Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

HOSPITAL REPORTING TO THE NATIONAL PRACTITIONER DATA BANK

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EXECUTIVE SUMMARY

PURPOSE

To conduct a preliminary inquiry to help the Public Health Service determine how hospitals are responding to their legal obligation to report to the National Practitioner Data Bank adverse actions they take against health care practitioners.

BACKGROUND

Under the direction of the Health Resources and Services Administration in the Public Health Service, the National Practitioner Data Bank has been operating since September 1, 1990. Since that time it has received and maintained records of medical malpractice payments and adverse actions taken by hospitals, other health care entities, licensure boards, and professional societies against licensed health care practitioners. At the same time, the Data Bank has been making these data available to hospitals, other health care entities, and licensure boards to facilitate their credentialing and investigatory activities.

As indicated in the Health Care Quality Improvement Act of 1986, which established the Data Bank, hospitals have a particularly important role to play in determining its effectiveness. For each practitioner seeking clinical privileges, they must query the Data Bank to determine if it has any information on that person. Once a practitioner receives privileges, they must then make a follow-up query every two years. In addition, hospitals, as well as other health care organizations, must report to the Data Bank all adverse actions they take that affect a practitioner's clinical privileges for more than 30 days. Hospitals that fail to meet their reporting responsibilities, risk losing the liability protections afforded their professional review activities under the Health Care Quality Improvement Act.

In this report, we focus on the hospitals' responsibilities to report information to the Data Bank. We do that because the Health Resources and Services Administration asked us to conduct a preliminary investigation to determine if there might be any basis for concern about how hospitals were responding to the Data Bank reporting requirements.

EXTENT OF HOSPITAL REPORTING

From September 1, 1990 to December 31, 1993, about 75 percent of all hospitals in the United States never reported an adverse action to the Data Bank.

The State-by-State variation in the rate of nonreporting hospitals is considerable - ranging from 93.2 percent of all hospitals in South Dakota to 51.7 percent in New Jersey. The median rate is 76.4 percent.

Among the nonreporting hospitals are many large ones. For instance, in Massachusetts, among 112 hospitals that did not report an adverse action to the Data Bank in its first 3 1/3 years of operation, 18 have 300 or more beds.

Less populated and/or predominately rural States are heavily represented among those with the highest level of nonreporting. On the other end, among the States with the lowest rates of nonreporting, the more populous and/or more urban ones are strongly represented.

From September 1, 1990 to December 31, 1993, the approximately 6,500 hospitals in the United States submitted 3,154 adverse action reports to the Data Bank. This represents 2.6 reports per 1,000 hospital beds during the 3 1/3 year period.

With the focus on the number of reports rather than on number of nonreporting hospitals, the State-by-State picture changes somewhat. For instance, New Jersey, which ranks first in the proportion of hospitals sending at least one report to the Data Bank, ranks 18th in the number of reports per 1,000 hospital beds.

Reporting rates per 1,000 hospital beds vary greatly State to State - ranging from 8.5 in Nevada to .7 in South Dakota. In most States, the reporting rate is between 1.5 and 4.0. The median rate is 2.5 adverse action reports.

Some of differences among States are considerable. For example, in California, the State with the largest number of hospital beds, the rate of adverse actions is 3.7 per 1,000 beds. In New York, the State with the second largest number of hospital beds, the rate is much less - 2.1. In Ohio, the rate is 2.9; in nearby Illinois, it is 1.5

BASIS FOR CONCERN

Our review suggests a sufficient basis for concern about the hospitals' response to the Data Bank reporting requirements. The wide variation in reporting rates from State to State is in itself troubling. It could suggest differences in the quality of care rendered or perhaps in the capacity or willingness of hospitals to submit reports to the Data Bank. The explanation is unclear.

Further, the level of reporting in the nation as a whole may be unreasonably low.

- In a 1989 planning document submitted to the Office of Management and Budget, the Public Health Service estimated there would be 5,000 hospital adverse action reports a year. Others had estimated levels more than twice that. The actual average has been about 1,000 a year.

- During the September 1, 1990 - December 31,1993 period, when hospitals reported 3,154 practitioners to the Data Bank, State medical boards took disciplinary actions against about 8,000 physicians.

- A 1991 Harvard Medical Practice study of hospitalized patients in New York State found that in 1984, one percent of the hospitalizations in its random sample involved adverse events caused by negligence. On the basis of this sample, the study team estimated that during 1984, negligent care in the State accounted for 27,179 injuries, including 6,895 deaths and 877 instances of "permanent and total disability."

ISSUES WARRANTING FURTHER ANALYSIS

That there is a basis for concern is not the same as finding there is a problem that must be addressed. To determine if that is, indeed, the case, further inquiry is necessary. On the basis of our own preliminary review, we have identified four issues that warrant further analysis.

There may be few practitioners with serious performance problems. The current level of reporting may be appropriate. The early estimates, based on little hard evidence, may simply have been unrealistic. Further, hospital quality assurance efforts may be contributing significantly to improved practice.

Some hospitals may be responding to poorly performing practitioners in ways that do not require reporting to the Data Bank. They may be taking preventive actions that lessen the need for adverse action. Another possibility is that some may be circumventing the reporting requirements by deliberately taking actions that fall below the threshold that calls for reporting.

Some hospitals may be deemphasizing or avoiding adverse actions against poorly performing physicians. The reporting requirements raise the stakes associated with an adverse action and thus may serve as a deterrent to such action. Continuous quality improvement programs, in seeking to create a safe environment for physicians to assess practice data, may discourage hospital actions against outliers.

Some reportable actions may not in fact be reported to the Data Bank. In one State where we were able to get some information, we found that because of administrative mix-ups, some reportable actions were not submitted to the Data Bank. It is not clear how often such failures occur in other States. It is clear that neither the Medicare Conditions of Participation for Hospitals, nor the standards of the Joint Commission on Accreditation of Healthcare Organizations specify hospital responsibilities concerning the Data Bank.

RECOMMENDATIONS

The Public Health Service, through the Health Resources Services Administration, should support further inquiry to foster a better understanding of the factors influencing hospital reporting to the Data Bank. Intensive case studies that examine the extent and nature of adverse actions, and more generally of peer review efforts in particular hospitals, probably offer the best approach. Although they would not result in generalizable findings, they could result in deeper insights into hospital practices that could facilitate effective implementation of the Data Bank law.

The Public Health Service should sponsor a conference to focus attention on issues influencing reporting to the Data Bank. The conference should include representatives from the Public Health Service and the Health Care Financing Administration as well as representatives from the American Hospital Association, the American Medical Association, the Joint Commission on Accreditation of Healthcare Organizations, the Federation of State Medical Boards, and other organizations. The conference should pay particular attention to the issues identified in this report as warranting further analysis. It should also address actions that might be taken to ensure that hospitals meet their reporting responsibilities as called for in the Health Care Quality Improvement Act of 1986.

The Public Health Service and the Health Care Financing Administration should work together to ensure that the Joint Commission on Accreditation of Healthcare Organizations assesses more fully hospitals' compliance with the intent and particulars of the Data Bank law. Toward this end, they might consider the following options:

A Letter. Send a joint communication to the Joint Commission urging that it incorporate the Data Bank requirements into its standards, conduct a more thorough review of hospital peer review efforts and adverse actions as part of its survey process, and seek to identify any indications of hospitals circumventing the intent of the Data Bank's reporting requirements.

Regulatory Change. Amend the Medicare Conditions of Participation in a manner that will specify hospitals' responsibilities under the Data Bank law. This, in turn, would call for the Joint Commission to devote greater oversight to the hospitals' performance of their responsibilities.

Legislation. Propose legislation that would call for hospitals' Data Bank responsibilities to be addressed in the Medicare Conditions of Participation and for the Joint Commission to focus more attention on the fulfillment of these responsibilities during its survey process.

COMMENTS ON THE DRAFT REPORT

We solicited and received comments on the draft report from the Public Health Service (PHS), the Health Care Financing Administration (HCFA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Hospital Association (AHA), Public Citizen's Health Research Group (PCHRG), and the American Medical Association (AMA). Their comments appear in full in appendix B. Below we summarize the comments, and, in italics, our responses.

