Hospitals Drop the Ball on Physician Oversight

Failure of Hospitals to Discipline and Report Doctors Endangers Patients

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# Table of Contents

Executive Summary ................................................................. 2

**Reporting and Disciplining of Doctors by U.S. Hospitals**

- National Practitioner Data Bank ........................................................................... 6

**Analysis of Hospital Compliance**

- State Variation in Hospital Reporting ................................................................. 9
- Importance of Hospital Reporting for State Licensure Board Actions ................. 11
- Factors Affecting Hospital Reporting ................................................................. 16
  - Failure to Report ............................................................................................... 16
  - Failure to Act .................................................................................................... 19
- OIG Investigations of Hospital Under-Reporting and Peer Review ....................... 23
- 1996 Consensus Agreement that Under-Reporting is a Problem .......................... 26
- Failure of Hospitals to Voluntarily Comply in a Study on Hospital Reporting ....... 28

**Conclusions and Recommendations**

- Public Citizen’s Health Research Group Conclusion ........................................... 29
- Status of Previous Recommendations .................................................................. 30
- Public Citizen’s Health Research Group Recommendations ............................ 31

**Appendices**

- A: Total Number of Adverse Hospital Privileges Reports by Year ..................... 37
- B: Currently Active Registered Non-Federal Hospitals that Have Never Reported to the National Practitioner Data Bank by State .................................................. 38
Executive Summary

*Lack of detection and widespread under-reporting to the National Practitioner Data Bank raise serious questions about hospital peer review.*

The National Practitioner Data Bank (NPDB) was established by the Health Care Quality Improvement Act of 1986 to protect patients from questionable physicians. The legislation included a requirement that hospitals report to the NPDB whenever they revoke or restrict a physician’s hospital privileges for more than 30 days for problems involving medical competency or conduct. As the only national repository for the records of doctors disciplined by their peers for unprofessional or incompetent behavior, the usefulness of the data bank has been historically handicapped by the failure of thousands of hospitals to report to the NPDB. As of December 2007, almost 50 percent of the hospitals in the U.S. had never reported a single privilege sanction to the NPDB. Prior to the opening of the NPDB in September 1990, the federal government estimated that 5,000 hospital clinical privilege reports would be submitted to the NPDB on an annual basis, while the health care industry estimated 10,000 reports per year. However, the average number of annual reports has been only 650 for the 17 years of the NPDB’s existence, which is 1/8th of the government estimate and about 1/16th of the industry estimate.

Hospital reporting varies by state. For example, about 70 percent of the hospitals in Louisiana have never reported while only about 25 percent of the hospitals in Connecticut have never reported.

Public Citizen, through its Health Research Group, compiled this report by reviewing a number of studies by the Office of Inspector General (OIG), work by the Citizen Advocacy Center, medical journal articles, and recommendations from an October 1996 national meeting on hospital under-reporting. Public Citizen also analyzed the NPDB Public Use File to examine the relationship between hospital reports and actions taken by state medical boards on the same physicians.

Operated by the Health Resources and Services Administration (HRSA), part of the Department of Health & Human Services (HHS), the NPDB was designed as a searchable resource for hospitals and other medical entities to check practitioners’ backgrounds and to consider taking their own action based on the information in the data bank. Prior to its launch, this function was not being provided in any systematic way. The NPDB’s goal was to reduce the likelihood that disciplined doctors might continue to injure patients by relocating to another hospital or state where their reputations and track records were not known.

The OIG at HHS did an initial assessment after the NPDB had been in operation for three years. This assessment found that a wide variation in reporting rates from state to state could suggest differences in the
quality of care rendered, or perhaps in the capacity or willingness of hospitals to discipline doctors and to submit reports to the NPDB. In response to the OIG report, HRSA convened a national conference in October 1996 of many stakeholders such as the American Hospital Association, American Medical Association, the Joint Commission on Accreditation of Healthcare Organizations (“Joint Commission”), Center for Medicare and Medicaid Services, Public Citizen and OIG. The consensus report from the conference found that the number of reports in the NPDB is unreasonably low, compared with what would be expected if hospitals pursued peer review effectively.

Collectively, the OIG report, the 1996 national conference, and a 2002 HRSA funded study of hospital compliance made a total of 10 different recommendations to remedy this serious problem. However, as of December 31, 2008, only one of the recommendations has been fully implemented.

The Journal of the American Medical Association (JAMA) has called hospital peer review one of the pillars of quality assurance in the United States. Hospital under-reporting raises questions about the effectiveness of hospital peer review. Under-reporting to the NPDB suggests that hospital peer review is not fulfilling the public trust.

Our review identified and focused on two factors associated with under-reporting: failure of hospitals to report and failure of hospitals to take action on questionable physicians. For example, a HRSA funded study reported in the American Journal of Public Health noted that, to avoid reporting, hospitals imposed disciplinary periods of less than 31 days thereby avoiding the need for reporting physicians to the NPDB; a medical board official informed Public Citizen that some hospitals avoid reporting by changing their bylaws or by having physicians take a “leave of absence.” In one of the most egregious recent examples of the breakdown of hospital peer review, two physicians at Redding Medical Center in Redding, California performed clearly unnecessary bypass and valve surgeries between 1992 and 2002 on hundreds of patients. Peer review of the cardiac program and discipline of these physicians was not done because of the “prestige” of one of the physicians involved and the revenue for the hospital generated by the surgeries. Furthermore, although both state and Joint Commission surveys had identified peer review deficiencies at Redding, there was no oversight follow-up.

State medical board officials report that hospital clinical privilege sanctions are a valuable source of information for identifying physicians with performance or conduct problems, and many boards use this information to launch investigations that can lead to disciplinary action. However, our analysis of the NPDB Public Use File found that almost 1,000 physicians who had at least two adverse clinical privilege reports to the NPDB did not have any subsequent licensure board disciplinary action. One physician had nine adverse clinical privilege reports but no licensure board actions.
Public Citizen’s report offers specific recommendations for making hospital peer review, hospital reporting, and hospital oversight more accountable to the public. These recommendations include:

- HRSA and CMS should work together to achieve a regulatory and statutory change so that the Medicare conditions of participation require fulfillment of hospitals’ reporting responsibilities to the NPDB under the Health Care Quality Improvement Act.

- CMS should require that the standards for compliance with the Medicare conditions of participation include all aspects of peer review.

- Congress should provide CMS with the statutory authority to impose financial and other sanctions on hospitals and physicians for failure to perform peer review.

- Congress should amend the Health Care Quality Improvement Act to impose a civil money penalty on hospitals for failure to report.

- HRSA should seek legislative authority for conducting compliance reviews of clinical privilege reporting, including authority to mandate access to peer review records.

- The OIG should review hospital peer review practices relating to granting and renewing hospital admitting privileges.

- HRSA should initiate corrective educational and compliance activities involving hospitals that have not reported.

- To address hospitals’ concerns about the effectiveness of peer review immunity, HRSA should update its 1996 survey of case law which found that the peer review immunity provisions of the statute were protecting peer review in the vast majority of cases.

- State medical boards should request their respective state legislatures to adopt those provisions of the Citizen Advocacy Center model act that have the potential to increase reporting.

- Congress should provide the OIG with authority to investigate state medical boards’ handling of adverse hospital clinical privilege reports.

- Hospital compliance officers should be required to monitor hospital peer review and reporting to the NPDB.

- The OIG, HHS, should use corporate integrity agreements to assure hospital compliance with NPDB reporting requirements.
Reporting and Disciplining of Doctors by U.S. Hospitals


Federal law requires hospitals to report a physician to the National Practitioner Data Bank (NPDB) whenever a hospital revokes or restricts the physician’s privileges for more than 30 days for an issue involving medical competency or conduct. The NPDB opened for reporting and querying September 1, 1990. Although the NPDB has been open for nearly two decades, 49 percent of U.S. hospitals (2,845 of 5,823) have never submitted a clinical privilege sanction report on a physician; at the end of CY 2007, the NPDB contained only 11,221 adverse hospital clinical privilege reports,¹ which is significantly below government and private sector estimates.

Prior to the opening of the NPDB, there was a range of estimates of annual hospital reports, as follows:

- The Public Health Service (PHS) submitted a planning document to the Office of Management and Budget in 1989 that estimated 5,000 hospital adverse actions a year would be reportable.

- The American Medical Association (AMA) estimated 10,000 reports per year. This estimate was based on an American Hospital Association (AHA) study, which found that the number of hospital disciplinary actions averaged 2.5 per year per hospital for hospitals in the study.

Contrary to these initial estimates, since the NPDB opened, the range of total reports per year has varied from a high of 830 in 1991 to a low of 532 in 2006 (see Appendix A). The trend has been toward fewer reports recently than in the first years after the NPDB opened. The average number of reports per year has been 650, which is $1/8$ of the PHS estimate and about $1/16$ of the AMA estimate.

Failure to report disciplinary actions to the NPDB violates the law and deprives health care organizations such as hospitals and state licensure boards of potentially useful information for their credentialing and regulatory activities, respectively.

