NATIONAL PRACTITIONER DATA BANK

NPDB



NPDB Guidebook

April 2015

U.S. Department of Health and Human Services
Health Resources and Services Administration
Bureau of Health Workforce





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CHAPTER A: INTRODUCTION AND GENERAL INFORMATION

PREFACE

The NPDB Guidebook serves as a policy manual. It is one of a number of efforts to inform the U.S. health care community and others about the National Practitioner Data Bank (NPDB) and the requirements established by the laws governing the NPDB, primarily:

- Title IV of the Health Care Quality Improvement Act of 1986 (HCQIA), Public Law 99-660 (referred to as "<u>Title IV</u>");
- Section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, codified as Section 1921 of the Social Security Act (referred to as "Section 1921"); and
- Section 221(a) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, codified as Section 1128E of the Social Security Act (referred to as "Section 1128E").

By law, certain entities (referred to as "eligible entities") report to the NPDB, query the NPDB, or both. Eligible entities include medical malpractice payers, hospitals

and other health care entities, professional societies, health plans, peer review organizations, private accreditation organizations, quality improvement organizations, and certain Federal and State agencies. Health care practitioners,

By law, eligible entities report to the NPDB, query the NPDB, or both.

entities, providers, and suppliers are authorized to query on themselves for information reported to the NPDB, since they may be the subjects of NPDB reports.

Final regulations implementing the laws referenced above governing the NPDB are found at <u>45 CFR Part 60</u>. The U.S. Department of Health and Human Services (HHS) is responsible for administering the NPDB.

The NPDB Guidebook is divided into broad topical sections:

- Chapter A: Introduction and General Information (this chapter) contains general
 information on the NPDB, including its history and information on the laws and
 regulations that govern it
- <u>Chapter B: Eligible Entities</u> describes the eligible entities that query and/or report to the NPDB directly, and the processes for registering with the NPDB
- <u>Chapter C: Subjects of Reports</u> details the types of individuals and organizations that may be the subjects of reports submitted to the NPDB

- Chapter D: Queries addresses querying the NPDB
- Chapter E: Reports addresses reporting to the NPDB
- <u>Chapter F: Subject Statements and the Dispute Process</u> outlines the procedures available through the NPDB to subjects of reports who disagree with a report in the NPDB about themselves
- Chapter G: Fees addresses NPDB fees
- <u>Chapter H: Information Sources</u> provides a variety of information sources about the NPDB
- Appendix A: Glossary is a glossary of terms used in this Guidebook
- Appendix B: Acronym Guide is a guide to the acronyms used in this Guidebook

This edition of the NPDB Guidebook reflects the entire range of NPDB policies, including those that have changed or expanded since the NPDB opened in September 1990. It briefly describes NPDB operational features and includes links to the NPDB website for more information. This edition of the NPDB Guidebook replaces all previous versions of the National Practitioner Data Bank Guidebook and the Guidebook for the Healthcare Integrity and Protection Data Bank (HIPDB) (see below).

BACKGROUND

Congress enacted legislation leading to the creation of the NPDB because it perceived that the increasing occurrence of medical malpractice litigation and the need to improve the quality of medical care had become nationwide problems that warranted greater efforts than could be undertaken by any individual State. Congress also identified the need to restrict the ability of incompetent physicians and dentists to move from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance. Congress felt that the threat of private money damages liability under Federal laws, including treble damages liability under Federal antitrust law, unreasonably discouraged physicians and dentists from participating in effective professional peer review. Therefore, Congress sought to provide incentives and protection for physicians and dentists engaging in effective professional peer review.

Title IV led to the establishment of the NPDB, an information clearinghouse, to collect and release certain information related to the professional competence and conduct of physicians, dentists, and, in some cases, other health care practitioners. The creation of the NPDB represented an important step by the U.S. Government to enhance professional review efforts by making available to eligible entities and individuals certain information concerning medical malpractice payments and adverse actions.

Subsequent laws expanded the information collected and disclosed by the NPDB and modified its operations.

- In 1987, Congress passed Section 1921, authorizing the Federal Government to collect information concerning sanctions taken by State licensing authorities against health care practitioners (not just physicians and dentists) and health care entities.
- Congress later amended Section 1921 with the Omnibus Budget Reconciliation Act of 1990, Public Law 101-508, to add the reporting of "any negative action or finding" by State licensing authorities, peer review organizations, or private accreditation entities. Final regulations for Section 1921 were published in the Federal Register on January 28, 2010, and Section 1921 was officially implemented in the NPDB system on March 1, 2010.
- Congress also passed Section 1128E, which required the HHS Secretary, acting through the HHS Office of Inspector General (OIG) and the U.S. Attorney General, to create a national health care fraud and abuse control program. A major component of the program was the establishment of the HIPDB. Final regulations for Section 1128E were published in the Federal Register on October 26, 1999. The HIPDB began collecting reports in November 1999 and became fully operational in March 2000. (The HIPDB was a national data bank that received and disclosed certain final adverse actions taken by Federal and State agencies and health plans against health care practitioners, providers, and suppliers. Final adverse actions included licensure and certification actions, health care-related criminal convictions and civil judgments, exclusions from Federal or State health care programs, and other adjudicated actions or decisions.)
- To eliminate duplication between the NPDB and the HIPDB, Congress passed Section 6403 of the Patient Protection and Affordable Care Act of 2010, Public Law 111-148. The section below describes this law and its impact in greater detail.

Eliminating Duplication Between the NPDB and the HIPDB

On May 6, 2013, NPDB operations were consolidated with those of the former HIPDB. As a result of this consolidation, information previously collected and disclosed by the HIPDB is now collected and disclosed by the NPDB.

While the NPDB and the HIPDB were established for different purposes, overlap existed in some reporting and querying requirements. To eliminate this duplication, Congress passed Section 6403 of the Patient Protection and Affordable Care Act of 2010. This legislation, which amended both Section 1128E and Section 1921, established the NPDB as the single Data Bank to receive and disclose information collected under Title IV, Section 1921 and Section 1128E. The primary impact of this merger was to eliminate duplication and streamline internal operations. The merger did not significantly alter NPDB and HIPDB reporting requirements or access to information. As part of these legislative changes, the Secretary of HHS was required to set up a transition period to transfer all data in the HIPDB to the NPDB, and, once completed, to cease HIPDB operations. Final regulations implementing Section 6403 were published in the Federal Register on April 5, 2013.

Laws Governing NPDB Operations

The three significant laws that currently govern NPDB operations are summarized below. NPDB regulations implementing these laws are codified at 45 CFR Part 60.

Title IV of Public Law 99-660, Health Care Quality Improvement Act of 1986

The intent of <u>Title IV</u> is to improve the quality of health care by encouraging State licensing boards, professional societies, hospitals, and other health care entities to restrict the ability of incompetent physicians, dentists, and other health care practitioners to move from State to State without disclosure or discovery of previous medical malpractice payment and adverse action history. These adverse actions include certain licensure, clinical privileges, and professional society membership actions, as well as Drug Enforcement Administration (DEA) controlled-substance registration actions and exclusions from participation in Medicare, Medicaid, and other Federal health care programs.

Section 1921 of the Social Security Act

Section 1921 was enacted to provide protection from unfit health care practitioners to beneficiaries participating in Medicare and State health care programs and to improve the anti-fraud provisions of these programs. Information collected and disclosed by the NPDB under Section 1921 includes State licensure and certification actions against health care practitioners, entities, providers, and suppliers; negative actions or findings by peer review organizations and private accreditation organizations; and certain final adverse actions taken by certain State agencies, including State law enforcement agencies, State Medicaid fraud control units, and State agencies administering or supervising the administration of State health care programs. These final adverse actions include exclusions from a State

health care program, health care-related criminal convictions and civil judgments in State court, and other adjudicated actions or decisions specified in regulations.

Section 1128E of the Social Security Act

The original purpose of Section 1128E was to establish a national data collection program, formerly known as the HIPDB, to combat health care fraud and abuse. Section 1128E information is now collected and disclosed by the NPDB and includes certain final adverse actions taken by Federal agencies and health plans against health care practitioners, providers, and suppliers. These actions consist of Federal licensure and certification actions, exclusions from participation in a Federal health care program, health care-related criminal convictions and civil judgments, and other adjudicated actions or decisions specified in regulations.

Table A-1 outlines these statutes.

Table A-1: Significant Laws Governing the NPDB

Title IV

Established the NPDB as a clearinghouse of information on medical malpractice payments and adverse actions related to licensure, clinical privileges, and professional society memberships of physicians, dentists, and, in some cases, other health care practitioners. Information also includes DEA registration actions and Medicare/Medicaid exclusions.

Section 1921

Adds certain adverse actions taken by State licensing and certification authorities, State law enforcement agencies, Medicaid fraud control units, State agencies administering State health care programs, peer review organizations, and private accreditation organizations.

Subjects of reports can include health care practitioners, entities, providers, and suppliers.

Section 1128E

Adds certain final adverse actions taken by Federal agencies and health plans against health care practitioners, providers, and suppliers.

GENERAL INFORMATION

Disclosure of NPDB Information

Title IV, Section 1921, and Section 1128E limit the disclosure of information in the NPDB. Information is available to certain eligible entities based on the requirements of each law.

Information on medical malpractice payments and on adverse actions related to

licensure, clinical privileges, and professional society membership of physicians, dentists, and, in some cases, other health care practitioners, as well as DEA-controlled substance registration actions and exclusions from Medicare, Medicaid, and other Federal health care programs (see Table A-1: Significant Laws Governing the NPDB) is available to:

- Hospitals requesting information concerning a practitioner on their medical staffs or to whom they have granted clinical privileges, or with respect to professional review activity
- Health care entities (including hospitals and professional societies) that have entered or may be entering into employment or affiliation relationships with a health care practitioner or to which the health care practitioner has applied for clinical privileges or appointment to the medical staff, or with respect to professional review activity
- Boards of medical examiners or other State licensing boards
- Health care practitioners requesting information reported to the NPDB on themselves
- Attorneys, or individuals representing themselves, upon submission of proof that a hospital failed to submit a mandatory query
- Persons or organizations <u>requesting information</u> in a form that does not identify any particular health care entity, physician, dentist, other practitioner, or patient

As more fully described in <u>Chapter D: Queries</u>, with a few limited exceptions, certain adverse actions taken against health care practitioners, entities, providers, and suppliers (see Table A-1: Significant Laws Governing the NPDB) by State licensure and certification authorities, State law enforcement agencies, State Medicaid fraud control units, State agencies administering or supervising the administration of State health care programs, peer review organizations, and private accreditation organizations against health care practitioners, entities, providers, and suppliers are available to:

- Hospitals and other health care entities (including professional societies) with respect to licensed health care practitioners who have entered (or may be entering) into employment or affiliation relationships with, or have applied for clinical privileges or appointments to the medical staffs of, such hospitals or other health care entities
- Quality improvement organizations
- State licensing and certification authorities
- State law enforcement agencies*
- State Medicaid fraud control units*
- State agencies administering or supervising the administration of State health care programs*

- Agencies administering Federal health care programs (including those providing payment for health care services) and private entities administering such programs under contract
- Federal agencies responsible for the licensing and certification of health care practitioners, providers, and suppliers
- Federal law enforcement agencies and officials
- Health plans
- Health care practitioners, entities, providers, and suppliers requesting information reported to the NPDB concerning themselves
- Persons or organizations requesting information in a form that does not identify any particular individual or organization
- * NPDB regulations define "state law or fraud enforcement agency" as including but not limited to these entities.

In addition, in the case of a medical malpractice action or claim, and under <u>specific circumstances</u>, an attorney (or an individual representing himself or herself) may request information from the NPDB for use in litigation against a hospital, upon showing that the hospital failed to request information from the NPDB about a specific health care practitioner.

Interpretation of NPDB Information

The purpose of the NPDB is to improve health care quality, protect the public, and combat health care fraud and abuse in the United States. The NPDB is primarily a flagging system that may serve to alert users that a more comprehensive review of

the qualifications and background of a health care practitioner, entity, provider, or supplier may be prudent. NPDB information is intended to be used in combination with information from other sources in making determinations on employment, affiliation, clinical privileges,

The information in the NPDB should serve only to alert eligible entities that there may be a problem with the performance of a particular health care practitioner, entity, provider, or supplier.

certification, licensure, or other decisions. NPDB information should *not* be used as the sole source of verification of professional credentials. The information in the NPDB should serve only to alert eligible entities that there *may* be a problem with the performance of a particular health care practitioner, entity, provider, or supplier.

For example, a settlement of a medical malpractice claim may occur for a variety of reasons that do not necessarily reflect negatively on the professional competence or conduct of the physician, dentist, or other health care practitioner. Thus, as specifically indicated in Title IV, a payment made in settlement of a medical

malpractice action or claim should not be construed as a presumption that medical malpractice has occurred.

Civil Liability Protection

Immunity provisions in Title IV, Section 1921, and Section 1128E protect individuals, entities, and their authorized agents from being held liable in civil actions for reports made to the NPDB unless they have actual knowledge that the information in the report is false.

In addition, Part A of Title IV provides additional protections to encourage and support professional review activity of physicians and dentists.

Confidentiality and Security of NPDB Information

Information reported to the NPDB is considered confidential and may not be disclosed except as specified in NPDB regulations at 45 CFR Part 60. The confidential receipt, storage, and disclosure of information are essential components of NPDB operations.

The NPDB maintains a comprehensive security system. Consistent with recognized

Information reported to the NPDB is considered confidential and may not be disclosed except as specified in NPDB regulations.

standards and guidelines, the NPDB has rigorous operational, management, and technical controls that ensure the security of the system and protect data in the system. Controls are also in place to ensure that transactions over the Internet are secure and that sensitive financial and

personal information is properly protected from unauthorized access.

Civil Money Penalties

The OIG has been delegated the authority to impose civil money penalties on those who violate the confidentiality provisions of Title IV. The civil money penalties for violating the confidentiality provisions of Title IV are to be imposed in the same manner as other civil money penalties pursuant to Section 1128A of the Social Security Act, 42 USC § 1320a-7a. Regulations governing civil money penalties under Section 1128A are set forth at 42 CFR Part 1003.

For each violation of confidentiality, a civil money penalty of up to \$11,000 can be levied. In any case in which it is determined that more than one party was responsible for improperly disclosing confidential information, a penalty of up to the maximum \$11,000 limit can be imposed against each responsible individual, entity, or organization. The amount of the penalty is subject to change through regulation.

Persons or entities who receive information from the NPDB either directly or indirectly are subject to the confidentiality provisions and the imposition of a civil money penalty if they violate those provisions. When an authorized agent is designated to handle NPDB queries, both the entity and the agent are required to maintain confidentiality in accordance with Title IV requirements.

The Privacy Act

Pursuant to the requirements of the Privacy Act of 1974 (<u>5 USC § 552a</u>), HHS has published a Privacy Act Systems of Record Notice (system no. 09-15-0054) describing the NPDB system of records. The NPDB system of records has been exempted from certain Privacy Act access and amendment requirements, and access and correction rights are governed by NPDB regulations.

Appropriate Use of NPDB Information

Information reported to the NPDB is considered confidential and may not be disclosed except as permitted by law. The confidentiality provisions of 45 CFR Part 60 allow an eligible entity receiving information from the NPDB to disclose the

An eligible entity receiving information from the NPDB may disclose the information to others who are part of the same investigation or peer review process, as long as the information is used for the purpose for which it was provided.

information to others who are part of the same investigation or peer review process, as long as the information is used for the purpose for which it was provided. In those instances, everyone involved in the investigation or peer review

process is subject to the confidentiality provisions of NPDB.

Examples of appropriate uses of NPDB information include:

A hospital may disclose the information it receives from the NPDB to hospital
officials responsible for reviewing a practitioner's application for a medical staff
appointment or clinical privileges. In this case, both the hospital officials who
receive the information and the hospital officials who subsequently review it
during the employment process are subject to the confidentiality provisions.

- In some instances private accreditation organization surveyors require evidence of compliance with the NPDB querying requirements. Generally, a private accreditation organization *cannot* view any document that a health care entity has obtained from the NPDB that shows the confidential results of an NPDB query (e.g., an NPDB report or the query response document). The Query History page that is returned with the results of a query history search does not include confidential information and generally is sufficient evidence that a query has been performed.
- If the health care entity being reviewed is using <u>Continuous Query</u>, the private accreditation organization may be provided with a printed or electronic copy of the Manage Continuous Query Subjects list, which lists all enrolled health care practitioners and the latest disclosure date for all reports disclosed after initial
 - enrollment. This list may be compared with the Continuous Query Report Disclosures list, which provides the names of the enrolled health care practitioners, the types of reports, the report disclosure date, whether the report was reviewed, and the date and name of

NPDB's provisions do not apply to the original documents or records from which the reported information is obtained.

- the person who reviewed the report. In these instances, the private accreditation organization personnel who review the information are subject to the confidentiality provisions of the NPDB.
- A health plan may disclose the information it received from the NPDB to health plan officials responsible for reviewing a health care practitioner's application for affiliation. In this case, both the health plan personnel who receive the information and the health plan officials who subsequently review it during the employment process are subject to the confidentiality provisions of the NPDB.

The confidentiality provisions prohibit the release of NPDB reports except as permitted by law. These provisions do not apply to the original documents or records from which the reported information is obtained. The NPDB's confidentiality provisions do not impose any new confidentiality requirements or restrictions on those documents or records. Thus, the confidentiality provisions do not bar or restrict the release of the underlying documents, or the information itself, by the entity taking an adverse action or making a payment in settlement of a written medical malpractice complaint or claim. For instance, a State freedom of information law that requires the release of records may require the release of the records underlying an NPDB report but would not permit the release of the NPDB report itself.

Individuals or organizations that obtain information reported to the NPDB naming them as the subject of a report are permitted to share that information with

whomever they choose. <u>Statistical data</u> that do not identify any individual or organization are available to the public for research purposes.

FEES

Fees are assessed to cover all operating costs of the NPDB, including the processing costs for all queries for NPDB information. Refer to <u>Billing and Fees</u> on the NPDB website and <u>Chapter G: Fees</u> for details regarding the payment of NPDB user fees.

