The Division of Health Service Regulation as an Eligible Entity Reporting to the Data Bank

By

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Abstract
Bethany A. Burgon: The Division of Health Service Regulation as an Eligible Entity Reporting to the Data Bank
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The North Carolina Department of Health and Human Services, Division of Health Service Regulation is required to report and may query the National Practitioners Data Bank and the Health Integrity Protection Data Bank. This paper provides an overview of the requirements and process for the Division to report to the Data Bank along with suggestions to ensure compliance in an efficient and effective manner. The purpose of the Data Bank is discussed through a review of literature and overview of associated laws. The process and procedure of the database is explained in relation to eligible entities, individual subjects, queries, reports, disputes, and fees. A summary of improvements of the Data Bank delineates the use of public health leadership in operation and improvement of the database.
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List of Abbreviations

AAR - Adverse Action Report
ACL – Adult Care Licensure Section
AHCL – Acute and Home Care Licensure Section
BHPPr - Bureau of Health Professionals
DBID - Data Bank Identification Number
DCN - Data Bank Control Number
DIET - Data Integrity and Evaluation Team
DHHS - Department of Health and Human Services
DHSR - Division of Health Service Regulation
DPDB - Division of Practitioner Data Banks
EMS - Emergency Medical Services
EFT - Electronic Funds Transfer
FOIA - Freedom of Information Act
HCPR - Health Care Personnel Registry
HCQIA - Health Care Quality Improvement Act of 1986
HIPAA - Health Insurance and Portability and Accountability Act of 1996
HIPDB - Health Integrity and Protection Data Bank
HRSA - Health Resources and Services Administration
ICD - Interface Control Document
IQRS - Integrated Querying and Reporting Service
ISSO - Information System Security Officer
JCAHO - Joint Commission on Accreditation of Healthcare Facilities
JCR - Judgment or Conviction Report

ITP - ICD Transfer Program

MHLHC - Mental Health Licensure and Certification Section

MMPR - Medical Malpractice Payment Report

NHLC – Nursing Home Licensure and Certification Section

NPDB - National Practitioners Data Bank

OEMS - Office of Emergency Medical Services

OIG – Office of the Inspector General

PDS - Proactive Disclosure Service

PREP - Practitioner Remediation and Enhancement Partnership

PUF- Public Use Data File

SSN - Social Security Number

SPSS- Statistical Package for the Social Sciences
Introduction

Health care quality and patient safety in the United States is weighed down by the massive financial burden created by health care fraud and abuse. Estimated annual cost of this fraud ranges from 3 to 10 percent of national health care expenditures. With expenditures over 1 trillion dollars, between 30 billion to 100 billion dollars are lost to health care fraud. The Data Bank is a national information clearinghouse intended to improve health care quality, protect the public, and reduce health care fraud and abuse in the nation.¹ The Data Bank consists of the National Practitioner Data Bank (NPDB) and the Healthcare Integrity and Protection Data Bank (HIPDB) combined into a single database. The Data Bank a national tool to help protect patients from incompetence and unprofessionalism related to health care practitioners. Eligible entities are required to report certain information about adverse actions of health care practitioners, providers, and suppliers to the database. Certain entities have access to query the Data Bank for information regarding these individuals.

The NPDB was first created in 1986 in response to a perception from U.S. Congress of the increasing amount of medical malpractice claims and the need to improve the quality of health care across the nation. The Health Care Quality Improvement Act of 1986 (HCQIA) was passed into legislation because Congress believed that these problems had elevated beyond a level that could be handled by individual States. The legislation led to the establishment of the NPDB which collects and releases specific information related to professional competence and conduct of physicians, dentists, and other health care practitioners. By collecting and

disseminating the information, physicians and dentist are unable to move from one jurisdiction to another without disclosure of previous incompetence or unprofessionalism. Before establishment of the NPDB, physicians and dentists had been discouraged from participating in professional peer review from the threat of private money damage liability. Previously, a peer review decision to deny a physician staff privileges could be characterized as an illegal restraint on trade under Federal antitrust law. Physicians and dentists were subject to the possibility of treble damages under this law.\(^2\) Congress felt that more effective peer review would help limit the ability of incompetent health care practitioners to move from State to State without disclosure of adverse employment actions.\(^3\) The enacted legislation helped by providing protection to the individuals participating in the professional peer review process thus encouraging participation. With the establishment of the NPDB, individuals who serve on peer review committees were provided antitrust immunity. The beginning of the NPDB marks a major step by the Federal Government to improve professional review across State lines by making information involving medical malpractice payments and adverse actions accessible to eligible individuals and entities on a nation-wide scale.\(^4\) The HIPDB was enacted through the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) which established more comprehensive reporting requirements for the database related to certain adverse actions taken against health care providers, suppliers, and practitioners. The HIPDB is intended to help combat fraud and abuse

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in health insurance and health care delivery and to promote quality care. The HIPDB was created to assist Federal and State Government agencies along with health care entities in law enforcement and qualification review of health care practitioners, providers, and suppliers. Eligible entities are required to report and allowed to query the database regarding the additional final adverse actions.

The U.S. Department of Health and Human Services (DHHS) and the Office of the Inspector General (OIG) are responsible for administration and operation of the Data Bank. The Data Bank is developed and maintained through agreement of an Interagency Memorandum of Understanding between the Division of Practitioner Data Banks (DPDB) of the Bureau of Health Professionals (BHPPr) and the Health Resources and Services Administration (HRSA) of HHS. The mission of HRSA is, “to improve health and achieve health equity through access to quality services, a skilled health workforce, and innovative programs.” The DPDB developed and now operates the database; a cost-effective and efficient system that ensures accurate, reliable, and timely information on practitioners, providers, and suppliers, to credentialing, privileging, and government authorities. The Data Bank helps ensure the mission of the HRSA by providing essential information about health care practitioners and entities through its administration managed by the DPDB.

5 Ibid.


The Data Bank serves as an alert or flagging system intended to facilitate a more comprehensive review of professional credentials by providing a safeguard to help ensure quality health care. The NPDB and HIPDB should not be the sole source of verification of professional credentials. The database is intended to supplement information from other sources (e.g., quality improvement studies, peer recommendations, training, and experience) when making decisions on employment or authorization to provide health care services. The database function is to alert agencies and health plans that there may be a problem with a health care practitioner’s performance. Under this system, health care entities and government agencies now have access to the disciplinary records of health care professionals and can use this information when making licensing and hiring decisions for doctors, dentists, nurses, nurse aides, physical therapists, and many other health related personnel resulting in a safer provider workforce.

**Literary Review**

The following literary review offers a summary of published information relating to the NPDB-HIPDB including articles, a report, and a letter. Much of the information reviewed was presented over the past decade. Many of the issues discussed in the literature have been addressed by the Data Bank in the succeeding years.

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The National Practitioners Data Bank: the First 4 Years is authored by three individuals that manage the operation of the database. This article was authored before the HIPDB had been established. The article begins by giving a background of the NPDB’s governing laws. The primary purpose of the NPDB is to collect and distribute information on medical incompetence of practitioners. The database is intended to be a flagging system rather than the primary source of information. The authors explain that the licensing and credentialing authorities should further examine records after a flagging.

By the end of 1994, the NPDB had processed 4,586,262 queries. 1,504,824 queries were reported in 1994, coming out to about 6,000 queries a day. The increase in query volume signifies that the reports in the database are found useful in decision making. The NPDB contained 97,537 reports by the end of 1994. At this time, 80,559 reports (83 percent) involved medical malpractice and 16,978 reports (17 percent) of adverse licensure actions. Some groups have recommended that malpractice payment reports should have a dollar threshold amount so that small payments do not misrepresent actual malpractice. Others argue that a threshold would be inequitable because of certain types of specialties only have small malpractice payments while others only have large. The adverse licensure action reports has a threshold period requirement of an action which affect a license for more than 30 days, the average number in 1994 was 1.3 reports per practitioner. Several practitioners in the NPDB have multiple reports. Some practitioners have more than 100 reports. 84.7 percent of the practitioners had reports

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involving malpractice payment only, 12.5 percent involved only adverse action, and 2.8 percent involved both.\textsuperscript{14}

The Data Bank has been used for research several different ways. The NPDB is the only comprehensive national malpractice payment database which describes nearly all malpractice payments made on behalf of practitioners. The data can be viewed as a whole nation or by geographic region. This information can be used to assess medical liability issues. A legislator might compare malpractice payments in neighboring states in consideration of adopting statutes. Physicians could use the data to target quality assurance data. Because of the comprehensive nature of the information, the database can also be used to study the underlying context of medical incompetence. The information should however be used with caution and include further examination in conjunction with other available information related to the practitioner.\textsuperscript{15}

The article by, Croft et al, shows that the nation has started to comply with the Federal regulations for reporting and querying the Data Bank in the 1990s. The NPDB can be a very useful tool but has some limitations. Awareness of the limitations helps one to properly interpret the data when querying the database.

Limitations of the NPDB involve the need to interpret the information with caution. Interpretation of medical incompetence from medical malpractice payments in the database does not necessarily have definitive and comprehensive reflection of a practitioner since a majority of malpractice claims do not result in payment. Many times a claim is not considered defensible by the insurer and the claim is dropped. Furthermore, many malpractice payments are made in

\textsuperscript{14} Ibid, pp. 385-389.

\textsuperscript{15} Ibid, pp. 385-386.
situations where medical incompetence did not occur. Practitioners may provide their own statement explaining a report which can create a notification to queriers of when a payment was made only for “convenience” purposes. Convenience payments are made in situations where the claim may not be defensible but a party does not want to bear the expense of litigation. Many times significance of these payments can be determined through the explanation in the provided statement.16

The United States General Accounting Office’s 2000 report entitled, National Practitioners Data Bank Major Improvements Are Needed to Enhance Data Bank’s Reliability, addresses questions about the operational efficiency and effectiveness of the NPDB.17 The report points out that the Data Bank, operated by HRSA, is the nation’s only central source of information on physicians, dentists, and other health care practitioners who are the subject of a malpractice payment or have been disciplined with an adverse licensure action. This report assesses the efforts of HRSA during the early 1990’s to address potential underreporting to the NPDB, evaluates the accuracy, completeness, and timeliness of reporting to the database, and also expenditures and user fees to determine if the fees are set at an appropriate level.