Furthermore, in discussions with Bill Moran, senior vice president for Strategic Management, a hospital compliance consulting company, he advised us that “a hospital compliance officer informed him that while his hospital reports to the

¹ Unpublished data from the Health Resources and Services Administration, Department of Health & Human Services
NPDB when required, he and his staff are disheartened that many other hospitals do not.”

National Practitioner Data Bank

The Health Care Quality Improvement Act of 1986 (hereafter referred to as “the Act”), as amended, created the National Practitioner Data Bank. Since it became operational in September 1990, the NPDB has received and maintained records of medical malpractice payments and adverse actions taken against licensed health care practitioners by hospitals, other health care entities, licensure boards, and professional societies. The NPDB makes these reports, with doctor identification, available to hospitals, licensure boards, and managed care organizations to facilitate their background checks and credentialing. As a result of resistance from the AMA and other health care organizations, the NPDB statute does not allow for public access to the doctor-specific information.

The NPDB is operated by the Health Resources and Services Administration (HRSA) within the Department of Health & Human Services. The NPDB does not currently receive a congressional appropriation; it is self-supporting through user fees (Congress provided funds for start up costs). Users are charged $4.75 per query. Hospitals, by law, are required to query in certain circumstances, such as when a physician applies for clinical privileges at the hospital and every two years thereafter. Other health care organizations, such as HMOs, may query provided they have a formal peer review process. Medical licensing boards may also query. Health care practitioners may query but only to get their own reports. One-third of all queries are mandatory, i.e. from hospitals; two-thirds are optional. In 2007, the NPDB received 3.8 million queries and about 537,600 of these queries matched practitioner reports in the NPDB (a match rate of 14 percent).

HRSA has estimated that, based on a national survey, for a one year period, 48,075 licensure, credentialing, or membership decisions were affected by new information provided in NPDB responses.

2 Public Law 99-660, 42 USC 11101
3 See AMA congressional testimony at September 20, 2000 hearing on H.R. 5122, the Patient Protection Act of 2000; this legislation would have partially opened up the NPDB to the public. http://bulk.resource.org/gpo.gov/hearings/106h/67118.txt. 56
4 42 U.S.C.§ 11135 (a)
5 42 U.S.C. § 11137 (a)
6 42 CFR 60.11 (a) (2)
7 Teresa Waters, O. Almagor, P. Budetti, National Practitioner Data Bank User and Non-User Survey Final Report, April 2001, Table IV.C.94. The survey question was “Would your decision regarding the practitioner have been different if you had not received the NPDB response.” 9.04 percent of the responses answered “yes.” Applying this percentage to the 531,802 matches for 2007 results in an estimated 48,075 decisions that were affected by an NPDB report.
The legislative history is clear as to why Congress enacted this legislation. The House Committee on Energy and Commerce report noted, as follows:

The Committee has reviewed testimony from numerous sources indicating that this legislation is essential to protect the public health and safety. This bill is needed to deal with one important aspect of the medical malpractice problem in this country - incompetent and unprofessional physicians [...]. The bill’s focus is on those instances in which physicians injure patients through incompetent or unprofessional service, are identified as incompetent or unprofessional by their medical colleagues, but are dealt with in a way that allows them to continue to injure patients. Unfortunately, groups such as state licensing boards, hospitals and medical societies that should be weeding out incompetent or unprofessional doctors often do not do so. Even when such bodies do act against bad physicians, these physicians find it all too easy to move to different hospitals or states.8

Section 423 of the Act addresses incompetent or unprofessional physicians in hospital settings. Section 423 requires that each hospital or health care entity which takes a professional review action that adversely affects the clinical privileges of a physician for a period of longer than 30 days report to the NPDB the name of the physician involved and a description of the acts or omissions or other reasons for the action. Hospitals are also required to forward a copy of the NPDB report to each board of medical examiners where the practitioner is licensed.9

The House Report further noted:

The purpose of requiring reports even for circumstances in which physicians surrender their privileges is to ensure that health care entities will not resort to ‘plea bargains’ [...]. While such agreements may serve the immediate self interests of the two parties involved, they may jeopardize the health and safety of future patients.10

Congress was also concerned that the threat of private money damage liability under federal law, or lawsuits against hospital peer review physicians, including treble damage liability under federal antitrust law, would discourage physicians from participating in peer review.

Thus, to encourage effective hospital professional review activities (i.e. peer review), Section 411(a) of the Act provides immunity for such activities. Specifically, the statute states, “any person who participates with or assists

9 42 U.S.C. § 11133 (a)
the body with respect to the action, shall not be liable in damages under any law of the United States or of any state.”\textsuperscript{11} The statute stipulates that in order for hospital professional review actions to qualify for immunity, the peer review action must be taken as follows:

- In the reasonable belief that the action was in the furtherance of quality health care.
- After a reasonable effort to obtain the facts of the matter.
- After adequate notice and hearing procedures are afforded to the physician.
- In the reasonable belief that the action was warranted by the facts.\textsuperscript{12}

Hospitals that fail to report reportable actions to the NPDB risk losing the liability protection afforded to their professional review activities under the Act. The regulations implementing the Act require the Secretary of HHS to (1) investigate hospitals that appear to be substantially failing to comply with reporting requirements, (2) provide them with an opportunity to correct their practices if they are found to be in non-compliance, and (3) remove the liability protections for three years if they are found in non-compliance.\textsuperscript{13}

For a hospital to lose its immunity, the hospital has to “substantially” violate the reporting requirement, meaning there has to be a pattern of non-compliance.

Although HRSA has investigated a small number of cases of non-compliance, as of November 2008, 18 years after the NPDB began, no hospital has ever been penalized through the loss of peer review immunity.\textsuperscript{14}

Finally, the importance of hospital credential and privilege reviews cannot be overstated. \textit{The Journal of the American Medical Association} has noted the following:

Historically, there have been three pillars of quality assurance in health care: self-regulation by hospital credentialing committees, malpractice litigation, and external regulation by licensure boards. Hospital oversight of credentials and privileges [...] reflects the professional commitment to [...] self-regulation.\textsuperscript{15}

\textsuperscript{11} 42 U.S.C. § 11111(a) (1) (D). The Act’s immunity provision does not apply to civil rights claims and it does not apply to government antitrust prosecutions. However, the Act’s immunity does cover a private antitrust claim.
\textsuperscript{12} 42 U.S.C § 11112 (a)
\textsuperscript{13} 45 C.F.R. § 60.9 (c) (1)
\textsuperscript{14} According to HRSA staff, after identifying hospitals, usually through media reports or public court records, and contacting these hospitals, HRSA has always received a report or a satisfactory explanation of why no report was required.
\textsuperscript{15} Troyen A. Brennan, MD, JD, MPH, \textit{Hospital Peer Review and Clinical Privileges Actions}, Journal of the American Medical Association, July 28, 1999, V. 281, 4, 381.
A random sample survey in 2000 of NPDB users who had received matched responses from the NPDB about the physician for whom they were making a query found that it is an important aspect of the credentialing process for these users. The user survey included a wide variety of health care entities such as hospitals, managed care organizations, group practices, professional societies, state licensing boards, and ambulatory surgical centers.

The survey found that:

... a wide variety of different committees and individuals [...] used practitioner NPDB reports in their credentialing and disciplinary decision making [...]. On average, between 4 and 5 different individuals or committees reviewed each NPDB matched report. The entity’s credentialing committee was most likely to use the report [...]. Other organizational groups that frequently reviewed NPDB reports included the medical staff committee [...]. Individuals who were likely to use the report included the chief of medical staff, the department chair and the chief executive officer.\textsuperscript{16}

\section*{Analysis of Hospital Compliance}

\subsection*{State Variation in Hospital Reporting}

As of December 31, 2007, according to HRSA data, 2,845 of all 5,823 U.S. NPDB-registered hospitals (49 percent) had never reported a clinical privilege sanction to the NPDB (see Appendix B).

A 2007 analysis of accumulated HRSA data shows that extremely large state-by-state variation in the rate of non-reporting hospitals exists (See Appendix B).

For example, 75 percent of the 56 hospitals in South Dakota have never reported; 70 percent of the 47 hospitals in North Dakota have never reported; 69 percent of the 150 hospitals in Kansas have never reported; and 69 percent of the 29 hospitals in Wyoming have never reported. About one-third of the hospitals in Illinois, New Jersey, and California have never reported. And about 48 percent of the 110 hospitals in Massachusetts have never reported.

However, only 24.1 percent of hospitals (7 of 29 hospitals) in New Hampshire, 25 percent of hospitals (10 of 40) in Connecticut, and 28.5 percent of hospitals (68 of 239) in New York have never reported.\textsuperscript{17}

The HRSA analysis that used hospital-specific data found that “clinical privilege reporting seemed to be concentrated in a few facilities even in

\textsuperscript{16} Teresa Waters, et al., The Role of the National Practitioner Data Bank in the Credentialing Process, American Journal of Medical Quality, ” 2006, 34

\textsuperscript{17} Unpublished HRSA data
States with comparatively high overall hospital clinical privileging reporting levels.”

Several previous studies of hospital reporting have used “bed size” or “admissions” as a surrogate for physician exposure.