OFFICIAL LANGUAGE

The official language of the NPDB is English, and all documents submitted to the NPDB must be written in English. Documents submitted in any other language are not accepted.

TERMINOLOGY DIFFERENCES

An action must be reported to the NPDB based on whether it satisfies NPDB reporting requirements and not based on the name affixed to the action. For example, <u>administrative fines</u> may or may not be reportable, depending upon whether they meet NPDB reporting criteria, not on what they are called. A <u>suspension</u> or restriction of clinical privileges is reportable if it meets reporting criteria, whether the suspension or restriction is called summary, immediate, emergency, precautionary, or any other term.

Q&A: GENERAL INFORMATION

1. A health plan that credentials health care practitioners for participation in various networks includes NPDB query results in the materials presented to its credentialing committee for peer review approval, denial, or termination from the networks. If a health care practitioner appeals a denial or termination, the appeal goes to a separate review body that was not involved in the original decision. The appeal body is composed of a statewide representation of health care practitioners who are not employees of the health plan and who are paid for their services. The decision of the appeal body is final. Is providing NPDB query results to the appeal body a violation of the NPDB confidentiality rules?

No. NPDB confidentiality provisions do not prohibit an eligible entity receiving information from the NPDB from <u>disclosing the information</u> to others who are part of the peer review process, as long as the information is used for the purposes for which it was provided.

2. Are researchers permitted to obtain relevant information from the NPDB?

Yes. While the NPDB is prohibited by law from disclosing information on a specific health care practitioner, entity, provider, or supplier to a member of the general public, statistical data are available to the public in a <u>form that does not identify any individual or organization</u>. In order to access the data, researchers will be asked to review and agree to a Data Use Agreement that spells out specifics of how the data provided may be used in accordance with the law.

3. What happened to the HIPDB?

While the NPDB and the HIPDB were established for different purposes, overlap existed in some reporting and querying requirements. To <u>eliminate this duplication</u>, Congress passed Section 6403 of the Patient Protection and Affordable Care Act, which consolidated NPDB operations with those of the former HIPDB. Information previously collected and disclosed by the HIPDB is now collected and disclosed by the NPDB.

CHAPTER B: ELIGIBLE ENTITIES

OVERVIEW

The NPDB is an information clearinghouse created by Congress with the primary goals of improving health care quality, protecting the public, and reducing health care fraud and abuse in the United States. To facilitate comprehensive reviews of the credentials of health care practitioners, entities, providers, and suppliers, eligible entities receive information the NPDB has collected on medical malpractice payments and certain adverse actions. These payments and adverse actions are required to be reported to the NPDB under Title IV of Public Law 99-660, the Health Care Quality Improvement Act of 1986 (Title IV); Section 1921 of the Social Security Act (Section 1921); Section 1128E of the Social Security Act (Section 1921); and their implementing regulations found at 45 CFR Part 60.

This chapter describes what entities are eligible to access the NPDB. It also describes what entities are required to or permitted to report to and query the NPDB. Finally, the chapter addresses how eligible entities register with the NPDB and how individuals and authorized agents can be empowered to query and report on behalf of eligible entities.

WHAT IS AN ELIGIBLE ENTITY?

Entities that participate in the NPDB are defined in the provisions of Title IV, Section 1921, Section 1128E, and implementing regulations. In addition, a few Federal agencies also participate with the NPDB through Federal memorandums of understanding. Eligible entities are responsible for complying with all reporting and/or querying requirements that apply; some entities may qualify as more than one type of eligible entity. Each eligible entity must certify its eligibility in order to report to the NPDB, query the NPDB, or both.

Information from the NPDB is available only to those entities specified as eligible in the statutes and regulations. Not all entities have the same reporting requirements or level of query access.

Each of the three major statutes governing NPDB operations has its own set of <u>eligible entities</u>, with specific reporting and querying requirements. The terminology and requirements under each statute are distinct. While the NPDB operates as a single data bank, the information that entities are required to report and are authorized to receive when they query is based on their eligibility under each statute. In some cases, the information required to be reported to the NPDB under each statute overlaps with information reported under another statute, but

certain eligible entities may only be authorized to receive information collected under one of those statutes. Likewise, entities that are authorized to report under one or more statutes must comply with each unique reporting requirement.

To be eligible to *query* the NPDB, an entity must be:

- Under the authority of Title IV
 - o A hospital
 - o A health care entity that provides health care services and follows a formal peer review process for the purpose of furthering quality health care
 - o A professional society that follows a formal peer review process for the purpose of furthering quality health care, or
 - o A board of medical examiners or other State licensing board
- Under the authorities of Section 1921 and Section 1128E
 - o A hospital
 - o A health care entity that provides health care services and follows a formal peer review process for the purpose of furthering quality health care
 - o A professional society that follows a formal peer review process for the purpose of furthering quality health care
 - o A health plan
 - o A quality improvement organization
 - o A State licensing or certification authority
 - o A State law enforcement agency
 - o A State Medicaid fraud control unit
 - o A State agency administering or supervising the administration of a State health care program
 - o An agency administering a Federal health care program, including a private entity administering such a program under contract
 - o A Federal agency responsible for the licensing or certification of health care practitioners, providers, or suppliers, or
 - o A Federal law enforcement official or agency

To be eligible to *report* to the NPDB, an entity must be:

- Under the authority of Title IV
 - o An entity that makes a medical malpractice payment
 - o A hospital or other health care entity that takes an adverse clinical privileging action as a result of professional review

- o A professional society that takes an adverse membership action as a result of professional review
- o A board of medical examiners that takes an adverse action
- o The Drug Enforcement Administration (DEA) when it takes a controlled substance registration action, or
- o The Department of Health and Human Services (HHS) Office of Inspector General (OIG) when it makes an exclusion from Federal health care programs
- Under the authority of Section 1921 and Section 1128E
 - o A State licensing or certification authority
 - o A peer review organization
 - o A private accreditation organization that takes a negative action or finding against a health care entity, provider, or supplier
 - o A State law enforcement agency
 - o A Federal or State prosecutor
 - o A State Medicaid fraud control unit
 - o A State agency administering or supervising the administration of a State health care program
 - o A Federal Government agency, or
 - o A health plan

In addition, the Department of Defense (DOD), the Department of Veterans Affairs (DVA), and certain agencies within HHS report to the NPDB under memorandums of understanding that generally govern reporting, rather than this Guidebook.

Eligible entities may use <u>authorized agents</u> to assist with reporting and/or querying.

Table B-1 summarizes the reporting and querying authorities of eligible entities.

NPDB Guidebook Chapter B: Eligible Entities

Table B-1: Eligible Entities that Report to and Query the NPDB, Part 1

Each of the three major statutes governing NPDB operations has its own set of eligible entities with specific reporting and querying requirements. Eligible entities are responsible for complying with all reporting and/or querying requirements that apply; some entities may qualify as more than one type of eligible entity.

Title IV Requirements		
<u>Entity</u>	<u>Report</u>	<u>Query</u>
Medical malpractice payers	Required	Not Authorized
Hospitals	Required	Required
Health care entities that provide health care services and follow a formal peer review process for the purpose of furthering quality health care	Required	Optional
Professional societies that follow a formal peer review process for the purpose of furthering quality health care	Required	Optional
Boards of medical examiners	Required	Optional
Other State licensing boards	Not Authorized	Optional
DEA	Required	Not Authorized
OIG	Required	Not Authorized

Refer to Table B-1, Part 2, for additional information on reporting and querying requirements.

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[&]quot;Not Authorized" indicates that the statute contains no provision for an entity reporting to or querying the NPDB.

NPDB Guidebook Chapter B: Eligible Entities

Table B-1: Eligible Entities that Report to and Query the NPDB, Part 2

Each of the three major statutes governing NPDB operations has its own set of eligible entities with specific reporting and querying requirements. Eligible entities are responsible for complying with all reporting and/or querying requirements that apply; some entities may qualify as more than one type of eligible entity.

Section 1921 and Section 1128E Requirements		
<u>Entity</u>	<u>Report</u>	Query
Hospitals*	Not Authorized	Optional**
Health care entities that provide health care services and follow a formal peer review process for the purpose of furthering quality health care	Not Authorized	Optional**
Professional societies that follow a formal peer review process for the purpose of furthering quality health care	Not Authorized	Optional**
Health plans	Required (§ 1128E)	Optional
Quality improvement organizations	Not Authorized	Optional**
State licensing and certification authorities	Required (§ 1921)	Optional
Peer review organizations	Required (§ 1921)	Not Authorized
Private accreditation organizations	Required (§ 1921)	Not Authorized
State law enforcement agencies, including State prosecutors***	Required (§ 1921)	Optional
State Medicaid fraud control units***	Required (§ 1921)	Optional
State agencies administering or supervising the administration of State health care programs***	Required (§ 1921)	Optional
Agencies administering Federal health care programs, including private entities administering such programs under contract	Required (§ 1128E)	Optional
Federal licensing and certification agencies	Required (§ 1128E)	Optional
Federal law enforcement officials and agencies, including Federal prosecutors	Required (§ 1128E)	Optional

^{*} Under Title IV, hospitals are required to query the NPDB.

Refer to Table B-1, Part 1, for additional information on reporting and querying requirements.

^{**} As described in Chapter D: Queries, these entities have access to most of the information reported under Section 1921 and Section 1128E.

^{***} NPDB regulations define "state law or fraud enforcement agency" as including but not limited to these entities.

[&]quot;Not Authorized" indicates that the statutes contain no provision for an entity reporting to or querying the NPDB.

DEFINING ELIGIBLE ENTITIES

Each entity is responsible for determining its eligibility to report to and/or query the NPDB and must certify that eligibility to the NPDB when registering with the NPDB. Although the sections below describe eligible entities, entities are responsible for verifying their legal obligation or eligibility under applicable laws and regulations. The terms defined below are not mutually exclusive, and entities may qualify as more than one type of eligible entity. Entities should carefully review all terms and definitions prior to registering. When registering with the NPDB, entities certify their eligibility to participate based on the most appropriate eligible entity category. However, if an entity meets the definition of multiple entity categories, the entity must comply with all applicable querying, reporting, and other requirements. For example, if an entity is registered as a hospital under all three statutes but is also a self-insured medical malpractice payer, the entity is responsible for reporting any medical malpractice payments made for the benefit of a practitioner in addition to its querying and reporting responsibilities as a hospital.

Boards of Medical Examiners

A <u>board of medical examiners</u> (also referred to as a State medical or dental board) is a State licensing board that licenses, monitors, and disciplines physicians or dentists. This term includes a board of osteopathic examiners or its subdivision, a board of dentistry or its subdivision, or an equivalent body as determined by the State. See also <u>State licensing boards</u>.

Drug Enforcement Administration

The DEA is the U.S. agency tasked, in part, with enforcing the controlled substances laws and regulations of the United States, including provisions of the Controlled Substances Act as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances.

Federal Agencies

<u>Federal agencies that are authorized to query</u> the NPDB under Section 1921 and Section 1128E include:

- Agencies administering Federal health care programs (including private entities administering such programs under contract and private entities providing payment for services)
- Federal agencies responsible for the licensing and certification of health care practitioners, providers, or suppliers (also referred to as Federal licensing and certification agencies)

- Law enforcement officials and agencies, such as:
 - o Attorney General
 - o Chief postal inspector
 - o Inspectors general
 - o U.S. attorneys
 - o Comptroller general
 - o DEA
 - o Nuclear Regulatory Commission
 - o Federal Bureau of Investigation

<u>Federal agencies that must report</u> to the NPDB under Section 1128E include, but are not limited to:

- HHS
- Department of Justice
- Federal law enforcement agencies, including law enforcement investigators
- Any other Federal agency that either administers or provides payment for the delivery of health care services, including, but not limited to, the DOD and the DVA
- Federal agencies responsible for the licensing and certification of health care practitioners, providers, or suppliers (also referred to as Federal licensing and certification agencies)

Health Care Entities

The definition of a <u>health care entity</u> includes both hospitals and other health care entities.

Examples of hospitals and other health care entities are listed in Table B-2.

Hospitals

A hospital is defined under Section 1861(e)(1) and (7) of the Social Security Act.

Other Health Care Entities

A <u>health care entity</u> must provide health care services and follow a formal peer review process to further quality health care. The phrase "provides health care services" means the delivery of health care services through any of a broad array of coverage arrangements or other relationships with practitioners, either by employing them directly or through contractual or other arrangements. This definition specifically excludes indemnity insurers that have no contractual or other arrangement with physicians, dentists, or other health care practitioners.

A formal peer review process is the conduct of professional review activities through formally adopted written procedures that provide for adequate notice and an opportunity for a hearing.

Examples of other health care entities *may* include health maintenance organizations (HMOs), preferred provider organizations (PPOs), group practices, nursing facilities, rehabilitation centers, hospices, renal dialysis centers, free-standing ambulatory care and surgical service centers, patient-centered medical homes (PCMHs), accountable care organizations (ACOs), and other health care delivery models that meet the definition.

Table B-2: Examples of Entities that May Qualify as Hospitals and Other Health Care Entities		
Hospitals*	Other Health Care Entities*	
All Federal and non-Federal short-term care general and specialty hospitals that are licensed or otherwise authorized by the State. All Federal and non-Federal long-term care general and specialty hospitals that provide diagnostic and/or therapeutic care under the supervision of a physician and/or psychologist that are licensed or otherwise authorized by the State. All long-term skilled nursing facilities that are licensed as hospitals by the State, as long as care is provided under the supervision of a physician or psychologist. All hospices that provide skilled nursing and comfort care under the supervision of a physician and are licensed by the State.	Ambulatory or outpatient care centers, even when otherwise part of a hospital. "One-day surgery" centers, even when otherwise part of a hospital. Nursing facilities that provide skilled nursing care not under the supervision of a physician or psychologist. Hospices that provide care not under the supervision of a physician or psychologist. Skilled nursing facilities or hospices that provide only daily care.	

^{*} See definitions above

Health Plans

The term <u>health plan</u> refers to a plan, program, or organization that provides health benefits, whether directly, through insurance, through reimbursement, or otherwise. Health plans include, but are not limited to:

- A policy of health insurance
- A contract of a service benefit organization
- A membership agreement with an HMO or other prepaid health plan
- A plan, program, agreement, or other mechanism established, maintained, or

made available by a self-insured employer or group of self-insured employers; a health care practitioner, provider, or supplier group; a third-party administrator; an integrated health care delivery system; an employee welfare association; or a public service group or organization or professional association

- An insurance company, insurance service, or insurance organization that is licensed to engage in the business of selling health care insurance in a State and is subject to State law that regulates health insurance
- An organization that provides benefit plans with coverage limited to outpatient prescription drugs

Medical Malpractice Payers

A medical malpractice payer is an entity that makes a medical malpractice payment, through an insurance policy or otherwise, for the benefit of a health care practitioner in settlement of, or in satisfaction in whole or in part of, a claim or judgment against the practitioner.

Peer Review Organizations

A <u>peer review organization</u> is an organization with the primary purpose of evaluating the quality of patient care practices or services ordered or performed by health care practitioners against objective criteria that define acceptable and adequate practice, using a sufficient number of health care practitioners specializing in the area of review to ensure adequate peer review. The peer review organization also has due process mechanisms available to health care practitioners.

This definition specifically excludes utilization and quality control peer review organizations described in <u>Part B of Title XI of the Social Security Act</u> (referred to as quality improvement organizations [QIOs]) and other organizations funded by the Centers for Medicare & Medicaid Services (CMS) to support the QIO program.

Private Accreditation Organizations

A <u>private accreditation organization</u> evaluates and seeks to improve the quality of health care provided by a health care entity, provider, or supplier by measuring performance based on a set of standards and assigning a level of accreditation, as well as conducting ongoing assessments and periodic performance reviews of the quality of health care provided. A private accreditation organization must have due process mechanisms available to the health care entities, providers, or suppliers that it evaluates and accredits.

Professional Societies

A professional society is a membership association of health care practitioners at the national, State, or local level that follows a formal peer review process for the purpose of furthering quality health care.

Examples of professional membership societies may include national, State, county, and district medical and dental societies and academies of medicine and dentistry. Examples of professional organizations that ordinarily *do not* meet the definition of a professional society include medical and surgical specialty certification boards, independent practice associations, managed care organizations, and PPOs, although these organizations may meet one or more other eligible entity definitions.

Professional societies are not automatically eligible to query and/or report to the NPDB. A professional society must qualify as a "health care entity" as defined in section 60.3 of the NPDB regulations. To meet NPDB eligibility requirements, a professional society must follow a formal peer review process for the purpose of furthering quality health care.

Quality Improvement Organizations

QIOs are private companies that hold contracts with CMS to monitor the quality of care provided to Medicare beneficiaries. One company for each U.S. State and territory is designated as the QIO for that region.

A QIO is a utilization and quality control peer review organization (as defined in Part B of Title XI of the Social Security Act) that is composed of, or has available to it in the area, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery to assure adequate peer review of the services provided by various medical specialties and subspecialties, and is able to perform reviews of the pattern of quality of care in an area of medical practice where actual performance is measured against objective criteria for acceptable and adequate practice. The QIO must have at least one consumer representative on its governing body.

State Agencies Administering or Supervising the Administration of State Health Care Programs

State agencies administering or supervising the administration of a State health care program include State agencies that administer or supervise the administration of a State health care program, as well as those that provide payment for services, as defined in Section 1128(h) of the Social Security Act. These entities also are included in the definition of a State law or fraud enforcement agency because they have a role in investigating and preventing health care fraud and abuse and take certain final adverse actions consistent with that role.

State Law Enforcement Agencies

A State law enforcement agency is included in the definition of a State law or fraud enforcement agency.

State Law or Fraud Enforcement Agencies

A State law or fraud enforcement agency includes, but is not limited to: (1) a State law enforcement agency; (2) a State Medicaid fraud control unit (as defined in section 1903(q) of the Social Security Act); and (3) a State agency administering (including those providing payment for services) or supervising the administration of a State health care program (as defined in Section 1128(h) of the Social Security Act).