The report notes that efforts to address underreporting have been unsuccessful because the agency has not included steps to address the issue in its strategic plan. Medical malpractice underreporting has been a long standing problem. Malpractice is underreported by insurers using the technicality of a “corporate shield” in these cases. Only practitioners have to be reported so when the corporation puts its name on the malpractice payment, the physician does not have to

16 Ibid, p. 385.
be reported. A suggestion was made to change the reporting to any practitioner for whose benefit a malpractice payment is made. GAO et al explain that underreporting of clinical privilege restriction has also been a long standing problem. HRSA estimated around 10,000 adverse licensure action reports annually but fewer than 9,000 were reported from 1990 through 1999. A proposal was made to fine non-reporting providers. The report notes that HRSA had not implemented laws passed in 1987 that would significantly increase the information reported to the NPDB. A proposal was made to combine the NPDB and the HIPDB into a single database to avoid duplication and confusion.

The next section of this report analyzes the weaknesses in the NPDB data and the limits in the usefulness. Malpractice payment reports were problematic because they did not meet the criteria for completeness. Licensure reports were, on occasion, untimely, inaccurate, and submitted in duplicate which made it appear as if multiple actions had been taken against a practitioner. Furthermore, when mistakes were made in the reporting, practitioners have problems getting the information corrected.

Operations for the NPDB are funded by user fees and the HRSA does not receive a separate appropriation. The HRSA has not ensured that all collections from the NPDB were received or were used for authorized purposes. Although the NPDB had a positive cash flow in 2000, The HRSA did not have a plan for its future financial operation. The HRSA was responsible for developing this policy and procedure.

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19 Ibid, p. 16.
As discussed in the Leadership section of this thesis, many of the tools and concepts of public health leadership have been used to implement the suggestions and concerns about the operational efficiency and effectiveness of the NPDB since the GAO et al report in 2000. Reports such as *National Practitioners Data Bank Major Improvements Are Needed to Enhance Data Bank’s Reliability* are helpful in bringing specific areas for improvement to the attention of program leadership.

On March 22, 2006, Michael D. Maves wrote a letter on behalf of the American Medical Association to Betsy Ranslow of the BHP, HRSA, Re: RIN 0906-AA43 National Practitioner Data Bank for Adverse Information on Physicians and Health Care Practitioners: Reporting on Adverse and Negative Actions. The purpose of the letter was to comment on a proposed regulation to expand the scope of reporting to the NPDB by expanding regulations under Sections 410 through 432 of the HCQIA. The amendment would require each state to adopt a system for reporting adverse licensure actions against health care entities and practitioners to the NPDB and require the state to report negative actions or findings from a state licensing authority, peer review organization, or private accreditation agency. The AMA supported the vision of the NPDB to assist states in protecting the public from health care practitioners crossing state lines as a way to avoid the consequences of discipline. The AMA however objected to the establishment and methodology of the NPDB based on HHS exceeding its statutory authority in drafting the original regulations of the NPDB. The AMA held that the

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NPDB exceeds the scope of its intended legislative purpose and is structured in a way which prevents the actual mission of flagging questionable competence or conduct of a practitioner.\textsuperscript{22}

The AMA argued that the data gathered by the NPDB does not reflect the quality of care provided by a practitioner. A majority of the data is from medical negligence claims and there is little correlation between a finding of negligence by a jury with actions reviewed by a professional board. Furthermore, the information does not reflect if the physician practices a high risk specialty which results in more medical claims. Many times economic decisions are made to settle “nuisance cases” rather than expending resources on the merits of the case. However, the AMA notes that false reflection may have severe professional and economic ramifications including, “denial of credentialing, loss or limitation of privileges or licensure, exclusion from participation in health plans, and increase in insurance premiums.”\textsuperscript{23}

The AMA objected to the proposed amendment because the organization believed the expansion of data collection went beyond the intended purpose involving competence and conduct to loosely defined “adverse licensure actions.” These actions as reported by peers include lesser offenses that do not reflect quality of care. Peer review reporting of “negative findings” will result in a large volume of reports with little practical value because the serious allegations are already reported to the state licensing agencies. The AMA suggests a tighter definition of peer review to include findings that involved due process. A reportable negative action should be required to involve findings that indicate a substantial risk of safety to a patient or quality of care. The AMA concluded by noting that the proposal included significant expansion for reporting but nothing about additional safeguards for rebuttal and correction.

\textsuperscript{22} Ibid, p. 3.
\textsuperscript{23} Ibid, p. 2.
Many of the new reportable actions would not involve due process so the AMA suggested the NPDB should exercise statutory authority to permit the physicians to rebut the information.\textsuperscript{24}

This letter is important as it demonstrates to individuals being reported to the Data Bank that they have advocates trying to balance the power. The AMA is trying to support the physicians who might be affected by the NPDB by recommending clearer guidelines for information reported to the database. The Overview of Laws section will explain more about the guidelines for reporting.

Laura A. Chernisky weighs the evidence for and against disclosure in her law review article \textit{Constitutional Arguments in Favor of Modifying the HCQIA to Allow the Dissemination of Physician Information to Health Consumers}.\textsuperscript{25} The general public can currently access a series of scattered databases on physician information but do not have access to the most complete and efficient database, the NPDB. Several attempts have been made to grant the general public access to the database through federal legislation but have failed.

The majority of scholarly articles about the NPDB argue that the general public should not have access to the database. The arguments against public access to physician information are operational concerns and reliability, unintended consequences and the need to facilitate error reporting. Operational concerns and reliability relate to the accuracy of the information reported and whether the information will adequately predict physician competency for consumers. The unintended consequences argument includes deterring performance of high-risk procedures and

\textsuperscript{24} Ibid, p. 6.

provocation of litigation. The error reporting argument describes the need to keep medical error reporting confidential to promote communication resulting in improvement.\footnote{Ibid, p. 748.}

Chernitsky’s article focuses on the arguments for access to physician information in the NPDB by the general public access. This would benefit consumers through giving more information to make better-informed decision while selecting health care practitioners. The commercialism of health care supports the need for the consumer to be informed. The article argues that information parallels commercial free speech which receives constitutional protection. If the information in the NPDB was considered commercial speech then the consumer would have standing to bring a suit challenging the federal restriction on access to the general public. The basis of the argument is that the consumer has an interest in the free flow of commercial information. This interest applies to health care services including selection of a competent physician. Dissemination of information about healthcare providers is analogous to the dissemination of information about political candidates therefore the physicians do not have a professional right to privacy.\footnote{Ibid, p. 771.} The article also outlines rebuttal arguments to the ideas which oppose public access to the NPDB.

The authors of \textit{State Medical Boards Fail to Discipline Doctors With Hospital Actions Against Them} analyze the data collected in the NPDB to review the number of physicians receiving a clinical privilege action but escaped state licensure action.\footnote{Levine, Alan & Oshel, Robert, PhD & Wolfe, Sydney, MD (2011). \textit{State Medical Boards Fail to Discipline Doctors With Hospital Actions Against Them}. 40 Years Public Citizen. Retrieved January 27, 2012 from http://www.citizen.org/documents/1937.pdf} 10,672 physicians received a clinical privilege action of either revocation or restriction of privileges from 1990

\begin{thebibliography}{9}
\bibitem{Ibid} Ibid, p. 748.
\bibitem{Ibid} Ibid, p. 771.
\end{thebibliography}
through 2009. Of that group, 45% also had a state licensing action. However, more than half, 55% or 5,887 did not have a state medical board action. Of those not receiving a state licensing action; 220 physicians were disciplined for being “an immediate threat to health or safety”; 1,119 were disciplined because of “incompetence, negligence, or malpractice”; and 605 were disciplined for “substandard care.” Other categories of discipline included sexual misconduct, inability to safely practice, and fraud. A total of 2,071 physicians had a violation in the most serious categories of sexual misconduct, inability to safely practice, or fraud but, had no state licensure action. 3,218 physicians had lost their clinical privileges permanently but had not state medical board action.

Medical board oversight depends highly on peer review actions through hospital disciplinary reports. Subsequent state licensure action against the physician would provide a greater reassurance that the practitioners medical practice would be monitored and that other state medical boards would be aware of the violation. The results of this analysis raises questions as to whether the state medical boards are adequately responding to the hospital disciplinary reports and whether the state medical boards are receiving the disciplinary reports as required by law. The NPDB de-identifies the physicians through code numbers so www.citizen.org would like the state medical boards to work with the NPDB to identify the physicians in the study and take appropriate action.

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This article supports an evaluation of the effect of the NPDB in society. The reporting has had a positive effect with some licensure action but more needs to be done to fill the gap. As discussed in the Leadership section, the Data Bank staff has taken steps to address this issue.

Although questions and concerns are addressed in the literature review of the NPDB-HIPDB, most organizations tend to support the vision of the Data bank. The Data Bank has responded to many of the concerns raised in this information and have implemented policy and procedure to deal with the issues. Furthermore, although there are some areas that create alarm with the reporting, knowledge of the shortfalls help to implement efficient and effective use of the information.

**Overview of Laws**

Title IV of Public Law 99-660, the *Health Care Quality Improvement Act of 1986*, 42 USC Sec. 11101, first established the NPDB. The HCQIA addresses several findings by Congress including: increased medical malpractice and the inability of the individual States to undertake the problem; the national need to restrict the ability of incompetent physicians to move from State to State without disclosure of status; and the ability to remedy the these problems through a national peer review. The findings continue by noting that physicians are unreasonably discouraged from participating in effective professional peer review because of the threat of private money damage liability. Congress found that, “there is an overriding national

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need to provide incentive and protection for physicians engaging in effective professional peer review.”

Subchapter I of Code 42 lays out the guidelines and standards for the promotion of professional review activities and for encouraging good faith professional review. Subchapter II governs the requirements and procedure for the reporting of information to the NPDB. The required reporting involves professional competency and conduct. The HCQIA specifically requires reports of medical malpractice payments, sanctions by the Board of Medical/Dental Examiners, review actions taken by health care entities affecting the clinical privileges of a physician for more than 30 days, and adverse actions taken by the Office of Inspector General or the Department of Enforcement Administration.