A 1995 Office of Inspector General (OIG) study of hospital reporting for the period September 1990 (when the NPDB opened) to December 31, 1993, found that:

- The approximately 6,500 hospitals in the U.S. submitted only 3,154 adverse action reports to the NPDB. This represented 2.6 reports per 1,000 hospital beds during the 3 1/3 year period.

- With the focus on the number of reports per 1,000 hospital beds rather than on number or percent of reporting hospitals, the state-by-state picture changed somewhat. For instance, New Jersey, which ranked first in the proportion of hospitals sending at least one report to the NPDB, ranked 18th in the number of reports per 1,000 beds. More striking, New York shifts from 4th to 33rd.

- Reporting rates per 1,000 hospital beds varied greatly state to state - ranging from 8.5 in Nevada to 0.7 in South Dakota. In most states, the reporting rate was between 1.5 and 4.0. The median rate was 2.5 adverse action reports per 1,000 hospital beds.

- Some of the differences among states in reporting rates per 1,000 hospital beds were considerable. For example, California, the state with the largest number of hospital beds, the rate of adverse actions was 3.7 per 1,000 beds. In New York, the state with the second largest number of hospital beds, the rate was “considerably less,” 2.1. In Ohio, the rate was 2.9; in nearby Illinois, the rate was 1.5.19

The OIG report also noted that “Whatever the State-to-State differences, there is also reason to suspect that the level of reporting in the nation [...] may be unreasonably low.”20 As an example, OIG cites the 1991 Harvard Medical Practice study of hospitalized patients in New York State that found 1 percent of hospitalizations in a random sample involved adverse events caused by negligence. On the basis of the sample, it was estimated that during one year, negligent care provided in New York State was responsible

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18 2005 HRSA Annual Report, 8
20 Ibid., 4
for 27,179 injuries, including 6,895 deaths and 877 “permanent and total disabilities.”

A July 28, 1999, article in the JAMA addressed hospital reporting to the NPDB. The article, which was based on a HRSA funded-study by the University of Washington, examined the variation in clinical privilege reporting, the changes in reporting over time, and the association of hospital characteristics with reporting. The study looked at 4,743 hospitals between 1991 and 1995; the majority of the hospitals were non-governmental, not-for-profit, and accredited by the Joint Commission; they were equally distributed between urban and rural hospitals. The study, which found evidence of a low and declining level of reporting, noted the following:

- About a third of the hospitals (34.2 percent) reported at least one action over the study period. The range of the privileges action rates for individual hospitals that had taken actions was between 0.40 and 52.27 per 100,000 admissions. The overall privileges action rate for the study hospitals in aggregate was 2.36 per 100,000 admissions.

- Urban hospitals and hospitals accredited by the Joint Commission were more likely to have reported one or more privileges actions and had higher rates of reported actions per 100,000 admissions than their counterparts for nearly all bed size categories. State and local hospitals were least likely to have reported.

- The majority of hospitals that were members of the Council of Teaching Hospitals of the American Association of Medical Colleges, and had bed sizes of 300 or more, had lower rates of reporting than non-member hospitals.

- There were significant regional differences in privilege action reporting. Hospitals in the east south Central region, such as Alabama, Kentucky, Mississippi and Tennessee, had some of the lowest reporting rates.

**Importance of Hospital Reporting For State Licensure Board Actions**

The OIG report noted earlier found that, during the period of the OIG review, 1990 - 1993, hospitals reported about 3,154 practitioners to the NPDB. During

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21 Ibid., 4
the same time period, state medical boards took disciplinary actions against about 8,000 physicians. The OIG notes “these numbers are not directly comparable, but […] 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.”

A similar observation was made in the July 1999 JAMA article, which noted that “there were nearly three times the number of licensing actions […] than privileges actions over the study period. In addition, licensing actions increased between 1991 and 1995, while privileges actions decreased.”

Every year HRSA calculates a ratio comparing the sum of adverse action reports for both hospitals and managed care organizations to adverse licensure reports for in-state physicians. According to HRSA data, during the seventeen-plus year history of the NPDB, state licensure adverse action reports have been more than double the number of adverse (hospital and HMO) clinical privilege reports: 32,748 vs. 13,618. From state to state, the ratio of adverse clinical privilege reports to adverse licensure action reports range from a low of one clinical privilege report for every five state licensure actions in Colorado and Connecticut to a high of 1.51 clinical privilege reports in Hawaii for every adverse licensure action report. According to HRSA, “While these ratios reflect variations in the reporting of both State licensure actions and clinical privileges actions, the extreme variation from State to State is instructive. It seems likely that the extent of the observed differences may at least in part reflect variations in willingness [of hospitals and medical boards] to take actions rather than a substantial difference in the conduct or competence of the physicians practicing in various States.” This is reinforced by the lack of evidence that the overall quality of physician practice varies from one state to another.

A 1999 article in the *American Journal of Law and Medicine* makes a point about the role of hospital peer review and its relationship to state licensing boards:

> The peer review system [...] should address problems of physicians before they impact a physician’s license to practice medicine. Notwithstanding the differences between what the hospital peer review system is designed to accomplish and the state physician licensing system, the significantly higher rate of state actions

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23 OIG, Op.Cit., 4  
25 Managed care organizations “adverse actions” are when physicians are removed from panel membership in the organization because of competency or conduct. HRSA uses “in-state” adverse licensure data to avoid including reciprocal actions based on a licensure action taken by another State.  
26 HRSA NPDB Annual Report, 2005, 36
raises the question of whether hospital peer review is taking place at an adequate level.27

From the perspective of state medical licensure boards, hospital reports are an important source of data for regulatory oversight. Results of a Citizen Advocacy Center (CAC) survey on hospital reporting highlighted the importance of hospital reports to state medical boards:

- Several medical boards emphasized the high quality of the information in hospital reports. Boards value hospital reports because they are based on peer investigation and review. Because hospitals are so concerned about being sued by doctors against whom they take clinical privilege actions, when a hospital does report, there is substantial evidence of a serious problem.

- The acting director of the Office of Professional and Medical Conduct in New York State said that 31 percent of the facility reports her board receives have led to charges of misconduct or surrender of license. This means that nearly one in three mandatory reports results in the board opening a disciplinary action. In many states, fewer than 10 percent of consumer complaints lead to disciplinary action.

- The executive director of the Arizona board indicated that while only 2 percent of the complaints received by his board in 1995 were from hospital mandatory reports, 66 percent of these had to do with quality of care (as opposed to 54 percent of complaints from all sources) and 17 percent of hospital reports ultimately led to discipline and 11 percent to stipulated limitations on practice, as opposed to 2 percent and 5 percent complaints from all sources.28

Representative responses to the CAC survey included:

- ‘This information would be kept confidential [from the board] if not for mandatory reporting laws.’

- ‘The mandatory reports provide useful ‘leads’ for the Board about the possibility of substandard practice which otherwise may not be known. The Board would never receive the information without mandatory reporting.’29

CAC also asked boards about oversight of state hospital reporting laws. “Many state medical boards replied that they had no jurisdiction over hospitals. […]

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28 Rebecca Cohen and David Swankin, Citizen Advocacy Center, Hospital Reporting to State Regulators and to the National Practitioner Data Bank, March 1997, 21
29 Ibid., 21
While their state statute may require a hospital to report adverse actions to the medical board, actual enforcement authority is usually the responsibility of another state office, such as the agency that licenses hospitals.”30

Under-reporting of hospital privilege sanctions deprives state regulators and other users of the NPDB of critical information.

To help increase hospital reporting, CAC, in collaboration with the Administrators in Medicine, an organization composed of the Executive Directors of State Medical Boards, wrote and issued a Model Act in March 1999 that addressed hospital reporting to state boards.31

The Model Act’s many recommendations include: (a) requiring the chief executive officer of every health care organization to file an annual disciplinary report that covers all disciplinary actions taken or state that no actions were taken; submission of the report provides the licensing authority with an affirmative declaration on file; (b) requiring the medical director of a hospital to be the responsible party for reporting, with failure to report being grounds for a disciplinary offense; (c) giving the medical board authority to enforce hospital reporting; (d) establishing penalties of up to $1,000 per day per unreported adverse action, up to a maximum of $100,000 for each incident of failure to report.

To examine the relationship between hospital reports and state licensure actions, and the extent to which state actions follow hospital actions, Public Citizen analyzed the NPDB Public Use File for the period September 1, 1990, through September 30, 2008. The Public Use File does not contain any data which would identify individuals or reporting entities; however, it does contain coding that allows the user to identify all reports associated with each specific number-coded practitioner. Our analysis found that 25,136 physicians were included in the NPDB because they had been reported one or more times for an adverse action by a state licensure board, while 9,877 physicians had been reported at least once for an adverse action by a hospital.32

There were 3,566 physicians in the database that had both adverse state licensure and adverse hospital clinical privileges reports. Of the physicians that had both adverse state licensure and adverse hospital clinical privileges reports, the majority, 2,538 (71 percent), had at least one adverse hospital clinical privileges action preceding their first adverse licensure action. We also found that 1,028 physicians had one or more licensure actions followed by at least one adverse clinical privilege action, but no preceding adverse clinical

30 Ibid., 39
31 Citizen Advocacy Center, in collaboration with the Administrators in Medicine, A Model Act to Improve Reporting of Adverse Actions by Health Care Organizations to State Health Professional and Occupational Licensing Authorities. March 1999
32 The 9,877 physicians reported by hospitals for adverse clinical privileges actions is lower than the total number of hospital reports, 11,221, because some physicians have more than one report.
privilege report. It is unclear why these 1,028 physicians had hospital actions following licensure board reports. If a license is revoked, automatic loss of hospital privileges is not reportable. Without additional research we can only speculate. One possibility is that these physicians were either put on the medical staff or retained on the staff despite a licensure action and that they subsequently got into trouble for some new reason.