State Licensing and Certification Authorities

The term State licensing or certification authority includes, but is not limited to, any authority of a State (or of a political subdivision thereof) responsible for the licensing or certification of health care practitioners (or of any peer review organization or private accreditation entity reviewing the services provided by health care practitioners), health care entities, providers, or suppliers. Examples of such State agencies include departments of professional regulation, health, social services (including State survey and certification and Medicaid single State agencies), commerce, and insurance. See also Boards of Medical Examiners.

State Licensing Boards

A State licensing board is a generic term used to refer to State medical and dental boards, as well as those bodies responsible for licensing, certifying, or otherwise authorizing physicians, dentists, and other health care practitioners to provide health care services. See also Boards of Medical Examiners.

State Medicaid Fraud Control Units

A State Medicaid fraud control unit (as defined in <u>section 1903(q) of the Social Security Act</u>) is included in the definition of a <u>State law or fraud enforcement agency</u>.

Table B-3 provides examples of entities that may qualify as more than a single entity type for NPDB reporting and querying purposes.

NPDB Guidebook Chapter B: Eligible Entities

Table B-3: Examples of Entities that May Qualify as Multiple Eligible Entity Types		
Organization	Eligible Entity Types	NPDB Requirements
A private sector hospital that is a self-insured malpractice payer	Hospital	Must report certain clinical privileges actions Must query as required; may query
	Medical malpractice payer	Must report medical malpractice payments May not query the NPDB
A Federal hospital	Hospital	Must report certain clinical privileges actions Must query as required; may query
	Agencies administering Federal health care programs (including private entities administering such programs under contract and private entities providing payment for services)	Must report certain final adverse actions under Section 1128E, including other adjudicated actions or decisions May query
A managed care organization that provides health care services and performs peer review for the purpose of furthering quality health care	Health care entity	Must report certain clinical privileges actions May query
	Health plan	Must report certain final adverse actions under Section 1128E, including health care-related civil judgments and other adjudicated actions or decisions May query
A State Medicaid agency	State licensing or certification authority	Must report State licensure and certification actions May query
	State agency administering a State health care program	Must report certain final adverse actions under Section 1921, including exclusions from a State health care program and other adjudicated actions or decisions May query
A State medical or dental board	Board of medical examiners	Must report certain adverse licensure actions related to professional competence or professional conduct May query
	State licensing or certification authority	Must report State licensure and certification actions May query

REGISTERING WITH THE NPDB

Eligible entities are responsible for certifying their eligibility to report to and/or query the NPDB by registering with the NPDB. The online registration and certification process determines and sets an entity's requirements and restrictions regarding querying and reporting to the NPDB.

Eligible entities not currently registered with the NPDB should complete an <u>Entity Registration form</u>. The information requested on the Entity Registration form provides the NPDB with essential information concerning the entity, such as the

Eligible entities are responsible for certifying their eligibility to report to and/or query the NPDB by registering with the NPDB.

organization's name, address, point of contact for reports, Federal Taxpayer Identification Number, type of ownership, the

organization's authority to participate in the NPDB under each of the statutes governing the NPDB, and the organization's primary function or service.

Each entity that initiates the entity registration process is given a Data Bank Identification Number (DBID) and must create a user ID and a password for its account. Once an entity completes the entity registration documents, the entity's certifying official must sign the documents before returning them to the NPDB for processing. An entity is not successfully registered until the NPDB receives all registration and verification documents and the registration forms are confirmed by the NPDB. The registration process must be completed before an entity is able to submit reports and queries.

E-Authentication and Identity Proofing

Eligible entities access the NPDB through the Internet. For security reasons, NPDB users must be properly authorized and authenticated before they are granted access to the NPDB. In addition, Federal entities, such as the NPDB, that allow access to Internet-based information systems must meet certain technical and operational requirements that are published by the National Institute of Standards and Technology.

The NPDB uses a combination of security measures to accomplish its security goals, including but not limited to perimeter boundary protection, encryption, eauthentication, and identity proofing. Each eligible entity is e-authenticated through a positive and unique identification process. During the registration process, the entity submits information that uniquely identifies it, which is validated by the NPDB before querying or reporting access is granted by the NPDB.

Likewise, individuals authorized by an eligible entity must be identity proofed and provide proof of entity affiliation in order to perform certain actions appropriate to their role (i.e., querying, reporting, or both) through a positive and unique identification process. Eligible entity administrators are responsible for identity-proofing authorized users and must complete administrator training before performing this function.

Certifying Official

A certifying official is the individual selected and empowered by an entity to certify the legitimacy of registration for participation in the NPDB. The certifying official is responsible for:

- Completing the Entity Registration form
- Notifying the NPDB of any change in eligibility: If the entity relinquishes
 eligibility to participate in the NPDB, the certifying official must notify the
 NPDB to deactivate the entity's DBID

Each entity may change its designated certifying official at any time. The entity must notify the NPDB when changes occur because the NPDB keeps a record of the staff title and name of the individual assigned as the certifying official.

Administrator

Each eligible entity is responsible for designating an administrator, who may be, but need not be, the entity's certifying official. The <u>administrator</u> is responsible for

updating the entity's registration profile and, if desired, may designate one or more authorized agents to query and/or report on behalf of the entity by completing an Authorized Agent Designation

The administrator manages NPDB activities and is responsible for creating and maintaining NPDB user accounts for all individuals in the organization who are querying or reporting.

form and submitting it to the NPDB. The administrator manages NPDB activities and is responsible for creating and maintaining NPDB user accounts for all individuals in the organization who are querying or reporting. The administrator is responsible for ensuring that all users have their <u>identities proofed or authenticated</u> as part of an organization's registration or renewal process. Each entity may designate more than one administrator if it so chooses. Administrators must complete administrator training prior to identity-proofing users and creating user accounts. The self-guided training provides instructions for identity proofing and maintaining user accounts. To access the administrator training, go to the Administrator Options page after logging into the NPDB. In addition, the NPDB

Administrator Handbook serves as a reference document for the administrator.

Registration Renewal

Entities are required periodically to recertify their eligibility by <u>renewing their registration</u>. This mandatory registration renewal encourages periodic review of eligibility requirements to interact with the NPDB. Registration renewals also ensure that the information that the NPDB maintains on each organization is accurate and current. Failure to renew registration will result in the entity's inability to access the NPDB until the registration has been renewed.

NPDB IDENTIFICATION NUMBERS

Each entity that registers with the NPDB is assigned a unique DBID. A DBID is a number that is randomly generated by the NPDB and is used to uniquely identify registered entities and authorized agents. The assignment of a DBID is not a validation by HHS that an entity meets the eligibility criteria for participation in the NPDB. As stated previously, each entity is responsible for determining whether it meets the eligibility criteria and for certifying its eligibility to the NPDB.

DBIDs are assigned to entities when they register with the NPDB, as well as to authorized agents that act on behalf of registered entities. *DBIDs are not assigned to certifying officials, authorized users, or other individuals associated with a reporting or querying entity.* However, entities may <u>create multiple user accounts (user IDs)</u> for a given DBID.

In addition, certain eligible entities may choose to register two or more departments separately under different DBIDs. For example, some hospitals and health care entities choose to register their human resources departments separately from their medical staff services departments. The advantage of registering departments separately is that each department will have its own DBID and queries will be charged to the separate accounts. The advantage to a single registration is that all eligible queriers will have online access to all query results.

Entities should safeguard their DBIDs to prevent inadvertent disclosures. The DBID is revealed only to the entity or agent to which it is assigned. In the event that an entity's DBID is compromised, the DBID should be deactivated.

Deactivating a DBID

An eligible entity may request, at any time, that its current DBID be deactivated by notifying the NPDB *in writing*. An eligible entity may choose to deactivate a DBID because, for example, the entity's DBID may have been compromised in some way,

or the entity has merged with another entity. (Note: An entity's DBID cannot be reactivated. The entity must reregister with the NPDB to obtain a new DBID.)

Additionally, if at any time an entity loses or relinquishes eligibility to participate in the NPDB, the entity's certifying official must immediately notify the NPDB *in writing* to deactivate the entity's DBID.

Entities that need to deactivate their DBID should contact the <u>NPDB Customer</u> Service Center for further instructions.

Lost DBID

If an entity misplaces or cannot remember its DBID, contact the <u>NPDB Customer</u> <u>Service Center</u> for assistance.

UPDATE ENTITY INFORMATION

Entities must <u>keep important profile information up to date</u>, including information such as a change in the entity's point of contact for reports, the name of the organization, agent-entity relationship preferences, or notification preferences. Some information can be changed directly online, while other information requires the entity to print, sign, and mail a form to the NPDB.

WHO MAY REPORT AND QUERY ON BEHALF OF ELIGIBLE ENTITIES

Authorized users and authorized agents may submit queries and reports and retrieve responses from the NPDB on behalf of registered entities.

Authorized NPDB Users

An authorized user (also known as an authorized submitter) is the individual or individuals selected and empowered by a registered entity to certify the legitimacy of information provided in a query or report to the NPDB (using the entity's DBID). In most cases, an authorized user is an employee of the organization submitting the report or query, such as an administrator, a risk manager, or a member of the medical staff services department.

Entities are responsible for selecting one or more authorized users. For example, an entity may designate a particular individual within the organization to be the authorized user for reporting and another individual to be the authorized user for querying. Entity administrators are responsible for identity-proofing authorized users when creating user IDs (although the administrator also may serve as the

entity's authorized user). Each authorized user is required to have a unique user account with a unique user ID. Authorized users must each provide their name, title, and phone number at the time a query or report is submitted. Entities are responsible for their authorized users. Entities may change authorized users' query and reporting privileges, or deactivate authorized users, at any time without notifying the NPDB. Entities must deactivate any authorized user accounts when the authorized user is no longer affiliated with the entity or if the user account has been compromised.

Authorized Agents

Registered entities may elect to have outside organizations query or report to the NPDB on their behalf. Such an organization is referred to as an <u>authorized agent</u>. Authorized agents must register with the NPDB and comply with all registration requirements. Authorized agents also may assign authorized users who have been identity proofed and granted user access. In many cases, an authorized agent is an independent contractor used in conjunction with verifying credentials, called a credentials verification organization. In addition, an authorized agent may be an organization representing a group of eligible entities, such as the National Council

Before an authorized agent may act on behalf of an entity, the entity must designate the agent to interact with the NPDB on its behalf. of State Boards of Nursing or the Federation of Chiropractic Licensing Boards, that submit reports to the NPDB on behalf of the organization's participating members. The NPDB prohibits an authorized agent from re-

delegating some or all of its responsibilities to another authorized agent.

An authorized agent may be an agent for multiple eligible entities. Authorized agents must query the NPDB *separately* on behalf of each eligible entity they represent. The response to an NPDB query submitted for one entity cannot be disclosed to another entity. For more information on the confidentiality of NPDB information and civil money penalties for those who violate the <u>confidentiality provisions</u>, see Chapter A: Introduction and General Information.

Designating Authorized Agents

Before an authorized agent may act on behalf of an entity, the entity must <u>designate</u> the agent to interact with the NPDB on its behalf. Authorized agents must register with the NPDB and comply with all registration requirements before they can be designated. As part of the reporting and querying requirements, eligible entities are responsible for creating a written agreement between themselves and any authorized agents.

Q&A: ELIGIBLE ENTITIES

1. How do I know if my organization is an eligible entity?

To determine if your organization is an eligible entity, review the descriptions of eligible entities in this chapter, as well as NPDB regulations codified at <u>45</u> <u>CFR Part 60</u>. Definitions for certain eligible entities are included in <u>section 60.3</u> of the regulations. Other entities are specified in sections relating to reporting and disclosure of information.

2. Can the NPDB certify or verify that an organization is eligible to report or query?

No. Each entity must determine its own <u>eligibility to participate</u> in the NPDB and must certify that eligibility to the NPDB. NPDB officials reserve the right to review and verify all elements of the documentation submitted with a registration and also reserve the right to reject the registration if the entity is determined to be ineligible. Eligible entities are responsible for complying with all statutory and regulatory requirements that apply to them.

3. Does an organization have to notify the NPDB when it has a new certifying official?

Yes. The eligible entity gives its certifying official the authority to certify the legitimacy of registration information provided to the NPDB. The person authorized by the entity to act as the certifying official may change at any time at the discretion of the entity. However, the NPDB keeps a record of the staff title and name of the individual assigned as the <u>certifying official</u> and must be notified when changes occur.

4. A hospital merged with another hospital, and both have medical staff offices. Should they continue to query separately using two different DBIDs?

It depends. If the hospitals maintain separate medical staff credentialing, the hospitals must query separately (two DBIDs). If by applying to one hospital a health care practitioner is granted privileges to practice at both institutions, the peer review process is <u>centralized</u>, and the institutions have a single decisionmaking body, one hospital may query on behalf of both institutions (one DBID). For more information on query responses, see <u>Chapter D</u>: Queries.

5. A hospital's human resources department and medical staff services staff will both need to query the NPDB. Can one organization have more than

one DBID?

An organization can have more than one DBID. However, rather than registering for multiple DBIDs, an entity is encouraged to simply create multiple user accounts (i.e., user IDs) under the organization's single DBID. An entity can establish as many user accounts as necessary and can deactivate those accounts when needed without deactivating its DBID.

If the hospital chooses to register its human resources department and medical staff services staff separately with the NPDB, each department may obtain separate DBIDs. However, departments with different DBIDs cannot download a response from a query entered by another department with a different DBID. Also, special care must be taken to be sure that the same report is not submitted twice.

6. If an organization queries the NPDB, is it also required to report? Conversely, if an organization reports to the NPDB, is it automatically eligible to query?

Not necessarily. Each law governing the NPDB has different requirements for reporting and querying. Reporting and querying authorities for eligible entities under each law are described at the beginning of this chapter. In addition, Chapter D: Queries and Chapter E: Reports, respectively, provide additional information regarding querying and reporting eligibility criteria.

7. Are PCMHs eligible to participate in the NPDB as a health care entity?

In order to be eligible to participate in the NPDB as a health care entity, an organization must meet one or more of the parts of the definition. It must be:

- A hospital
- An entity that provides health care services and engages in professional review activity through a formal peer review process for the purpose of furthering quality health care, or a committee of that entity, or
- A professional society, or a committee or agent thereof, including those at the national, State, or local level, of health care practitioners that engages in professional review activity through a formal peer review process, for the purpose of furthering quality health care

For purposes of the second bullet of the definition above, an entity includes an HMO that is licensed by a State or determined to be qualified as such by HHS, and any group or prepaid medical or dental practice that meets the criteria of the second bullet.

A formal peer review process is the conduct of professional review activities through formally adopted written procedures that provide for adequate notice and an opportunity for a hearing.

PCMHs normally would be considered to be "providing" health care services. If the PCMH provides health care services and also conducts formal peer review to further the quality of health care, it would be eligible to participate in the NPDB as a health care entity and would be required to report.

8. Are ACOs considered eligible entities for the purposes of reporting to and querying the NPDB?

It depends. An ACO may be considered a "health care entity" depending on the particular activities it engages in. If ACOs are credentialing and privileging practitioners, they would be considered health care entities for the purposes of reporting and querying, so long as they are engaged in professional review activities through a formal review process.

9. A medical malpractice insurance company has eight regional offices and one main office. May the company register once with the NPDB (with one DBID) and create a different User ID for each of the eight regional offices?

Yes. The company may register once with the main office address and receive one DBID and, subsequently, create multiple user accounts. Each authorized user is required to have a unique user account. Each user account will have a separate User ID and password. Each employee that is required to access the NPDB must have his or her own User ID and password.

10. If an eligible entity replaces an employee, does the entity keep and re-use the former employee's user ID?

No. Each authorized user is required to have a unique user account with a unique user ID. Entities must deactivate any authorized user accounts when the authorized user is no longer affiliated with the entity or if the user account has been compromised.

11. Can an eligible entity designate more than one authorized agent to query on its behalf?

Yes. The NPDB can accommodate multiple authorized agents for each entity.

CHAPTER C: SUBJECTS OF REPORTS

OVERVIEW

The NPDB is an information clearinghouse created by Congress with the primary goals of improving health care quality, protecting the public, and reducing health care fraud and abuse in the United States. The NPDB collects information on medical malpractice payments and certain adverse actions and discloses that information to eligible entities to facilitate comprehensive reviews of the credentials of health care practitioners, entities, providers, and suppliers. These payments and actions are required to be reported to the NPDB under Title IV of Public Law 99-660, the Health Care Quality Improvement Act of 1986 (Title IV); Section 1921 of the Social Security Act (Section 1921); Section 1128E of the Social Security Act (Section 1921); and their implementing regulations found at 45 CFR Part 60.

NPDB information is intended to be used in combination with information from other sources in making employment, certification, licensure, clinical privilege,

affiliation, or other decisions. Entities that are authorized to report to or query the NPDB include medical malpractice payers, hospitals and other health care entities, professional societies, health plans, peer review organizations, private accreditation organizations, and

Identifying terms used by the NPDB are not intended to describe distinct, mutually exclusive categories, nor are the examples provided intended to be exhaustive.

certain Federal and State agencies. In addition, health care practitioners, entities, providers, and suppliers may request information concerning themselves from the NPDB.

The terms "physician," "dentist," "health care practitioner," "health care entity," "health care provider," and "health care supplier" are not intended to describe distinct, mutually exclusive categories, nor are the examples provided intended to be exhaustive. For example, a skilled nursing facility is an institutional provider, but also can be a supplier of health care items and equipment.

DEFINITIONS

A health care practitioner, licensed health care practitioner, licensed practitioner, or practitioner, as used in this Guidebook, is defined as an individual who is licensed or otherwise authorized by a State to provide health care services; or any individual who, without authority, holds himself or herself out to be so licensed or authorized. See <u>Table C-1</u>, parts 1 and 2.