Recommendation #1 Calling for PHS to Conduct Further Inquiry

PHS concurred but suggested that the case study analysis we suggested be deferred until a study it has underway is completed. The JCAHO and PCHRG strongly supported further inquiry. The AHA and AMA did not comment specifically on the recommendation. *We continue to urge that PHS give high priority to an in-depth case study inquiry. The AHA, in its comments, provides further rationale for such inquiry by emphasizing that concerns about insufficient immunity protections are exerting a "powerful disincentive" for hospital peer review activity. Focused case reviews could help indicate the extent and nature of this problem.*

Recommendation #2 Urging PHS to Sponsor a Conference

The PHS agreed with the thrust but not the specific content of the recommendation. It stated that in the near-term it will be holding ad hoc meetings at professional associations that would provide a better opportunity for discussion. At a later point, it indicated, a conference, as we call for, might be more desirable. The JCAHO supported a conference as "a solid first step toward defining the reporting problem." The AMA regarded it as premature. Others did not comment. *We strongly urge that PHS consider the conference as a near-term priority. It could help frame the agenda for further inquiry. And, if accompanied by a report on conference deliberations that were widely disseminated, it could help hospitals around the country examine more fully the factors that may be influencing peer review and Data Bank reporting in their own settings.*

Recommendation #3 Calling for PHS and HCFA to Ensure that JCAHO Assess More Fully Hospitals' Compliance with the Data Bank Law

The PHS and HCFA agreed with the recommendation and agreed that a joint letter to JCAHO was the best means of follow-up action at this time. The HCFA added that a joint letter should also be sent to the American Osteopathic Association (AOA), which accredits 150 hospitals for Medicare purposes. The JCAHO and AMA regarded any such follow-up action as premature. The PCHRG urged strong follow-action involving a change in the Medicare Conditions of Participation. The AHA did not comment on this point. *We regard a joint letter to be a reasonable means of follow-up at this time. Although our inquiry did not address AOA accreditation practices, we support a joint letter to it as well if PHS and HCFA find that appropriate. We have retained the options*

involving regulatory and legislative change. Over the long term, depending on the response to the joint letter, they may still warrant consideration.

Methodology

The AHA and AMA raised some methodological objections. Both questioned the relevance of the "considerations" we offered in supporting our finding that there is a sufficient basis for concern about the hospitals' response to Data Bank reporting requirements. In this regard, they cited as misleading our references to prior estimates of adverse action reports from hospitals, the Harvard Medical Practice study, and the number of disciplinary actions taken by State medical boards (only AMA cited the latter). Both AHA and AMA sought more refined measures of hospital reporting than we offered. *We recognize the potential value of more refined measures of hospital reporting. Our purpose, as indicated, was to conduct a limited inquiry to help PHS determine how hospitals are responding to their Data Bank obligations. Given that about 75 percent of the hospitals in the United States never reported an adverse action during the first 3 1/3 years of the Data Bank's operation and the wide variation in reporting levels among the States, we continue to find that there is sufficient basis for our modest recommendations.*

TABLE OF CONTENTS

PAGE

EXECUTIVE SUMMARY i

INTRODUCTION 1

FINDINGS

- Extent of Hospital Reporting 3
- Basis for Concern 4
- Issues Warranting Further Analysis 5

RECOMMENDATIONS 7

COMMENTS ON THE DRAFT REPORT 9

APPENDICES

A: Hospital Adverse Action Reporting, by State A-1

B: Complete Comments on the Draft Report B-1

C: Notes C-1

INTRODUCTION

PURPOSE

To conduct a preliminary inquiry to help the Public Health Service determine how hospitals are responding to their legal obligation to report adverse actions to the National Practitioner Data Bank.

BACKGROUND

In the Health Care Quality Improvement Act of 1986, Congress called for the establishment of the National Practitioner Data Bank (hereafter referred to as the Data Bank). It did so to help health care entities and licensing boards make well- informed decisions concerning the credentialing, the licensing, and, where necessary, the disciplining of health care practitioners. Toward that end, it stipulated that information on practitioners reported to the Data Bank would be made available, upon request, to health care entities and State licensing boards.[1] For hospitals in particular, Congress went further and mandated that they regularly query the Data Bank as part of the application process for physicians, dentists, and other practitioners seeking clinical privileges and every two years for those having such privileges.

The Congress also specified the types of information that had to be reported to the Data Bank. The Data Bank was to include medical malpractice payments, sanctions taken against practitioners by professional societies and State medical and dental boards, and adverse actions taken against practitioners by hospitals and other health care entities. The adverse actions reportable by hospitals and other health care entities would be those that affected a practitioner's clinical privileges for a period greater than 30 days. They would also include cases where a practitioner surrendered such privileges while an investigation was underway or in exchange for not conducting an investigation.

Hospitals that fail to carry out their responsibilities to report to the Data Bank risk losing the liability protections afforded to their professional review activities under the Health Care Quality Improvement Act. The regulations implementing the Act calls for the Secretary of the Department of Health and Human Services (1) to investigate hospitals that appear to be violating their reporting responsibilities, (2) to provide them with an opportunity to correct their practices if they are found to be in noncompliance, and (3) to remove the liability protections if the noncompliance continues.[2]

The Data Bank, administered under the direction of the Health Resources and Services Administration of the Public Health Service (PHS), began operation on September 1, 1990. In late 1992 and early 1993, we issued reports examining the usefulness and impact of the Data Bank to hospitals and licensing boards during the first year and a half of its operation.[3] Currently, at the request of PHS, we are updating that work by examining its usefulness and impact in the ensuing period.

In this brief report, we focus on one discrete and very significant aspect of the Data Bank's operation: hospitals' reporting of adverse action information to the Data Bank. We do that because the Health Resources and Services Administration asked us to determine if there might be a basis for concern associated with the hospitals' response to the reporting requirements. Any evidence, for example, of hospitals not complying with the requirements would certainly cause concern. These would also be a basis for concern if hospitals are taking actions that serve to circumvent the general intent of the law to identify practitioners who may pose a danger to the public.

The hospitals' full cooperation in carrying out the reporting requirements is vital for a number of reasons. One is the sheer number of hospitals involved. With about 6,500 hospitals across the country, they represent a major potential source of information for the Data Bank. A second reason has to do with the nature of the information reported. A loss or reduction in clinical privileges is a serious action that raises important questions about the competence and/or professionalism of a practitioner. Finally, and more basically, hospitals have considerable data on the medical practice patterns of physicians and are in a good position to identify those practitioners who are poor performers.

APPROACH AND METHODOLOGY

Per our understanding with the PHS our inquiry was a limited one intended to help it begin its consideration of hospital reporting issues. In that context, we focused our examination on the extent of hospital reporting during the first 3 1/3 years of the Data Bank's operation.[4] In the first section of the report we present data indicating (1) the number of hospitals that made no reports or 1 or more reports during the 3 1/3 year period and (2) the number of reports per 1,000 hospital beds. In both cases, we indicate the variation among the States.

After presenting the data, we seek, in the second section, to help PHS assess if they present sufficient basis for concern. We draw on interviews with representatives of national organizations, State governments, and PHS; and include a review of pertinent literature concerning health care quality assurance.

We close with three recommendations. Two directed to PHS and the other jointly to PHS and the Health Care Financing Administration.

Our review was conducted in accordance with the ***Quality Standards for Inspections*** issued by the President's Council on Integrity and Efficiency.

FINDINGS

EXTENT OF HOSPITAL REPORTING

From September 1, 1990 to December 31, 1993, about 75 percent of all hospitals in the United States never reported an adverse action to the Data Bank.

The nonreporting hospitals include all types of hospitals in urban and rural locations. And they include many large ones as well as small ones.[5] For example, in Massachusetts, among the 112 hospitals that did not report an adverse action to the Data Bank in its first 3 1/3 years of its operation, 18 have 300 or more beds.

The State-by-State variation in the rate of nonreporting hospitals is considerable - ranging from 93.2 percent of all hospitals in South Dakota to 51.7 percent in New Jersey. The median rate is 76.4 percent.

Among the States with the highest level of nonreporting, the less populated and/or predominately rural ones are heavily represented. In addition to South Dakota, they include Idaho, Montana, Mississippi, Alaska, Alabama, and North Dakota. On the other end, among the States with the lowest rates of nonreporting, the more populous and/or more urban ones are very much in evidence. Along with New Jersey, they include the District of Columbia (classified as a State for purposes of this study), Maryland, New York, California, Ohio, and Rhode Island (see appendix A, table 1).