Although hospital reports are an important source of information for state boards, the Public Citizen analysis of the NPDB Public Use File also found that 5,359 physicians (out of the 9,877 physicians who had been reported at least once for an adverse action by a hospital) have at least a single adverse hospital clinical privileges action that was not followed by a state licensure action. As can be noted from the table below, 952 physicians have two or more adverse hospital clinical privileges reports but no subsequent state licensure action. In addition, 31 physicians had five or more adverse hospital clinical privilege reports but no subsequent state licensure action. Given the value of hospital reports to state boards, as noted earlier, the fact that all these reported hospital actions involved at least a suspension or restriction of clinical privileges for more than 30 days raises concern that state licensing boards may not be taking disciplinary actions needed to protect the public. It seems hard to believe that state licensure action would not be appropriate in most of these cases.

| Physicians With Adverse Clinical Privilege Reports But No Subsequent Licensure Board Action |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Number of Adverse Clinical Privilege Reports Per Physician | Number of Physicians With Hospital Adverse Clinical Privilege Reports But No Licensure Action |
| 1      | 4,407 |
| 2      | 690  |
| 3      | 186  |
| 4      | 45   |
| 5      | 19   |
| 6      | 6    |
| 7      | 3    |
| 8      | 2    |
| 9      | 1    |
| **Total Physicians with 2 or More Adverse Hospital Reports - 952** |

Because of our concern with the apparent lack of medical licensing board follow-up on these reports, we are recommending that the OIG, HHS, initiate a study of these cases. The OIG has in the past conducted evaluations of state health professional licensing and regulatory boards.
Factors Affecting Hospital Reporting

Failure to Report

In October 2005, the California legislature, because of concerns about under-reporting to the state medical board, requested an independent review of peer review in the state. The final report, issued in July 2008, involved a sample of 245 California health care entities (hospitals, health plans, professional societies, medical groups) and was based on the following methodology: on-line survey, analysis of peer review minutes, peer review cases, interviews and site visits. The report noted the following:

- There are inconsistencies in the way health care entities conduct peer review, select and apply criteria, and interpret the [state] law.\(^{33}\)
- These variations can result in physicians continuing to provide substandard care (at times for years) impacting the protection of the public.\(^{34}\) (emphasis added)
- The tracking of cases over time in most entities is poor or lacking.\(^{35}\)
- Entities try numerous remedial interventions (peer counseling, education, training, mentoring, observation, behavior counseling, UCSD Physician Assessment and Clinical Education Program) before informing the physician that a “final proposed action” is being taken. The process is almost never shorter than one year.\(^{36}\)
- The most common reasons for cases being referred for peer review were (1) disruptive behavior/impairment, (2) substandard technical skills and (3) failure to document/record patient treatment.\(^{37}\)

At the federal level, to better understand the variation in reporting, in 1994 HRSA funded a study of 144 rural hospitals in the Pacific Northwest. The study found that, since the NPDB opened, 20 percent of hospitals reported an increase in certain activities that allowed the hospitals to avoid the federal reporting requirement. The authors note “the most frequent changes were increases in monitoring clinical privileges (13 percent), requiring continuing medical education rather than restricting privileges (12 percent), having physicians resign or voluntarily surrender clinical privileges (7 percent) and imposing disciplinary periods of shorter than 31 days (5 percent)....” The authors further note that restricting clinical privileges for less than 31 days has the potential to adversely affect the quality of care and undermine the legislative intent of the NPDB.\(^{38}\)

\(^{34}\) Ibid., 1
\(^{35}\) Ibid., 64
\(^{36}\) Ibid., 64, 65
\(^{37}\) Ibid., 65
\(^{38}\) William E. Neighbor, MD, Lura-May Baldwin, MD, Peter .West, MD, L. Gary Hart, PhD, Rural Hospitals Experience With the National Practitioner Data Bank, 87 Am. J. Pub. Health (1997), 664, 665
The 1999 JAMA article cited earlier noted that the “low level of quality of care problems as an explanation for the low level of reporting is unlikely.”

The evidence from this study cannot be used to definitively identify the causes for the low and declining level of clinical privileges action reporting. Supporting evidence from other sources and the high degree of dissatisfaction with the concept of the NPDB [...] suggest that underascertainment of physicians with performance problems and the use of penalties that do not require reporting were the most significant contributors to these findings, however.”

Problems with hospital reporting to states provides insight into reporting to the NPDB. Most states have mandatory reporting laws governing hospitals’ clinical privilege actions. Some states require hospitals to report any action, regardless of the time period that the sanction covers. Other states mirror the NPDB reporting requirement more closely, limiting reporting to actions involving competency or conduct and requiring the reporting of actions that affect privileges for over a certain number of days. These laws also vary on the penalty for failure to report; state penalties range from a fine as high as $10,000 to no penalty. Only three states had a potential fine of $5,000 or more, while 14 states had a fine under $5,000. Thirty-three states and the District of Columbia lacked any penalty, according to a study published in 1999.

The CAC report quotes the President of the California Medical Board as stating the following in the January 1995 issue of the Board’s newsletter regarding the issue of hospital reporting:

The issue of 805 (peer review) reporting is one of the most important and most misunderstood Medical Practice Act requirements. Over the past year we have noted a deterioration in the cooperation required between hospitals and the Board in protecting consumer/patient safety. We have experienced incomplete reports [...] and, on some occasions, excuses for not reporting at all.

Based on a survey and subsequent workshop, the CAC suggested, among other factors, a “cultural aversion” to reporting. The CAC report quotes the chief administrative officer of the Rhode Island Board as stating:

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39 Baldwin, JAMA, Op.Cit. 351
40 Ibid., 354
41 Scheutzow, Op.Cit., 14
42 Cohen and Swankin, Op. Cit., 2,3
43 The other “factors” CAC cites are: deficiencies in state reporting laws; lax enforcement; and lack of knowledge on the part of hospitals to report.
Doctors and other professionals don’t like to ‘snitch’ on a colleague. This unwillingness to turn in a peer, laws to the contrary notwithstanding, has resulted in many licensing boards never receiving a complaint from a peer, even when laws require such reports.44

According to CAC, the “psychology” of hospital reporting may be similar, and every effort might be made to work out a solution to a problem in such a way as to make it “unreportable.” Furthermore, the hesitation to report a colleague may be reinforced by the adoption in hospitals of continuous quality improvement strategies which similarly discourage reporting of individual physicians. In the environment of continuous quality improvement, the reporting of adverse actions may be seen as punitive and counter-productive.45

A recent study published in the Annals of Internal Medicine found that “physician behavior did not always reflect the standards that they endorsed. For example, although 96 percent of respondents agreed that physicians should report impaired or incompetent colleagues to relevant authorities, 45 percent of respondents who encountered such colleagues had not reported them.”46

A second HRSA-funded study by the University of Washington Medical School concerning hospital reporting and state peer review protections statutes noted that “the adjusted analysis found that hospitals in states with strong penalties for not reporting adverse privilege actions had significantly higher numbers of reporting to the NPDB than hospitals in states with no penalty.”47 (emphasis added)

According to this study, after adjusting for differences in hospital characteristics, hospitals in states with strong penalties were 40 percent more likely to have reported an adverse action over the five years of the study than hospitals in states with no penalties. The author notes “converting this data to actual numbers, in states with a high penalty for failure to report adverse peer review actions, 100 urban, nongovernmental, nonprofit hospitals with between 100 and 300 beds and other characteristics typical of many hospitals could be expected to file eleven more adverse action reports [per 100 hospitals] over the five-year study period than hospitals with the same characteristics that are located in states with no penalties.”48

The study hypothesizes two possible explanations as to why a strong penalty for failure to report adverse actions to state authorities would generate more reporting to the NPDB. The author notes, as follows:

44 Cohen and Swankin, Op. Cit., 33
45 Ibid., 33,34
47 Scheutzow, Op.Cit., 17
48 Ibid., page 17
First, hospitals may render adverse peer review decisions but fail to report adverse actions to both the NPDB and the state authorities. When hospitals face stiff sanctions for failure to report adverse actions to the state, hospitals may fully comply with both state and federal reporting requirements. Second, because the law concerning the reporting of adverse peer review action is at times ambiguous, hospitals may interpret the law as not requiring such actions to be reported. However, if significant sanctions for nonreporting exist at the state level, hospitals may likely interpret ambiguities in their reporting obligation to favor reporting of adverse peer review actions.  