A **dentist** is defined as a doctor of dental surgery, dental medicine, or the equivalent who is legally authorized to practice dentistry by a State, or any individual who, without authority, holds himself or herself out to be so authorized

A **physician** is defined as a doctor of medicine or osteopathy legally authorized to practice medicine or surgery by a State, or any individual who, without authority, holds himself or herself out to be so authorized.

A **health care entity** means:

- A hospital
- An entity that provides health care services and engages in professional review activity through a formal peer review process for the purpose of furthering quality health care, or a committee of that entity, or
- A professional society, or a committee or agent thereof, including those at the national, State, or local level, of physicians, dentists, or other health care practitioners that engages in professional review activity through a formal peer review process for the purpose of furthering quality health care

For purposes of the second bullet of this definition, an entity includes a health maintenance organization (HMO) that is licensed by a State or determined to be qualified as such by the Department of Health and Human Services (HHS), and any group or prepaid medical or dental practice that meets the criteria of the second bullet.

A formal peer review process is the conduct of professional review activities through formally adopted written procedures that provide for adequate notice and an opportunity for a hearing.

A health care provider means:

- A provider of services as defined in section 1861(u) of the Social Security Act
- Any organization (including an HMO, preferred provider organization, or group medical practice) that provides health care services and follows a formal peer review process for the purpose of furthering quality health care, or
- Any other organization that, directly or through contracts, provides health care services

A health care supplier means:

- A provider of medical and other health care services as described in <u>section</u> 1861(s) of the Social Security Act
- Any individual or entity, other than a provider, who furnishes, whether directly

or indirectly, or provides access to, health care services, supplies, items, or ancillary services (including, but not limited to, durable medical equipment suppliers, manufacturers of health care items, pharmaceutical suppliers and manufacturers, health record services [such as medical, dental, and patient records], health data suppliers, and billing and transportation service suppliers)

- Any individual or entity under contract to provide such supplies, items, or ancillary services
- Health plans as defined in NPDB regulations (including employers that are self-insured), or
- Health insurance producers (including but not limited to agents, brokers, solicitors, consultants, and reinsurance intermediaries)

Table C-1 lists examples of health care practitioners. Table C-2 offers examples of health care entities, providers, and suppliers. Table C-3 provides a summary of reporting requirements and query access for the NPDB.

Table C-1: Examples of Health Care Practitioners, Part 1

The following lists of health care practitioners are provided solely for illustration. Since licensure and certification requirements vary from State to State, there may be additional categories of health care practitioners not reflected on the following lists, and there may be categories listed below that do not satisfy the definition of health care practitioner for particular States. Each entity that reports to or queries the NPDB is responsible for determining which categories of health care practitioners are licensed or otherwise authorized by their State to provide health care services.

Chiropractor

Counselor

Counselor, Mental Health

Professional Counselor

Professional Counselor, Alcohol

Professional Counselor, Family/Marriage

Professional Counselor, Substance Abuse

Marriage and Family Therapist

Dental Service Provider

Dentist

Dental Resident

Dental Assistant

Dental Therapist/Dental Health Aide

Dental Hygienist

Denturist

Dietitian/Nutritionist

Dietitian

Nutritionist

Emergency Medical Technician (EMT)

EMT, Basic

EMT, Cardiac/Critical Care

EMT, Intermediate

EMT, Paramedic

Eye and Vision Service Provider

Ocularist

Optician

Optometrist

Nurse - Advanced, Registered, Vocational

Registered (Professional) Nurse

Nurse Anesthetist

Nurse Midwife

Nurse Practitioner

Clinical Nurse Specialist

Licensed Practical or Vocational Nurse

Nurses Aide, Home Health Aide, Other Aide

Certified Nurse Aide/Certified Nurse

Assistant

Nurses Aide

Home Health Aide (Homemaker)

Health Care Aide/Direct Care Worker

Certified or Qualified Medication Aide

Pharmacy Service Provider

Pharmacist

Pharmacist Intern

Pharmacist, Nuclear

Pharmacy Assistant

Pharmacy Technician

Physicians

Physician (MD)

Physician Intern/Resident (MD)

Osteopathic Physician (DO)

Osteopathic Physician Intern/Resident (DO)

Table C-1: Examples of Health Care Practitioners, Part 2

Physician Assistant

Physician Assistant, Allopathic Physician Assistant, Osteopathic

Podiatric Service Provider

Podiatrist

Podiatric Assistant

Psychologist, Psychological Assistant

Psychologist

School Psychologist

Psychological Assistant, Associate, Examiner

Rehabilitative, Respiratory, and Restorative Service Practitioner

Art/Recreation Therapist

Massage Therapist

Occupational Therapist

Occupational Therapy Assistant

Physical Therapist

Physical Therapy Assistant

Rehabilitation Therapist

Respiratory Therapist

Respiratory Therapy Technician

Social Worker

Speech, Language, and Hearing Service Provider

Audiologist

Speech/Language Pathologist

Hearing Aid (or Instrument) Specialist,

Dealer, Dispenser, or Fitter

Technologist/Technician

Medical or Clinical Laboratory

Technologist

Medical or Clinical Laboratory Technician

Surgical Technologist

Surgical Assistant

Cytotechnologist

Nuclear Medicine Technologist

Radiation Therapy Technologist

Radiologic Technologist

X-Ray Technician or Operator

Limited X-Ray Machine Operator

Other Health Care Practitioner

Acupuncturist

Athletic Trainer

Homeopath

Medical Assistant

Midwife, Lay (non-nurse)

Naturopath

Orthotics/Prosthetics Fitter

Perfusionist

Psychiatric Technician

Table C-2: Examples of Health Care Entities, Providers, and Suppliers

The following list of health care entities, providers, and suppliers is provided solely for illustration and is not intended to be a comprehensive list.

Individuals

Health Care Facility Administrator

Adult Care Facility Administrator Hospital Administrator

Long-Term Care or Nursing-Home Administrator

Assisted Living Facility Administrator

Health Insurance Provider/Supplier

Insurance Agent Insurance Broker

Other Health Care-Related Occupation

Accountant

Bookkeeper

Business Manager

Business Owner

Corporate Officer

Researcher, Clinical

Salesperson

Organizations

Accountable Care Organizations

Ambulance Service/Transportation Company

Group or Practice

Chiropractic Group/Practice

Dental Group/Practice

Medical Group/Practice

Mental Health/Substance Abuse

Group/Practice

Optician/Optometric Group/Practice

Physical/Occupational Therapy

Group/Practice

Podiatric Group/Practice

Health Care Supplier/Manufacturer

Biological Products Manufacturer

Blood Bank

Durable Medical Equipment Supplier

Eyewear Equipment Supplier

Fiscal/Billing/Management Agent

Nursing/Health Care Staffing Service

Organ Procurement Organization

Pharmacy

Pharmaceutical Manufacturer

Portable X-Ray Supplier Purchasing Service

Health Insurance Company/Provider

Home Health Agency/Organization

Hospice/Hospice Care Provider

Hospital

Federal Hospital

General/Acute Care Hospital

Psychiatric Hospital

Rehabilitation Hospital

Hospital Unit

Psychiatric Unit

Rehabilitation Unit

Laboratory/CLIA Laboratory

Nursing Facility/Skilled Nursing Facility

Research Center/Facility

Other Health Care Facility

Adult Day Care Facility

Ambulatory Surgical Center

Ambulatory Clinic/Center

End Stage Renal Disease Facility

Health Center/Federally Qualified Health

Center/Community Health Center

Intermediate Care Facility for Individuals

with Mental Retardation/Substance Abuse

Mammography Service Provider

Mental Health Center/Community Mental

Health Center

Outpatient Rehabilitation Facility/

Comprehensive Outpatient Rehabilitation

Facility

Radiology/Imaging Center

Residential Treatment Facility/ Program

Rural Health Clinic

Managed Care Organization

Health Maintenance Organization

Preferred Provider Organization

Provider-Sponsored Organization

Religious/Fraternal Benefit Society Plan

Table C-3: Summary of Reporting Requirements and Query Access, Part 1				
Law	Who Reports?	What is Reported?	Who is Reported?	Who May Query/Request Information?
Title IV	Medical malpractice payers	Medical malpractice payments resulting from a written claim or judgment	Practitioners	Hospitals (required by law) Other health care entities with formal peer review Professional societies with formal peer review State medical and dental boards and other State licensing boards Plaintiff's attorney/pro se plaintiff (limited circumstances) Health care practitioners (self-query) Researchers (de-identified statistical data only)
	State medical and dental boards	Certain adverse licensure actions related to professional competence or conduct	Physicians and dentists	
	Hospitals Other health care entities with formal peer review	Certain adverse clinical privileges actions related to professional competence or conduct	Physicians and dentists Other practitioners (optional)	
	Professional societies with formal peer review to	Certain adverse professional society membership actions related to professional competence or conduct	Physicians and dentists Other practitioners (optional)	
	DEA	DEA controlled-substance registration actions*	Practitioners	
	OIG	Exclusions from participation in Medicare, Medicaid, and other Federal health care programs*	Practitioners	

^{*} This information is reported to the NPDB under Title IV based on a memorandum of understanding.

Table C-3: Summary of Reporting Requirements and Query Access, Part 2					
Law	Who Reports?	What is Reported?	Who is Reported?	Who May Query/Request Information?	
Section 1921	Peer review organizations	Negative actions or findings by peer review organizations	Practitioners		
	Private accreditation organizations	Negative actions or findings by private accreditation organizations	Entities, providers, and suppliers	Hospitals and other health care entities* Professional societies with formal peer review*	
	State licensing and certification authorities	State licensing and certification actions	Practitioners, entities, providers, and suppliers	Quality improvement organizations* State licensing and certification authorities	
	State law enforcement agencies***	Exclusions from a State health care program		Agencies administering Federal health care programs, including private entities administering such programs under contract Federal licensing and certification agencies Health plans State law enforcement agencies*** State Medicaid fraud control units*** State agencies administering or supervising the administration of State health care programs*** Federal law enforcement officials and agencies	
	State Medicaid fraud control units***	Health care-related civil judgments in State court	Practitioners, providers, and suppliers		
	State agencies administering or supervising the administration of	Health care-related State criminal convictions			
	State health care programs*** State prosecutors	Other adjudicated actions or decisions			
	rr	Federal licensing and certification			
		actions**			
Section 1128E	Federal agencies	Exclusions from a Federal health care program**			
	Federal prosecutors Health care-related Federal or State criminal convictions** Health plans Health care-related civil judgments in Federal or State court	Practitioners, providers, and	Practitioners, entities, providers, and suppliers (self-query)		
		judgments in Federal or State	suppliers	Researchers (de-identified, statistical data only)	
		Other adjudicated actions or decisions			

^{*} As more fully explained in Chapter D: Queries, these entities have access to most of the information reported under Section 1921 and Section 1128E.

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^{**} Reported by Federal agencies only.

^{***} NPDB regulations define "state law or fraud enforcement agency" as including but not limited to these entities.

SELF-QUERIES

Health care practitioners, entities, providers, and suppliers may query the NPDB regarding themselves at any time using the NPDB <u>Self-Query service</u>. Individuals may be able to use the NPDB's Express Self-Query service, which allows them to process and pay for the self-query online; otherwise, self-queriers should complete and print out a form provided through the Self-Query service, have it notarized, and mail it to the address indicated on the form. Individuals or organizations that do not have access to the Internet may call the <u>NPDB Customer Service Center</u> for assistance. A fee will be charged for each Self-Query submitted. Refer to <u>Billing and Fees</u> on the NPDB website and <u>Chapter G: Fees</u> for details regarding the payment of NPDB fees.

The response received from a Self-Query belongs to the subject of the Self-Query. Various licensing, credentialing, and insuring entities may require a copy of a Self-Query as a condition of consideration for participation in their programs. Subjects may share the information contained in their own Self-Query responses with whomever they choose. (Note: A hospital is required by law to query the NPDB at certain times. A copy of a subject Self-Query does not satisfy a hospital's legal requirement to query the NPDB.)

SUBJECT INFORMATION

The NPDB is committed to maintaining accurate information and ensuring that subjects of reports are informed when the NPDB receives reports about them. Reporting entities are responsible for the accuracy of the information they report. The content of reports is determined by the reporting entity and not by the NPDB. When the NPDB receives a report, the information is processed by the NPDB system exactly as submitted by the reporting entity. Any changes or corrections to a report may *only* be submitted by the reporting entity.

When the NPDB processes a report, a notification is sent to the subject of the report, and a copy of the report is made available to the reporting entity for verification purposes. The notification to the subject of a report (the Subject Notification Document) includes instructions for obtaining an official copy of the report through the Report Response Service on the NPDB website. The subject of a report should review the report for accuracy, including identifiers such as current address, telephone number, and place of employment.

Correcting an Address

The notification of a report is sent to the subject of a report's address provided by the reporting entity. If the report contains an incorrect address, the subject of a

report may update the home, work, or both addresses as maintained by the NPDB through the Report Response Service on the NPDB website. Future correspondence will be mailed to the subject of a report at the address specified; however, this does not change the subject of a report's address as reflected in the report that was submitted to the NPDB. Only the entity that originally submitted the report can modify or correct information provided in the report. The subject of a report should contact the entity identified in Section A of the report and request that it make the address correction.

Correcting Information in the Report

A subject of a report may not submit changes to a report. This includes information such as the subject of a report's date of birth, address, date of graduation, Social Security Number, or other identifiers, as well as the description of the reported event. At any time, the subject of a report may enter the report into Dispute Status, add a Subject Statement, or both. For more information regarding these options, go to Chapter F: Subject Statements and the Dispute Process.

Q&A: SUBJECTS OF REPORTS

1. Can eligible entities report on health care practitioners who are not physicians or dentists?

Yes. The definition of a <u>health care practitioner</u> is an individual who is licensed or otherwise authorized by a State to provide health care services, or any individual who, without authority, holds himself or herself out to be so licensed or authorized.

2. Can eligible entities submit reports on Navigators, who are trained to provide assistance to individuals and companies looking for health care coverage through marketplaces created by the Patient Protection and Affordable Care Act of 2010?

It depends on the reporting entity. For example, several States regulate Navigators as suppliers of health care, and those boards would report licensing and certification actions taken against Navigators. In general, the following types of entities may file reports with the NPDB against health care suppliers: health plans, private accreditation organizations, State licensing and certification authorities, State law enforcement agencies, State Medicaid fraud control units, State agencies administering or supervising the administration of State health care programs, State prosecutors, Federal agencies, and Federal prosecutors.

3. If a State board that regulates dietitians issues a cease and desist order against a person who is not a registered dietitian but who is practicing as one, is the issuance of the cease and desist order reportable to the NPDB?

Yes. In this example, the State regulates the practice of dietetics and prohibits individuals from practicing as dietitians – even if they do not refer to themselves as dietitians, licensed dietitians, or registered dietitians – without being licensed by the board. NPDB regulations require the reporting not only of individuals who are licensed, but also those who hold themselves out to be so licensed. Therefore, the cease and desist order issued by the board would be reportable.

4. Why must individuals such as bookkeepers, accountants, business managers, and eyewear equipment suppliers be reported to the NPDB? They are not health care practitioners. Isn't the NPDB a repository of adverse actions taken against health care practitioners?

Subjects of NPDB reports are not limited to health care practitioners. The NPDB also collects information related to certain adverse actions taken against health care entities, providers, and suppliers. These terms are defined in the NPDB regulations codified at <u>45 CFR Part 60</u>. See also <u>Chapter E: Reports</u> for information about reporting health care entities, providers, and suppliers.

5. How do I correct my address if it is wrong in a report?

Only the entity that originally submitted the report can correct information provided in a report. The subject of a report should contact the entity identified in Section A of the report and request that it make the address correction. The subject of a report may update the NPDB's address of record for the subject's home or work addresses using the Report Response Service on the NPDB website. Future correspondence will be mailed to the subject of the report at the address specified; however, this does not change the subject of the report's address as reflected in the report that was submitted to the NPDB.

CHAPTER D: QUERIES

OVERVIEW

The NPDB is an information clearinghouse created by Congress with the primary goals of improving health care quality, protecting the public, and reducing health care fraud and abuse in the United States. The NPDB collects information on medical malpractice payments and certain adverse actions and discloses that information to eligible entities to facilitate comprehensive reviews of the credentials of health care practitioners, entities, providers, and suppliers. These payments and actions are required to be reported to the NPDB under Title IV of Public Law 99-660, the Health Care Quality Improvement Act of 1986 (Title IV); Section 1921 of the Social Security Act (Section 1921); Section 1128E of the Social Security Act (Section 1921); and their implementing regulations found at 45 CFR Part 60.

NPDB information is intended to be used in combination with information from other sources when entities are making decisions regarding licensure, employment, contracting, membership or clinical privileges, or when conducting investigations. The information available to an entity that submits a query to the NPDB is determined by the legislation authorizing the entity's eligibility to query. Fees are charged for all queries submitted to the NPDB.

The limited access provisions of the laws governing the NPDB do not permit disclosure of NPDB information to the general public that identifies the subjects of reports. However, data for statistical analysis purposes are available on the NPDB's website and can be downloaded. The Data Analysis Tool allows researchers to define and generate de-identified data sets for NPDB reports submitted on practitioners from 1990 through the end of the most recent calendar year. The Public Use Data File supplies de-identified information to researchers, journalists, and others to use to report on trends in patient safety and State reporting. Deidentified NPDB Research Statistics are available and can be downloaded or viewed. More specific data requests may be honored upon request. However, under Federal law, NPDB information cannot be used alone or in combination with other data to identify any individual or organization.

Table D-1 summarizes the NPDB information that is available to each type of authorized querier under each of the three statutes described above. Refer to Chapter E: Reports for more information regarding the types of actions that are reported to the NPDB.

The sections following Table D-1 contain detailed information about what entities and individuals must or may query the NPDB, including information about the type

of information available to the specific entities or individuals and how the specific entities and individuals are permitted to use the information they obtain from the NPDB.