Under the HCQIA medical malpractice payers, the Boards of Medical/Dental Examiners, hospitals, other health care entities with formal peer review, professional societies with formal peer review, the Office of Inspector General, and the Drug Enforcement Administration are required to report to the NPDB. Hospitals, other health care entities with formal peer review, professional societies with formal peer review, state health care practitioner licensure and certification authorities (including medical and dental boards), plaintiff’s attorneys (under limited circumstances), health care practitioners (self-query), and researchers (statistical data) may be approved to query the Data Bank. Every hospital has a duty to request the information

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33 Ibid.
34 Ibid.
about a physician from the NPDB upon consideration for hire and every two years following employment.\textsuperscript{35}

The HCQIA has been developed with the intention of improving the quality of health care by requiring boards and entities to identify and discipline unprofessional behavior against physicians and dentists. The HCQIA further reduces the ability of a health care practitioner to move from State to State without disclosing past acts of medical malpractice and/or a history of professional adverse actions. The information is considered confidential and will only be released to eligible entities or to health care practitioners performing a self-query.\textsuperscript{36}

Section 1921 of the Social Security Act, (Section 5(b) of PL 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987, as amended) authorizes the NPDB to collect additional information beyond the scope allowed by Title IV.\textsuperscript{37} The expansion is intended to protect beneficiaries participating in health related programs of the Social Security Act from receiving services from unfit health care professionals. The additions further intend to improve the anti-fraud provisions within the health related programs. The additions for reporting include information concerning negative findings and sanctions against health care practitioners and entities imposed by state licensing authorities, peer review organizations, and private accreditation organizations. All adverse licensure actions, not just those related to competence and conduct must be reported under Section 1921 along with all publicly available adverse


\textsuperscript{36} Ibid.

\textsuperscript{37} Section 1921 of the Social Security Act, (Section 5(b) of PL 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987, as amended).
licensing actions. Section 1921 further includes reporting findings and sanctions against all health care personnel, not just physicians and dentists.38

Section 1921 expanded those required to report to the NPDB to now include other state health care practitioner licensing authorities (in addition to medical and dental boards), state health care entity licensing and certification authorities, peer review organizations, and private accreditation organizations. Queriers of the NPDB were expanded under Section 1921 to include state health care entity licensing and certification authorities, State agencies administering State health care programs, agencies or contractors administering Federal health care programs, State Medical Fraud Control Units, U.S. Comptroller General, U.S. Attorney General/other law enforcement officials, quality improvement organizations, and health care entities for self-query.39

Section 1921 gave authority for the NPDB to require each state to adopt a system of reporting to the Secretary of HHS certain adverse licensure actions against health care practitioners and health care entities by any authority in the State responsible for licensing the practitioners and entities. The types of actions under 1921 (a)(1) include:

(A) Any adverse action taken by such licensing authority as a result of the proceeding, including any revocation or suspension of a license (and the length of any such suspension), reprimand, censure, or probation.

(B) Any dismissal or closure of the proceedings by reason of the practitioner or entity surrendering the license or leaving the State or jurisdiction.

(C) Any other loss of the license of the practitioner or entity, whether by operation of law, voluntary surrender, or otherwise.

38 Ibid.

(D) Any negative action or finding by such authority, organization, or entity regarding the practitioner or entity.\textsuperscript{40}

The Final Regulation for Section 1921, 45 CFR Part 60, was published in the \textit{Federal Registry}, Volume 54, number 206, on October 17, 1989.

Section 1128E of the Social Security Act, (P.L. 104-191, the \textit{Health Insurance Portability and Accountability Act of 1996}), overlaps with the requirements of the HCQIA and Section 1921 with reporting to the Data Bank. Section 1128E as added by Section 221(a) of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 resulted in the creation of the HIPDB. The Secretary of HHS, acting through the Office of Inspector General and the U.S. Attorney General, created a central health care fraud and abuse data collection program for the reporting and disclosure of certain final adverse actions against health care practitioners, providers, and suppliers within 30 days of the date the action became final. The adverse actions do not include malpractice claims or settlements in which no findings of liability have been made. Section 1128E directs the Secretary to avoid duplicating the reporting requirements that were established for the NPDB under the HCQIA.\textsuperscript{41}

A final adverse action under Section 1128E includes civil judgments against a health care practitioner, provider, or supplier related to the delivery of health care and Federal or State criminal convictions related to the delivery of health care. Several actions, including revocations and suspensions, of Federal or State agencies responsible for the licensing and certification of health care providers, suppliers, and practitioners are also included. The agencies must report formal actions such as revocation or suspension of a license, reprimand, censure, or probation.

\textsuperscript{40} Ibid.

\textsuperscript{41} Section 1128E of the Social Security Act, (P.L. 104-191, the Health Insurance Portability and Accountability Act of 1996).
The authority must also report any loss of a license or the right to apply for, or renew, a license of the provider, supplier, or practitioner regardless of whether the actions occurred by operation of law, voluntary surrender, non-renewability, or otherwise. All negative actions or findings by the Federal and State agencies that are publicly available information must be reported to the database. 42

Government agencies and health plans are required to report to the Secretary final adverse actions along with the name of the health care practitioner, provider, or supplier who is the subject of the final adverse action, the name of the health care entity that the individual is associated with, the nature of the action, whether the action is on appeal, and a description of the acts or omissions, and injuries upon which the final adverse action was based. No person or entity reporting to the database can be held liable in a civil action in relation to the report made unless the reporter had knowledge of falsity of the information contained in the report. Section 1128E(b)(6)(B) requires the Secretary to provide, for a publication in a public report, of a listing government agencies that have failed to report the adverse actions as required by 1128E. The final adverse actions are to be reported regularly and not less than once a month. The Secretary is further required to establish a procedure to ensure that the privacy of the individuals receiving the health care services is protected. 43

Upon request, the information reported to the Secretary under Section1128E will be disclosed to the health care provider, supplier, or practitioner who is the subject of the final adverse action. Section 1128E(c)(1)(B) requires the Secretary to establish a procedure to dispute the accuracy of the information reported to the Data Bank. Government agencies and health

42 Ibid.
43 Ibid.
plans are required to report any corrections by the agency or plan related to information previously reported to the database in a form and manner outlined by the Secretary. Federal and State government agencies along with the health care plans are to have access to the information reported under Section 1128E pursuant to procedures that the Secretary shall provide. The procedure to access the information is provided in the Queries Section of this paper. Reasonable fees will be approved for the disclosure of the information from the database. The fees will be established in an amount sufficient to recover the costs of operating the database.\textsuperscript{44}

The Final Regulation for section 1128E, 45 CFR Part 61, was published in the \textit{Federal Registry}, Volume 64, number 206, on October 26, 1999.\textsuperscript{45} The Final Rule for section 1921, 45 CFR Part 60, was published in the \textit{Federal Registry}, Volume 75, Issue 18, on January 28, 2010 which revised the existing regulations of the \textit{Health Care Quality Improvement Act of 1986}, sections 410 through 432. The Data Bank instated Section 1921 on March 1, 2010 with the opening of the querying and reporting under the Rule. Under this implementation, the data reported to the HIPDB is also reported to the NPDB, however those who can query each database remain different. Reporters must only submit one report to the Data Banks and the system makes the determination to send the report to the NPDB, HIPDB, or the both database. This process came into play as part of the directive to the Secretary of HHS to avoid duplicative reports.\textsuperscript{46}

\textsuperscript{44} Ibid.


\textsuperscript{46} Section 1921 of the Social Security Act, (Section 5(b) of PL 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987, as amended).
Overview of the Data Bank

Introduction

The information used in this overview of NPDB comes from the National Practitioners Data Bank Guidebook which is available at the official Data Bank website from the U.S. DHHS, HRSA. The Guidebook serves as a resource for the NPDB to comply with the requirements by Title IV of Public Law 99-660, the HCQIA of 1986. It provides the information authorized users (e.g., State licensing authorities, medical malpractice payers, hospitals, health care entities, physicians, dentists, and other health care practitioners) need to interact with the NPDB.47 The information used in relation to the HIPDB overview comes from the Health Integrity and Protection Data Bank Guidebook which is available at the same website. The Guidebook serves as a resource for the HIPDB to comply with the requirements in Section 1128E of the Social Security Act. It provides the information authorized users (e.g., government agencies, health plans, and health care practitioners, providers, and suppliers) need to interact with the HIPDB.48

The NPDB was created through legislation from Congress based on a perceived need related to the increasing occurrence of medical malpractice litigation along with the need to improve the quality of medical care across the nation. The U.S. House of Representatives held hearings on the proposed HCQIA of 1986, on March 18 and July 15, 1986 by the Subcommittee on Health and the Environment, Committee on Energy and Commerce, and on October 8 and 9, 1986 by the Subcommittee on Civil and Constitutional Rights, Committee on the Judiciary.


Testimony was heard at the public hearings from physicians, attorneys, insurance company officials, health care representatives, and others. President Ronald Reagan signed the proposed legislation into Public Law 99-660 on November 14, 1986. The intent of the proposed legislation was two-fold: to improve the quality of health care by identifying incompetence and to restrict the ability of health care practitioners to move from State to State without disclosure of adverse actions.49

The Health Insurance and Portability and Accountability Act of 1996, also referred to as Section 1128E of the Social Security Act, directed the Secretary of DHHS to create a national fraud and abuse control program. A national database, the HIPDB, containing information about certain adverse actions against health care practitioners, providers, and suppliers was created in response to the mandate. The HIPDB contains information involving licensure and certification actions, exclusions from participation in Federal and State health care programs, criminal convictions, and civil judgments related to health care. The HIPDB legislation requires that there be protection of privacy, civil litigation protection, coordination with the NPDB, user fees for queries, regular reports (not less than one a month), and dispute procedures.50

The Data Bank serves as a flagging system intended to alert users to undertake a further comprehensive inquiry of a practitioner’s professional credentials. The database is intended to serve as a supplement, not a replacement, of a traditional credentialing review. For example, evidence of a medical malpractice payment should not be construed as a presumption of medical


malpractice because settlement may occur for a wide variety of reasons that do not reflect on competence or conduct. The database information should be considered with all other relevant data in evaluating the credentials of a practitioner including current competence studies, peer recommendations, health status, verification of training and experience, and relationship with colleagues and patients.  

The information in the Data Bank is confidential and can only be disclosed as allowed by law. The NPDB and HIPDB operate within a comprehensive security system designed to ensure confidential receipt, storage, and disclosure that prevents unauthorized access from staff or external sources. In addition, the Data Bank staff members undergo in-depth background security checks and the facility housing the database meets DHHS security specifications. DHHS security specifications require administrative, physical, and technical safeguards to ensure confidentiality, security, and integrity of electronic protected health information. The Data Base has a workforce station security program, facility access controls, and a policy for breach of security.  