A member of a medical board in the Mid-Atlantic region, who requested anonymity, advised Public Citizen on January 27, 2009, and March 24, 2009, emails that “hospitals often avoid reporting by fashioning by-laws in such a way that reporting can be avoided [...]. I’ve also learned that hospitals are giving docs leaves of absence instead of suspensions in order to avoid reporting.”

**Failure to Act**

There is evidence that under-reporting (and patient harm) is also caused by the failure of hospital peer review to take timely action against physicians who practice substandard care.

In October 2002, in response to a whistleblower complaint, the FBI raided Redding Medical Center, a 240-bed hospital in Redding, California. An FBI affidavit estimated that at up to fifty percent of cardiac surgeries performed by two cardiac physicians may have been medically unnecessary. According to a June 2008 study, evidence from the FBI raid showed that these physicians performed unnecessary cardiac procedures on more than 600 patients between 1995 and 2002.  

The study states:

...hundreds of patients underwent unnecessary bypass and valve surgery from which some suffered debilitating injuries and others died. The Redding case, while singular for the number of patients abused and the length of time it went on, is hardly unique. There is a long history of similar cases in which effective peer review and oversight could have made a difference.

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49 Ibid., 3  
51 Ibid., 4
The study further notes that one of the physicians at Redding Medical Center was able to use his influence, which was based on earnings generated by unnecessary surgery, to block hospital peer review.\textsuperscript{52} The study notes, “motivated by income generated by its rainmaker physicians, Redding Medical Center [...] preferred to support them rather than identify quality problems.”\textsuperscript{53} For example, according to hospital by-laws, one of the physicians should have been suspended every day for 1992 because he refused to complete medical records. He was never suspended because his “production bought him power and influence within Redding Medical Center.”\textsuperscript{54} According to the California Medical Board web site, as of April 13, 2009, one of the physicians has had his license revoked while the other is awaiting a hearing (the web site states that he is not practicing because he has not paid his license renewal fee). Also, according to a November 17, 2005, \textit{Medical News Today} article the hospital owners paid about $54 million to settle the federal case and established a $395 million fund for the 769 cardiac patients and their families to settle a civil lawsuit.

The authors of the Redding Medical Center study conclude that “it wasn’t peer review alone that failed in Redding and elsewhere. The larger and more difficult problem, but also perhaps the one most susceptible to legislative solution, is the failure of \textit{state and federal} oversight.”\textsuperscript{55} For example, a June 1999 state survey of Redding found that the hospital:

\begin{quote}
...failed to regularly review cardiovascular surgery cases, both preoperatively and postoperatively, and failed to implement proper quality controls. It further found that the medical staff did not consider a serious patient care adverse event caused by a cardiovascular surgeon, when reappointing that physician to the medical staff [...]. Concurrently but independently the Joint Commission and the California Medical Association’s Institute for Medical Quality inspected Redding Medical Center. Both of these non-government organizations found the same peer review deficiencies, which also violated Joint Commission’s accreditation standards [...]. Although Joint Commission asked Redding Medical Center to correct these peer review deficiencies, it immediately accredited Redding Medical Center for three more years.\textsuperscript{56}
\end{quote}

Redding is not the only example of problematic peer review.

On July 10, 2002, an orthopedic surgeon left the operating room at a hospital in Cambridge, Massachusetts during a complex back operation. Seven hours into surgery, the patient was left under anesthesia with an open incision in his back, while the surgeon went to a bank to cash his paycheck. He was gone 35

\begin{flushright}
\textsuperscript{52} Ibid., 8  
\textsuperscript{53} Ibid., 31  
\textsuperscript{54} Ibid., 8  
\textsuperscript{55} Ibid., 6  
\textsuperscript{56} Ibid., 10, 11
\end{flushright}
minutes. Although the doctor had a history of disruptive behavior and two brushes with the law, there was apparently no peer review intervention prior to July 10, 2002.\(^{57}\)

In Hawaii in 2001, a surgeon operated on a man to stabilize a disc injury to his spine. The titanium rod he needed to insert was not available in the operating room, so he used a nearby screwdriver. After three more surgeries by the doctor to correct the problem, the patient was left a bedridden, incontinent paraplegic. He subsequently died. At the time of the surgery, the physician had been charged with drug addiction and incompetence; his medical license had been suspended in Oklahoma and revoked in Texas. Despite these problems, his surgery was apparently not monitored by peers.\(^{58}\)

The authors of the Redding report provide additional examples of failed peer review; we provide details on two of these cases, as follows:

For six years ending in 2001, physicians, administrators and management company Executives at Edgewater Medical Center in Chicago conspired to defraud Medicare of tens of millions of dollars in a scheme that would have been impossible to implement had there been effective peer review and oversight. [A cardiologist], admitted performing unnecessary angioplasties and angiograms on more than 750 patients, two of whom died as a result of these unnecessary procedures.

[A surgeon] at the University of Kansas Medical Center, Bethany Medical Center and Providence Medical Center [...] convinced patients to undergo unnecessary surgery to fill his surgical schedule resulting in bodily harm to at least one patient. [The surgeon] was sentenced to six years in prison and his medical license was revoked, but it took 15 years and the involvement of federal law enforcement agencies to stop him.\(^{59}\)

The authors of the paper on Redding Medical Center have noted:

In each of these cases, effective peer review would have cut short the careers of these malefactors and saved innocent patients from having to undergo unnecessary invasive procedures, some of which caused permanent damage or even death. While peer review functions well in many hospitals - identifying opportunities for improvement, errors caused by mistake or gross negligence-there are structural problems that need to be addressed to improve the chances that it will work well everywhere.\(^{60}\)

\(^{57}\) Boston Globe, August 18, 2002 and March 21, 2004
\(^{58}\) Dr. Ira E. Williams, First Do No Harm, The Cure for Medical Malpractice, 2004, 1
\(^{59}\) G.Rogan, Op.Cit.,5
\(^{60}\) Ibid., 5
According to the authors, although Redding Medical Center complied with most of the Medicare Conditions of Participation, “one critical element, peer review for cardiac services (Element 54), remained violated [...]. According to the Centers for Medicare & Medicaid Services, a violation of an element of a Condition is not sufficient to rule the entire Condition is violated. Partial compliance is good enough.”

The study made 17 recommendations, which included the following:

- The standards for compliance with the [Medicare] Conditions of Participation must include all aspects of peer review and quality oversight. Violation of any element must be sufficient to find the entire Condition is violated.
- Congress should determine how conflicts of interest impair the peer review process and consider appropriate remedies.
- Congress should provide the Centers for Medicare and Medicaid Services with the authority to impose intermediate sanctions against hospitals and physicians, including loss of provider status for selected services until patient safety and quality is assured, and stopping payment for elective services in a department where peer review is absent.

Finally, Dr. Ira Williams, a board certified oral and maxillofacial surgeon who served as chairman of the dental department and executive committee at Methodist Hospital in Madison, Wisconsin wrote the following about hospital peer review:

Instead of shining a searchlight on the performance of their own members, hospital peer review committees prefer to stay in the shadows. They are willing to identify past problems and may recommend a slow, orderly change in standards of care, but they will not make substantial changes. Most important, their first priority is to preserve the rights and privileges of doctors. Their work is dictated by the desires of the medical staff and is rarely influenced by the needs of patients. Members of a peer review committee, it must be noted, are not evil or sinister people. Nor are they megalomaniacs. They are individuals who have been burned by circumstances and have learned to become robots who see no evil, hear no evil, speak no evil, in order to survive. The weaknesses of the peer review system are human weaknesses. [...] Because licenses to practice give doctors a monopoly on medical care, the characteristics of a monopoly are obvious in medical organizations - arrogance, complacency, and abuse of power.

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61 Ibid., 15, 16
62 Ibid., 35, 36
63 Williams, Op.Cit., 97,98
OIG Investigations of Hospital Under-Reporting and Peer Review

The 1995 OIG study of hospital reporting that was noted earlier was initiated because of HHS concerns about the low number of hospital reports. The final report noted:

Our review suggests a sufficient basis for concern about the hospitals’ response to [NPDB] 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 [NPDB]. The explanation is unclear.64

The OIG also noted that the Joint Commission, which is the national hospital oversight organization, reviews hospital adverse actions affecting the clinical privileges of physicians to determine if they were reportable to the NPDB. However, according to the 1995 OIG report on hospital under-reporting, this aspect of the Joint Commission surveys “is very limited and a very minor part of the survey process [...]. It does not result in apparent violations of the NPDB reporting law being reported to the Department of Health and Human Services for investigation. And, it does not lead to any probing to determine whether or not a hospital might be circumventing the intent of the Health Care Quality Improvement Act by taking adverse actions of less than 31 days or by other means.”65 (emphasis added).

The 1995 OIG report on under-reporting recommended that HRSA (1) study the problem further, possibly through case studies, and (2) sponsor a national conference on the issue to explore causes and remedies. In addition, OIG recommended that HRSA collaborate with the Centers for Medicare and Medicaid Services (CMS) to ensure that the Joint Commission assesses more fully hospitals’ compliance with the NPDB reporting requirement. The OIG also recommended that such collaboration include the following:

(a) Send a joint letter to the Joint Commission urging that it incorporate the [NPDB] 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 [NPDB’s] reporting requirements.