When an entity queries the NPDB, the NPDB determines how the entity is registered with the NPDB before releasing information, and it releases only lawfully permitted information based on the entity's registration. Consequently, queriers do not have to know what categories of information are available to them, although the sections below explain the type of information available. However, because the NPDB releases information based upon an entity's registration, entities that query the NPDB must make sure they are properly registered. Most authorized entities are only permitted to query the NPDB at specific times, such as when a practitioner is applying for privileges or a license, or for a specific reason. Entities must be certain that they are querying only for authorized purposes.

NPDB Guidebook Chapter D: Queries

Table D-1: Information Available to Queriers as Authorized by Law, Part 1				
Law	Authorized Queriers	Available Information*	Subjects of Reports	
	Hospitals (required by law)	Medical malpractice payments	Practitioners	
	Other health care entities with formal peer review	Certain adverse licensure actions taken by State medical and dental boards	Physicians and dentists	
	Professional societies with formal peer review	Certain adverse clinical privileges actions	Primarily physicians and dentists	
Title IV	State medical and dental boards and other State licensing boards	Certain adverse professional society membership actions	Primarily physicians and dentists	
	Plaintiff's attorney/pro se plaintiff (limited circumstances)	DEA controlled-substance registration actions	Practitioners	
	Health care practitioners (self-query)	Exclusions from Medicare, Medicaid, and other Federal health care programs	Practitioners	

^{*}All authorized queriers are entitled to information in this column for subjects listed in the fourth column.

NPDB Guidebook Chapter D: Queries

	Table D-1: Information Available to Queriers as Authorized by Law, Part 2			
Law	Authorized Queriers	Available Information	Subjects of Reports	
	Hospitals* Other health care entities with formal peer review*	Negative actions or findings by peer review organizations	Practitioners	
	Health plans	Negative actions or findings by private accreditation organizations	Entities, providers, and suppliers	
	Professional societies with formal peer review*	State licensure and certification actions	Practitioners, entities, providers, and suppliers	
	Quality improvement organizations*			
	State licensing and certification authorities			
Section 1921 and Section 1128E	State law enforcement agencies** State Medicaid fraud control units** State agencies administering or supervising the administration of a State health care program** Agencies administering Federal health care programs, including private entities administering such programs under contract Federal licensing or certification agencies Federal law enforcement officials or agencies Practitioners, entities, providers, and suppliers requesting information concerning themselves (self-query)	Federal licensure and certification actions Exclusions from Federal or State health care programs* Health care-related civil judgments in Federal or State court* Health care-related criminal convictions in Federal or State court* Other adjudicated actions or decisions*	Practitioners, providers, and suppliers	

^{*} Hospitals, other health care entities, professional societies, and quality improvement organizations are not authorized to receive certain adverse actions reported under Section 1921, including exclusions from State health care programs, health care-related criminal convictions and civil judgments in State court, and other adjudicated actions or decisions.

^{**} NPDB regulations authorize State law or fraud enforcement agencies to query the NPDB. The regulations define a "state law or fraud enforcement agency" as including, but not limited to, these entities.

Hospitals

<u>Hospitals</u> are the only health care entities mandated by law to query the NPDB. Each hospital *must* request information from the NPDB as follows:

- When a physician, dentist, or other health care practitioner applies for medical staff appointment (courtesy or otherwise) or for clinical privileges at the hospital, including temporary privileges.
- Every 2 years (biennially) on all physicians, dentists, and other health care practitioners who are on its medical staff (courtesy or otherwise) or who hold clinical privileges at the hospital.

The biennial query may be done in accordance with regular medical staff reappointment and clinical privilege re-delineation. Additionally, hospitals are required to query the NPDB each time a practitioner wishes to add to or expand

Hospitals are the only health care entities mandated by law to query the NPDB.

existing privileges. Hospitals also must query when a practitioner applies for temporary privileges. Hospitals are not required to query more than once every 2 years on a practitioner who is

continuously on staff unless the practitioner wishes to add to or expand existing privileges or when a practitioner submits an application for temporary privileges. For example, if a practitioner applies for temporary clinical privileges four times in 1 year, the hospital must query the NPDB on each of those four occasions.

Hospitals are required to query on courtesy staff who are considered part of the medical staff, even if afforded only nonclinical professional courtesies such as use of the medical library and continuing education facilities. If a hospital extends nonclinical practice courtesies without appointing practitioners to a medical staff category, querying is not required on those practitioners.

Locum Tenens

A hospital is required to query the NPDB each time a locum tenens practitioner makes an application for temporary privileges. To reduce the query burden, hospitals that frequently use particular locum tenens practitioners may choose to appoint such practitioners to their consultant staff or other appropriate staff category in accordance with their bylaws and then query on the practitioners when their 2-year appointment is due for renewal.

Residents and Interns

Whether a hospital is required to query on an intern or resident depends upon whether the intern or resident is a member of the medical staff. Health care entities are not required to query the NPDB on medical and dental residents, interns, or staff fellows (collectively referred to as housestaff), even though they are often licensed, when they are trainees in structured programs of supervised graduate medical education and not members of the medical staff.

There is no difference between the housestaff of the clinical facility belonging to the formal medical education program and the housestaff rotating to a clinical facility providing a clinical training site for the formal medical educational program. Hospitals *are not required* to query the NPDB on housestaff providing services as part of their formal medical education.

However, hospitals *are required* to query on housestaff when such individuals are appointed to the medical staff or granted clinical privileges to practice outside the parameters of the formal medical education program (e.g., moonlighting in the intensive care unit or emergency department of that hospital).

Physicians, Dentists, and Other Health Care Practitioners

In addition to the mandatory requirements for querying, hospitals may request information from the NPDB at any time they deem necessary with respect to professional review activity. Furthermore, hospitals and their human resources and recruiting departments may query on all types of health care practitioners (e.g., nurses, nurse aides, physical therapists) with respect to making determinations regarding employment or affiliation relationships.

Results of Hospital Queries

Hospitals must query in the following situations:

- When a physician, dentist, or other health care practitioner applies for medical staff appointment (courtesy or otherwise) or for clinical privileges, including temporary privileges
- Every 2 years (biennially) on all physicians, dentists, and other health care practitioners who are on the medical staff (courtesy or otherwise) or who hold clinical privileges
- When a health care practitioner wishes to add to or expand existing privileges and when a practitioner submits an application for temporary privileges
- Each time a locum tenens health care practitioner makes an application for temporary privileges
- On residents and interns when such individuals are appointed to the medical staff or granted clinical privileges to practice outside the parameters of a formal medical education program

Generally, hospitals may query when the hospital is entering into an employment or affiliation relationship with the health care provider, or when the hospital is engaging in professional review activity.

Hospitals receive the following types of information in response to their queries:

- Medical malpractice payment information
- Licensure actions by boards of medical examiners
- Licensing and certification actions taken by States
- Federal licensing and certification actions
- Adverse actions taken by health care entities against clinical privileges, including professional review actions taken by professional societies
- Negative actions or findings by peer review organizations or private accreditation entities
- Health care-related criminal convictions
- Health care-related civil judgments
- Exclusions from participating in Federal or State health care programs
- Other health care-related adjudicated actions or decisions

Failure to Query

If a hospital does not query on a practitioner when required, the hospital is presumed to be aware of the information reported to the NPDB concerning the practitioner. A hospital's failure to query on a practitioner may give a plaintiff's attorney or plaintiff representing himself or herself access to NPDB information on that practitioner for use in litigation against the hospital.

Other Health Care Entities

Other health care entities generally may query the NPDB

- When they have or may be entering into employment or affiliation relationships with health care practitioners
- When health care practitioners apply for clinical privileges or medical staff appointments
- When they are engaging in professional review activity

Other health care entities receive the following types of information in response to their queries:

- Medical malpractice payment information
- Licensure actions by boards of medical examiners
- Licensure and certification actions taken by States

- Adverse actions taken by health care entities against clinical privileges, including professional review actions taken by professional societies
- Negative actions or findings by peer review organizations or private accreditation entities
- Health care-related criminal convictions when reported by Federal agencies or health plans
- Health care-related civil judgments when reported by Federal agencies or health plans
- Exclusions from participating in Federal or State health care programs when reported by Federal agencies or health plans
- Other health care-related adjudicated actions or decisions when reported by Federal agencies or health plans

Agencies Administering Government Health Care Programs, Including Private Entities Administering Such Programs Under Contract

Agencies administering Government health care programs, including private entities administering such programs under contract, may query the NPDB

- When they are determining the fitness of individuals to provide health care services
- When they are protecting the health and safety of individuals receiving health care through programs they administer
- When they are protecting the fiscal integrity of programs they administer

Agencies administering Government health care programs, including private entities administering such programs under contract, receive the following types of information in response to their queries:

- Licensure and certification actions taken by States
- Federal licensing and certification actions
- Negative actions or findings by peer review organizations or private accreditation entities
- Health care-related criminal convictions
- Health care-related civil judgments
- Exclusions from participating in Federal or State health care programs
- Other health care-related adjudicated actions or decisions

Federal Law Enforcement Officials and Agencies

Federal law enforcement officials and agencies may query the NPDB

- When they are determining the fitness of individuals to provide health care services
- When they are protecting the health and safety of individuals receiving health care through programs they administer
- When they are protecting the fiscal integrity of programs they administer

Federal law enforcement officials and agencies receive the following types of information in response to their queries:

- Licensure and certification actions taken by States
- Federal licensing and certification actions
- Negative actions or findings by peer review organizations or private accreditation entities
- Federal or State health care-related criminal convictions
- Health care-related civil judgments
- Exclusions from participating in Federal or State health care programs
- Other health care-related adjudicated actions or decisions

Federal Licensing and Certification Agencies

<u>Federal licensing and certification agencies</u> responsible for the licensing or certification of health care practitioners, providers, or suppliers may query the NPDB

- When they are determining the fitness of individuals to provide health care services
- When they are protecting the health and safety of individuals receiving health care through programs that they administer
- When they are protecting the fiscal integrity of the programs they administer

Federal licensing and certification agencies responsible for the licensing or certification of health care practitioners, providers, or suppliers receive the following types of information in response to their queries:

- Licensure and certification actions taken by States
- Federal licensing and certification actions
- Negative actions or findings by peer review organizations or private accreditation entities
- Federal or State health care-related criminal convictions
- Health care-related civil judgments
- Exclusions from participating in Federal or State health care programs
- Other health care-related adjudicated actions or decisions

Health Plans

Health plans may query the NPDB

- When they are determining the fitness of individuals to provide health care services
- When they are protecting the health and safety of individuals receiving health care through programs they administer
- When they are protecting the fiscal integrity of programs they administer

Health plans receive the following types of information in response to their queries:

- Licensure and certification actions taken by States
- Federal licensing and certification actions
- Negative actions or findings by peer review organizations or private accreditation entities
- Federal or State health care-related criminal convictions
- Health care-related civil judgments
- Exclusions from participating in Federal or State health care programs
- Other health care-related adjudicated actions or decisions

Professional Societies

Professional societies generally may query the NPDB

- When entering into an employment or affiliation (membership) relationship with a health care practitioner
- When engaging in a professional review activity

Professional societies receive the following types of information in response to their queries:

- Medical malpractice payment information
- Licensure actions by boards of medical examiners
- Licensure and certification actions taken by States
- Adverse actions taken by health care entities against clinical privileges, including professional review actions taken by professional societies
- Negative actions or findings by peer review organizations or private accreditation entities
- Health care-related criminal convictions when reported by Federal agencies or health plans
- Health care-related civil judgments when reported by Federal agencies or health plans
- Exclusions from participating in Federal or State health care programs when

- reported by Federal agencies or health plans
- Other health care-related adjudicated actions or decisions when reported by Federal agencies or health plans

Quality Improvement Organizations

Quality improvement organizations may query the NPDB

- When they are determining the fitness of individuals to provide health care services
- When they are protecting the health and safety of individuals receiving health care through programs they administer
- When they are protecting the fiscal integrity of programs they administer

Quality improvement organizations receive the following types of information in response to their queries:

- Licensure and certification actions taken by States
- Negative actions or findings by peer review organizations or private accreditation entities
- Health care-related criminal convictions when reported by Federal agencies or health plans
- Health care-related civil judgments when reported by Federal agencies or health plans
- Exclusions from participating in Federal or State health care programs when reported by Federal agencies or health plans
- Other health care-related adjudicated actions or decisions when reported by Federal agencies or health plans

State Agencies Administering or Supervising the Administration of a State Health Care Program

<u>State agencies</u> administering or supervising the administration of a State health care program may query the NPDB

- When they are determining the fitness of individuals to provide health care services
- When they are protecting the health and safety of individuals receiving health care through programs they administer
- When they are protecting the fiscal integrity of programs they administer

State agencies administering or supervising the administration of a State health care program receive the following types of information in response to their queries:

- Licensure and certification actions taken by States
- Federal licensing and certification actions
- Negative actions or findings by peer review organizations or private accreditation entities
- Federal or State health care-related criminal convictions
- Health care-related civil judgments
- Exclusions from participating in Federal or State health care programs
- Other health care-related adjudicated actions or decisions

State Law Enforcement Agencies and State Medicaid Fraud Control Units

State law enforcement agencies and State Medicaid fraud control units may query the NPDB

- When they are determining the fitness of individuals to provide health care services
- When they are protecting the health and safety of individuals receiving health care through programs they administer
- When they are protecting the fiscal integrity of programs they administer

State law enforcement agencies and State Medicaid fraud control units receive the following types of information in response to their queries:

- Licensure and certification actions taken by States
- Federal licensing and certification actions
- Negative actions or findings by peer review organizations or private accreditation entities
- Federal or State health care-related criminal convictions
- Health care-related civil judgments
- Exclusions from participating in Federal or State health care programs
- Other health care-related adjudicated actions or decisions

State Licensing and Certification Agencies

State licensing and certification agencies may query the NPDB

- When they are determining the fitness of individuals to provide health care services
- When they are protecting the health and safety of individuals receiving health care through programs that they administer
- When they are protecting the fiscal integrity of the programs they administer

State licensing and certification agencies receive the following types of information in response to their queries:

- Licensure and certification actions taken by States
- Federal licensing and certification actions
- Negative actions or findings by peer review organizations or private accreditation entities
- Federal or State health care-related criminal convictions
- Health care-related civil judgments
- Exclusions from participating in Federal or State health care programs
- Other health care-related adjudicated actions or decisions

State Medical Boards of Examiners or Other State Authorities that License Health Care Practitioners

<u>State medical boards of examiners</u> or other State authorities that license health care practitioners may query the NPDB at any time. These authorities receive the following types of information in response to their queries:

- Medical malpractice payment information
- Licensure actions by boards of medical examiners
- Adverse actions taken by health care entities against clinical privileges, including professional review actions taken by professional societies

Note that entities that qualify as State medical boards of examiners or other State authorities that license health care practitioners also qualify as State licensing and certification agencies and therefore are eligible to receive information listed under that section.

Health Care Practitioners, Entities, Providers, and Suppliers

Health care practitioners, entities, providers, and suppliers may request information concerning themselves from the NPDB (<u>Self-Query</u>) at any time.

Attorney Access

A plaintiff's attorney or a plaintiff representing himself or herself is permitted to obtain certain information from the NPDB under the following limited conditions:

- A medical malpractice action or claim must have been filed by the plaintiff against a hospital in a State or Federal court or other adjudicative body;
- The practitioner on whom the information is requested must be named in the action or claim; and
- Evidence must be submitted to the Department of Health and Human Services

demonstrating that the hospital failed to submit a mandatory query to the NPDB regarding the practitioner named by the plaintiff in the action.

Evidence that the hospital failed to query the NPDB must be obtained by the plaintiff from the hospital through discovery in the litigation process. This evidence is not available to the plaintiff through the NPDB.

The plaintiff's attorney must submit all of the following to the NPDB:

- A letter requesting authorization to obtain information
- Supporting evidence that the hospital did not make a mandatory query of the NPDB regarding the practitioner named by the plaintiff in the action or claim
- Identifying information about the practitioner on whom the attorney wishes to query

The letter should be sent to one of the following addresses:

Standard Mail	Overnight Mail
National Practitioner Data Bank P.O. Box 10832 Chantilly, VA 20153-0832	National Practitioner Data Bank 4094 Majestic Lane PMB-332 Fairfax, VA 22033

Examples of evidence may include a deposition, a response to an interrogatory, an admission, or other evidence of the failure of a hospital to request information. The plaintiff's attorney must submit a separate request for information disclosure for each practitioner named in the action or claim. If the NPDB concludes that attorney access is appropriate in a specific case, it will give the hospital an opportunity to respond to the request before releasing the requested information.

The approval of a request by a plaintiff's attorney is limited to a one-time-only disclosure; the approval of such a request does not allow a plaintiff's attorney to obtain NPDB information on a continuing basis. Subsequent disclosures of NPDB information require the plaintiff's attorney to initiate a new request. A fee is assessed when the NPDB discloses such information.

An approved query request entitles the plaintiff's attorney to receive only that information available in the NPDB at the time the hospital was required to query but did not. It also includes information on any reports that subsequently were voided. Information that will be made available to the plaintiff's attorney is limited to reports submitted to the NPDB under the authority of Title IV, including medical malpractice payments, State licensure actions taken by a State medical or dental board, clinical privileges actions, professional society membership actions, Drug

Enforcement Administration controlled-substance registration actions, and exclusions from Medicare, Medicaid, and other Federal health care programs.

There are limitations on the use of information obtained by the plaintiff in a judicial proceeding. Specifically, the information obtained from the NPDB on the practitioner can be used only with respect to a legal action or claim against the hospital, not against the practitioner. Any further disclosure or use violates the NPDB <u>confidentiality provisions</u> and subjects the plaintiff's attorney and/or plaintiff to a civil money penalty of up to \$11,000.

AUTHORIZED AGENTS

Eligible entities may elect to have an <u>authorized agent</u> query the NPDB on their behalf. Authorized agents may be agents for more than one eligible entity. Authorized agents must query the NPDB *separately* on behalf of each eligible entity. The response to an NPDB query submitted for one entity cannot be disclosed to another entity.