The OIG has authority to impose civil money penalties up to $11,000 per violation on those involved in a breach of confidentiality. However, eligible entities are not prohibited from disclosing the database information as part of the peer review process as long as the information is used for its intended purposes. Examples include officials of the hospital reviewing information as part of a practitioner’s application for medical staff placement, or private accreditation entities’ review of the information in relation to playing a part in the peer review process. Of note is that a practitioner who performs a self-query is not barred from disclosing

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the information to a third party. Disclosure of the Data Bank information is limited to certain entities as outlined in the overview of laws. 45 CFR Part 60 and 61 outline key aspects of the confidentiality of the information in the database. For example, medical malpractice payers are required to report but they may not request information. The information can be released to any person or entity which requests the information in a form that does not identify a specific entity or practitioner.53

Federal systems of records on individuals, such as those in the NPDB and HIPDB, are protected from disclosure without the individual’s consent through the Privacy Act, 5 USC §552a, unless the disclosure is part of a routine use of the system. The routine use of the Data Bank does not include disclosure to the general public. The Freedom of Information Act (FOIA) does not trump the limited access provisions governing the NPDB or the HIPDB. Eligible entities however are allowed to query and disclose the information to others if they are involved in an investigation or peer review process. Furthermore, the confidentiality provisions are not applicable to evidence involved in the underlying action such as documents and records. These underlying documents and records can be released in a FOIA request. The Secretary is charged with ensuring the Data Bank is operated in a manner that does not reveal any protected health information of a patient. The laws governing the Data Bank do not specify a sanction for violation of the confidentiality provision however other Federal statues may subject individuals to financial penalties for disclosure. Information from the HIPDB limits disclosure to: Federal and State Government agencies; health plans; health care practitioners’ providers, and suppliers self-query; persons or organizations requesting reports with redacted identification information.

Individuals, authorized agents, entities, and DHHS are protected from civil liability through immunity provisions in Section 1128E for the reports made to the NPDB and HIPDB unless the report is made with knowledge that the information contained within is false.\textsuperscript{54} Furthermore, those who knowingly and willingly query the Data Bank under false pretenses or who frequently obtain information from the database may face civil and criminal penalties.\textsuperscript{55}

**Eligible Entities**

Eligible entities are defined by the HCQIA and are required to report and/or query as specified in the Act. To participate individual entities must certify eligibility with the NPDB and/or the HIPDB. Eligibility for the NPDB requires that an entity is a board of medical examiners or state licensing authority, a hospital, a health care entity that provides health care services and follows a formal review process, or a professional society that follows a formal peer review process in furtherance of the quality of health care. The phrase “provides health care services” includes the delivery of health care services through a wide array of coverage arrangements or relationships which may be direct or contractual. Importantly, indemnity insurers are not included. Entities required to report to the NPDB include entities making malpractice payments, a board of medical examiners or state licensing boards taking an adverse action against a practitioner, health care entities that take adverse licensure action based on professional review, or a professional society that takes an adverse membership action based on professional review. Examples of health care entities include preferred provider and health


maintenance organizations, nursing homes, group practices, hospice, dialysis centers, and surgical service centers. Medical malpractice payers are required to report but they may not request information. Reporting entities conducting professional review activities have civil liability protection when the professional review activities are conducted with reasonable belief of furthering the quality of health care, with proper regard for due process including notice and a hearing. To receive immunity protection the activity also must be taken after a reasonable effort to obtain the facts of the matter with a reasonable belief that that action was warranted by the known facts.56

Entities required to report and able to query the HIPDB are outlined in Section 1128E and include health plans and Federal or State Government agencies. Entities are responsible for determining eligibility to participate and for certifying the eligibility in writing. Section 1128E has mandatory requirements related to reporting but in 1999 there were no mandates involved with queries. Examples of Federal or State Government agencies include: the Department of Justice, the Federal Bureau of Investigation, the Drug Enforcement Agency, the Department of Health and Human Services, the Food and Drug Administration, the Office of Inspector General, the Department of Defense, the Department of Veteran Affairs, States Attorneys General, District Attorneys, County Police Departments, Medicaid Fraud Control Units, and agencies responsible for licensure or certification of health care practitioners, providers, and suppliers. A health plan refers to program, plan, or organization that provides health benefits directly or through insurance or reimbursement. Examples of health plans include: a policy of health insurance, a contract of a service benefit organization, membership agreement with a prepaid

health plan, an agreement made available by an employer, an integrated health care delivery system, a health care insurance organization, Medicare and Medicaid.\(^5^7\)

The responsibility to request NPDB and/or HIPDB reporting and/or querying is placed on each entity via written certification and completion of the *Entity Registration* form. The form provides the essential information about the entity including the organization’s name, address, Federal Taxpayer Identification Number, type of ownership, and the organization’s primary function or service. The registration information permits the Data Bank to authorize participation with the database and to determine reporting and/or querying restrictions and requirements. An eligible entity must empower a certifying official as the individual responsible for certifying the legitimacy of the registration with an original ink signature and a signature date. The certifying individual must also provide his or her official title, telephone number, and email address. Entities can simultaneously register for the NPDB and the HIPDB with the consolidated *Entity Registration Form*. The form requires the essential information about the entity and the authority to participate in the HIPDB and/or the NPDB under the laws governing the Data Banks. If the entity is authorized to participate with both Data Banks information must be provided as to whether queries will be sent to the HIPBD, the NPDB, or both. The information will determine how to direct query and report responses appropriately.

Once the registration has been processed, the Data Bank will assign the entity a confidential Data Bank Identification Number (DBID), user ID, and password and will send this information in the *Entry Registration Verification* document. A DBID is used to identify a registered entity and must be provided with all reports and queries. Only one DBID is assigned

per entity however multiple user accounts with different user IDs and password can be assigned. An Authorized Agent Designation form may be completed by the certifying agent to designate other individuals to report and/or query on behalf of the eligible entity. An authorized agent is an outside organization elected by the entity to report or query on its behalf. Entities need to have a written agreement with an authorized agent confirming the agent has the authority to conduct business in the State, the agent’s facility is secure, the agent will not improperly disclose information from the Data Bank, and the agent is aware of associated sanctions. An entity may also designate one or multiple authorized submitters. An authorized submitter is an individual, usually an employee, selected by the entity to certify the legitimacy of the information in a query or report. The entity is responsible for the actions of the individuals.

The certifying agent will periodically be asked to complete entity recertification to verify the current information and update as needed. The entity may also update information by going onto the Integrated Querying and Reporting Service (IQRS) and selecting Update Entity Profile. An eligible entity may deactivate a DBID at any time and request a new one. The reasoning should be provided in the request which might include the DBID had been compromised. A DBID should also be deactivated if the entity is no longer eligible for participation. An entity must reactivate the DBID if the entity were to become re-eligible. The entity must also notify the Data Bank if there are any changes associated with an authorized agent by completing the Update Previous Agent Designation form.\textsuperscript{58}

Subjects

The reporting and querying requirements of the NPDB apply to physicians, dentists, and other health care practitioners. Health care practitioners are defined as, “individuals other than physicians or dentists who are licensed or otherwise authorized (certified or registered) by a State to provide health care services; or individuals who, without authority, hold themselves out to be so licensed or authorized.”\(^59\) It varies among States as to which health care practitioners are licensed or authorized to provide health care services. Eligible entities are responsible to determine which categories of health care practitioners are licensed or authorized to provide health care services in the State. A broad list of possible categories for health care practitioners can be found in the NPDB Guidebook and on the website. The HIPDB is a database of information concerning health care practitioners, providers, and suppliers with a final adverse action. Examples of final adverse actions include revocation of affiliation, certification, credentialing, contracting, hiring, suspension, and licensure. The terms practitioner, provider, and supplier are not used as mutually exclusive, specific categories because there is much overlap in roles. A provider of services is defined by 1861(u) of the Social Security Act meaning a hospital, skilled nursing facility, outpatient rehabilitation facility, home health agency, or hospice program. Provider also includes any health care entity that provides health care services and follows a formal peer review process for the intention of improving quality of care and any other health care entity which directly or through contracts provides health care services. A supplier of health care is defined by 1861(s) of the Social Security Act which includes an extensive list of medical and other health care services. A supplier is an individual or entity who directly or indirectly provides access to health care services, items, or ancillary services.

\(^{59}\) Ibid.
Practitioners, providers, and suppliers may self-query the NPDB/HIPDB at anytime. Practitioners, providers, and suppliers are notified whenever an adverse action is reported in which they are the subject.\footnote{U.S. Department of Health and Human Services, Health Resources and Administration (2001). \textit{HIPDB Guidebook Health Integrity and Protection Data Bank}. Retrieved December 10, 2011 from \url{http://www.npdb-hipdb.hrsa.gov/resources/HIPDBGuidebook.pdf}}

Queries

The NPDB serves as a resource for State licensing boards, hospitals, and other health care entities to assist in credentialing a health care practitioner by providing information related to conduct and competence. There are certain times when an entity is mandated to check the information on the NPDB and other times when a query is simply an option. Hospitals are required to query the NPDB when a practitioner applies for staff membership or for additional privileges. The hospital must also query medical staff or holding privileges’ of the practitioners every two years. Hospitals do not have to query residents or interns even though they are licensed because they are trainees of a structured program rather than medical staff. Other health care entities have the option of checking the NPDB when staffing a practitioner or forming an affiliation. State licensing boards have the option of querying at any time. Health care practitioners can, but are not required to, check at anytime. Plaintiff’s attorneys have the ability to query at certain times if the query involves a medical malpractice action where the hospital had failed to make the required query of the NPDB for the physician involved. Medical malpractice payers do not have the ability to query.\footnote{U.S. Department of Health and Human Services, Health Resources and Administration (2000). \textit{NPDB Guidebook National Practitioner Data Bank}. Retrieved December 10, 2011 from \url{http://www.npdb-hipdb.hrsa.gov/resources/NPDBGuidebook.pdf}}
The HIPDB is queried by Federal and State Government agencies to commence law enforcement investigations and review qualifications of health care practitioners, providers, and suppliers in an effort to prevent fraud and abuse in the national health care system and to improve the quality of care. Eligible entities may also query the database for information while making decisions on such things as affiliation, verification, employment, contracting, and licensure. Information provided from a query of the HIPDB may include health care related civil judgments, health care related criminal convictions, injunctions, licensing and certification actions, exclusions from participation in Federal and State health care programs, and any other adjudicated action or decision as defined by regulation.62

Federal and State Government agencies, criminal justice authorities, government investigators, and prosecutors may query the HIPDB to further an investigation or for information in making decisions to accept a plea or in making a sentence recommendation. Governmental organizations may also query while making decisions regarding licensing and credentialing. Health plans may query the HIPDB while making decisions on practitioners who are being considered for association with a plan. Health plans may also use information from the database while investigating potential fraud or abuse related to payments with the delivery of health care. A self-query may be performed at anytime for any purpose by a practitioner, provider, or supplier.63


Eligible entities access the Data Bank via the internet to submit queries through the Integrated Querying and Reporting Service (IQRS) found at www.npdb-hipdb.com. A DBID, user ID, and password are required to enter the IQRS. The IQRS will not accept an incomplete query so it is suggested that as much information as possible be gathered before beginning the process. Queries may be submitted using the ICD Transfer Program (ITP), an electronic transaction file submission. The ITP can transmit an Interface Control Document (ICD) query submission file and can receive a response file from the NPDB-HIPDB. Entities that chose to query via the ITP must format the data as specified in the NPDB-HIPDB ICD. Certain equipment is needed to query electronically. An appropriate version of Internet Explorer and a program that can read Portable Document Format is required. Details are provided in the NPDB and HIPDB Guidebooks.