(b) [Through a regulatory change,] amend the Medicare Conditions of Participation in a manner that will specify hospitals’ responsibilities under the [NPDB] law.

64 OIG, Hospital Reporting to the National Practitioner Data Bank, Op.Cit., ii
65 Ibid., 6
(c) Propose legislation that would call for hospitals [NPDB] 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.66

The Joint Commission’s written response to the OIG report called for additional research into the issue and indicated that it was “premature” for the Joint Commission to address hospital reporting until there was a better understanding of the problem.

The American Hospital Association, in its response to the OIG report, noted that when the NPDB legislation was enacted “it was recognized that mandatory reporting requirements would lead to an increase in litigation as physicians faced with disciplinary action challenged peer review actions. In an effort to reduce the chilling effect such litigation would have on effective peer review, Congress provided qualified immunity in the peer review process.”67 The American Hospital Association further stated:

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 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.68

Public Citizen responded to the OIG report with the following recommendation:

We urge the Public Health Service [what is now HHS] 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 […]. This would make hospital penalties at least comparable to those applied to malpractice insurers who fail to submit payment reports [to the NPDB as mandated by law].69

66 Ibid., 8
67 Ibid., Appendix B
68 Ibid., Appendix B
69 Ibid., Appendix B
The OIG, as a follow-up to its 1995 report, issued a memorandum report in 1999 entitled “Legislative Recommendation to Improve Hospital Reporting to the National Practitioner Data Bank.” The report concluded:

To more fully encourage hospitals to follow the intent of Section 423 of the Health Care Quality Improvement Act, we recommend that HRSA propose legislation that would establish a civil money penalty of up to $10,000 for each instance of a hospital’s failure to report to the [NPDB] [...]. This penalty is consistent with the current civil money penalty sanction that can be imposed for failure to report a malpractice payment.70

In response to the OIG recommendation to establish a civil money penalty for hospital non-compliance, HRSA initiated a legislative proposal for Fiscal Year 2001 that provided for a civil money penalty of up to $25,000 for each instance of a hospital’s failure to report an adverse action to the NPDB. The legislative proposal was not approved by HHS, and therefore it was never submitted to Congress.

The Joint Commission, in a recent email to Public Citizen, noted the following:

As of a couple of years ago, there had not been a single action taken against a hospital who ignored this regulation [...] even if there was an action, the penalty is minimal at best. The hospital industry is well aware of this history of no penalty and well understands that there is no significant punishment associated with not following the requirement.71

Because HHS has still not approved such a legislative proposal, the OIG recommendation appears in the 2008 OIG publication, “Compendium of Unimplemented Recommendations.” This annual OIG publication, which is sent to senior HHS officials and Congress, contains significant unimplemented programmatic and fiscal recommendations.72

In addition to the problem of Joint Commission’s oversight of hospital reporting to the NPDB, there is evidence that accreditation surveys do not adequately focus on the granting and renewing of hospital privileges, the peer review process that establishes a physician’s scope of practice within a

71 July 21, 2008 email to Public Citizen Health Research Group from the Vice President, Division of Standards and Survey Methods, The Joint Commission
A July 1999 OIG investigation of the Joint Commission addresses accreditation surveys’ focus on privileging, as follows:

The Joint Commission surveys are unlikely to detect substandard patterns of care or individual practitioners with questionable skills. Quick-paced, tightly structured, educationally oriented surveys afford little opportunity for in-depth probing of hospital conditions or practices.

In reviewing medical records, surveyors focus more on processes than appropriateness of care: surveyors “do not judge directly whether the care given is good or bad, right or wrong.” Likewise the review of physician credentials and privileges falls short of identifying individuals whose skills may be questionable.

Further evidence of the Joint Commission’s lackluster focus on hospital peer review and privileging activities can be found in OIG reports on credentialing and privileging at three Indian Health Service hospitals, all of which had been accredited by the Joint Commission. At the Blackfeet Community Hospital, OIG found that “For more than half the practitioners tested, Blackfeet Hospital did not perform a complete credentialing review […] the hospital had not issued current privileges to six percent of the practitioners we tested.” At the Crow Hospital, OIG found that “for more than half the practitioners tested, Crow Hospital did not perform a complete credentialing review […]. Additionally, the hospital had not issued current privileges for 20 percent of the practitioners we tested.” At the Shiprock Hospital, OIG determined that, of the 84 practitioners reviewed, 67, or 80 percent, did not have current privileges.

1996 Consensus Agreement That Under-Reporting Is a Problem

In response to the February 1995 OIG report on under-reporting, HRSA sponsored a national conference (called “roundtable”) of major medical and health organizations in Chicago in October 1996 to discuss the problem. The attendees included representatives from the American Medical Association, American Hospital Association, the Joint Commission on Accreditation of Healthcare Organizations (now called the Joint Commission), Health Care Financing Administration (now called the Centers for Medicare and Medicaid Services), Public Citizen Health Research Group, the Federation of State

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74 Ibid., 2
75 Ibid., 15
76 OIG, Credentialing and Privileging Practices at HIS Blackfeet Community Hospital (A-07-03-00152), June 2005, 1
77 OIG, Credentialing and Privileging Practices at HIS Crow/Northern Cheyenne Hospital (A-07-03-00159), June 2005, 1
78 OIG, Credentialing and Privileging Practices at Northern Navajo Medical Center (Shiprock) (A-06-04-00023), August 2004, 3
Medical Boards, and the OIG, HHS. The Institute for Health Services Research and Policy Studies, Northwestern University, also participated and served as a facilitator.  

Prior to the conference, all participants received a case survey on court decisions concerning the use of peer review immunity under the Act. The survey concluded that the immunity provisions of the Act were protecting professional review activities in the vast majority of cases. Out of 47 surveyed decisions, 39 were adjudicated in favor of defendant peer reviewers. Twenty-nine of these favorable decisions were based on immunity. Most cases were decided at the summary judgment stage.

The final report from the October 1996 HRSA sponsored conference noted “substantial participant consensus” on a number of reporting issues, including the following:

- The number of reports in the NPDB on adverse actions against clinical privileges is unreasonably low, compared with what would be expected if hospitals pursued disciplinary actions aggressively and reported all such actions.

- There are numerous factors that might be contributing to this conclusion, some of which will be difficult to subject to research: these include divergent explanations ranging from nondisciplinary approaches to quality improvement to outright evasion of reporting.

- Researching these factors is nevertheless desirable, because the results can be used to improve hospital peer review.

- Hospital peer review, as envisioned by the Act, focuses on restricting the clinical privileges of the so-called ‘outlier physician’ and thereby leads to improved patient care at the margins.

There was “near consensus” on the following: (1) “The perceived or actual high expense of litigation under the Act has an impact on hospital reporting activity, at least in part because the effectiveness of the Act’s legal protections in most recent court cases is not widely known,” (2) “There are emerging tensions between peer review with disciplinary actions and Continuous Quality Improvement.”

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There were also participants from: American Osteopathic Healthcare Association; Citizens Advocacy Center; Northwestern Memorial Hospital (Chicago); Doctor’s Hospital (Columbus, Ohio); Illinois Hospital and Healthcare System Association; New Jersey State Hospital Association; law firm of Horts, Springer and Mattern, Pittsburg, Pennsylvania.


Ibid., 2
Improvement programs,” and (3) “There is a need for increased education of medical professionals and hospital administration on these topics.”

Based on conference discussions, the Conference Facilitator made the following recommendations:

- Since the existence of professional review activity is easily discernable in their surveys, the Joint Commission on Accreditation of Healthcare Organizations should immediately make reporting by hospitals of adverse actions taken against clinical privileges a specific point of review.

- The [AHA], other hospital associations and hospital legal representatives should educate their hospital members and clients, as soon as is practicable, on the effectiveness of legal protections under the [Act’s] immunity provisions as they have been interpreted by most courts.

- The [AMA], other physician associations, and physician legal representatives should educate their physician members and clients, as soon as is practicable, on the effectiveness of legal protections under the [Act’s] immunity provisions as they have been interpreted by most courts.

- HRSA should sponsor a study examining the effects of proposing amendments to the Act to allow immediate appeal of a denial of immunity, and to provide for monetary sanctions against any violation with the reporting provisions.

Failure of Hospitals to Voluntarily Comply In a Study on Hospital Reporting

In 2002, HRSA contracted with PricewaterhouseCoopers (PwC) LLP to examine, in greater depth, hospital (and managed care organization) reporting. Underlying the contract was HRSA’s hope that HRSA could obtain cooperation of health care organizations in conducting the analysis. Under the statement of work for the contract, PwC was to develop methodologies for conducting compliance reviews and recruit a sample of nine hospitals and nine managed care organizations. HRSA and PwC offered five incentives for participation: “amnesty for any reporting errors found; exemption from future audits for a period of time to be determined by HRSA; guarantees of confidentiality from NPDB (and PwC) of their participation in the study and its

82 Ibid., 3
83 Ibid., 4
findings; help improve the quality of data reported; [and] the opportunity to provide input on the access and feedback mechanisms used to report and verify the data in the NPDB.”

