact for each registered entity.

We also recommend, as an effective management practice, that each agency designate an individual to do data entry for NPDB reporting. This would provide agencies with full control of their NPDB-related responsibilities.

SUMMARY OF THE DEPARTMENT'S COMMENTS

We received a response from the HRSA Administrator on behalf of the Secretary. This response, which is attached as Appendix A to this report, indicated that the Department is working to develop a final action plan. In developing this action plan the Department is reviewing policy options relating to what the future HHS reporting policy should be; it is anticipated that final action on a reporting policy will be completed in the fall of 2005.

The Department's response also noted that agencies have implemented revised procedures to track new malpractice reports and that recommendations will be made to the Secretary to ensure greater compliance in the future.

Finally, the response provided technical comments from HRSA, NIH, and IHS. We have revised the report, as appropriate, in response to a number of the technical comments provided by these agencies. In addition to the changes in the body of the report, we have responded to agency technical comments as follows:

NIH and IHS Comments Regarding VA and DOD Reporting

Both NIH and IHS suggested in their technical comments that we include VA and DOD reporting policies and practices. Although the background section of this report noted the existence of such policies, the purpose of this study was limited to HHS's compliance with its own reporting policy. We did not examine VA and DOD practices.

HRSA's Comments Regarding the OIG Work Plan

HRSA's technical comments indicated that this study "was not part of the OIG Work Plan for FY 2004 or FY 2005."

Page 7 of the FY 2004 OIG Work Plan's Public Health Agencies Section included the following work plan proposal: "Medical Malpractice Claims Against Health Centers." This study was to evaluate the timeliness of the review process for medical malpractice claims against health centers funded by HRSA. During research for the study, we determined that we should stop work because the Department was reorganizing the processing function for medical malpractice claims, i.e., moving the Claims Office from PSC to OGC. However, before the project was cancelled, we had asked for data on the reporting of completed malpractice cases to the NPDB. Based on the results of this request, we decided to review agency compliance with NPDB malpractice reporting requirements.

HRSA Comments Regarding OIG Calculation of Unreported Cases

According to HRSA's technical comment, our finding that as many as 474 cases have not been reported might be misunderstood because "several of the cases included in this

computation were still under review and a determination of system breakdown could not have been made.”

We discussed this issue extensively with the Claims Office and it reaffirmed what it had initially advised us: based on peer review findings presented to the Claims Office, none of the cases included in our computations for this report involved a peer review determination of system breakdown.

IHS Comments Regarding Missing Information

IHS notes in its technical comments that PSC is also missing payment information from OGC on some claims, so that reporting to the NPDB is not possible for these claims.

This technical comment apparently applies to IHS’s experiences since they once again started reporting in April 2005. The focus of our discussion in the report on “Missing Information” was for the period covered by our review, June 1997 through September 2004. After IHS provided the technical comments to OIG as part of the signed departmental response, IHS advised OIG that the agency has been able to work with PSC to deal with the missing payment information.

APPENDIX A



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services
Administration

Rockville MD 20857

AUG - 8 2005

TO: Inspector General

FROM: Administrator

SUBJECT: Office of Inspector General Report: "HHS Agencies' Compliance with the National Practitioner Data Bank Malpractice Reporting Policy" OEI-12-04-00310

Secretary Leavitt has asked me to respond on behalf of the Department to your May 2, 2005, draft report entitled "HHS Agencies' Compliance with the National Practitioner Data Bank Malpractice Reporting Policy" that was sent to the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), and the Indian Health Service (IHS). Since receiving this report, we have been working closely together to review and develop a consolidated response. Several meetings have taken place and we are developing an action plan.

To date, revised procedures have been implemented to track new reports of malpractice payments to help prevent future backlogs in reporting to the National Practitioner Data Bank (NPDB). HRSA, NIH, and IHS share the common goals of improving the timeliness of reporting to the NPDB and improving the overall process involved.

Policy options for reporting to the NPDB are currently being reviewed, and we will be providing recommendations to the Secretary to ensure greater compliance in the future. Final action on a reporting policy and procedures should be completed by this fall. At that point, we will provide you with a comprehensive response to this report.

I am attaching technical comments from HRSA, NIH, and IHS.