CENTRALIZED CREDENTIALING

Health systems composed of multiple health care entities (e.g., several hospitals, outpatient surgery centers, and clinics) often have practitioners providing health care services at more than one of their health care entities. If a health care system conducts its credentialing centrally, has a centralized peer review process, and has one decisionmaking body, the health care system may query the NPDB once on each practitioner during the professional review process, regardless of whether the practitioner provides health care services in one or multiple entities. However, if the system's health care entities each conduct their own credentialing, and each health care entity grants privileges to provide health care services only in its facility, each health care entity must query the NPDB separately on its own practitioners. In these instances, sharing query responses is prohibited. See Data Bank Identification Numbers in Chapter B: Eligible Entities.

The work of querying in a health system environment composed of multiple health care entities is often performed by a Credentials Verification Organization (CVO), which gathers data and verifies credentials of physicians and other health care practitioners on behalf of its own organization or other organizations. CVOs examine numerous sources in addition to the NPDB as they gather credentialing information.

A CVO operating in an environment with a centralized peer review process and decisionmaking body should register with the NPDB as a single entity. A CVO should register with the NPDB as an agent if each health care entity for which it

works conducts its own credentialing and grants privileges at its own facility. When a CVO is registered as an agent, each facility for which it works must register separately with the NPDB as a health care entity.

DELEGATED CREDENTIALING

Delegated credentialing occurs when a health care entity gives another health care entity the authority to credential its health care practitioners (e.g., a preferred provider organization [PPO] delegates its credentialing to a hospital). Delegated credentialing goes beyond credentials verification, because the delegated health care entity (e.g., the hospital) is responsible for evaluating practitioners' qualifications and making credentialing decisions on behalf of the delegating health care entity (e.g., the PPO).

In a delegated credentialing arrangement, the health care entity that delegates its credentialing responsibilities (e.g., the PPO) is not considered part of the credentialing process and is prohibited from receiving NPDB query results. In contrast, a health care entity that uses an authorized agent to query on its behalf still retains responsibility for credentialing its practitioners.

Therefore, if a PPO or similar health care entity delegates its credentialing to a hospital or other health care entity and also designates the hospital as its authorized agent, the following apply:

 An NPDB query submitted by the hospital as a delegate cannot be shared A hospital's mandatory query must be submitted either directly by the hospital or through an authorized agent.

- with the PPO because the PPO is neither responsible for the credentialing nor part of the decisionmaking process. The query, in this instance, is for the exclusive use by the hospital in credentialing.
- In contrast, if an NPDB query is submitted by the hospital as an authorized agent on behalf of the PPO, the query response is for the PPO's use and the hospital is prohibited from using the same query as part of its credentialing.

A hospital may not delegate its responsibility to query the NPDB. A hospital's mandatory query must be submitted to the NPDB either directly by the hospital or through an authorized agent.

SUBMITTING A QUERY

Eligible entities that are registered with the NPDB may query the NPDB in one of two ways:

- A <u>One-Time Query (formerly known as Traditional Query)</u> involves submitting
 the name of a health care practitioner, entity, provider, or supplier and receiving
 a query response that includes all NPDB reports on that individual or
 organization that the eligible entity is authorized to receive.
- A <u>Continuous Query</u> involves enrolling practitioners for a 12-month period.
 Once practitioners are enrolled, the eligible entity receives a confirmation of
 enrollment, all current reports (a One-Time Query response), and notice of new
 reports within 24 hours of NPDB's receipt of the reports during the enrollment
 period. Hospitals that enroll their practitioners in Continuous Query fulfill the
 mandatory requirements for querying the NPDB.

Both One-Time Queries and Continuous Queries can be submitted via the Integrated Querying and Reporting Service (IQRS) on the NPDB website or through an external application.

The <u>Self-Query service</u> is available on the NPDB website for health care practitioners, entities, providers, and suppliers that wish to find out if there is a report on them in the NPDB.

Querying Through an Authorized Agent

The NPDB's response to a query submitted by an authorized agent on behalf of an entity is based upon two eligibility standards:

- The entity must be eligible to receive the information, and
- The agent must be designated to receive that information on behalf of that entity.

Both the entity and the agent must be properly registered with the NPDB prior to the authorized agent's query submission.

Before an <u>authorized agent</u> submits queries on behalf of an eligible entity, the entity must designate the agent by completing an online Authorized Agent Designation form. The eligible entity must indicate whether it would prefer the NPDB to send query responses to the entity, to the authorized agent, or to both. An eligible querier that has designated an authorized agent also is permitted to query the NPDB directly. Responses to queries submitted by the entity will be returned to the entity, regardless of the routing designated for queries submitted by their agent.

Authorized agents cannot use a query response on behalf of more than one entity. NPDB regulations specify that information received from the NPDB must be used solely for the purpose for which it was provided. If two different entities designate the same authorized agent to query the NPDB on their behalf, and both entities wish

to request information on the same subject, the authorized agent must query the NPDB separately on behalf of each entity. The response to a query submitted for one entity cannot be disclosed to the other entity. Such a disclosure would be a violation of the NPDB confidentiality restrictions.

However, if a health care system uses an authorized agent and conducts its <u>credentialing centrally</u>, has a centralized peer review process, and has one decisionmaking body, the health care system may query the NPDB once on each practitioner during the professional review process, regardless of whether the practitioner provides health care services in one or multiple entities.

Subject Information

When submitting a query or enrolling a practitioner in Continuous Query, the entity is required to provide certain information regarding the subject of the query. The NPDB system requires queries to include information in all mandatory fields. An entity's lack of mandatory information does not relieve the entity of its querying requirements as mandated by law.

QUERY PROCESSING

When the NPDB receives a properly completed query, the NPDB performs a validation process that matches the query subject's identifying information with

information previously reported to the NPDB. Information reported about a specific subject is released to an eligible querier *only* if the identifying information provided in the

The NPDB performs a validation process that matches the query subject's identifying information with information previously reported to the NPDB.

query matches the information in a report submitted to the NPDB. If the information submitted in a query does not accurately identify the intended practitioner, the query may not match any NPDB reports naming the intended practitioner that include the correct identifying information.

Each query processed by the NPDB is assigned a unique Data Bank Control Number (DCN). The DCN is used by the NPDB to locate the query within the system and is prominently displayed on any electronic response. If a question arises concerning a particular query, the entity must reference the DCN in any correspondence to the NPDB.

Subject Database

Maintaining a Subject Database (which may include practitioners and

organizations) on the IQRS eliminates the need to re-enter information into a query or report form. The IQRS retrieves all pertinent information from the entity's Subject Database and places it on the appropriate query screens. However, if a record in the Subject Database is incomplete (i.e., information is missing in required fields), the IQRS does not allow a query to be generated for that subject until the missing information is added. Creating and maintaining a Subject Database can make entering the required information for a query or report faster by automatically pre-populating forms with identifying information, eliminating the need to retype data.

Query Responses

A query response identifies whether there are any reports in the NPDB on the subject of the query and presents copies of all reports. Queriers can view, print, and download their query responses online. Entities must retrieve official query responses within 45 days of processing, or they will be required to resubmit their queries and pay the associated query fee. Entities that wish to save query responses should download them. Continuous Query enrollment confirmations are available for the entire enrollment period as long as the enrollment is not canceled.

Missing Query Responses

If an entity does not receive a query response within one business day of submission, the entity should contact the <u>NPDB Customer Service Center</u> to request a query status. The entity should not resubmit a query on the subject in question, as this will result in duplicate transactions and duplicate query fees.

Notifying the NPDB of a Missing Report

If, based on information received in a query response, an entity believes that a reportable action was not submitted to the NPDB, the entity should go to the Subjects Queried page (or the Multiple-Name Query Responses page for bundled responses), click the Reporting Compliance link, and provide the information regarding the missing report.

RETRIEVING HISTORICAL QUERY SUMMARIES

When an eligible entity initially submits a query, the results are available for 45 days and can be saved either electronically or in hard copy. There may be times, however, when an eligible entity needs to verify or search for specific organizations or individuals on which the entity previously queried. Eligible entities also may want to verify their querying activity within a certain time period. Historical query summaries are available and provide the history of when an eligible entity queried

the NPDB. The historical query summaries do not include the query results. See Retrieving Historical Report and Query Summaries.

CONFIDENTIALITY

Information reported to the NPDB is considered <u>confidential</u> and will not be disclosed except as specified in the NPDB statutes (Title IV, Section 1921, and Section 1128E) and implementing regulations (45 CFR Part 60). Confidential receipt, storage, and disclosure of information are essential ingredients of NPDB operations. The confidentiality provisions of Title IV, Section 1921, and Section 1128E allow an eligible entity receiving information from the NPDB to disclose the information to others who are part of an investigation or peer review process, as long as the information is used for the purpose for which it was provided. In those instances, everyone involved in the investigation or peer review process is subject to the confidentiality provisions of the NPDB.

Q&A: QUERIES

1. Under what conditions are hospitals required to query every 2 years on courtesy staff members?

Hospitals are required to query on courtesy staff considered part of the medical staff, even if afforded only non-clinical professional courtesies such as use of the medical library and continuing education facilities. If a hospital extends non-clinical practice courtesies without first appointing practitioners to a medical staff category, querying is not required on those practitioners.

2. Are hospitals required to query the NPDB on medical and dental interns and residents?

When <u>interns and residents</u> are trainees in structured programs of supervised graduate medical education and are not members of the medical staff in a formal sense, there is no requirement to query on them. Hospitals may choose to query on residents and interns, since medical malpractice payments made for the benefit of, and certain adverse actions taken against, licensed residents and interns are reported to the NPDB.

However, if the resident or intern is being considered for clinical privileges outside his or her structured program (e.g., moonlighting in an emergency room), the hospital must query the NPDB.

3. Are hospitals required to document and maintain records of their requests for information?

The NPDB implementing regulations do not require hospitals to document or maintain records of their NPDB queries. However, the query responses may serve as evidence that a hospital queried the NPDB as mandated. Query responses are available for 45 days in the NPDB system. The NPDB also has a Historical Query and Report Summary feature that provides a summary of an eligible entity's query history and provides a history of when an eligible entity queried the NPDB. The historical query summaries do not include the query results.

4. If a health care entity cannot find or did not receive a response to a query, may the health care entity request a copy from the NPDB?

No. The NPDB does not have the capability to produce duplicate responses. If the health care entity did not receive a response to a query and was not charged for the query, the query has not been processed by the NPDB and should be resubmitted. Once processed by the NPDB, <u>query responses</u> will be maintained in the NPDB system for 45 days. After the response is no longer available, the health care entity will have to resubmit the query to receive a response. If a health care entity was charged for a query that it did not receive, the entity should contact the <u>NPDB Customer Service Center</u> within one business day of submission to ask about the status of a query. The health care entity should not resubmit a query on the subject in question, because this will result in duplicate transactions and duplicate query fees.

5. A hospital would like to enroll its medical staff in Continuous Query. Will the hospital still have to submit One-Time Queries when the hospital's mandated 2-year review is due?

No. A hospital meets its statutory requirements to query as long as the hospital's practitioners are enrolled in <u>Continuous Query</u> at the time of the mandated 2-year review.

6. May self-queries be used to satisfy a hospital's mandatory query requirements?

No. While practitioners may share the information contained in their own Self-Query responses with whomever they choose, such shared information *does not* satisfy a <u>hospital's legal requirement</u> to query the NPDB.

7. A hospital is in bankruptcy. Is it still required to query the NPDB?

If a hospital has ongoing business and is functioning as a hospital while

concluding its <u>liquidation</u>, even as a debtor-in-possession, it *must* continue to query the NPDB. If the hospital is in liquidation solely for the purpose of a sale of assets, and there is no ongoing business as a hospital, there is no reason to query the NPDB.

8. During a hospital's credentialing process, an NPDB query is included in the materials presented to the credentialing committee for peer review. A health care practitioner appeals a decision made by the credentialing committee, and the appeal goes to a separate review body that was not involved in the original decision. Is providing the NPDB query result to the appeal body a violation of NPDB confidentiality rules?

No. The NPDB confidentiality provisions allow an eligible entity receiving information from the NPDB to disclose the information to others who are <u>part</u> of the <u>peer review process</u> as long as the information is used for the purposes for which it was provided.

9. What are the benefits of using Continuous Query instead of submitting One-Time Queries?

Continuous Query keeps eligible entities continually informed about reports of medical malpractice payments and certain adverse actions concerning enrolled practitioners. Enrolling practitioners in Continuous Query provides ongoing monitoring of NPDB reports. It eliminates the need for staff to manually submit queries. Eligible entities receive email notifications within 24 hours of a report being received by the NPDB on an enrolled practitioner.

10. May hospitals query on health care practitioners who they do not credential or privilege but who they hire, such as nurses?

Yes. Hospitals and other health care entities may query on practitioners when making determinations regarding employment or affiliation. For example, the human resources departments of hospitals and health care entities may query the NPDB on nurses, nurse aides, radiological technicians, physical therapists, and other health care practitioners when making hiring decisions.

11. A hospital recently queried the NPDB on a physician who was subsequently granted privileges. If the hospital obtains written consent from the physician, may the hospital share the NPDB query results with another health care entity that is not part of the hospital's investigation or peer review process but is registered with the NPDB?

No. The confidentiality provisions of Title IV, Section 1921, and Section 1128E allow an eligible entity receiving information from the NPDB to disclose the information to others who are part of the investigation or peer review process, as long as the information is used for the purpose for which it was provided. Sharing the practitioner's query with a health care entity that is not part of the hospital's investigation or peer review process would violate the confidentiality provisions of the NPDB, regardless of the written consent from the physician. The other registered health care entity may perform its own query, as authorized by NPDB statutes and regulations.

12. An advanced practice nurse (APRN) is applying for a position at a hospital. Does the hospital have to query the NPDB on the nurse?

It depends. If the hospital considers the position the APRN is applying for to be on the hospital's medical staff, or if the APRN will hold clinical privileges at the hospital, the hospital must query on the APRN when the APRN applies and biennially thereafter while the APRN is on staff or holds privileges. If the hospital does not consider the position to be on the medical staff or if the APRN will not hold clinical privileges, the hospital is not required to query on the APRN. It may do so if it desires, however.

CHAPTER E: REPORTS

OVERVIEW

The NPDB is a confidential information clearinghouse created by Congress with the primary goals of improving health care quality, protecting the public, and reducing health care fraud and abuse in the United States. Acting primarily as a national flagging system, the NPDB provides information that permits queriers to perform comprehensive reviews of the credentials of health care practitioners, entities, providers, and suppliers. The NPDB collects information on medical malpractice payments and certain adverse actions and discloses that information to

The information required to be reported to the NPDB concerns health care practitioners, entities, providers, and suppliers.

eligible entities. These payments and actions are required to be reported to the NPDB under Title IV of Public Law 99-660, the Health Care Quality Improvement Act of

1986 (Title IV); Section 1921 of the Social Security Act (Section 1921); Section 1128E of the Social Security Act (Section 1128E); and their implementing regulations found at 45 CFR Part 60.

Entities that are required to report to the NPDB include medical malpractice payers, hospitals and other health care entities, professional societies, health plans, peer review organizations, private accreditation organizations, Federal Government agencies, State law enforcement agencies, State Medicaid fraud control units, State agencies administering or supervising the administration of a State health care program, and State licensing and certification authorities (including State medical and dental boards). The information required to be reported to the NPDB concerns health care practitioners, entities, providers, and suppliers.

The NPDB is meant to be used as one of many tools available to health care entities of all types as they make licensing, certification, hiring, credentialing, contracting, and similar decisions. The NPDB can provide valuable background information, but health care entities should use the NPDB in conjunction with other resources when making personnel and contracting decisions.

Reporting Requirements

Eligible entities are responsible for meeting specific querying and/or reporting requirements and must <u>register with the NPDB</u> in order to query or report to the NPDB. Entities may qualify as more than one type of eligible entity. In such cases, the entity must comply with all associated querying and reporting responsibilities.

Table E-1 summarizes NPDB reporting requirements.

The reporting requirements summarized in Table E-1 are described in greater detail in this chapter. As shown in the table, each of the three major statutes governing NPDB operations has its own reporting requirements. In some instances, actions must be reported based on memorandums of understanding. In certain cases, requirements may exist under more than one statute, or under both a statute and a memorandum of understanding. For example, as discussed in Chapter B: Eligible Entities, the Drug Enforcement Administration's (DEA's) controlled-substance registration actions are reported to the NPDB under Title IV based on a memorandum of understanding; the Department of Health and Human Services (HHS) Office of Inspector General's (OIG's) exclusions from Medicare, Medicaid, and other Federal health care programs are reported to the NPDB under Title IV based on an interagency agreement. Both DEA and OIG actions also must be reported to the NPDB under Section 1128E.

Terminology Differences

An action must be reported to the NPDB based on whether it satisfies NPDB reporting requirements and not based on the name affixed to the action by a reporting entity. For example, whether an <u>administrative fine</u> is reportable to the NPDB depends upon whether the fine meets NPDB reporting requirements, not on the name affixed to the fine. A <u>suspension</u> or restriction of clinical privileges is reportable if it meets reporting criteria, whether the suspension or restriction is called summary, immediate, emergency, precautionary, or any other term.

Time Frame for Reporting

Eligible entities must report medical malpractice payments and other required actions to the NPDB within 30 calendar days of the date the action was taken or the payment was made.

The time frame for reporting each type of action described in Table E-1 is summarized in Table E-2.

The NPDB cannot accept reports with a date of payment or a date of action prior to September 1, 1990, with the exception of Medicare and Medicaid exclusions submitted by the OIG.

If an eligible entity discovers documentation of medical malpractice payments, adverse actions, or judgments or convictions that the eligible entity had not reported to the NPDB, the entity must promptly submit the related report(s). All required reports must be filed with the NPDB regardless of whether they are late.