PwC contacted 42 hospitals and 36 managed care organizations, but only three hospitals and five managed care organizations elected to participate in the pilot study.

As a result of the small numbers, the study was aborted. However, PwC recommended that HRSA seek legislative authority and funding for conducting compliance reviews of clinical privilege reporting, including authority to access peer review records. The PwC report noted:

The largest obstacle experienced in this study was obtaining the voluntary participation of hospitals and [managed care organizations]. HRSA has no direct authority that insures access to clinical privileging and peer review records. This absence or lack of legislative authority hampered participation in this study. Many organizations chose not to participate once they confirmed that participation in the reviews was not required (i.e., mandatory) [...]. If HRSA possessed legislative authority that insured access to peer review records gaining participation for this study (and future compliance reviews) would have been greatly simplified. HRSA should seek legislative authority and funding for conducting compliance reviews of clinical privileges reporting [...]. This authority would enable HRSA to assess the level of clinical privileges reporting compliance through a statistically valid study and/or engage in an ongoing compliance monitoring program.

Conclusion and Recommendations

Public Citizen’s Health Research Group Conclusion

HRSA data, HRSA-funded studies, the 1995 and 1999 OIG reports, and the 1996 HRSA-sponsored conference involving OIG and major health care stakeholders (e.g. AMA, AHA), plus reports on how peer review itself has sometimes failed, point to the need to address both hospital peer review and hospital reporting to the NPDB. Although many of the studies and other activities documenting the under-reporting problem were completed a number of years ago, the recommendations for the most part have not been implemented and thus, not surprisingly, the level of reporting has not improved. In addition, there is evidence from the 2008 Lumetra in-depth study of peer review in California, and what happened at Redding Medical Center, as well at other hospitals cited

85 Ibid., 8
86 Ibid., 31
in this report, that greater oversight of the hospital peer review process is necessary.

Public Citizen Health Research Group has determined that of the numerous recommendations made by (1) the OIG reports, (2) the 1996 national conference, and (3) the PwC consulting report for HRSA, only one of 10 recommendations has been fully acted upon, namely the OIG recommendation that HRSA hold a national conference on the under-reporting issue, which was 12 years ago. Although HRSA and CMS, in response to an OIG recommendation, wrote a joint letter to the Joint Commission, the Joint Commission has not taken positive steps to address HHS concerns. Also, although HRSA funded the PwC study, it was ultimately unsuccessful in achieving its objective. The following chart shows the status of the recommendations cited in this report.

<table>
<thead>
<tr>
<th>Status of Previous Recommendations</th>
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<tbody>
<tr>
<td>1. HRSA should study the problem further, possibly through case studies.</td>
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<tr>
<td>Status: The only “case study” was a HRSA-funded contract with PricewaterhouseCoopers to look at possible compliance reviews, but the contract was unsuccessful due to industry’s failure to cooperate.</td>
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<tr>
<td>2. HRSA should sponsor a national conference on the issue.</td>
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<tr>
<td>Status: National conference held in Chicago in October 1996.</td>
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<tr>
<td>3. HRSA and CMS should send a joint letter to the Joint Commission urging that it incorporate the NPDB’s reporting requirement into its standards, and conduct a more thorough review of hospital peer review efforts as part of its survey process.</td>
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<tr>
<td>Status: Letter sent Feb. 27, 1995 but no action yet by the Joint Commission.</td>
</tr>
<tr>
<td>4. HRSA and CMS should work together to achieve a regulatory and statutory change so that the Medicare Conditions of Participation specifies hospitals’ responsibilities under the Health Care Quality Improvement Act.</td>
</tr>
<tr>
<td>Status: CMS has taken no action despite HRSA’s written request.</td>
</tr>
<tr>
<td>5. The Joint Commission should immediately make reporting by hospitals of adverse actions taken against hospital privileges a specific point of review.</td>
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<tr>
<td>Source: Conference Facilitator, Oct. 1996, National Conference on Hospital Reporting to the NPDB.</td>
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<tr>
<td>Status: Joint Commission has taken no action.</td>
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<tr>
<td>6. The AHA and hospital legal representatives should educate their hospital members and clients, as soon as practical, on the effectiveness of legal protections under the Health Care Quality Improvement Act’s immunity protections, as they have been interpreted by most courts.</td>
</tr>
<tr>
<td>Source: Conference Facilitator, Oct. 1996, National Conference on Hospital Reporting to the NPDB</td>
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<tr>
<td>Status: The American Hospital Association (AHA) could not find any record of an AHA response to this recommendation. The AHA advised Public Citizen Health Research Group that “…Based on the information currently available we do not know how AHA may have responded to the report…”</td>
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</table>
7. The American Medical Association and physician legal representatives should educate their physician members and clients, as soon as practicable, on the effectiveness of legal protections under the Health Care Quality Improvement Act’s immunity provisions.
   - **Source:** Conference Facilitator, October 1996, National Conference on Hospital Reporting to the NPDB
   - **Status:** The AMA provided Public Citizen Health Research Group a list of three NPDB links from the AMA web site. Although two of the web links, which contain duplicative wording, describe the statutory protection for “medical peer review,” the links do not address the conference recommendation asking the AMA to advise members about the effectiveness of such protections.

8. HRSA should sponsor a study, to begin within the next 12 months, examining the effects of proposing an amendment to the Act to allow immediate appeal of denial of the Act’s immunity provision.
   - **Source:** Conference Facilitator, Oct. 1996, National Conference on Hospital Reporting to the NPDB
   - **Status:** No action taken.

9. HRSA should propose legislation that would establish a civil money penalty of up to $10,000 for each instance of a hospital’s failure to report to the NPDB.
   - **Source:** OIG Report, July 21, 1999, OEI-12-99-00250
   - **Status:** In response to the OIG recommendation, HRSA initiated a legislative proposal that would impose a civil money penalty of $25,000; however, the proposal was not approved by HHS. Therefore, the proposal was not sent to Congress.

10. HRSA should seek legislative authority and funding for conducting compliance reviews of clinical privilege reporting, including authority to access peer review records.
    - **Source:** PricewaterhouseCoopers LL.P, Nov. 15, 2002
    - **Status:** No action taken.

Public Citizen Health Research Group Recommendations

**A. HRSA and CMS should work together to achieve a regulatory and statutory change so that the Medicare conditions of participation specifies hospitals’ reporting responsibilities under the Health Care Quality Improvement Act.**

The 1995 OIG report recommended such a regulatory and statutory change. The OIG noted that “this inclusion would compel the Joint Commission to devote greater oversight to hospitals’ performance of the responsibilities.”

Also, since the Medicare Improvements for Patients and Providers Act of 2008 allows organizations other than the Joint Commission to conduct accreditation reviews, our recommendation would impact all hospital accreditation organizations.

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87 OIG, Hospital Reporting to the National Practitioner Data Bank, Op.Cit., 8
B. CMS should require that the standards for compliance with the Medicare conditions of participation include all aspects of peer review.

Events at Redding Medical Center demonstrate that ineffective or non-existent peer can affect patient safety. Currently, a violation of an element of a Medicare Condition of Participation is not sufficient to rule the entire Condition violated. According to CMS, partial compliance is good enough. Although one critical element, peer review for cardiac services, remained in non-compliance, Redding was still accredited.

C. Congress should provide CMS with the authority to impose sanctions on hospitals and physicians for failure to perform peer review.

For hospital departments where peer review is absent, CMS should stop payment for selective services in such departments.

D. Congress should amend the Health Care Quality Improvement Act to impose a civil money penalty for failure to report.

Research has shown that states with financial penalties for failure to report have higher levels of hospital reporting to the NPDB. The “Model Act” developed by CAC and the Administrators in Medicine recommends a penalty of $1,000 per day per unreported adverse action. Even the Joint Commission believes that a strong penalty provision would likely encourage reporting. Furthermore, a July 1999 Inspector General Report recommended a civil money penalty of up to $10,000 or each instance of non-compliance. In response to the OIG recommendation, HRSA developed a legislative proposal that would have created a $25,000 civil monetary penalty for failure to report. As noted in the body of this report, HHS did not approve the HRSA proposal. Congress should amend the Act to authorize a civil money penalty of up to $25,000 for each instance of a hospital or other health care entity’s (e.g. HMO) failure to report an adverse action to the National Practitioner Data Bank.

E. HRSA should also seek legislative authority for conducting compliance reviews of clinical privilege reporting, including authority to access peer review records.

In 2002, HRSA contracted with PricewaterhouseCoopers LLP (PwC) to establish a pilot assessment of the extent of hospital non-compliance with NPDB reporting. The assessment was to use the voluntary cooperation of hospitals. As noted earlier, the study could not be conducted because of the failure of the sample hospitals to cooperate. We support the PwC recommendation to HRSA that the agency seek legislative authority for HRSA to access peer review records for the purpose of assessing the level of clinical privileges compliance reporting.