The query process enters information into the computer system once a properly completed query is received by the Data Bank. A validation process then matches the subject identifying information from the query with information already in the database. A distinctive Data Bank Control Number (DCN) is assigned to each query processed by the system. An eligible entity may create a subject database to more efficiently query and report. This feature offers a straightforward process for maintaining information on a subject with routine reports. Query responses are usually available within 4 to 6 hours of a request. Additional processing time may be required in some situations. When a submission is made through the IQRS it will be available for retrieval at the IQRS. When a query is marked complete it can be retrieved. A query marked pending is still being processed. A query marked as rejected has been processed.

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but the query has one or more errors which have been identified. When a submission is made through the ITP, the query response will be retrieved using the file transfer program specified in the ITP instructions. When a subject does a self-query the response will be sent via First Class U.S. Mail. If there is no information about a subject in the database a response will be sent indicating so. There is no recorded information in the database as to how many query requests have been made for a subject. Separate response files are sent when an entity submits a query request for 10 or fewer subject. A batch of downloaded consolidated query files is sent for requests of 11 or more subjects. Query responses can be saved by downloading the file to the hard drive. If an entity does not receive a query response within two to three days the entity should not resubmit. The NPDB-HIPDB customer service should be contacted and a status will be provided.65

Reports

The Data Bank acts as a flagging system to trigger a comprehensive review of a practitioner’s professional credentials and by disseminating adverse actions to and from eligible entities. The NPDB requires certain information applicable to licensed or authorized physicians, dentists, and other health care practitioners to be reported. Medical malpractice payments and adverse actions from on or after September 1, 1990 must be reported to the NPDB by eligible entities. September 1, 1990 was the date the NPDB started operations so no reports prior to this date can be accepted.66

65 Ibid.
66 Ibid.
Health plans and Government agencies are responsible for reporting final adverse actions to the HIPDB when the action is taken against practitioners, providers, or suppliers. Examples include health care related civil judgments, health care related criminal convictions, licensing and certification actions, exclusion from participation in Federal or State health care programs, and any other adjudicated action. The HIPDB came into effect on August 21, 1996 therefore eligible entities are mandated to report all adverse actions occurring on or after that date.\(^{67}\)

Computation of time periods for the Data Bank is consistent with the *Federal Rules of Civil Procedure* 6. The date of the act or event shall not be included in calculating time periods required by the NPDB-HIPDB from statute or regulation. Weekends and Federal holidays should be included in computation of time but if the date for submitting a report falls on the weekend or holiday, the due date will be the following day.\(^{68}\)

Medical Malpractice Payment reports (MMPRs) must be made to the NPDB by any entity that makes a payment for the benefit of a physician, dentist, or health care practitioner within 30 days of the date the payment is made. The claim must be based on a practitioner’s provision of or failure to provide health care services. A narrative description of the action upon which the payment was made should be provided by the entity and should include the subject’s age, sex, patient type, initial event, procedure preformed, claimant’s allegation, associated legal issues, and outcome. Narratives are not allowed to include the names of patients, witnesses, or others involved in the case. A payment made based on a claim against an entity does not have to

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be reported if a practitioner is not individually named. A payment made by an individual for the
individual’s own benefit does not have to be reported to the NPDB. A payment made by an
entity on behalf of the entity is not reportable unless the entity is comprised of a sole practitioner.
A payment made on behalf of a deceased practitioner is required to be reported in an effort to
reduce the occurrence of identity theft by a fraudulent practitioner. The MMPR document
provides a field to indicate if the report is being made for a deceased practitioner. When
insurance covers a malpractice payment from a policy covering multiples practitioners only the
subject for whose benefit the payment was made should be reported. An entity must report when
a payment is made for the benefit of a licensed intern or resident. Payments made on behalf of a
student do not have to be reported. 69

Adverse Clinical Privilege Action reports (AARs) must be made to the NPDB by health
care entities within 15 days from the date the adverse action was taken or clinical privileges were
voluntarily surrendered. Clinical privilege actions are reportable when they are based on a
practitioner’s professional competence or conduct that adversely affects, or could adversely
affect, a patient’s health or welfare. Adverse actions taken against the clinical privileges of a
dentist or physician must be reported, while these types of actions taken against other health care
practitioners may be reported. Only one report should be submitted to the NPDB even when a
review action produces multiple adverse clinical privilege actions. Denial of an application
based solely on inability to meet the institution’s established threshold should not be reported
because this is not considered the result of a review action. Investigations are not reportable to
the NPDB unless it involves the surrender of a license during an investigation. A summary
suspension must be reported if it is for more than 30 days as the result of a professional review.

69 Ibid.
State licensing boards are also required to report adverse licensure actions against physicians and dentists within 30 days from the date the action was taken. Fines or monetary sanctions alone are not reportable. Professional societies are required to report adverse actions within 15 days from the date the action was taken. Professional societies taking adverse actions involving conduct or competence of a dentist or physician must be reported, while these types of actions taken against other health care practitioners may be reported.70

The HIPDB maintains reports of health care related civil judgments, criminal convictions, injunctions, licensing and certification actions, exclusions from Federal and State health care programs, and other adjudicated actions.71 Entities reporting to the HIPDB must report final adverse actions within 30 days of the date the action was taken or the date the reporting entity became aware of the action. Civil liability protection is provided through the immunity provisions of Section 1128E unless the reporting entity has actual knowledge of the falsity of information. The same immunity applies to DHHS with maintaining the HIPDB.

Judgments and convictions must be reported to the HIPDB when related to health care including: criminal convictions, civil judgments, injunctions, and no contest pleas. Criminal convictions include cases with a judgment entered against an individual regardless of whether there is an appeal pending, findings of guilt, guilty plea, and deferred prosecution. Civil judgments against practitioners, providers and suppliers related to the delivery of health care must also be reported regardless of whether there is a pending appeal. Adverse actions that must

70 Ibid.
be reported to the HIPDB include: licensure and certification actions, Government health care program certification actions, exclusions from Federal and State health care programs, and other adjudicated actions or decisions. Reportable final adverse licensure actions need not be related to competence or conduct. Examples include: formal or official actions such as revocation or suspension of license, loss of license or certification, and any other negative action by a Federal or State agency that is publicly available information rendered by a licensing or certification authority. This includes final adverse actions in conjunction with settlements that are publicly available information even when no finding of liability has been made (although the settlement would not be reported). This excludes administrative fines or citations, corrective action plans, and certain personnel actions unless connected to the delivery of health care services and taken in conjunction with a licensure or certification action. Federal and State agencies must report exclusions from participation in Federal or State health care programs. Exclusion is defined as temporary or permanent debarment from participation in a Federal or State health-related program such that the person or entity will not be reimbursed by the program. Other adjudicated actions or decision that are reportable must be a formal or official action taken against a health care practitioner, provider, or supplier by a Federal or State Government agency or health plan which includes the availability of a due process mechanism and is based on an action that affects or could affect the payment, provision, or delivery of a health care item or service.\textsuperscript{72}

Certain subject information is required to submit a report to the Data Bank and all required fields must be completed before a report can be generated. An eligible entity is encouraged to provide as much information as is known even in the fields that are not required.

An incomplete report will not be accepted so the entity should gather as much information as possible before there is a cause to file a report. A Social Security Number (SSN) is required for reporting adverse licensure actions as mandated in the Section 1128. Under Title VI for medical malpractice payments or adverse clinical privilege, a SSN should be provided if known. The NPDB-HIPDB will only disclose a SSN as allowed by the HCQIA. Inclusion of SSN is encouraged to help ensure accurate identification of the subjects.

The IQRS may be used to prepare and submit reports from eligible entities to the NPDB-HIPDB. Two different report formats are used for the NPDB: the Adverse Action Report (AAR) and the Medical Malpractice Payment Report (MMPR). The HIPDB also uses the AAR and further has a Judgment or Conviction Report (JCR). An automated system has been created to allow an entity to only report once when the entity is required to report an AAR to the HIPDB and NPDB. The entity submits one report and the IQRS determines if the action goes to the NPDB, HIPDB, or both databases.

Each report form includes the necessary fields to complete a submission. The IQRS field for the description of the act allows for 2,000 characters and responses should be drafted accordingly. If the entity maintains a subject database in the IQRS then the subject information will not have to be reentered into the report. A Temporary Record of Submission document with a confirmation number will be sent to the entity once a report has been submitted to the IQRS. An Official Verification Report will be sent 4 to 6 hours later and the entity is responsible for reviewing the report and making corrections as needed. The subject will receive a copy of the report from the Data Bank by mail. The reporting entity is required to mail a copy of the report to the suitable State licensing board. The IQRS has the ability to save a document in draft
status for up to 30 days. After 30 days, the draft is automatically deleted. Entities may also choose to submit reports via electronic transaction file submission through the ICD ITP.

There are several different types of reports that are submitted to the Data Bank. An Initial report is the first record of a medical malpractice payment, adverse action, judgment, or conviction. Each initial report will be issued a DCN. A Correction report is information which will supersede the content of a current version of a report. A Correction report should be submitted as soon as possible once a mistake has been identified. Corrections may be made as often as necessary. A Void report will retract a previous report in its entirety and it will be removed from the subject’s record. A Revision to Action report supplements information previously reported to the NPDB-HIPDB but does not negate anything. The DCN must be used to pull up the initial report for modification. Report output is maintained on the server for 30 days so the entity should save or print the report before it is deleted. If an entity does not receive report verification within two to three days the entity should not resubmit, instead NPDB-HIPDB customer service should be contacted and a status will be provided.