From September 1, 1990 to December 31, 1993, the approximately 6,500 hospitals in the United States submitted 3,154 adverse action reports to the Data Bank. This represents 2.6 reports per 1,000 hospital beds during the 3 1/3 year period.

When the frame of reference shifts from nonreporting hospitals to the total number of reports per hospital, the State-by-State picture changes somewhat. For example, we find that New Jersey, which ranks first in the proportion of hospitals sending at least one report to the Data Bank, ranks 18th in the number of reports submitted per 1,000 hospital beds. Even more striking is that New York shifts from 4th to 33rd.

Looking more closely, we find that in New Jersey, among the 58 hospitals that submitted adverse action reports to the Data Bank, 25 submitted only 1. In New York, among the 110 hospitals reporting, 57 submitted only 1 (see appendix A, table 2).

Reporting rates per 1,000 hospital beds vary greatly from State to State - ranging from 8.5 in Nevada to .7 in South Dakota. In most States, the reporting rate is between 1.5 and 4.0. The median rate is 2.5 adverse action reports.

Some of the differences among States are considerable (see appendix A, table 2). For instance, the rate of adverse action reports in California, the State with the largest number of hospital beds, is 3.7 per 1,000 beds; the rate in New York, the State with the second

largest number of hospital beds, is considerably less - 2.1. In Ohio, the rate is 2.9; in nearby Illinois it is 1.5. In Virginia, the rate is 4.2; in neighboring Tennessee, which has about the same number of hospitals and hospital beds, the rate is 1.3.

BASIS FOR CONCERN

Our review suggests that there is sufficient basis for concern about the hospitals' response to the Data Bank's reporting requirements.

This is most clearly the case because of the wide variation in hospital reporting rates from State to State. The reporting period for these data is long enough - more than 3 years - to discount short-term aberrations in the States. What, then, might account for the extensive variation? Does it reflect differences in the quality of care being rendered in hospitals? In the capacity or willingness of hospitals to take adverse actions? In other factors associated with the reporting requirements? The answers are not at all clear.

Whatever the State-to-State differences, there is also reason to suspect that the level of reporting in the nation as a whole may be unreasonably low. Some considerations which may support such a suspicion are as follows:

- During the planning stage for the Data Bank, the PHS, in a 1989 planning document submitted to the Office of Management and Budget, estimated there would be 5,000 adverse action reports a year from hospitals.[6] Other estimates from other sources were even higher. Although all estimates were based on little empirical evidence, the gap between them and the actual yearly average of about 1,000 adverse action reports is striking.

- During the 1990 to 1993 period, when hospitals reported about 3,154 practitioners to the Data Bank, State medical boards took disciplinary actions against about 8,000 physicians.[7] These numbers are not directly comparable, but, again, the discrepancy is sufficiently large to raise legitimate questions about whether hospitals are being sufficiently rigorous in taking adverse actions against practitioners on their staffs.[8]

- A 1991 Harvard Medical Practice study of hospitalized patients in New York State found that, in 1984, one percent of the hospitalizations in its random sample involved adverse events caused by negligence. On the basis of its sample, the study team estimated that during 1984, negligent care provided in New York State hospitals was responsible for 27,179 injuries, including 6,895 deaths and 877 instances of "permanent and total disability."[9] To be sure, all of these cases did not warrant the hospital taking an adverse action against the practitioners involved. Yet, in contrast, it is striking to find that in the first 3 1/3 years of the Data Bank's operation, close to three-fourths of the hospitals in the country have not reported a single physician to the Data Bank.

RECOMMENDATIONS

The effectiveness of the Data Bank depends greatly on the cooperation of hospitals. They must query the Data Bank in a timely manner when they review the credentials of practitioners. And they must identify and report to the Data Bank practitioners responsible for serious quality-of-care problems. This report supports further inquiry and oversight to determine if hospitals are cooperating fully in carrying out their reporting responsibilities. Toward that end, we offer the following three recommendations.

The Public Health Service, through the Health Resources and Services Administration, should support further inquiry to foster a better understanding of the factors influencing hospital reporting to the Data Bank.

Given the lack of any central repository of information on hospital peer review actions and the considerable diversity among States and hospitals (even within the same State), intensive case studies probably offer the best near-term approach for further examination. Case studies of hospitals in a few States could help to elucidate the extent and nature of adverse actions and more generally of peer review efforts in particular hospitals. They could also identify some of the operational realities that influence hospital disciplinary efforts. In this context, the case studies could provide information that facilitates effective implementation of the Data Bank law and of broader quality assurance objectives of the Department of Health and Human Services.

In choosing case study sites, it may be particularly helpful to include States with substantially different rates of hospital reporting to the Data Bank. Although the results would not allow for generalizable conclusions on a national scale, they could allow for deeper insights into what factors contribute to differential rates of reporting.

The Public Health Service should sponsor a conference to focus attention on issues influencing reporting to the Data Bank.

The conference should include representatives from the Public Health Service and the Health Care Financing Administration as well as representatives from the American Hospital Association, the American Medical Association, the Joint Commission on Accreditation of Healthcare Organizations, the Federation of State Medical Boards, and other organizations. The conference should pay particular attention to the issues identified in this report as warranting further analysis. It should also address actions that might be taken to ensure that hospitals meet their reporting responsibilities as called for in the Health Care Quality Improvement Act of 1986.

The Public Health Service and the Health Care Financing Administration should work together to ensure that the Joint Commission on Accreditation of Healthcare Organizations assesses more fully hospitals' compliance with the intent and particulars of the Data Bank law.

Given that the Joint Commission's efforts serve as the Department's vehicle for overseeing hospital compliance with the Data Bank law and given its current limitations in that regard, this recommendation calls for a strengthening of the Joint Commissions's reviews that apply to hospital reporting to the Data Bank.

In 1994, the Joint Commission amended its scoring guidelines for surveyors by specifying that hospital queries and reports to the Data Bank should be "timely" and by spelling out more precisely some facets of the Data Bank law.[14] At the same time, the Joint Commission considered including the Data Bank requirements in its statement of standards, but chose not to do so. Such action would have given more prominence to and underscored the importance of the hospitals' obligations under the Data Bank law.

Because of its ongoing accreditation reviews of hospitals, the Joint Commission is in a good position to help the Federal government better understand if there are problems associated with hospitals' reporting to the Data Bank. But to take advantage of this opportunity, the Joint Commission clearly must devote greater attention to this issue during its survey visits to hospitals. We recommend that the Public Health Service and the Health Care Financing Administration collaborate on how best to achieve this end. Among the options they might consider are the following:

A Letter. Send a joint communication to the Joint Commission urging that it incorporate the Data Bank requirements into its standards, conduct a more thorough review of hospital peer review efforts and adverse actions as part of its survey process, and seek to identify any indications of hospitals circumventing the intent of the Data Bank's reporting requirements.

Regulatory Change. Amend the Medicare Conditions of Participation in a manner that will specify hospitals' responsibilities under the Data Bank law. Those responsibilities are not addressed at present in the Medicare Conditions of Participation. This inclusion would compel the Joint Commission to devote greater oversight to hospitals' performance of the responsibilities.

Legislation. Propose legislation that would call for hospitals' Data Bank responsibilities to be addressed in the Medicare Conditions of Participation and for the Joint Commission to focus more attention on the fulfillment of these responsibilities during its survey process.

Each of these approaches has been taken previously with respect to other matters - for example, discharge planning and organ recovery procedures. The first would most likely be the quickest to carry out and may have a stimulative effect, but it would lack the authority of the second or third measures. The third would be the most authoritative approach with the greatest likely impact, but would be likely to take longer to have an effect. The second represents a likely mid-point between the other two in terms of time to implement, expected impact, and degree of authority.

COMMENTS ON THE DRAFT REPORT

We solicited and received comments on the draft report from the Public Health Service (PHS), the Health Care Financing Administration (HCFA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Hospital Association (AHA), the Public Citizen's Health Research Group (PCHRG), and the American Medical Association (AMA). We include the complete text of the comments in appendix B. Below we summarize the comments of the respondents and then, in italics, offer our responses. We do that first, and at most length, with respect to our recommendations. We then summarize and respond to the methodological concerns raised by two respondents.

RECOMMENDATIONS

Recommendation #1: The Public Health Service, through the Health Resources and Services Administration, should support further inquiry to foster a better understanding of the factors influencing hospital reporting to the Data Bank.