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Table E-1: Summary of Reporting Requirements, Part 1					
Law	Who Reports?	What is Reported?	Who is Reported?		
Title IV	Medical malpractice payers, including hospitals and other health care entities that are self-insured	Medical malpractice payments resulting from a written claim or judgment	Practitioners		
		Certain adverse licensure actions related to professional competence or conduct			
	State medical and dental boards	(Medical and dental boards that meet their reporting requirements for Section 1921, described in Part 2 of this table, will also meet their requirements to report under Title IV)	Physicians and dentists		
	Hospitals	Certain adverse clinical privileges actions related to	Physicians and dentists		
	Other health care entities with formal peer review	professional competence or conduct	Other practitioners (optional)		
		Certain adverse professional society membership actions	Physicians and dentists		
	Professional societies with formal peer review	related to professional competence or conduct	Other practitioners (optional)		
	DEA	DEA controlled-substance registration actions*	Practitioners		
	OIG	Exclusions from participation in Medicare, Medicaid, and other Federal health care programs*	Practitioners		

^{*} This information is reported to the NPDB under Title IV based on a memorandum of understanding.

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	Table E-1: Summary of Reporting Requirements, Part 2				
Law	Who Reports?	What is Reported?	Who is Reported?		
	Peer review organizations	Negative actions or findings by peer review organizations	Practitioners		
	Private accreditation organizations	Negative actions or findings by private accreditation organizations	Entities, providers, and suppliers		
Section	State licensing and certification authorities	State licensure and certification actions	Practitioners, entities, providers, and suppliers		
Section 1921	State law enforcement agencies* State Medicaid fraud control units* State agencies administering or supervising the administration of a State health care program* State prosecutors	Exclusions from participation in a State health care program Health care-related civil judgments in State court Health care-related State criminal convictions Other adjudicated actions or decisions	Practitioners, providers, and suppliers		
Section 1128E	Federal agencies Federal prosecutors Health plans	Federal licensure and certification actions** Health care-related civil judgments in Federal or State court Health care-related criminal convictions in Federal or State court** Exclusions from participation in a Federal health care program** Other adjudicated actions or decisions	Practitioners, providers, and suppliers		

^{*} NPDB regulations define "state law or fraud enforcement agency" as including but not limited to these entities.

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^{**} Reported only by Federal agencies.

Table E-2: Time Frame for Reporting				
Types of Actions that Must Be Reported	When Information Must be Reported			
Medical malpractice payments				
Certain adverse licensure actions related to professional competence or conduct (reported under Title IV)				
Certain adverse clinical privileges actions related to professional competence or conduct	Within 30 days of the date the action was taken			
Certain adverse professional society membership actions related to professional competence or conduct	or the payment was issued, beginning with actions occurring on or after September 1, 1990			
DEA controlled-substance registration actions on practitioners (reported under Title IV)				
Exclusions from participation in Medicare, Medicaid, and other Federal health care programs (reported under Title IV)				
Negative actions or findings taken by peer review organizations	Within 30 days of the date the action was taken,			
Negative actions or findings taken by private accreditation organizations	beginning with actions occurring on or after January 1, 1992			
State licensure and certification actions				
Federal licensure and certification actions				
Health care-related criminal convictions in Federal or State court	Within 30 days of the date the action was taken,			
Health care-related civil judgments in Federal or State court	beginning with actions occurring on or after August 21, 1996			
Exclusions from participation in a Federal or State health care program.				
Other adjudicated actions or decisions				

Entities are not excused from reporting simply because they missed a reporting deadline. The Secretary of HHS will conduct an investigation if there is reason to believe an entity substantially failed to report required medical malpractice payments or adverse actions. Entities have the opportunity to correct the noncompliance (see Sanctions for Failing to Report to the NPDB in the sections

discussing the reporting requirement for each type of action).

Deceased Practitioners

One of the principal objectives of the NPDB is to restrict the ability of incompetent physicians, dentists, and other health care practitioners to move from State to State without the disclosure or discovery of their previous damaging or incompetent performance. Reports concerning deceased practitioners must be submitted to the NPDB because a fraudulent practitioner could assume the identity of a deceased practitioner. When submitting a report on a deceased practitioner, indicate that the practitioner is deceased in the appropriate data field.

Report Retention

Information reported to the NPDB is maintained permanently in the NPDB, unless it is corrected or voided from the NPDB by the reporting entity or by the NPDB as a result of the Dispute Resolution process.

Civil Liability Protection

The immunity provisions in Title IV, Section 1921, and Section 1128E protect individuals, entities, and their authorized agents from being held liable in civil actions for reports made to the NPDB unless they have actual knowledge of falsity of the information contained in the report. These provisions provide the same immunity to HHS in maintaining the NPDB.

Official Language

The NPDB's official language is English. All reports must be submitted in English. Files submitted in any other language or containing non-alphanumeric characters (e.g., tildes, accents, umlauts) are not accepted.

SUBMITTING REPORTS TO THE NPDB

Report Formats

The NPDB uses three report formats to capture the necessary information for report submissions. These report formats are:

- Medical Malpractice Payment Report (MMPR), for reporting medical malpractice payments
- Judgment or Conviction Report, for reporting health care-related criminal convictions and civil judgments in Federal or State court
- Adverse Action Report, for reporting all other actions required to be submitted

to the NPDB

All fields required by specific report formats must be completed successfully before a report can be generated. If an entity does not have all the required information, the entity is responsible for obtaining the information so that the entity can comply with its reporting requirements. An entity's lack of mandatory information does not relieve the entity of its reporting requirements.

The NPDB recommends that each reporting entity review the report form fields and make an effort to routinely collect information on health care practitioners, entities, providers, and suppliers (as appropriate) before there is a reason to submit a report (e.g., during the application process for a license or clinical privileges). In submitting a report, all required information must be completed properly.

For assistance with submitting a report, contact the <u>NPDB Customer Service</u> Center.

Types of Reports

Reporting entities are responsible for the accuracy of information they report to the NPDB and for keeping information reported to the NPDB up to date. Reports submitted to the NPDB are permanently maintained unless corrected or voided by the reporting entity or by the NPDB through the <u>Dispute Resolution</u> process. The following report types facilitate accurate reporting.

Initial Report

The first report of a medical malpractice payment, adverse action, or judgment or conviction submitted to and processed by the NPDB is considered the Initial Report. When the NPDB processes an Initial Report, the NPDB provides the reporting entity with a Report Verification Document. The NPDB also sends a notification to the subject of the report. The reporting entity and the subject of the report should review the report information to ensure that it is accurate. For certain types of actions, reporters also must provide a copy of the report to the appropriate State licensing board or State licensing or certification authority.

Correction Report

A Correction Report corrects an error or omission in a previously submitted report by replacing it. The reporting entity must submit a Correction Report as soon as possible after the discovery of an error or omission in a report. The reporting entity may submit a Correction Report as often as necessary.

When the NPDB processes a Correction Report, the NPDB provides the reporting entity with a Report Verification Document. In addition, the NPDB sends a

notification to the subject of the report and a copy to all queriers who received the previous version of the report within the past 3 years. The reporting entity and the subject of the report should review the report information to ensure that it is accurate, and past queriers should note the changed report. For certain types of actions, reporters must provide a copy of the processed report to the appropriate State licensing board or State licensing or certification authority.

Example: A hospital reports a clinical privileges action to the NPDB, generating an Initial Report. Upon receiving the Report Verification Document, the hospital identifies an error in the practitioner's address. The hospital must submit a Correction Report with the corrected address. The Correction Report replaces the Initial Report.

Void Report

A Void Report, also referred to as a Void, is the withdrawal of a report in its entirety. When the reporting entity voids a report, the report is removed from the disclosable record of the subject of the report. A reporting entity may void a report at any time. The three reasons for voiding a report are:

- The report was submitted in error
- The action was not reportable because it did not meet NPDB reporting requirements
- The action was overturned on appeal

When the NPDB processes a Void, the NPDB provides the reporting entity with a Report Void Confirmation. The NPDB also sends a notification to the subject and to all queriers who received the previous version of the report within the past 3 years. All queriers who received the previous version of the report within the past 3 years are directed to destroy the prior report and any copies of it. The reporting entity and the subject of the report should review the information to ensure that the intended report was voided, and past queriers should note that the report was voided. For certain types of actions, the reporting entity also must provide a copy of the Report Void Confirmation to the appropriate State licensing or certification authority.

Example: A State medical board submits an Initial Report to the NPDB when it revokes a physician's license. Six months later, the revocation is overturned by a State court. The State medical board must void the Initial Report.

Revision-to-Action Report

A Revision-to-Action Report is a report of an action that modifies an adverse action previously reported to the NPDB. A Revision-to-Action Report does not replace a

previously reported adverse action but rather is treated as a separate action that pertains to the previous action. Both reports become part of the disclosable record. The entity that reports an initial adverse action also must report any modification of that action

Examples of when a Revision-to-Action Report should be submitted include:

- When additional sanctions have been taken against the subject of a report based on a previously reported incident
- When the length of action has been extended or reduced
- When clinical privileges, professional society membership, accreditation, program participation, or a license has been reinstated
- When the original suspension or probationary period has ended

Reporting entities do not need to submit a Revision-to-Action Report in cases in which the subject of the report will be reinstated automatically after the adverse action period is complete and the reporting entity selected "Yes" to the question on the related report regarding whether the subject of the report will be reinstated automatically without conditions.

The NPDB system will not accept a Revision-to-Action Report unless a related report was submitted previously. A Revision-to-Action Report is not available for submitting Medical Malpractice Payment Reports.

A Revision-to-Action Report is separate and distinct from a Correction Report. For example, if a hospital enters the date of action incorrectly on an Initial Report, a Correction Report must be submitted to make the necessary change to the date, and

the Correction Report replaces the Initial Report. However, if the hospital reports an initial action to the NPDB to suspend a physician's clinical privileges for 60 days and

A Revision-to-Action Report is not available for submitting Medical Malpractice Payment Reports.

subsequently reinstates the physician's privileges after reducing the suspension to 45 days, the hospital must submit a Revision-to-Action Report regarding the reinstatement. A Revision-to-Action Report is treated as an addendum to the Initial Report. Together, the Initial Report and the Revision-to-Action Report provide a more complete explanation of the events.

Example 1: A hospital reports a clinical privileges action when it suspends a practitioner's clinical privileges for 90 days for unprofessional conduct. The hospital later reduces the suspension to 45 days. Since this reduction in the length of the suspension modifies a previously reported action, the hospital must submit a Revision-to-Action Report. The Initial Report documents that

the hospital suspended the subject's clinical privileges for 90 days, and the Revision-to-Action Report documents that the hospital reduced the suspension to 45 days. Note that in this example both reports – the 90-day suspension report and the 45-day suspension report – were correct when they were filed. Therefore, the change is noted with a Revision-to-Action Report, not a Correction Report.

Example 2: A State medical board reprimands a physician and mandates that she complete 5 hours of continuing education units (CEUs) within 3 months. The State board must submit an Initial Report, which documents that the State medical board reprimanded the physician and required her to complete the CEUs. The physician does not complete the CEUs within the allotted time, and the medical board places her license on probation until she completes the required CEUs. The medical board then must submit a Revision-to-Action Report, which documents that the State medical board placed the physician's license on probation until she completes the CEUs.

A Revision-to-Action Report is appropriate only if it *modifies* the previously submitted report.

Example 3: A State licensing board issues an order suspending a pharmacist's license for 3 months. In the order, the board states that the pharmacist must take additional training before the license is reinstated, and it states that the board must approve the pharmacist's choice of training. The board files an Initial Report with the NPDB reflecting the details of the order. The pharmacist returns to the board to seek approval of his choice of training, which the board grants in another formal order. The licensing board should not submit a Revision-to-Action Report after it approves the pharmacist's choice of training – even if the board publishes the second formal order – because nothing about the second order modified what was described in the Initial Report. (In addition, the published second order is not the type of adverse action that would require the board to file another Initial Report.)

When the NPDB processes a Revision-to-Action Report, the NPDB provides the reporting entity with a Report Verification Document. The NPDB also sends a notification to the subject of the report. The reporting entity and the subject of the report should review the information to ensure that it is correct. For certain types of actions, reporters also must provide a copy of the Report Verification Document for the Revision-to-Action Report to the appropriate State licensing or certification authority.

Notice of Appeal

A Notice of Appeal notifies the NPDB that a subject of a report has formally appealed a previously reported adverse action with the entity taking the action. A Notice of Appeal is attached to an existing report. It is separate and distinct from a <u>subject's dispute of an NPDB report</u>. Reporters must submit a Notice of Appeal for the following actions when the previously reported action is on appeal:

- State licensure and certification actions
- Federal licensure and certification actions
- Federal or State criminal convictions related to the delivery of a health care item or service
- Federal or State civil judgments related to the delivery of a health care item or service
- Exclusions from participation in Federal or State health care programs
- Other adjudicated actions or decisions

When the NPDB processes a Notice of Appeal, the NPDB provides the reporting entity with a Report Verification Document. In addition, the NPDB sends a notification to the subject of the report and to all queriers who received the previous version of the report within the past 3 years.

Narrative Descriptions

For each report submitted to the NPDB, reporting entities are required to specify the action taken and include a detailed narrative describing the acts or omissions of the subject of the report upon which the action is based. MMPRs require a description of the alleged acts or omissions and injuries upon which the action or claim was based, and a separate description of the judgment or settlement and any conditions, including the terms of payment.

The <u>narrative description</u> must include sufficient detail to ensure that future queriers have a clear understanding of what the subject of the report is alleged to have done and the nature of and reasons for the event upon which the report is based. Narratives may not exceed 4,000 characters, including spaces and punctuation. Any characters over 4,000 will be truncated.

Narrative descriptions should be limited to statements of fact and should:

- Summarize the official findings or state the facts of the case
- Include a description of the circumstances that led to the action taken

Narrative descriptions *must not* include:

- URLs or references to external websites
- The proper names of or identifying information about any individuals (except the subject of the report), including patients, staff members, and the like

Narrative descriptions may include the name of the subject of the report, and individuals may be characterized in terms of their relationship (e.g., the patient, the chief of staff). Entities may wish to consult with their legal counsel regarding the wording of the narrative before submitting reports to the NPDB.

The NPDB reserves the right at any time after submission of a report to determine that a narrative description does not provide sufficient detail to ensure that future queriers have a clear understanding of what the subject of the report is alleged to have done. If the NPDB makes such a determination, the reporter is required to submit a Correction Report. Failure to submit a Correction Report in these circumstances may be treated by the NPDB as a failure by the reporting entity to have filed a required report.

Methods for Submitting a Report

Eligible entities may <u>submit reports electronically</u> through the Integrated Querying and Reporting Service (IQRS) on the NPDB website. Entities that prefer to generate reports using custom software may choose to submit reports through an <u>external application</u>. Entities that report via the Querying and Reporting XML Service (QRXS) must submit data using the format specified by the NPDB.

Report Processing

Each version of a report submitted to the NPDB system is assigned a unique Data Bank Control Number (DCN). This number is used to locate the report within the NPDB system.

When the NPDB processes a report, the NPDB provides the reporting entity with an electronic Report Verification Document. The DCN is prominently displayed in the Report Verification Document. The DCN assigned to the most current version of the report always must be referenced in any subsequent action involving the report.

The reporting entity should review the report information to ensure that it is accurate. If the reporting entity identifies incorrect information in the report, a Correction Report must be submitted. If the entity inadvertently reported information for the wrong subject, the reporting entity must void the inaccurate report and submit a new report naming the correct subject. See also <u>Types of Reports</u>.

The NPDB also sends a notification to the subject of the report. The subject of the

report should review the report information to ensure that it is accurate. (See Reviewing a Report in Chapter F: Subject Statements and the Dispute Process.)

Submitting a Copy of the Report to the Appropriate State Licensing Board or State Licensing or Certification Authority

Eligible entities that report certain actions to the NPDB also are required to provide a copy of the NPDB Report Verification Document for an Initial Report, Correction Report, Revision-To-Action Report, or Void Report to the appropriate State licensing board or State licensing or certification authority. These actions include:

- Medical malpractice payments entities must report information to the appropriate State licensing board(s) in the State in which the act or omission upon which the medical malpractice claim was based occurred or did not occur
- Clinical privileges actions reporters must provide a copy to the appropriate State licensing board in the State in which the health care entity is located
- Professional society membership actions against physicians or dentists reporters must provide a copy to the appropriate State licensing board in the State in which the health care entity is located
- Negative actions or findings by a peer review organization reporters must provide a copy to the appropriate State licensing or certification authority
- Negative actions or findings by a private accreditation organization reporters must provide a copy to the appropriate State licensing or certification authority

Report Forwarding by the NPDB

As an alternative to the reporting entity directly providing the Report Verification Document to State licensing and certification authorities (State boards), certain NPDB reporters may elect to send an electronic version of the report to the appropriate State boards through the NPDB's Electronic Report Forwarding service, provided that the State board has agreed to accept electronic notices of an action. Both the State board and the reporting entity must agree to use the Electronic Report Forwarding service in advance of forwarding an NPDB report. In addition, the reporting entity is responsible for selecting the appropriate State board. If a State board declines to participate in the Electronic Report Forwarding service, or if a reporting organization prefers not to use this feature for submitting a report, reporting entities remain responsible for mailing a copy of the report to the appropriate State board. In addition, if the State board does not view the electronically forwarded report, the reporting entity is notified and the reporting entity must mail a copy of the report to the appropriate State board.

IQRS Draft Capability

The IQRS includes a draft report feature for entering report data into input screens, then saving the document in draft status. The draft version of a report can be modified later. Draft reports may be saved for 30 days before they are automatically deleted. Reports saved as drafts are not considered official report submissions. Draft reports must be completed, submitted, and successfully processed by the NPDB to fulfill reporting requirements.

Subject Database

Creating and maintaining a <u>Subject Database</u> (which may include practitioner and organization subjects) can make entering the required information on the subject of a report or query quicker by automatically pre-populating forms with identifying information. This eliminates the need to retype data on these individuals and organizations.

When reporting or querying using a Subject Database, the IQRS retrieves all pertinent information from the entity's Subject Database to complete the appropriate screens. However, if a record in the Subject Database is incomplete (i.e., information is missing in required fields), the IQRS does not allow that subject data to populate the appropriate screens until the missing information is added.