Several sanctions are associated with failure to report to the Data Bank. Failure to report malpractice payments to the NPDB may result in sanctions of civil money penalty up $11,000 per payment involved. Federal or State government agencies that substantially fail to report as required by Section 1128E will have the name of the agency published in the Federal Registry. Health plans that fail to report an adverse action that should be reported to the HIPDB may be sanctioned up to $25,000 in civil money penalty per adverse action not reported.

Investigations against health care entities and professional societies will be conducted when there is reason to believe the entity or society has substantially failed to report required
actions. Written notice will be sent to entities describing the non-compliance when an investigation is substantiated. The notice will also provide information on the procedure to correct the non-compliance or to request a hearing. A request for hearing must be submitted within 30 days of receipt of written notification and must include a statement of the material facts at issue that demonstrate a cause for hearing. A hearing will be denied if it does not meet the requirements. Hearings are held in Washington D.C. The name of the entity or society will be published in the Federal Registry if it is determined that the organization has failed to substantially report the required information to the Data Bank. At this point, the entity loses its immunity in relation to professional review activities for 3 years from 30 days from relevant Federal Registry date of publication. Professional societies that fail to report can have their immunity privileges for professional review activities taken away for 3 years. State medical and dental boards that fail to report to the NPDB can have the responsibilities to report removed by the Secretary of HHS. Written notification of failure to comply is sent to the board which gives the procedure to the board for the opportunity to correct. When correction does not happen another qualified entity will be designated to take over the reporting requirements.73

Disputes

The Data Bank processes information in a report exactly as it is received so the eligible entity is responsible for ensuring the accuracy of the report. The Data Bank employs a dispute process in an effort to make certain the accuracy of information presented in reports. A thorough review of the information for accuracy should be done by the subject upon receiving a Notification of a Report in the Data Bank in the mail. When information in the report is

inaccurate the subject must go through the reporting entity to have the information corrected. The NPDB and HIPDB do not have authority to modify a report. When a reporting entity refuses to change a report the subject may add a statement to the report and/or initiate the dispute process. A statement may be added to the report at anytime by the subject. Once processed, notification of the addition of a statement is sent to all past queriers and will be sent with future queries.\textsuperscript{74}

The dispute process is not a forum to contest the underlying adverse action or medical malpractice claim. A subject dispute may be initiated to review the factual accuracy of the report or to challenge whether the report was submitted as required by the Data Bank. The dispute becomes part of the processed report. The entity may then chose to correct the report to the satisfaction of the subject, void the report in its entirety, or decline to change the report. The subject can request to have the report reviewed by the Secretary of DHHS if the entity refuses to change the report. The subject must send a brief statement giving the facts in dispute, send documentation to support that the report is inaccurate, and send proof that the issue could not be resolved with the entity. The subject must wait 30 days from the date resolution was initiated with the entity to request a review by the Secretary. The Secretary may then conclude the report was accurate, conclude the report was inaccurate, or conclude that the issues in dispute are outside the scope of Secretarial Review. If the report is deemed inaccurate, the Secretary will direct the Data Bank to correct the information. The report will be voided from the database if the Secretary determines that it was submitted in error. The Secretary will send an explanation of the decision if the report is found accurate or if the Secretary believes it is outside the scope of review. The subject may then send an additional statement to be added to the report. There is

\textsuperscript{74} Ibid.
not a formal appeal process from the Secretary’s decision, however requests for reconsideration will be considered. The subject should present new evidence that was not available at the initial review. The Secretary will affirm the prior decision or will issue revised findings.\textsuperscript{75}

\textbf{Query Fees}

A fee is associated with every query submitted to Data Bank on a per name basis. The fee is based on the cost of processing the requests. Submitting a query is considered an agreement to pay the fee. Section 1128E exempts Federal entities from paying the fee associated the Data Bank.\textsuperscript{76} If a query is sent by an entity registered with the NPDB and the HIPDB the entity will be assessed the current fee for each Data Bank. A fee is assessed when the query is processed by the NPDB and/or HIPDB regardless of whether there is information on the subject or when the query is rejected by the database because it is incomplete. An entity is responsible for fees when the query is initiated by an authorized agent. Query fees are subject to change. In March 2003, the fee for a query is $4.75 per practitioner about whom information is requested. The fee for self-query is $8.00. The additional amount is due to the manual intervention required to process a self-query. The Data Bank only accepts credit card or Electronic Funds Transfer (EFT). A form must be completed to set up an EFT account. The entity will then be automatically billed each time it queries. Checks and cash are not accepted. Entities may view their charges on the \textit{Billing History} screen of the IQRS.\textsuperscript{77}

\textsuperscript{75} Ibid.


Statistical Data

Confidential information in the NPDB is only available to authorized queriers such as hospitals, health care entities with formal peer review, medical and state licensing boards, and to practitioners requesting performing a self query as mandated by law. HRSA is required by 42 U.S.C. § 11137(b) to maintain the public disclosure file in a form that prohibits use of the data alone or in combination with other accessible information from another dataset in a manner to prevent identification of any health care entity, physician, other health care practitioner, or patient. HRSA committed to disclosing information to the public over ten years ago by posting the Public Use Data File (PUF) through the Data Bank with de-identified information. The PUF contains records from the NPDB and also records that were added as a result of Section 1921. Therefore records which are contained in both the NPDB and HIPDB are included but not records only contained in the HIPDB. There is no public use file with the information contained only in the HIPDB. The PUF contains information from the NPDB which is intended to be used for statistical reporting and analysis. Researchers, journalists, and others may use the information to report on trends in patient safety and State reporting, medical malpractice, licensing, discipline, and quality assurance.⁷⁸

HRSA had to remove the PUF from the NPDB website on September 1, 2011 after discovering that information could be used to identify individual practitioners. HRSA has since reposted the file with updated information and the appropriate protections so that research can continue. Since reposting, users must now agree, as a condition of using the data in the PUF, to specific terms in the Data User Agreement. The first condition is that the dataset will not be

presented alone or in arrangement with other data as to identify an individual or entity or to somehow connect data from this file with other data in a manner to identify an entity or individual. The second condition is that upon the request of HRSA after data has been used in an identifying manner, the information from the dataset in the possession of a user must be returned, deleted, and/or permanently disposed of in all forms. The last condition is that the user may only report, disclose, or post data from the data set in connection with statistical reporting or analysis in a way that does not identify an entity or individual. In order to help ensure the confidentiality of identity, the smallest geographic component acknowledged in the file is a State. The Data Bank may choose to provide smaller geographic units to researchers upon demonstration that an individual practitioner could not be identified though disclosure of the information. The unit will normally have to include several counties and the requester is responsible for paying the costs associated with compiling the data. Specialty in adverse action data will not be provided because individual practitioners can be identified when combined with other available data. Aggregate statistics for adverse actions only may be provided and the requester is responsible for the costs associated with preparing the data. Correction Reports and Void reports are not disclosable. Disclosable reports do not double count corrected reports or present erroneous information so they are the most accurate to use for analysis.

The NPDB PUF is updated quarterly to include the data periods through March 31, June 30, September 30, and December 21. Generally the updated file will be available two months after the period. The files are available for download from http://www.npdb-hipdb.hrsa.gov.

The Statistical Package for the Social Sciences (SPSS) file is the PUF in a portable format for download. The file may be too large to import into spreadsheet programs such as EXCEL or QUATRO PRO so it is suggested that user employ SPSS. The file cannot be analyzed by word processing programs. A report or publication which uses data from the PUF should cite the source of data as “National Practitioner Data Bank Public Use Data File [date], U.S. Department of Health and Human Services, Human Resource and Service Administration, Bureau of Health Professions, Division of Practitioner Data Banks.” It is incorrect to only mention the NPDB as a source without including use of the PUF.80

Summary reports are also available through the Data Banks. These reports provide a summary of the type and number of reports processed by the NPDB and the HIPDB for professional and organizational categories. The Data Banks also produce annual reports which provide specific information such as data Bank operating procedures, improvements along, and statistical tables. The NPDB information includes statistics on reporting, malpractice payments, adverse actions, disputed reports, queries, and matches. The HIPDB information includes statistics on report and query of health care related civil judgments, criminal convictions, and other adjudicated actions.

Public Health Leadership and the Data Bank

The leadership at the Data Bank has implemented a number of the concepts and tools associated with public health throughout the administration of the NPDB-HIPDB. The vision of the project has brought together numerous agencies to help ensure quality health care for this nation. The Data Bank staff has planned the process and procedure for the vision of the database

80 Ibid.
to accomplish the objectives and activities to support the vision, and put the plan into action. The ongoing activity is evaluated and improved through oversight and project management.

**Education and Training**

Education and training is an important part of the implementation of the Data Bank. Compliance from eligible entities is much higher when the organizations understand what they need to do and how they need to it. Educational and promotional efforts have been made by the Data Bank staff through extensive outreach and presentations to medical organizations and practitioners. The *NPDB-HIPDB Guidebook* and the Web site’s *Frequently Asked Questions* are continuously updated for accuracy. In 2001, the Data Bank started an Interactive Education and Training Program on-line at the NPDB-HIPDB website to help educate eligible entities. The training provides basic information on reporting, querying and eligible entities.  

An on-line correspondence system was created allowing registered entities to receive newsletters, upcoming events, and other information directly to an electronic mailbox. In 2003, the Joint Commission on Accreditation of Health Care Organizations (JCAHO) issued standards requiring long term care and sub-acute care facilities to query the NPDB-HIPDB. The Data Bank started an education campaign with letters and brochures to notify these entities of the need to register and query. The Data Bank continuously sends letters to different eligible entities educating the

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83 Ibid.
organizations regarding requirements for reporting and querying with the database.\textsuperscript{84} These educational and training efforts help to ensure compliance with the requirements of the NPDB-HIPDB.