The PHS agreed but indicated that consideration of the in-depth case study analysis we suggested is best deferred until a current study they are supporting is completed and the results reviewed. The JCAHO was more enthusiastic about further inquiry, indicating that it should be a "first priority" and was "an essential prerequisite to any informed action" concerning hospital reporting. The PCHRG also expressed strong support. The HCFA, AHA, and AMA did not comment specifically on this recommendation.

We urge PHS to give higher priority to near-term inquiry that would examine in some depth the factors influencing hospital reporting to the Data Bank. Such inquiry is likely to require more than the survey work it currently has underway and, as we suggest in the report, would call for focused inquiry at particular hospitals. The AHA, even though it did not comment specifically on this recommendation, offers additional rationale for the kind of inquiry we suggest. It pointed out that the peer review immunity provisions set forth in the Health Care Quality Improvement Act of 1986 have proven to be insufficient and have served as a "powerful disincentive " for hospital peer review activity. The PCHRG raised a similar concern. Focused case studies could examine the extent and nature of the problems associated with the immunity provision, along with other factors. We incorporated this consideration into the text of this final report.

Recommendation #2: The Public Health Service should sponsor a conference to focus attention on issues influencing reporting to the Data Bank.

The PHS agreed with the thrust but not the specific content of this recommendation. It noted that it "will be engaged in a series of ad hoc work group meetings and presentations at various professional society meetings." It pointed out that such efforts would reach a broader audience and allow for more one-on-one interaction. It further noted that if these

efforts prove unsuccessful, it would consider the conference approach we recommended. The JCAHO was more supportive, calling a conference "a solid first step toward defining the reporting problem." The AMA regarded a conference as "premature," given its concerns about the "accuracy and completeness" of data. Others did not comment specifically on this recommendation.

We strongly suggest that PHS reconsider our conference recommendation and, in fact, accord it a higher priority than our first recommendation. Such a conference, attended by knowledgeable participants from the various sectors, would allow for more concerted attention and interaction than the ad hoc meetings PHS cited. It could help outline the scope of a subsequent, in-depth inquiry. And, if accompanied by a report on the deliberations that were then widely distributed, it could help others around the country examine more fully the factors (such as insufficient immunity protection) that may be influencing hospital reporting in their own settings.

Recommendation #3: The PHS and HCFA should work together to ensure that the JCAHO assesses more fully hospitals' compliance with the intent and particulars of the Data Bank law. (We elaborated on three possible options toward this end: (1) a joint letter to JCAHO calling for it to give greater attention to hospital compliance with Data Bank reporting laws, (2) regulatory change involving an amendment to the Medicare Conditions of Participation, and (3) legislation calling for hospitals' Data Bank responsibilities to be addressed in the Medicare Conditions.)

The PHS supported the letter option and indicated that it already has had initial discussion with HCFA concerning it. The HCFA also expressed support for a letter and added that in addition to JCAHO, it should be sent to the American Osteopathic Association, which accredits 150 hospitals for Medicare purposes. The JCAHO regarded each of the options as "somewhat premature," without a better understanding of the problem. The AMA, even more strongly, felt that the options were premature. On the other hand, PCHRG sought action stronger than a letter and called for changes in the Medicare Conditions of Participation. The AHA did not comment on this recommendation.

We welcome the commitment of PHS and HCFA to proceed with a joint letter. Our inquiry did not address the accreditation practices of the American Osteopathic Association (AOA). If HCFA and PHS find it appropriate to send the joint letter to AOA as well as JCAHO, we certainly support their action. We have still included the regulatory and legislative options under the recommendation; they could be reasonable longer term actions depending on the results of further inquiry and the joint letter.

METHODOLOGY

Both the AHA and the AMA raised methodological concerns associated with our report. Both sets of concerns, in effect, have to do with the factors we rely upon to support our finding that "there is sufficient basis for concern about the hospitals' response to the Data Bank's reporting requirements." The AHA pointed out the lack of any reliable estimates of adverse action reports from hospitals, the inadequacy of reporting rates per 1,000

hospital beds as a measure of hospital reporting, and the inappropriateness of the Harvard Medical Practice study as a point of comparison. The AMA indicated concerns with both tables we presented, noting that they do not reflect adjustments for the size of nonreporting hospitals or the size of the medical staffs. As did AHA, it raised concerns about our reference to the prior estimates of hospital reporting (even with the caveats we offered) and our use of the Harvard study as a point of comparison. It also found our reference to the number of disciplinary actions taken by medical boards to be misleading.

We recognize that an understanding of the hospital reporting issue could be advanced through further analysis and more refined measures of hospital reporting. We would welcome additional inquiry of that sort. Our own purpose, as stated, was to conduct a preliminary inquiry. Given the limits of our data, we deliberately did not make an unqualified assertion that there was a problem involving the extent of hospital reporting. Instead, we concluded that there was sufficient basis for concern. Such concern, we added, was sufficient to warrant further inquiry by PHS (through a study and a conference), and, more immediately, some joint action by PHS and HCFA to assess more fully hospital compliance with the Data Bank law. Given that 75 percent of the hospitals never reported an adverse action during the first 3 1/3 years of the Data Bank's operation, given the wide variation in reporting levels among the States, and given the other "considerations" we noted, we continue to find that there is adequate basis for our modest recommendations.

APPENDIX A

HOSPITAL ADVERSE ACTION REPORTING, BY STATE

TABLE 1
HOSPITALS SUBMITTING NO ADVERSE ACTION REPORTS TO THE DATA BANK, BY STATE, SEPTEMBER 1, 1990 - DECEMBER 31, 1993

State	Number of Hospitals	Hospitals Not Reporting Adverse Actions	Nonreporting Hospitals as a Percentage of Hospitals in the State
S. DAKOTA	59	55	93.2%
IDAHO	52	48	92.3%
MONTANA	59	54	91.5%
MISSISSIPPI	114	103	90.4%
ALASKA	34	30	88.2%
MINNESOTA	158	138	87.3%
ALABAMA	137	119	86.9%
LOUISIANA	181	157	86.7%
N. DAKOTA	56	48	85.7%
TENNESSEE	147	126	85.7%
NEBRASKA	102	87	85.3%
IOWA	127	107	84.3%
OKLAHOMA	160	132	82.5%
ARKANSAS	85	70	82.4%
KANSAS	153	125	81.7%
N. CAROLINA	157	127	80.9%
HAWAII	26	21	80.8%
NEW MEXICO	61	49	80.3%
MISSOURI	158	126	79.8%
TEXAS	540	429	79.4%
WYOMING	29	23	79.3%
W. VIRGINIA	62	49	79.0%
WISCONSIN	148	114	77.0%
S. CAROLINA	78	60	76.9%
MASSACHUSETTS	146	112	76.7%
KENTUCKY	123	94	76.4%

NEVADA	38	29	76.3%
GEORGIA	197	150	76.1%
ILLINOIS	233	176	75.5%
UTAH	58	43	74.1%
VIRGINIA	138	100	72.5%
VERMONT	18	13	72.2%
PENNSYLVANIA	277	198	71.5%
FLORIDA	314	222	70.7%
CONNECTICUT	54	38	70.4%
NEW HAMPSHIRE	39	27	69.2%
MAINE	41	28	68.3%
OREGON	68	46	67.7%
MICHIGAN	192	128	66.7%
ARIZONA	102	68	66.7%
DELAWARE	15	10	66.7%
INDIANA	165	109	66.1%
COLORADO	90	59	65.6%
RHODE ISLAND	20	13	65.0%
OHIO	212	136	64.2%
CALIFORNIA	557	355	63.7%
WASHINGTON	97	61	62.9%
NEW YORK	294	184	62.6%
MARYLAND	81	50	61.7%
D.C.	16	9	56.3%
NEW JERSEY	120	62	51.7%
U.S. TOTAL	6588	4917	NA
STATE MEAN	127	95	74.6%
STATE MEDIAN	117	90.5	76.4%

Source: *Adverse Actions by State, 1990 - 1993*, Health Resources & Services Administration, U.S. Public Health Service.