F. The Office of Inspector General should review hospital practices relating to granting and renewing privileges.
When a hospital grants privileges to a physician, the institution has evaluated the physician’s education and experience and determined that physician can perform within a specified scope of practice. This peer review, which takes place at the time of hiring and periodically thereafter, is critical to assuring that the practitioner has the necessary knowledge and skills to provide patient care within the designated scope of practice.

Unfortunately, there are numerous examples of physicians who provided questionable and/or unnecessary care. There is also evidence that Joint Commission surveys do not go far enough in evaluating hospital privileging activities.

According to the Medicare Conditions of Participation, hospitals must ensure that all patient care is provided in accordance with medical staff criteria for the granting and renewing of privileges. 88

Although OIG has reviewed credentialing and privileging activities at HHS funded hospitals, i.e. at Indian Health Service facilities, OIG has apparently not focused on “private sector” hospitals. The OIG should investigate non-federal hospitals’ compliance with the Medicare Conditions of Participation relating to medical staff privileges.

G. HRSA should initiate educational and compliance activities involving hospitals that have not reported.

As a first step, HRSA should send letters to all hospitals reiterating reporting responsibilities, asking if they understand the reporting requirement and expressing a willingness to discuss their concerns in a confidential manner. A copy of the letter should be shared with Public Citizen and other members of the National Practitioner Data Bank Executive Committee. 89

At the end of six months, HRSA should identify those hospitals that still have not reported and refer them to the OIG for follow-up.

H. HHS should implement specific recommendations from the 1996 Chicago National Conference on Under-Reporting.

1. The conference recommended that HRSA study the problem further, possibly through case studies. As soon as possible, HRSA should address the issue of “peer review immunity.” Notwithstanding the peer review immunity protection afforded by NPDB legislation, hospitals apparently remain concerned

88 42 CFR § 482
89 In addition to Public Citizen, the NPDB Executive Committee includes representatives from all the major NPDB constituencies including the AHA, AMA, The Federation of State Medical Boards, malpractice insurers, accreditation organizations such as the Joint Commission, OIG/HHS, and, of course, HRSA.
about lawsuits. HRSA should update the survey of court decisions that was prepared for the October 1996 national conference in Chicago. As noted earlier, the survey concluded that the immunity provisions of the Act were protecting professional review activities in the vast amount of cases. HRSA should make results of the updated survey available to the AHA and AMA to share with the hospital and medical community, respectively.

2. The 1996 national conference recommended that the Joint Commission make reporting by hospitals of adverse actions taken against hospital privileges a specific point of review. Following the national conference, HRSA and CMS wrote the Joint Commission asking for assistance. To date, the Joint Commission has not taken steps to include hospital reporting in its accreditation surveys. The Joint Commission should amend its standards to incorporate compliance with NPDB reporting.

1. State medical boards should request their respective state legislatures to adopt those provisions of the CAC model act that have the potential to increase reporting.

Strong state laws (such as monetary penalties) and enforcement activities have the potential to improve hospital reporting to the NPDB.

J. State medical boards and HRSA should work together to facilitate reporting to the NPDB.

According to the Citizen Advocacy Center, “a number of states report that they frequently visit with hospital executives on their responsibilities under state mandatory reporting laws.” CAC recommended, and Public Citizen agrees, that HRSA staff should explore with state officials the feasibility of including hospitals responsibilities to report to the NPDB as part of these “educational” visits.

K. Congress should provide the Office of Inspector General, HHS, with authority to review state medical boards’ handling of adverse clinical privilege reports.

The value of hospital mandatory reports is clear. This raises the question of how to explain the fact that 952 physicians with two or more clinical privilege reports in the NPDB had no disciplinary action imposed by a licensing board. Until 1993, the OIG at HHS conducted evaluations of the performance of state medical boards.  

90 Cohen and Swankin, Op.Cit. vi
However, because of legal concerns involving OIG authority to conduct reviews of state health professional licensing boards, OIG no longer considers performing such studies. OIG believes that since state health professional boards do not receive HHS funding, it has no authority to focus on state medical boards. However, these boards regulate the practitioners who provide medical services to millions of Medicare and Medicaid beneficiaries. Therefore, Congress should give OIG the authority to conduct such reviews.

L. Hospital compliance officers should monitor hospital peer review and reporting to the NPDB.

Hospital Compliance Programs have their origin in the Federal Sentencing Guidelines of 1987 (Guidelines). On May 1, 1991, the Guidelines, which had focused only on the behavior of individuals, were broadened to include “organizations.” The organizational guidelines “provide incentives for far reaching compliance programs and have produced a new occupation that advises organizations on how to build effective programs that promote ethical behavior. Furthermore, by promoting compliance and ethics programs, the organizational guidelines not only provide incentives for substantial changes in organizational behavior, but also further some of the main goals of the Sentencing Reform Act: the prevention and deterrence of criminal conduct.”

On February 23, 1998, the OIG, HHS, issued a guidance entitled “Compliance Program Guidance for Hospitals.” This guidance covers quality of care and financial risk areas. According to Strategic Management Systems, a consulting company to hospitals on compliance issues, there are four elements of the quality of care risk area: accuracy of quality-reporting data; medically unnecessary services; deficient care (failure to meet accepted standards of care) and, practitioner qualifications.

The Health Care Compliance Association (HCCA) is a national non-profit professional membership organization made up of health care compliance and ethics professionals. According to HCCA, it has approximately 6,000 members. Many of these compliance and ethics professionals work in hospitals while others work for health care organizations such as health plans and nursing homes.

Hospital compliance officers are in the unique position of independence from medical and management staff. Compliance officers should therefore monitor hospital peer review, including sitting in on such reviews, and evaluate hospitals compliance with NPDB reporting law. To achieve this, we specifically recommend the following:

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1. HRSA and the Health Care Compliance Association should work together in publicizing the NPDB reporting requirement through joint letters, webinars, and other training opportunities.

2. The Health Care Compliance Association should include NPDB reporting in its agenda for national and regional conferences.

3. The OIG should consider revising the Feb. 23, 1998 Compliance Guidance for Hospitals to include hospital peer review and NPDB reporting as risk areas.

M. The Office of Inspector General, HHS, should use corporate integrity agreements to assure hospital compliance with NPDB reporting requirements.

OIG often negotiates compliance obligations with health care providers including hospitals as part of a settlement of federal health care program investigations arising from a variety of civil false claim statutes. A provider consents to these obligations as part of the civil settlement and in exchange to the OIG’s agreement not to seek an exclusion from Medicare or Medicaid or other federal health care programs. There are currently over 400 corporate integrity agreements and related agreements posted on the OIG web site.93 These agreements encompass both quality of care and/or financial issues. The agreements require the hospital to establish a program to monitor corrective action and compliance. One such agreement notes:

   Hospital Corporation ‘A’ has established, and shall maintain during the term of the CIA, a Clinical Quality Department […] for monitoring clinical quality at Hospital A’s hospitals, including the credentialing, privileging, and peer review programs.94

Currently OIG does not require hospital compliance programs to assure compliance with the NPDB reporting requirement. OIG should include compliance with NPDB reporting as part of future hospital Corporate Integrity Agreements.

93 http://www.oig.hhs.gov/fraud/cia/cia_list.asp
94 http://oig.hhs.gov/fraud/cia/agreements/TenetClIAFinal.pdf, 6
Appendix A: Total Number of Adverse Hospital Privileges Reports by Year - Source: Unpublished HRSA data

Total number of adverse hospital clinical privilege reports

Total Number of Adverse Hospital Clinical Privilege Reports for 17+ years = 11,221
Appendix B: Currently Active Registered Non-Federal Hospitals That Have Never Reported to the National Practitioner Data Bank by State,* September 1, 1990 - December 31, 2007, Source: Unpublished HRSA Data

<table>
<thead>
<tr>
<th>State</th>
<th>Number of Hospitals with &quot;Active&quot; NPDB Registrations</th>
<th>Number of &quot;Active&quot; Hospitals that Have Never Reported</th>
<th>Percent of Hospitals that Have Never Reported</th>
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<tbody>
<tr>
<td>Alabama</td>
<td>118</td>
<td>68</td>
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<tr>
<td>Alaska</td>
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<tr>
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<tr>
<td>Pennsylvania</td>
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<tr>
<td>South Carolina</td>
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<tr>
<td>Tennessee</td>
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<tr>
<td>Wyoming</td>
<td>20</td>
<td>20</td>
<td>69.0%</td>
</tr>
</tbody>
</table>

**Currently active** registered hospitals are those listed by the NPDB as having active status registrations on December 31, 2007. A few hospitals have more than one registration and are including more than once in this table. Non-federal are hospitals not owned and operated by the federal government.

**The total includes hospitals in American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and U.S. Virgin Islands (49 hospitals with active registrations, 33 hospitals which have never reported).

State variations in the percentage of hospitals reporting represents just one way, but not the only way, to compare states in hospital under-reporting. Depending on the data available to the researcher and the purpose of the study, state reporting rates can also be analyzed by such variables as hospital reports per 1,000 hospital beds in the state, reports per 1,000 admissions in the state, or other variables.