**Social Marketing**

The education and training aspect of the Data Bank also crosses over into the realm of social marketing of the NPDB-HIPDB. The Data Bank has promoted its program through the use of marketing in the community. The Practitioner Remediation and Enhancement Partnership (PREP) was launched by the Data Bank staff in an effort to foster a positive working relationship between the hospitals and State Medical Boards by promoting reporting as ethically and socially responsible rather than “reporting colleagues to the cops.”\textsuperscript{85} The Data Bank continuously develops new brochures to send out in the community. One brochure entitled, “The Practitioner’s Guide to the Data Bank: A Road Map for Physicians, Dentists, and Other Health Care Practitioners,” explains self-queries, error corrections, and dispute reports for the NPDB-HIPDB. The Data Bank staff members also participate in community outreach through presentations and exhibiting material at numerous conferences for organizations such as America’s Health Insurance Plans, Physician Association of America, and National Committee


for Quality Assurance.\textsuperscript{86} The Data Bank has also conducted a number of policy forums in conjunction with health care organization conferences. The forums are hosted by NPDB-HIPDB staff and focus on reporting requirements.\textsuperscript{87} The Data Bank staff members continuously publish articles related to the mission, requirements, and achievements of the NPDB-HIPDB. Through these efforts the NPDB-HIPDB staff is able to promote the attitudes and behaviors associated with the reporting and querying of the Data Bank.

Program Planning and Evaluation

The Data Bank conducts a wide-array of research activity with goals and objectives in an effort to plan, implement, and evaluate the activities of the NPDB-HIPDB. A pilot study on clinical privileges and malpractice payment reporting was initiated for hospitals and managed care organizations to test an audit tool designed to ascertain clinical privilege reporting compliance.\textsuperscript{88} In 2001, the Data Bank completed the User Survey, assessing user satisfaction with reporting and querying, methods for improving the process, and assessing the perception of usefulness. The Reporting Errors Project was completed and the Data Integrity and Evaluation Team (DIET) was formed to address correction of the commonly identified errors.\textsuperscript{89} A comparison was made of database reporting with information from the National Association of


Insurance Commissioners about medical malpractice payments in an effort to evaluate which insurance companies had failed to comply with the requirements of the NPDB. The companies were contacted about the failure and informed of the applicable requirements. Led by the Data Bank Integrity and Evaluation Team, the Data Bank monitored timeliness of reporting for licensure actions and medical malpractice reports resulting in a campaign to improve timeliness.\textsuperscript{90} Staff continue to improve the implementation of the Data Bank program by performing the evaluation of the program though this research and involving focus groups, surveys, and data collection.

**Health Policy**

The Data Bank helps implement its vision through forming policy to promote the goals. The Data Bank has made several policy achievements over the past decade including a decision to follow up with State medical boards that had not taken an action when an entity reported on an annual basis. The Data Bank made another policy decision through reviewing the “American Hospital Association Guidebook” and checking which hospitals had actually registered with the databases. Unregistered hospitals were contacted and made aware of requirements. A policy on stopping malpractice payment reporting loopholes (e.g. Corporate Shield, Low Adjustment Expenses, and High-Low Agreements) was examined and solutions were implemented through its development.\textsuperscript{91} A media search was conducted to explore whether medical mistakes covered by the media were being reported to the databases. A policy was developed to contact the


organizations that were presented in the media but had failed to report to the NPDB-HIPDB.\textsuperscript{92} The pilot program PreP4 Patient Safety was developed to aid State medical and nursing boards in working with health care organizations to identify, remediate, and monitor health care practitioners with deficiencies that do not rise to the level of needing disciplinary action.\textsuperscript{93} With this program the Data Bank adopted a policy to help protect quality care through identifying and addressing issues but with less severe sanctions to the practitioners. The policy decisions of the Data Bank play a key role in achieving the mission of the organization.

**Continuous Quality Improvement**

Numerous operational improvements and policy efforts have been implemented over the past decade with the NPDB-HIPDB in an effort to promote continuous quality improvement with the Data Bank. The Data Bank took a major operational step by removing the software based query and reporting system, QPRAC, and introducing the Internet-based system, IQRS in 2000. The IQRS was implemented with the aims to improving report timeliness, reducing input errors, and reducing operational costs. The Data bank further implemented the ICD/ITP Program to help with high volume queries. An IQRS Review Panel was formed to discuss issues, identify new requirements, review query and reporting issues, and address operational issues. The Review Panel helps solve IQRS problems and improve operations. The Data Bank conducted the Optimal Report Coding Study which examined how the reporting tool of the database could be improved. The study examined the main categories that needed to be added to result in less


use of the “Not Otherwise Classified” code.\textsuperscript{94} In 2003, the Data Bank made further improvements to the operational process starting with reducing the query response time from 3 to 4 hours to 1 to 2 hours. The entity registration process was improved through a new ability for entities to designate authorized agents to query, report and to authorize EFTs to pay online. The IQRS was enhanced with a new on-line self-query process, new abilities for entities to modify their registration information, enhancement of password security, and new screens to show billing histories.\textsuperscript{95} The IQRS continues to be improved in the areas of report summary services, entity-agent functionality, query screens, code re-organizations, and search capabilities.\textsuperscript{96} In 2007, the Proactive Disclosure Service (PDS) was implemented which provides continuous monitoring of a subject once enrolled in the database.\textsuperscript{97} New security enhancements have been implemented including only allowing the Customer Service Center to reset IQRS account passwords in an effort to protect the integrity of the database.\textsuperscript{98} An Information System Security Officer (ISSO) was assigned to the Data Bank to guide the direction of the security system and to implement security controls to ensure that security breaches do not occur by adapting procedures


to mitigate new risks on a continuous basis.” By implementing methods of continuous quality improvement the Data Bank is able to identify problem areas in its administration and make corrections to create a more functional, secure system resulting in completion of the objectives and goals of the program.

The leadership of the Data Bank has developed a program with a vision that will produce better health outcomes for this nation. The eligible entities, individual subjects, and numerous organizations have come together to help develop a system that works efficiently and effectively. Implementation of this vision will help to improve health care quality, protect the public, and reduce health care fraud and abuse in the nation.

**Division of Health Service Regulation and the Data Bank**

The Division of Health Service Regulation (DHSR) is part of the North Carolina Department of Health and Human Services. DHSR oversees medical, mental health, and adult care facilities along with emergency medical services and unlicensed health care personnel. Several of the Sections in the Division fall within the definition of an eligible entity for purposes of reporting to the Data Bank. This Section will give an overview of the eligible entities within the Division along with a description of the requirements for querying and reporting for each Section. The Office of Emergency Medical Services Section and the Health Care Personnel Registry Section currently report to the Data Bank. A brief overview of the procedure followed by the Sections will be presented with suggestions for compliance.

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Ibid.
On February 12, 2010, Kathleen Sebelius, the Secretary of DHHS, and Mary K. Wakefield, the Administrator of HRSA, sent a letter to the Governors in the United States.\textsuperscript{100} The letter outlined the purpose of the Data Bank and asked the States work with HRSA in assuring the accuracy, completeness, and timeliness of reporting to the Data Bank. HRSA had determined that the database contained some information gaps and began taking step to address the deficiencies and obtain the missing data. HRSA formed an action team to work with the States in improving the data reports. They set up a system to perform regular audits of State licensure boards for verification and correction of the missing data elements. Technical assistance was established to support the State licensing board staff with Health Information Technology. Education and training programs were developed for State licensing board staff on maintaining and reporting health practitioner licensure data. Opportunities were being explored to make reporting easier. Finally, HRSA established a process for reporting of entities that failed to meet their reporting requirements.\textsuperscript{101}

The February 12, 2010 letter specifically went to Governor Purdue in North Carolina.\textsuperscript{102} The letter outlined changes regarding the National Practitioner Data Bank (NPDB), as well as the Healthcare Integrity and Protection Data Bank (HIPDB) and efforts to protect the safety of patients across the country. These two data banks serve as flagging systems intended to facilitate a more comprehensive review of health care practitioners, providers and suppliers who have been disciplined or named in a medical malpractice settlement. The Federal Administration is a strong advocate for openness and transparency in health care across the country. Prior to 2010, the Division of Health Service Regulation had been considered exempt from the requirement of

\textsuperscript{100} Wakefield, Mary, Ph.D., R.N. (2010) \textit{Letter to Governor}. Health Resources and Service Administration.

\textsuperscript{101} Ibid.

\textsuperscript{102} Ibid.
reporting discipline actions into these databases. With the above referenced changes, it was determined the Division was no longer exempt from the reporting requirements and effective March 1, 2010, private hospitals and other entities concerned with safe, quality health care for patients needed to report.

The May 12, 2010 Federal Registry Volume 75, Issue 91 announced that HRSA would publish a report on the Data Bank website with a list of names of Government agencies that are not in compliance with the reporting requirements of the HIPDB. The listing of non-compliant government agencies is to be reviewed and updated on a periodic basis. HRSA determined the best way to start filling in the missing data was to identify non-reported professions along with the agencies failing to report on the profession. HRSA developed a list of State agencies charged with licensing or authorizing health care professionals. A determination was made as to whether these agencies had reported any actions to the NPDB and/or HIPDB. HRSA developed the Never Reported Professions Compliance Effort in an attempt to bring the State agencies into compliance. HRSA decided the first priority professions should be decided by reviewing the query records of the database. HRSA ranked each profession by the number of queries that had been performed on the specific profession. Emergency Medical Service Technicians and Nurse Aide both had a high number of queries performed and were therefore placed at the top of the list for the effort to bring reporting into compliance. The agencies

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responsible for reporting adverse findings or decisions involving these professionals were identified.104

Letters were sent to the identified agencies that had not been reporting to the NPDB/HIPDB notifying the entity of the failure to comply with Federal law requiring the reports. The Office of Emergency Medical Services Section and the Nurse Aide Registry of the Health Care Personnel Registry Section of DHSR received letters from HRSA.  HRSA informed the sections that within 30 days they should: (1) supply a written explanation why the data was not reported or why the data should not be reported; (2) report the findings and decisions taken by the agency and provide written notification that the agency will continue to report; or (3) provide a corrective action plan outlining how the agency plans on meeting the reporting requirements.  HRSA established a compliance review which contained the Reporting Compliance List with four status levels.105 The determination of status level for a profession is based upon the information received directly from the agency.  An agency is recognized as “Compliant” if the agency provided a written response either attesting there was no reportable adverse actions to report to the Data Bank for the identified profession and the agency provided assurance that they would report the adverse actions in the future.  An agency is identified as “Non-Compliant” if: the agency has not started reporting for the profession and there is no written response to HRSA in response to the request for action; or the agency has not started reporting for the profession and the written response was inadequate; or the agency did not substantially meet deadlines outlined in its corrective action plan; or the agency did not respond to a HRSA inquiry regarding its continued compliance status.  An agency is acknowledged as

“Working Towards Compliance” if after a written request for action: the agency supplies an acceptable corrective action plan outlining a time frame for coming into compliance; or the agency has not submitted an acceptable corrective action plan but it begins to report and makes acceptable progress towards full compliance; or the agency starts the reporting process for the adverse actions but has not completed the reporting as described in the corrective action plan. An agency is identified as “Under Review” if a letter requesting a response has been sent to the agency by HRSA and: the 30 day response period has not passed; or the corrective action plan has been submitted by the agency and is under review; or compliance status is prevented due to mitigating issues. An agency may have a status of “Not Reviewed” if the agency associated with a profession was not reviewed by the end date of the previous review period. HRSA has not finished reviews of the identified professions in every State.