TABLE 2
HOSPITAL ADVERSE ACTION REPORTS PER 1000 HOSPITAL BEDS,
BY STATE, SEPTEMBER 1, 1990 - DECEMBER 31, 1993

STATE	Number of Hospital Beds	Number of Reports Made by Hospitals	Reports Per 1000 Hospital Beds
NEVADA	4,144	35	8.5
D.C.	7,527	61	8.1
ARIZONA	13,629	94	6.9
COLORADO	13,691	90	6.6
WASHINGTON	15,735	88	5.6
VIRGINIA	29,349	124	4.2
DELAWARE	2,808	11	3.9
MAINE	6,083	23	3.8
OREGON	10,153	38	3.7
CALIFORNIA	105,270	390	3.7
UTAH	5,641	20	3.6
NEW HAMPSHIRE	4,831	17	3.5
MARYLAND	19,982	70	3.5
INDIANA	26,143	90	3.4
KANSAS	15,477	52	3.4
OKLAHOMA	15,100	50	3.3
ALASKA	1,909	6	3.1
NEW JERSEY	37,796	117	3.1
NEBRASKA	10,292	30	2.9
MICHIGAN	39,913	116	2.9
OHIO	51,701	149	2.9
FLORIDA	63,415	174	2.7
WYOMING	3,026	8	2.6
VERMONT	2,290	6	2.6
GEORGIA	36,334	91	2.5
NEW MEXICO	6,867	17	2.5
TEXAS	79,982	190	2.4
KENTUCKY	19,052	43	2.3
N. DAKOTA	5,213	11	2.1
MONTANA	4,742	10	2.1

RHODE ISLAND	4,301	9	2.1
WISCONSIN	23,971	50	2.1
NEW YORK	102,036	210	2.1
S. CAROLINA	15,166	29	1.9
MISSOURI	29,455	56	1.9
ARKANSAS	13,328	24	1.8
IOWA	17,009	30	1.8
CONNECTICUT	14,238	25	1.8
PENNSYLVANIA	66,298	116	1.8
N. CAROLINA	30,151	52	1.7
MASSACHUSETTS	31,973	55	1.7
W. VIRGINIA	10,590	18	1.7
IDAHO	4,045	6	1.5
ILLINOIS	57,343	84	1.5
LOUISIANA	23,980	35	1.5
MINNESOTA	24,019	35	1.5
HAWAII	4,274	6	1.4
ALABAMA	23,574	33	1.4
TENNESSEE	29,420	37	1.3
MISSISSIPPI	17,577	19	1.1
S. DAKOTA	5,450	4	0.7
U.S. TOTAL	1,206,293	3,154	NA
STATE MEAN	23,198	61	2.6
STATE MEDIAN	15,606	37.5	2.5

Sources: *Adverse Actions by State, 1990 - 1993*, Health Resources & Services Administration, U.S. Public Health Service; and *State Summary of Hospital Beds*, Quality Resource Systems, Inc. (from data provided by the American Hospital Association's *1991 AHA Annual Survey*).

APPENDIX B

COMMENTS ON THE DRAFT REPORT

In this appendix, we present in full the comments from the Assistant Secretary for Health and the Health Care Financing Administration. We also present the comments from the Joint Commission on Accreditation of Healthcare Organizations, the American Hospital Association, the Public Citizens Health Resource Group, and the American Medical Association.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date JAN 19 1995

From Assistant Secretary for Health

Subject Office of Inspector General (OIG) Draft Report "Hospital Reporting to the National Practitioner Data Bank," OEI-01-94-00050

To Inspector General, OS

Attached are the Public Health Service comments on the subject draft report. We concur fully or in part with the report's recommendations. The attached comments delineate the actions we plan to take to implement these recommendations.

Philip R. Lee, M.D.

Attachment

PUBLIC HEALTH SERVICE (PHS) COMMENTS ON THE OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT "HOSPITAL REPORTING TO THE NATIONAL PRACTITIONER DATA BANK," OEI-01-94-00050

General Comments

The OIG report focuses on the issue of hospital compliance with National Practitioner Data Bank (Data Bank) reporting requirements. The period studied encompasses 3 1/3 years, from the opening of the Data Bank on September 1, 1990 through December 31, 1993. During this period, 3,154 disclosable adverse clinical privileges reports were submitted to the Data Bank by hospitals. During this same period, State licensure boards reported almost 9,000 adverse licensure actions, and malpractice insurers reported over 60,000 malpractice payments.

The OIG report raises concerns about hospital compliance with reporting requirements based on the relatively low number of clinical privileges reports from hospitals in comparison to PHS's pre-Data Bank opening planning estimate of 5,000 clinical privileges reports per year from hospitals. The fact that the rate of hospital reporting varies widely from State to State also raises concerns, as does the number of clinical privileges reports in relation to the larger numbers of reports of other types.

We note that the issue is not one of the efficiency of Data Bank operations themselves. Hospitals use the same reporting forms and procedures that are successfully used by malpractice insurers, State licensing boards, and others to report to the Data Bank. During the study period, the Data Bank processed over 73,000 disclosable malpractice payment and adverse action reports and over 3 million queries from authorized entities. In addition, the Data Bank provided over 122,000 responses concerning malpractice payments and/or adverse actions to queriers. Data from other OIG reports indicate that Data Bank information provided to queriers may have resulted in decisions not to provide privileges to about 2,000 practitioners with poor records, who otherwise would have been granted privileges.

The Data Bank relies on voluntary compliance by hospitals with reporting requirements. The Data Bank uses several means to make the required reporting as easy as possible. For example, the Data Bank provides guidance materials on what is to be reported and how it should be reported. A new (third) edition of the Data Bank Guidebook is scheduled for mailing to all hospitals in late January 1995. In addition, a free telephone "help line" for questions about reporting requirements is available to hospitals.

Reporting forms and methods are also being improved. Paper reporting forms were revised in 1994 to simplify their completion. During 1995, the Data Bank's current system for electronic querying will be expanded to also provide a capability for electronic reporting. This will eliminate the necessity to fill out paper forms. The Data Bank will provide free reporting software to hospitals and other reporters and will provide tollfree modem connections for submitting reports electronically.

Despite these efforts to facilitate voluntary compliance with reporting requirements, the OIG report identifies two specific types of potential problems in hospital reporting to the Data Bank. Although PHS' Health Resources and Services Administration (HRSA) was aware of the possible problems identified in the report (in fact, HRSA requested that the OIG conduct this study), we believe the report is valuable because it highlights the problems. By documenting these problems, the report will serve as a basis for discussion and as a means to gain cooperation of others, including hospitals, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the Health Care Financing Administration (HCFA), in resolving them.

There are two types of under-reporting. The first is noncompliance with the law by failing to report disciplinary actions which are required to be reported to the Data Bank. The second type involves a change in the manner in which hospitals impose penalties in professional disciplinary cases to minimize the imposition of penalties which would require reporting to the Data Bank. For example, clinical privileges suspensions of more than 30 days must be reported; shorter suspensions are not reportable. By reducing the length of suspensions to less than 30 days, hospitals could avoid reporting to the Data Bank.

The first type of under-reporting is illegal. The second type is legal, but contrary to the intent of the law and detrimental to the general utility of the Data Bank program. Although the OIG report primarily focuses on the first type; the second type may actually be of much greater significance to the Data Bank, depending on the extent of each type. The OIG report identifies the second type as an issue warranting further analysis and suggests that HRSA conduct some intensive case studies on the issue. HRSA is focusing attention on this issue in a major survey of hospitals and other entities which interact with the Data Bank.

The HRSA's survey of Data Bank reporters and queriers, which is currently being conducted by Walcoff and Associates, is designed to examine, among other issues, the second type of under-reporting. Walcoff and Associates surveyed a sample of 1,500 entities, including 800 hospitals, to determine how they interact with the Data Bank, use Data Bank information (if the entities are asking for data), and how Data Bank reporting and querying procedures can be improved. Results are due in the early spring of 1995. If the survey results indicate that changes in hospital behavior are being made to avoid Data Bank reporting, we may want to conduct case studies as recommended in the OIG report.

The OIG report also contributes new information in relation to the first type of under-reporting. In one unnamed State, 16 actions by hospitals which should have been reported to the Data Bank were found to have not been reported. Since the OIG only examined incidents from hospitals which had reported to the State licensing board, but had made no reports to the Data Bank, we cannot determine: (1) the extent of under-reporting by hospitals which did make at least one report to the Data Bank; (2) the extent of under-reporting by hospitals which did not report some or all incidents which should have been reported to the State licensing board; or (3) the overall extent of under-reporting in the unnamed State. We only know for certain that there was some under-reporting in this one State, but we cannot determine either the true extent or the significance of the under-reporting. The documented fact of this under-reporting, however, indicates the possibility that similar under-reporting may take place in other States and may be a significant problem.