Betty James Duke

Enclosure

**TECHNICAL COMMENTS OF HRSA, NIH, AND IHS, ON THE OFFICE OF
THE INSPECTOR GENERAL REPORT: "HHS AGENCIES' COMPLIANCE
WITH THE NATIONAL PRACTITIONER DATA BANK MALPRACTICE
REPORTING POLICY" OEI-12-04-00310**

HRSA

Page 2, 3rd Paragraph under **BACKGROUND**, **National Practitioner Data Bank:**
The reporting policies and procedures of the VA and the DoD have been superseded and should be updated.

Page 3, 1st Paragraph under **BACKGROUND**, **Processing of Medical Malpractice Claims Within HHS:**

It should be clarified that the "sued practitioner" generally does not work for HRSA but for a deemed health center grantee funded by the Agency.

Page 4, under **METHODOLOGY**:

Following the first sentence, it should be noted that this work was not part of the OIG Work Plan for FY 2004 or FY 2005.

Page 5, 2nd Paragraph under **FINDINGS**, **Numerous HHS Cases Are Not Being Reported to the NPDB and State Licensure Board:**

In the second paragraph, the statement attributed to the PSC might be misunderstood. Several of the cases included in this computation were still under review and a determination of "system breakdown" could not have been made.

Page 7, 1st Paragraph under **FINDINGS**, **Agency Compliance Actions - Staff Level Discussions:**

The report states that "agency staff generally agreed to start reporting..." (emphasis added). HRSA staff agreed to work more closely with the PSC to provide the information required for reporting since the reporting process was still a PSC function.

Page 7, under **Agency Compliance Actions - Staff Level Discussions:**

The first sentence reads: - "At the December 4, 2003, meeting, HRSA and IHS staff indicated that the current PHS reporting policy should be revised ..." The report should make it crystal clear that this was not HRSA's official position.

NIH

Page 3, 1st Paragraph

The definition of 'system failure or breakdown' has never been established with precision. Many of the five NIH cases could fall in a reasonable definition of systems failure – i.e., these events occurred outside the direct control of the practitioner.

Page 4, 1st Paragraph

In general; the Federal government is sued, not individual practitioners. In each of our five cases a judgment would have to be made about the ‘responsible practitioner’ and this term is not well defined in the policy and the determination is not always straightforward.

Page 8, 1st Paragraph

The first full sentence, beginning, “This policy, if adopted,...” We believe that this statement is somewhat misleading. Although the policy would initially appear to be different from the current requirement for the private sector, Federal practitioners have little say over whether the Department of Justice decides to settle a case for convenience and have no opportunity to have their names withdrawn from the case in a settlement in which an institution or a corporation assumes the primary liability. NIH would also recommend that this sentence be reworded to state that such a policy would be consistent with current Department of Defense and Veterans’ Administration reporting procedures.

Page 8, 3rd Bullet

From the NIH perspective, the issue is not reporting according to HHS policy, but rather in accord with the practitioners in the remainder of the Executive Branch. The risk to NIH is associated with reporting practitioners whose care met acceptable standard of care. We believe that reporting such cases exceeds the initial intention of the NPDB.

IHS

Page 4, 1st Paragraph

First full sentence which states “...then forward the file to peer reviewers at the agency where the sued practitioner works.” Our providers are not sued and are not the subject of a claim or suit. Also, Claims Office staff forwards the file to the agency which then obtains peer review. Suggest “...then forward the file for peer review to the agency where the claim arose.”

Page 4, 1st Paragraph

3rd sentence: the OGC does not determine to “litigate,” the claimant does.

Page 4, 10th line from top

There is a typo “that includes medical staff from HRSA,...”

Page 5, Next to last paragraph

States that “Underreporting of the Department’s own medical malpractice cases compromise the integrity of the NPDB...” This is not a “finding” as the report section title would indicate but a conclusion or statement of opinion. It should be removed or moved to another section.

Page 6, 2nd paragraph under *Missing Information*

PSC is also missing payment information from OGC or DoJ on some claims, so that reporting to the NPDB is not possible for those claims as this is required information.

Page 6, Last bullet at bottom of the page
HRSA practitioners are not sued. (See comment above).

Page 8, Top paragraph, last sentence
Should read: "This policy, if adopted, would be different than the current requirement for the private sector, which is required to report all medical malpractice settlements and judgments, regardless of a standard of care determination but would be consistent with the Veterans Health Administration and Department of Defense reporting policies." It is important to add this information since withholding pertinent, factual information indicates a bias in the report.

Page 8, 3rd bullet
Should read: "IHS believes that its reporting providers who are not negligent in their care to the NPDB in accordance with current...."

Page 8, 4th bullet
Insert "contract" so it reads, "There are circumstances in which IHS contract providers...."