The Office of Emergency Medical Services (OEMS) is charged with fostering emergency medical systems and trauma systems along with credentialing Emergency Medical Service (EMS) personnel who provide responses to emergencies and disasters. The OEMS believes their mission will result in higher quality emergency medical care being delivered to the residents and visitors of North Carolina. As an agency that credentials EMS personnel, the OEMS is an eligible entity, State Government agency, required to report adverse actions taken against a health care supplier, provider, or practitioner, the EMS personnel.

The OEMS was contacted by the HRSA staff and notified that the agency was out of compliance with the reporting requirements for the HIPDB. The OEMS was required to report

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as a State agency that made negative actions or findings against a health care practitioner, provider, or supplier that is publicly available information. The information on negative actions or findings needed to be reported back through August 21, 1996, the opening date of the HIPDB, to be in compliance. In June 2010, OEMS completed the registration process and began reporting adverse actions to the NPDB and HIPDB data banks. In order to become compliant with the 2010 reporting requirements, healthcare entities had to review adverse actions taken since the 1990’s if possible and report those actions to the data bank. In accordance with records retention schedules, the Office of Emergency Medical Services was able to report adverse actions dating back to 2005 and this task was satisfied in February 2011. The OEMS reported thirty past actions and findings to the database. The OEMS was able to complete the registration process and submit the necessary reports to be deemed “Compliant” on the HIPDB website listing of Government agencies. Currently, negative actions and findings are reported within 30 days of these actions being final.

The Health Care Personnel Registry Section (HCPR) of the DHSR oversees unlicensed health care workers and regulates nurse aides, medication aides, health care technicians, and other unlicensed health care personnel. When certain allegations are made involving unlicensed health care workers, health care employers are required to submit reports to the HCPR Investigations Branch. The Investigations Branch receives reports of allegations from health care facilities, investigates allegations, takes administrative actions against unlicensed health care workers, and lists the substantiated actions on the Nurse Aide Registry and/or the Health Care Personnel Registry which is publicly available information. The HCPR Section was contacted

108 North Carolina Department of Health and Human Services, Division of Health Service Regulation, Health Care Personnel Registry Section Website, Retrieved January 28, 2012 from https://www.ncnar.org/index1.jsp
by the HRSA in relation to the Nurse Aide Registry. The HCPR was notified that the agency was out of compliance with the reporting requirements for the HIPDB in relation to nurse aides. The Nurse Aide Registry of the HCPR Section specifically maintains a database of certain adverse actions against nurse aides only. The HCPR was required to report to the HIPDB as a State agency that made negative actions or findings against a health care practitioner, provider, or supplier that is publicly available information. The Nurse Aide Registry reports to the HIPDB as a “Government Administrative Action” using the Adverse Action Classification Code, “1555 Employment Disqualification Based on Finding in the Nurse Aide Registry.”

The administrative actions needed to be reported back through August 21, 1996, the opening date of the HIPDB, to be in compliance. The Nurse Aide Registry needed to report over a thousand actions and findings against individuals to the database in relation to the nurse aides alone. The Nurse Aide Registry was able to complete the registration process but was not able to submit all of the necessary reports to be deemed compliant due to the large volume of findings. A corrective action plan was submitted to HRSA outlining the decision to submit reports from the registration day forward and to work on the back log in the future. The reporting status for the Nurse Aide Registry is listed “Working Toward Compliance” on the HIPDB website listing of Government agencies. Currently, negative actions and findings are reported within 30 days of these actions being final.

The HCPR decided that a determination should be made about reporting to the HIPDB in relation to the allegations in the Health Care Personnel Registry based on the communication from HRSA to the Nurse Aide Registry. The Nurse Aide Registry only includes substantiated

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findings involving nurse aides and that need to report had been determined and communicated by HRSA. The Health Care Personnel Registry is a separate registry which includes the adverse actions against the nurse aide and also includes adverse actions against a much broader group of health care personnel. The Health Care Personnel Registry includes certain adverse actions against unlicensed personnel working in a health care facility in North Carolina. The determination was made that the final adverse actions listed in the Health Care Personnel Registry against unlicensed, uncertified, and unregistered health care practitioners are reportable to the HIPDB as a State licensure action under 45 CFR § 61.7 as any negative action or finding by a Federal or State agency that is publicly available information. The unlicensed health care personnel listed in the Health Care Personnel Registry is a profession that has not been reviewed by HRSA therefore the status is “Not Reviewed” with the HIPDB. The decision however was made to report the adverse actions on the Health Care Personnel Registry that are also included in the Nurse Aide Registry in an effort to begin working towards compliance. The Health Care Personnel Registry has been reporting to the HIPDB from the date eligibility was determined forward. The Health Care Personnel Registry has a backlog of over six thousand actions and findings against individuals that need to be reported to the HIPDB. The HCPR is working with their Information and Technology Division to develop a plan to report the backlog of negative actions and findings. The corrective action plan will take several years.

The question was raised as to whether several other sections within DHSR would also be required to report to the Data Bank. The sections include: Acute and Home Care Licensure and Certification Section (AHCL), Adult Care Licensure Section (ACL), Mental Health Licensure and Certification Section (MHLC), and Nursing Home Licensure and Certification Section
(NHLC). These sections and their responsibilities are briefly described in the following paragraphs.

The AHCL conducts surveys and complaint investigations in order to assure state licensed and federally certified providers stay in compliance with the State and Federal laws governing the quality of health care. The program areas overseen include: clinical laboratories, acute care hospitals, nursing facility beds within hospitals, swing beds, organ transplant centers, rural primary care hospitals (called critical access hospitals), psychiatric hospitals, ambulatory surgery centers, cardiac rehabilitation programs, abortion clinics, home care agencies, home health agencies, hospice agencies, nursing pools, end stage renal disease facilities, rural health clinics, outpatient rehabilitation providers, comprehensive outpatient rehabilitation facilities, and portable x-ray suppliers. The AHCL takes administrative actions against licensees or facilities as warranted based on failure to comply with applicable statutes and rules related to the delivery of health care.

The ACL licenses and regulates adult care homes in North Carolina. The Adult Care Licensure Section of the Division of Health Service Regulation is responsible for: licensing of adult care homes (seven or more beds), licensing of family care homes (two to six beds), registration of assisted living facilities called (multi-unit housing with services), and issuing and renewing adult care home administrator certificates. The ACL takes administrative actions

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111 North Carolina Department of Health and Human Services, Division of Health Service Regulation, Adult Care Licensure Section Website, Retrieved January 28, 2012 from http://www.ncdhhs.gov/dhstr/acls/
against licensees or facilities as warranted based on failure to comply with applicable statutes and rules related to the delivery of health care services.

The MHLC is charged with licensing and regulating mental health facilities in North Carolina. These facilities include: intermediate care facilities for the mentally retarded (ICF/MR), group homes for children and adults with mental illness, developmental disabilities and substance abuse issues, and day services for children and adults with mental illness, developmental disabilities and substance abuse issues. The MHLC takes administrative actions against licensees or facilities as warranted based on failure to comply with applicable statutes and rules related to the delivery of health care services.

The NHLC is charged with regulating nursing homes by conducting routine surveys and complaint investigations. The section licenses some nursing homes as "combination homes" which contain both adult care beds and nursing home beds under one roof. The NHLC takes administrative actions against licensees or facilities as warranted based on failure to comply with applicable statutes and rules related to the delivery of health care services.

The Data Bank was contacted about these additional sections within DHSR and the question concerning eligibility to report. A determination was made that these sections (AHCL, ACL, MHLC, and NHLC) should be reporting final adverse actions taken against eligible

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112 North Carolina Department of Health and Human Services, Division of Health Service Regulation, Mental Health Licensure and Certification Section Website, Retrieved January 28, 2012 from https://www.ncnar.org/index1.jsp

individuals or entities to the HIPDB. Administrative fines that are not final adverse actions should also be reported to the HIPDB when the fine is connected to the delivery of health care services and the fine is imposed with at least one other licensing action, such as a revocation or suspension.

The sections that have been determined as eligible entities for reporting at the very least should consider registering with the Data Bank now. At some point in the future these agencies will come up for review as did the Office of Emergency Medical Services and the Nurse Aide Registry. By registering with the Data Bank now the agency will have the status of “Working Towards Compliance” rather than a “Non-Compliant” status upon review. The agencies should also consider available resources to determine if the back log of reports could be brought up to date. If entering the back log is possible, the agency would then have a “Compliant” status upon review by HRSA. The agencies should consider reporting adverse actions from their registration date forward, if bringing the back log up to date, now is not possible. The agency would still have a status of “Working Towards Compliance” in this situation and the agency would be making steps to move forward with compliance rather than creating more work and requiring more resources to gather historical information in order to reach compliance for reporting.

Conclusion

The Division of Health Service Regulation plays a major role ensuring that people obtaining services in health care facilities in North Carolina receive safe and appropriate care. The mission of the Division is to protect the health and safety of all North Carolinians and provide essential human services. DHSR furthers its mission to provide for the health, safety
and well-being of individuals through effective regulatory and remedial activities.\textsuperscript{114} The information maintained by DHSR is used for making licensing, certification, and employment decision related to health care in North Carolina – much like the information at the Data Bank is used to make decisions throughout the U.S. The mission and vision of DHSR is comparable to that of the Data Bank in that both have the goal of improving the quality of health care through regulating health care practitioners, providers, and suppliers by regulated reporting to document and hold the individuals responsible for adverse actions. The two organizations share the objective of promoting quality health care and by working with the Data Bank, DHSR can help promote its mission for the State and throughout the entire nation.

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Section 1921 of the Social Security Act, (Section 5(b) of PL 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987, as amended).