The report's other argument that there may be under-reporting by hospitals seems less explanatory. The report cites the fact that rates of reporting of adverse clinical privileges actions vary considerably from State to State. It should also be noted, however, that there is no evidence that the variation results from under-reporting (or a greater degree of under-reporting) in some States. Malpractice payment reporting also varies considerably from State to State. There is only a weak correlation between a State's malpractice report rate and its clinical privileges report rate. To date, the State-to-State variations are unexplained, but we have no particular reason to believe that some States have higher under-reporting rates than others for clinical privileges actions and that under-reporting explains the differences in clinical privileges reporting rates observed among the States.

OIG Recommendation

1. The PHS, through the HRSA, should support further inquiry to foster a better understanding of the factors influencing hospital reporting to the Data Bank.

PHS Comment

We concur. We are currently undertaking one such study (one portion of the Walcoff and Associates study discussed under the general comments above examines hospital reporting). In addition, we received some relevant information from the WAMI (Washington, Alaska, Montana, and Idaho) study of the experience of rural hospitals with the Data Bank. However, we note that data are limited on which to assess the issues specifically identified by the OIG as warranting further analysis. In particular, further examination may be required concerning the proportion of hospitals that either do not take actions against practitioners or take actions which are not reportable. The extent of failure by hospitals to make required reports also may require further examination. Intensive case studies involving review of peer review records, as recommended by the OIG, may be the best way to examine these issues even though it may be difficult to get hospitals to participate. It is important to note that HRSA does not have the staff or financial resources to perform the type of detailed examinations envisioned by the OIG. If resources became available, any studies would have to be performed by contractors.

OIG Recommendation

2. The PHS should sponsor a conference to focus attention on issues influencing reporting to the Data Bank.

PHS Comment

We concur with the thrust of this recommendation, but believe that we can achieve the desired results by taking a different approach. In order to establish stronger direct communication with hospitals, the HRSA's Division of Quality Assurance, which manages the operation of the Data Bank, will be engaged in a series of ad hoc work group meetings and presentations at various professional society meetings. These work group meetings and presentations should reach a broader audience than would a one-time conference. In addition, these types of fora will allow for more one-on-one interaction between the relevant parties and should be more effective at focusing

attention, from both the hospital and Data Bank points of view, on issues affecting reporting. However, if these meetings and presentations do not prove to be effective in identifying issues influencing reporting to the Data Bank, we will give further consideration to the conference approach recommended by the OIG.

OIG Recommendation

3. The PHS and the HCFA should work together to ensure that the JCAHO more fully assess hospitals' compliance with the intent and particulars of the Data Bank law.

PHS Response

We concur. The OIG proposed three options: (1) sending a joint letter from PHS and HCFA urging that it incorporate compliance with Data Bank requirements into its standards and identify hospitals which do not comply during its reviews; (2) amending the Medicare Conditions of Participation (regulatory change) to require compliance with Data Bank requirements, which would in turn lead to better JCAHO oversight in this area; and (3) proposing legislation requiring amendment of the Medicare Conditions of Participation, as proposed in (2) above. We support implementation of the first option.

Data Bank staff will work with HCFA on this letter. Initial discussions have already been held. A meeting will be scheduled soon between Data Bank and HCFA staff to discuss this issue and begin drafting the necessary correspondence.

If the joint letter to JCAHO approach does not result in the needed change, then we would support efforts to change the Medicare Conditions of Participation, through legislation if necessary (options 2 and 3).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

DATE DEC 12 1994

FROM Bruce C. Vladeck
Administrator

SUBJECT Office of Inspector General Draft Report: "Hospital Reporting to the National Practitioner Data Bank," (OEI-01-94-00050)

TO June Gibbs Brown
Inspector General

We reviewed the subject draft report which looks at how hospitals are responding to their legal obligation to report to the National Practitioner Data Bank adverse actions they take against health care practitioners.

The Health Care Financing Administration concurs with the report recommendations. Our comments are attached for your consideration.

Thank you for the opportunity to review and comment on this report. Please advise us [illegible] if we would like to discuss our position on the report's (2) amending the (regulatory change) to require compliance with [illegible] requirements, which would in turn lead to better JCAHO oversight in this area; and (3) proposing legislation requiring amendment of the Medicare Conditions of Participation, as proposed in (2) above. We support implementation of the first option.

Data Bank staff will work with HCFA on this letter. Initial discussions have already been held. A meeting will be scheduled soon between Data Bank and HCFA staff to discuss this issue and begin drafting the necessary correspondence.

If the joint letter to JCAHO approach does not result in the needed change, then we would support efforts to change the Medicare Conditions of Participation, through legislation if necessary (options 2 and 3).

Comments of the Health Care Financing Administration (HCFA) on
Office of Inspector General (OIG) Draft Report
"Hospital Reporting to the National Practitioner Data Bank."
(OEI-01-94-00050)

OIG Recommendation

The Public Health Service (PHS), through the Health Resources Services Administration, should support further inquiry to foster a better understanding of the factors influencing hospital reporting to the Data Bank.

HCFA Response

We defer to PHS.

OIG Recommendation

The PHS should sponsor a conference to focus attention on issues influencing reporting to the Data Bank.

HCFA Response

We defer to PHS.

OIG Recommendation

The PHS and the HCFA should work together to ensure that the Joint Commission on Accreditation of Healthcare Organizations assesses more fully hospitals' compliance with the intent and particulars of the Data Bank law. Toward this end, they might consider the following options: A Letter, Regulatory Change, and/or Legislation.

HCFA Response

We concur and recommend the "letter" approach as opposed to regulatory or statutory change. We also recommend including the American Osteopathic Association, which accredits 150 hospitals for Medicare purposes, in the communication.

Joint Commission
on Accreditation of Healthcare Organizations

December 19, 1994

June Gibbs Brown
Inspector General
Department of Health and Human Services
Wilbur J. Cohen Building - Room 5250
330 Independence Avenue S.W.
Washington, DC 20201

Dear Ms. Brown:

I am writing in response to your letter of November 15, 1994 which invites the comments of the Joint Commission on Accreditation of Healthcare Organizations on your draft inspection report, "Hospital Reporting to the National Practitioner Data Bank." Our comments are limited to the recommendations that appear in your draft report.

More in-depth Public Health Service (PHS) inquiry to achieve a better understanding of the factors influencing hospital reporting to the Data Bank should, we believe, be the first priority. Such an understanding is an essential prerequisite to any informed action concerning the issue of National Practitioner Data Bank (NPDB) reporting. We are persuaded that there are a host of factors influencing hospital reporting to the Data Bank. If a decision is made to explore these more fully, the Joint Commission would be pleased to cooperate in such an endeavor before new steps are taken to remedy the perceived problem with hospital reporting.

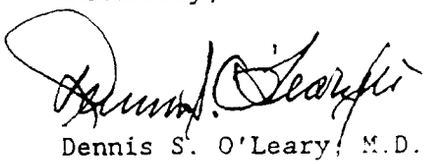
A PHS-sponsored conference focusing on issues which may influence Data Bank reporting sounds like a solid first step toward defining the reporting problem. We certainly support this approach, and would suggest that such a conference be limited in size and be structured in a manner designed to facilitate participation of appropriate experts. A conference designed in this fashion would be most likely to yield the concrete information and recommendations we all seek.

The third recommendation, that the PHS and the Health Care Financing Administration (HCFA) work together to ensure that the Joint Commission assesses more fully hospitals' compliance with the intent and particulars of the Data Bank law, seems somewhat premature when contrasted with the previous recommendations aimed at defining the problem. Absent a better understanding of this problem, we suggest there is a substantial risk that more costly and burdensome federal requirements may be placed on providers without a clear sense of the likely outcomes that may result. It is worthy of note that this recommendation ignores the fact that HCFA directly certifies approximately 2,000 unaccredited hospitals for Medicare participation.

We believe it is appropriate to expect the Joint Commission to collaborate with PHS and HCFA to "assess more fully hospitals' compliance with the intent and particulars of the Data Bank law." However, we suggest it is premature to draw conclusions about the most appropriate remedy for disparate reporting at this time.

Thank you for providing us the opportunity to comment on this important matter.

Sincerely,



Dennis S. O'Leary, M.D.
President

American Hospital Association

AHA

One North Franklin
Chicago, Illinois 60606
Telephone 312.422.3000

January 26, 1995

June Gibbs Brown
Inspector General
Office of Inspector General
Department of Health & Human Services
Washington, D.C. 20201

Re: Draft Report - Hospital Reporting to the National Practitioner Data Bank

Dear Ms. Brown

The American Hospital Association (AHA), on behalf of its 5,000 hospital members, welcomes this opportunity to comment on the Office of Inspector General's draft report on hospital reporting to the National Practitioner Data Bank. Because our members are principal contributors to and users of Data Bank information, the AHA has a significant interest in reporting patterns and the factors that influence them. Although we salute your office's continuing efforts to monitor and evaluate compliance with Data Bank requirements, we have serious concerns with some of the report's findings, omissions, and interpretations.

Methodological Concerns: As the report acknowledges, the PHS estimate that there would be 5,000 hospital adverse action reports per year was just that: an estimate without any empirical evidence, the Department's "best guess" as to what it would find once reporting requirements were implemented. To the extent that estimate in fact misses the mark, reliable conclusions about the reasonableness of hospital reporting are impossible. Moreover, as the OIG suggests, improvements in credentialing and quality assurance practices since the esumate was formulated can be expected to improve practitioner performance. To the extent they have done so, the 5,000 per year estimate becomes an even less reliance basis for evaluating the data.

Other indicators used in the report also are problematic. There is little to recommend reporting rates per 1000 hospital beds as a reliable measure of hospital reporting. Similarly, the Harvard Medical Plan study data, while interesting, fail to provide a basis for comparison; incidents of negligence are not interchangeable with adverse actions for Data Bank purposes.

Indeed, among the data presented, only the state-to-state reporting variations, presented in Table I of Appendix A, suggest that further analysis might be fruitful. In the discussion of issues it believes warrant further analysis, however, the OIG fails to focus on the insufficiency of the Health Care Quality Improvement Act's (HCQIA) immunity provisions and the powerful disincentive they create for hospital peer review activity.

Analytical Concern: When HCQIA was enacted, it was recognized that mandatory reporting requirements would lead to an increase in litigation as physicians faced with disciplinary action challenged adverse peer review actions. In an effort to reduce the chilling effect such litigation would have on effective peer review, Congress provided qualified immunity to participants in the peer review process.

HCQIA's peer review immunity, however, has been only partially effective because many courts have not required physicians to rebut the statutory presumption of immunity with credible evidence prior to trial. Early resolution in these cases is impossible, even where there is no objective evidence of improper peer review activity. Although by no means all the cases have misinterpreted the immunity provisions, some courts have substantially ignored them, denying motions for summary judgment and forcing trials. Unless the availability of these provisions is determined objectively and early in the litigation, they cannot help but fall short of their statutory purpose. The specter of baseless, time-consuming and expensive litigation serves as a powerful disincentive to effective peer review activity. Any study of reporting behavior needs to take this disincentive into account in order to accurately interpret adverse actions that fall below the threshold for Data Bank reporting.

The AHA appreciates the opportunity to provide our comments on the OIG's draft report on hospital reporting to the National Practitioner Data Bank. We hope our comments are helpful and will await receiving the final report.

Sincerely,

Fredric J. Entin
Senior Vice President
and General Counsel

Public Citizen

Buyers Up • Congress Watch • Critical Mass • Health Research Group • Litigation Group

Joan Claybrook, President

January 9, 1995

June Gibbs Brown
Inspector General
Department of Health and Human Services
Washington, DC 20201

Dear Ms. Brown:

Please find enclosed our comments on OIG's draft report: "Hospital Reporting to the National Practitioner Data Bank." We appreciate the opportunity to review and comment on this report. Please let us know if we can be of further assistance to you or your staff in your studies regarding the National Practitioner Data Bank.

Sincerely,

Sidney M. Wolfe, MD
Director

Joan Stieber, JD, MSW
Staff Attorney

Public Citizen's Health Research Group

Enclosure

Ralph Nader, Founder

2000 P Street NW • Washington, D.C. 20036 • (202) 833-3000

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COMMENTS ON "HOSPITAL REPORTING TO THE NATIONAL PRACTITIONER DATA BANK" (OEI-01-94-00050)

Submitted by Public Citizen's Health Research Group
January 9, 1995

We appreciate the opportunity to comment on this report by the Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS). The report represents an important first step toward understanding the factors influencing hospitals' reporting -- or failure to report -- to the National Practitioner Data Bank, as mandated by the Health Care Quality Improvement Act of 1986 (HCQIA). However, the report raises more questions than it answers, and follow up study on this issue is imperative.

As noted by the OIG, hospitals' cooperation is especially critical to the Data Bank's effective operation, since:

- the nation's approximately 6,500 hospitals represent a major source of information for the Data Bank;
- a loss or reduction of hospital privileges raises serious questions about a physician's competence and/or professionalism; and
- hospitals have considerable data on the practice patterns of individual doctors, and are in a good position to identify those who may be placing their patients at risk.

We share the OIG's concern about the suspiciously low rate at which hospitals are reporting adverse actions to the Data Bank. A shocking 75 percent of all hospitals never reported a single adverse action during the 3-1/3 year period covered by the OIG's report. While the OIG offers several possible hypotheses for this deficiency, we find the first -- that there may be few practitioners with serious performance problems -- to be highly improbable.

In fact, published estimates of negligence in hospitals strongly discredit this idea. The 1991 Harvard Medical Practice Study (as noted by the OIG) found that one percent of hospitalizations in New York state in one year involved adverse events caused by negligence, including almost 7,000 deaths. This result projected to hospitals nationwide suggests that 80,000 patients a year are killed by negligence, mostly by physicians, in hospital settings alone. At this rate, there would have been 266,400 patient deaths due to negligence in hospitals over the 3-1/3 year period in which hospitals reported only 3,154 adverse actions to the Data Bank.

For this reason as well as others noted by the OIG, we suspect that hospitals are either failing to take serious disciplinary actions against doctors as needed, or they are taking such actions but grossly underreporting them to the Data Bank. Therefore, we

strongly support the OIG's recommendation for further study, both to learn more about factors influencing hospitals' reporting practices, and as a basis for enforcement actions against hospitals found out of compliance with the law. We also support the OIG's other recommendations, with particular attention to the option of revising the Medicare Conditions of Participation to specify hospitals' responsibilities under the HCQIA.

Finally, we note that the current penalty provided by the HCQIA for noncompliance by hospitals may be insufficient to deter violations of the law. Hospitals that fail to report adverse actions to the Data Bank as required risk losing the HCQIA's liability protection for three years. That protection exempts peer reviewers from monetary damages in private lawsuits over professional review actions that meet certain standards. However, the law appears to provide only immunity from damages, not from suit, leaving peer reviewers still at risk of having to defend against claims for injunctive or declaratory relief. Even suits seeking damages may still go to trial to decide whether discipline was imposed in bad faith. Thus, some view the HCQIA's liability protection as relatively weak, and its loss may not appear to pose much of a threat.

The penalty for noncompliance by hospitals is also inconsistent with most other penalty provisions in the law. The HCQIA authorizes monetary penalties up to $10,000 per incident for failing to report payments on malpractice claims, as well as for violations of the confidentiality provision.

We urge the Public Health Service to propose legislation strengthening penalties for noncompliance by hospitals. That legislation should authorize (in addition to loss of the law's limited liability protection) monetary penalties up to $10,000 per incident for hospitals that fail to report to the Data Bank as mandated by law. This would make hospital penalties at least comparable to those applied to malpractice insurers who fail to submit payment reports.

Of course, even stronger penalties will be ineffective unless enforced by DHHS. We are unaware of any instance since the Data Bank's inception in which a hospital was penalized for failing to submit reports. We recommend that the OIG, in its follow up studies, consider whether DHHS is appropriately exercising its enforcement powers under the HCQIA.

American Medical Association
Physicians dedicated to the health of America

James S. Todd, MD
Executive Vice President

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312 464-5000
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February 1, 1995

The Honorable June Gibbs Brown
Inspector General
Office of Inspector General
Department of Health & Human Services
330 Independence Avenue, SW - Room 5246
Cohen Building
Washington, D.C. 20201

RE: Draft Inspection Report, "Hospital Reporting to the National Practitioner Data Bank"

Dear ~~Inspector General~~ June Brown:

The American Medical Association (AMA) appreciates your soliciting our comments on the Office of Inspector General's draft inspection report, "Hospital Reporting to the National Practitioner Data Bank," October 1994 (OIG Report). The OIG Report was written for the purpose of helping the Public Health Service (PHS) determine whether hospitals are reporting adverse actions to the National Practitioner Data Bank (NPDB), as required by the Health Care Quality Improvement Act (HCQIA). The AMA's review, however, concludes that the Report falls far short of its purported goal. Even given the "preliminary" status of the Report, our review has revealed important gaps in both accuracy and completeness of data, creating a misleading picture. We offer the following comments and suggestions for your consideration.

The data presented on the extent of hospital reporting is flawed and incomplete. For example, Table 1 of Appendix A does not take into account any adjustment for the size of the non-reporting hospitals or the number of physicians/dentists on their medical staffs. And although Table 2 does provide information on the number of reports per 1,000 hospital beds, the number of reports per 1,000 practicing physicians must also be presented in order to demonstrate significant state variation.

Because of the incomplete nature of the Report's data, the OIG's conclusion, based on this data, that the number of hospitals reporting adverse actions is "unreasonably low" seems unfounded. The AMA's concern is heightened by the Report's reliance on the following three items to support its case: (1) the 1989 planning document submitted to the Office of Management and Budget; (2) the disparity between the number of licensure actions against physicians and the number of adverse actions taken against hospital-based physicians only; and (3) the 1991 Harvard Medical Practice study of hospitalized patients

in New York state. None of these three items credibly supports the OIG's conclusions.

The 1989 Planning Document

The 1989 estimate that hospitals may report 5,000 adverse action reports per year is invalid. In OIG's words the estimate was "based on little empirical evidence" and was "widely acknowledged to be little more than informed guesses."

To determine if there has been a change in the frequency of reporting hospital adverse actions as a result of the implementation of HCQIA's reporting requirement to the NPDB, the OIG should contact the medical licensing boards, which require hospitals to report adverse actions. If the data shows no change in the reporting rate since September 1, 1990, it would confirm that the early estimates were simply way off the mark.

Comparison of the Number of Actions Reported by Licensing Boards and Hospitals

There is a difference between the number of actions reported by licensing boards and hospitals. This difference in and of itself does not indicate any particular problem; nevertheless, the OIG uses this difference to suggest that hospitals are not taking necessary actions to ensure the quality of their medical staff. The AMA disputes this conclusion.

The OIG should have analyzed the reasons these numbers may be different, in concert with information available on the 7,675 "prejudicial actions" taken by licensing boards against physicians. The differences could be based on a variety of factors not considered in the Report. Most significantly, how many of the physicians reported are on a hospital medical staff, and how many are office-based/ambulatory care-based physicians? How many of that number are multiple licensure actions against a single physician, perhaps even regarding the same event as sanctioned by multiple jurisdictions? What are the degrees of sanction involved and do they vary by state?

Evaluation of questions such as these may help to explain quantitative disparities and resolve concern about hospital under-reporting. The broadening of the OIG's evaluation to include qualitative data will lead us to a more complete and credible portrayal of what is actually happening. For example, the OIG might consider taking a random sample of reported licensure actions to determine if a hospital should have initiated an adverse action and/or reported an adverse action to the NPDB.

1991 Harvard Medical Practice Study of New York State

The reference to this study does not support a concern about an "unreasonably low level of hospital reporting." Clearly, adverse events do occur. In a majority of instances, though, the event is not the responsibility of a "bad physician." Rather, adverse events are frequently attributable to flawed systems or processes. It is universally recognized that punitive measures against physicians do not prevent adverse events from occurring and overall is not an effective patient safety/quality improvement measure. It is more effective to improve the process or system by which health care is delivered than to penalize a physician who practices in a bad system.

In conclusion, we urge the OIG to reconsider its data and the conclusions drawn from that data to either confirm or refute the charge that hospitals are not fully complying with their legal obligation to report adverse actions to the National Practitioner Data Bank. Without further analysis, it is premature to recommend that the PHS sponsor a conference on issues influencing reporting to the NPDB, or to take steps to have the Joint Commission on Accreditation of Healthcare Organizations increase its focus on assessing the hospital's compliance with the HCQIA. We offer our assistance to obtain the best available information and understanding of the factors influencing hospital reporting to the NPDB.

Sincerely,

James S. Todd, MD

APPENDIX C

NOTES

1. Information, under certain conditions, could also be made available to plaintiffs' attorneys.

2. 45 CFR Part 60 (1989).

3. See Department of Health and Human Services, Office of Inspector General, *National Practitioner Data Bank: Usefulness and Impact of Reports to Hospitals,* OEI-01-90-00520, February 1993 and Department of Health and Human Services, Office of Inspector General, *National Practitioner Data Bank: Usefulness and Impact of Reports to State Licensing Boards,* OEI-01-90-00523, March 1993.

4. At the time of our inquiry, December 31, 1993 was the latest date for which data were available to us.

5. Across the United States we are reporting on a total of 6,588 hospitals, based on data provided by the Health Resources and Services Administration. The total represents hospitals which were in existence sometime during the September 1, 1990 to December 31, 1993 period and which, therefore, could have submitted adverse action reports sometime during that period. The total is not a count of the number of hospitals in existence on December 31, 1993.

6. 54 Fed. Reg. 52,853, Dec. 22, 1989.

7. For calendar years 1991, 1992, and 1993, the Federation of State Medical Boards reports 7,675 "prejudicial actions" against physicians. These include license revocation, suspension, or surrender; probation or licensure restrictions of some kind; and other formal actions such as penalties or reprimands. We arrived at a 3 1/3 years estimated total of 8,000 prejudicial actions by assuming that at least 325 were taken in the last 4 months of 1990. Given that 2,361 were taken in all of 1993, the 325 estimate appears to be reasonable.

8. All physicians disciplined by boards are not necessarily on hospital staffs. On the other hand, some could be on the staff of more than one hospital.

9. Troyen A. Brennan, et al., "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I," *The New England Journal of Medicine* 324, no. 6 (February 7, 1991): 370-76.

10. Improving the overall performance of the medical staff and assuring that certain minimum standards of performance are maintained are not necessarily incompatible objectives. Indeed, the director of one well-respected quality insurance program told us that in his program involving multiple hospitals both objectives coexist. At the same time that the overall standard of care has been improved, a number of physicians have been disciplined and/or reported to the risk management program.

    Yet, in the quest to maintain a "safe" environment for physicians to participate in reviewing data on practice variations, it certainly is plausible that a hospital may choose to deemphasize or even avoid disciplinary activities, perhaps by allowing physicians whose performance is questionable over a substantial period of time to leave the staff and find other practice settings.

11. To obtain some information on the extent to which reportable hospital actions may not in fact be reported to the Data Bank, we sought the cooperation of medical licensure boards in eight States. Our intention had been to give them a list of all hospitals in their States that had not reported a single practitioner to the Data Bank in the 1990 - 1993 period and then to have asked them to identify any referrals they received and disciplinary actions they took involving physicians from those hospitals. With that information, we would then have checked to see if any of those cases involved hospital actions that should have been reported to the Data Bank.

    Unfortunately, during the brief period of our inquiry, only one State was able to provide us with sufficient information. Other States either were not readily able to identify referrals or disciplinary actions by source or to free up sufficient resources to review hospital referrals to determine if they should have been reported to the Data Bank. In the participating State, officials were able to provide such information and afforded us the opportunity to review hospital reports ourselves.

12. These actions included reductions, surrenders, suspensions, and terminations of physicians' clinical privileges. Information was obtained from case files.

13. Through the Health Care Financing Administration, the Department conducts validation surveys of a sample of hospitals to assure that they comply with the Medicare Conditions of Participation.

14. The more precise explanations that the Joint Commission inserted in the scoring guidelines respond to suggestions made by the Health Resources and Services Administration of the Public Health Service. The amendment concerning timely querying responds in part to a recommendation we made in a February 1993 report. In that report, *National Practitioner Data Bank: Usefulness and Impact of Reports to Hospitals* (OEI-01-90-00520), we called for the Joint Commission to

"establish guidelines on how quickly hospital should query the Data Bank after receiving applications for privileges."