Retrieving Historical Report and Query Summaries

There may be times when an eligible entity needs to search for specific organizations or individuals on whom it previously reported or queried (e.g., for a compliance audit). To address this need, the NPDB makes available to entities Historical Report Summaries and Historical Query Summaries. A Historical Report Summary is a listing by date of the reports submitted by the entity, and a Historical Query Summaries and Historical Query Summaries are available back to June 2000. See Retrieving Historical Query Summaries.

Q&A: Submitting Reports

1. How long are reports maintained in the NPDB?

Information reported to the NPDB is <u>maintained permanently</u> unless it is corrected or voided from the system.

2. May a reporting organization provide a copy of an NPDB report to the subject of the report?

Yes. However, the NPDB automatically mails to the subject of each report a notification that provides instructions for obtaining an official copy of the report through the Report Response Service on the NPDB website.

3. Certain NPDB reporting formats collect information concerning health care entities with which the subject of the report is "affiliated or associated." Does the definition of "affiliated or associated" include an employment relationship?

Yes. NPDB regulations state that "affiliated or associated" refers to health care entities with which a subject of a final adverse action has a business or professional relationship. Business or professional relationships include employment relationships.

4. Please explain when a Revision-to-Action Report should be used and when a Correction Report should be used.

A <u>Revision-to-Action Report</u> is used to submit an action that relates to and/or modifies an adverse action previously reported to the NPDB. It is treated as a second and separate action by the NPDB, but it does not negate the original action that was taken. For example, if a State medical board reports a license suspension, it must submit a Revision-to-Action report when the license is reinstated if it did not indicate in the original report that reinstatement would be automatic after a specified period. As another example, if an entity subsequently changed the penalty it imposed, or if it reconsidered the grounds on which it took an action, but the original report correctly described the penalty or grounds at the time the original report was filed, then a Revision-to-Action Report, not a Correction Report, should be filed.

A <u>Correction Report</u> is used to correct an error or omission in the current version of a report, and it should be filed only when the originally submitted report was erroneous or had an omission. A Correction Report negates and replaces the current version of a report. For example, if a State medical board reports a license revocation that contains incorrect information in the narrative description, a Correction Report must be submitted as soon as the error or omission is discovered.

5. How should a previously reported action that is overturned on appeal be reported to the NPDB?

When a previously reported action is overturned on appeal, the reporter should void the previously submitted report.

6. If a hospital's decision to terminate a physician is based on a licensure action, must the hospital file a Notice of Appeal if the physician appeals either the licensure or termination?

No. The regulations do not require the hospital to file a Notice of Appeal if a physician, who was terminated from the hospital based on a licensure action, appeals the decision the hospital made to terminate him or her. As well, the hospital would not be required to file a Notice of Appeal if the physician appealed the licensure action that was the basis of the hospital's termination; when a Notice of Appeal must be filed, only the entity taking the adverse action needs to file the Notice of Appeal. Only the licensing board, in this case, would be required to file a Notice of Appeal if the physician appealed a licensure action that had been reported to the NPDB.

7. Some entities are required to submit copies of NPDB reports to the appropriate State licensing board. Is it possible to do this electronically?

Yes. The NPDB's <u>Electronic Report Forwarding service</u> may be used if the State board has agreed to accept electronic notices of actions. The reporting entity is responsible for selecting the appropriate State licensing board. In cases when a State licensing board declines to participate, or if a reporting organization prefers not to use this feature for submitting a report, the reporting entity remains responsible for providing a copy of the NPDB Report Verification Document to the appropriate State board.

REPORTING MEDICAL MALPRACTICE PAYMENTS

Each entity that makes a payment for the benefit of a health care practitioner in settlement of, or in satisfaction in whole or in part of, a written claim or judgment for medical malpractice against that practitioner must report the payment information to the NPDB. A payment made as a result of a suit or claim solely against an entity (for example, a hospital, clinic, or group practice) that does not identify an individual practitioner should not be reported to the NPDB.

Medical malpractice payments are limited to exchanges of money and must be the result of a written complaint or claim demanding monetary payment for damages. The written complaint or claim must be based on a practitioner's provision of or failure to provide health care services. A written complaint or claim can include, but is not limited to, the filing of a cause of action based on the law of tort in any State or Federal court or other adjudicative body, such as a claims arbitration board. Eligible entities must report when a lump sum payment is made or when the first of

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multiple payments is made.

Table E-3 outlines these reporting obligations.

Table E-3: Authority for Reporting Medical Malpractice Payments			
Law	Who Reports?	What is Reported?	Who is Reported?
Title IV	Medical malpractice payers, including hospitals and other health care entities that are self- insured	Medical malpractice payments resulting from a written claim or judgment	Practitioners

Interpretation of Medical Malpractice Payment Information

As stated in <u>Title IV</u> and in <u>section 60.7(d)</u> of the NPDB regulations, "[A] payment in settlement of a medical malpractice action or claim shall not be construed as creating a presumption that medical malpractice has occurred." Some medical malpractice claims (particularly those referred to as nuisance claims) may be settled for convenience and, as such, are not a reflection on the professional competence or professional conduct of a practitioner.

Payments by Individuals

Individuals are not required to report to the NPDB payments they make for their own benefit. Thus, if a practitioner or other individual makes a medical malpractice payment out of personal funds, the payment should not be reported. However, a professional corporation or other entity composed of a sole practitioner that makes a payment for the benefit of a named practitioner must report that payment to the NPDB. (See next section.)

Previously, the NPDB had required that all medical malpractice payments made on behalf of a practitioner – even payments made out of personal funds – be reported. However, on August 27, 1993, in *American Dental Association v. Shalala*, the U.S. Court of Appeals for the District of Columbia Circuit held that an NPDB regulation requiring a report from each "person or entity" making a medical malpractice payment was invalid when applied to payments made by a practitioner on his or her own behalf, because the regulation was inconsistent with statutory language requiring any "entity" to report medical malpractice payments to the NPDB. The NPDB removed previously submitted reports on medical malpractice payments made by individuals for their own benefit.

The amount of the payment is irrelevant; there is no de minimis exception. In addition, payments not made in connection with litigation (e.g., those made resulting from professional peer review proceedings) may need to be reported. Peer review committees and others investigating and resolving patient complaints

against practitioners should consider notifying practitioners of reporting requirements before a payment is made.

Payments for Corporations and Hospitals

Medical malpractice payments made solely for the benefit of a corporation – such as a clinic, group practice, or hospital – should not be reported to the NPDB. A payment made for the benefit of a professional corporation or other business entity that consists of only a sole practitioner must be reported if the payment was made by the entity rather than by the sole practitioner out of personal funds.

Identifying Practitioners

An MMPR is submitted on a particular health care practitioner, not an organization. In order for an MMPR to be submitted to the NPDB on a particular health care practitioner, the practitioner must be named, identified, or otherwise described in both the written complaint or claim demanding monetary payment for damages *and* the settlement release or final adjudication, if any. Practitioners named, identified, or described in the release but not in the written demand or as defendants in a lawsuit should not be reported to the NPDB. So, if a practitioner is named, identified, or described in the body of the written complaint or claim and is not named as a defendant in the suit, the payment would be reportable if (1) the practitioner also is named, identified, or described in the settlement or final judgment and (2) a payment was made on behalf of the named, identified, or described practitioner.

A practitioner named, identified, or described in the written complaint or claim who is subsequently dismissed from the lawsuit and not named, identified, or described in the settlement release should not be reported to the NPDB unless the dismissal results from a condition in the settlement or release. The given name of the practitioner does not have to appear in the complaint, release, or final adjudication as long as the practitioner is sufficiently described as to be identifiable. A practitioner may be sufficiently identified by title or role in a procedure, such as "chief of surgery" or "the anesthetist who participated in the patient's surgery," without being specifically named.

Written Complaint or Claim

To be reported to the NPDB, a medical malpractice payment must be the result of a written complaint or a written claim demanding monetary payment for damages. The NPDB interprets this requirement to include any form of writing, including pre-litigation written communications. The NPDB, not any other entity, determines whether a written claim has occurred for purposes of filing a report.

Dismissal of a Defendant from a Lawsuit

If a defendant health care practitioner is dismissed from a lawsuit prior to settlement or judgment, for reasons independent of the settlement or release, a payment made to settle a medical malpractice claim or action should not be reported to the NPDB for that defendant health care practitioner. However, if the dismissal results from a settlement or release, the payment must be reported to the NPDB. In the first instance, there is no payment for the benefit of the health care practitioner because the individual has been dismissed from the action independently of the settlement or release. In the latter instance, if the practitioner is dismissed from the lawsuit in consideration of the payment being made in settlement of the lawsuit, the payment can only be construed as a payment for the benefit of the health care practitioner and must be reported.

Confidential Terms of a Settlement or Judgment

Confidential terms of a settlement or judgment do not excuse an entity from the statutory requirement to report a payment to the NPDB or from providing a narrative describing the payment. The reporting entity should explain in the narrative section of the MMPR that the settlement or court order stipulates that the terms of the settlement are confidential.

Insurance Policies that Cover More than One Practitioner

A medical malpractice payment made under an insurance policy that covers more than one health care practitioner should be reported only for the individual practitioner for whose benefit the payment was made, not for every practitioner named on the policy.

One Payment for More than One Practitioner

In the case of a payment made for the benefit of multiple health care practitioners, if it is impossible to determine the amount paid for the benefit of each individual practitioner, the insurer must report, for each practitioner, the total (undivided) amount of the initial payment and the total number of practitioners on whose behalf the payment was made. If a payment was made for the benefit of multiple practitioners, and it is possible to apportion payment amounts to individual practitioners, the insurer must report, for each practitioner, the actual amount paid for the benefit of that practitioner.

Residents and Interns

Reports must be submitted to the NPDB when medical malpractice payments are made for the benefit of licensed residents or interns, including those insured by their

employers.

If a supervisory practitioner is named in a lawsuit based on the actions of a subordinate practitioner (e.g., a licensed resident or intern), separate reports must be submitted for each practitioner. The report on the supervisory practitioner should be submitted using the same malpractice claim description code used in the subordinate practitioner's payment report. The reporting entity should use the narrative description to explain that the supervisory practitioner was named based on the subordinate practitioner's services.

Students

Payments made for the benefit of unlicensed students should not be reported to the NPDB. Unlicensed student practitioners provide health care services exclusively under the supervision of licensed health care practitioners in a training environment. The definition of health care practitioner does not include unlicensed students.

Practitioner Fee Refunds

If a health care practitioner's fee is refunded by an entity (including solo incorporated practitioners), the payment must be reported to the NPDB if the conditions described in the next paragraph are met. A refund made by an individual, out of personal funds, should not be reported to the NPDB.

For purposes of NPDB reporting, medical malpractice payments are limited to exchanges of money. A refund of a fee must be reported only if it results from a *written* complaint or claim demanding monetary payment for damages. The written complaint or claim must be based on a health care practitioner's provision of, or failure to provide, health care services. A written complaint or claim may include, but is not limited to, the filing of a cause of action based on the law of tort in any State or Federal court or other adjudicative body, such as a claims arbitration board.

Waiver of Debt

A waiver of a debt is not considered a payment and should not be reported to the NPDB. For example, if a patient has an adverse reaction to an injection and is willing to accept a waiver of fee as settlement, that waiver should not be reported to the NPDB.

Loss Adjustment Expenses

Loss adjustment expenses (LAEs) refer to expenses other than those in compensation of injuries, such as attorney fees, billable hours, copying costs, expert witness fees, and deposition and transcript costs.

LAEs should be reported to the NPDB only if they are included in a medical malpractice payment. The total amount of a medical malpractice payment, a description of and amount of the judgment or settlement, and any conditions (including terms of payment) should be reported to the NPDB. LAEs should be itemized in the narrative description section of the reporting format. If LAEs are not included in the medical malpractice payment amount, they should not be reported to the NPDB.

High-Low Agreements

A high-low agreement is a contractual agreement between a plaintiff and a defendant's insurer that defines the parameters of a payment the plaintiff may receive after a trial or arbitration proceeding. The benefit to insurers is to limit the amount they may be required to pay if the plaintiff wins the case. The benefit to plaintiffs is a guaranteed payment even if they lose the case or win only a small award. The defendant's insurer agrees to pay the "low end" amount to the plaintiff if the verdict or decision is for the defendant. The defendant's insurer is obligated to pay no more than the "high end" amount to the plaintiff if the verdict or decision is for the plaintiff.

A payment made at the low end of a high-low agreement *must* be reported to the NPDB *unless* the fact-finder (such as a judge, jury, or arbitrator) rules in favor of the defendant and assigns no liability to the defendant practitioner. If the fact-finder rules in favor of the defendant and assigns no liability to the defendant practitioner, the payment is not being made for the benefit of the practitioner in settlement of a medical malpractice claim. Rather, it is being made pursuant to an independent contract between the defendant's insurer and the plaintiff.

When a defendant practitioner has been found liable by a fact-finder, any payment made for the practitioner's benefit must be reported, regardless of the existence of a high-low agreement. If a high-low agreement is in place, and the plaintiff and defendant settle the case prior to trial, the existence of the high-low agreement does not alter the requirement to report the settlement payment to the NPDB.

Example 1: A high-low agreement is in place prior to trial. The parties agree to a low-end payment of \$50,000 and a high-end payment of \$200,000. The jury finds the defendant physician liable and awards \$40,000 to the plaintiff in damages. This \$40,000 payment must be reported to the NPDB because the jury found the defendant physician liable. The defendant's insurer must pay an additional \$10,000 as a result of the high-low agreement (\$40,000 +\$10,000 = \$50,000). The payment amount should be reported as \$40,000 and the additional \$10,000 explained in the narrative.

Example 2: A high-low agreement is in place prior to binding arbitration. The parties agree to a low-end payment of \$50,000 and a high-end payment of \$150,000. The arbitrator finds in favor of the defendant practitioner with no liability on the part of the practitioner. However, due to the existence of the high-low agreement, the defendant's insurer makes a payment of \$50,000 to the plaintiff (the low-end payment). This payment should not be reported because the arbitrator (fact-finder) explicitly found no liability and the payment is being made pursuant to an independent contract between the defendant's insurer and the plaintiff.

Example 3: A high-low agreement is in place prior to trial. The parties agree to a low-end payment of \$50,000 and a high-end payment of \$150,000. Before the fact finder returns a verdict, the parties agree to settle the case for \$100,000. The high-low agreement is no longer in effect due to the settlement. This \$100,000 payment must be reported because it is made in settlement of the claim.

Example 4: A high-low agreement is in place prior to trial. The parties agree to a low-end payment of \$50,000 and a high-end payment of \$200,000. Rather than go to trial, the parties agree to binding arbitration to assess the amount of damages the plaintiff will receive and *not* to determine liability. The arbitrator awards the plaintiff \$80,000. In this case, the arbitration proceeding was conducted to determine the amount of recovery by the plaintiff and not to determine liability. Because liability was not determined at this arbitration proceeding, there was no explicit finding that the practitioner had no liability. Therefore, the payment of \$80,000 is made in settlement of the claim, and not as a result of the high-low agreement, and must be reported.

Payments by Multiple Payers

Any medical malpractice payer that makes an indemnity payment for the benefit of a practitioner must submit a report to the NPDB. Generally, primary insurers and excess insurers are obligated to make an indemnity payment for the benefit of a practitioner and so must submit a report to the NPDB. Typically, reinsurers are obligated to make an indemnity payment directly to the primary insurer, not for the benefit of the practitioner, and are not required to submit a report to the NPDB.

Example: If three primary insurers contribute to a payment, all three insurers are required to submit separate reports to the NPDB. Each insurer should describe the basis for its payment in the narrative description of the settlement to avoid the impression of duplicate reporting.

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Subrogation-Type Payments

Subrogation-type payments made by one insurer to another are not required to be reported, provided the insurer receiving the payment has previously reported the total judgment or settlement to the NPDB. Subrogation often occurs when there is a dispute between insurance companies over which professional liability policy ought to respond to a lawsuit.

Example: A practitioner is insured in 2006 by Insurer X and changes over to Insurer Y in 2007. Both policies provide occurrence-type coverage. A medical malpractice lawsuit is filed in 2007. There is a dispute over whether the alleged medical malpractice occurred in late 2006 or early 2007. Under the 2007 policy, Insurer Y agrees to defend the lawsuit but obtains an agreement from the practitioner that it may pursue the practitioner's legal right to recover any indemnity and defense payments that should have been paid under Insurer X's policy. This is a subrogation agreement. The jury subsequently determines that the incident occurred in 2006 and awards \$500,000 to the plaintiff. Insurer Y makes the \$500,000 payment to the plaintiff and reports it to the NPDB. Insurer Y seeks subrogation of its indemnity and defense payment from Insurer X. Insurer X ultimately concedes and pays Insurer Y the \$500,000 plus defense costs. Insurer X is not required to report its reimbursement of Insurer Y to the NPDB.

Structured Settlements

A medical malpractice payer entering into a structured settlement agreement with a life insurance or annuity company must submit a payment report within 30 days of the date the lump sum payment is made by the payer to that company.

Offshore Payers

A medical malpractice payment made by an offshore medical malpractice insurer must be reported to the NPDB.

Payments Made Prior to Settlement

When a payment is made prior to a settlement or judgment, a report must be submitted within 30 days from the date the payment was made. Since the total amount of the payment is unknown, the medical malpractice payer should state this in the narrative description section of the report. When the settlement or judgment is finalized, the insurer must submit a Correction Report.

Reporting of Medical Malpractice Payments by Authorized Agents

The organization that makes the medical malpractice payment is the organization that must report the medical malpractice payment to the NPDB.

A medical malpractice payer may choose to use an adjusting company, claims servicing company, or law firm, for example, acting as its <u>authorized agent</u>, to complete and submit NPDB reports. An insurance company also may wish to have all of its NPDB correspondence relating to reports handled by an authorized agent. This is strictly a matter of administrative policy by the medical malpractice payer.

Submitting a Copy of the Report to the State Licensing Board

A copy of the Report Verification Document that medical malpractice payers receive after a report is successfully processed by the NPDB must be provided to the appropriate State licensing board(s) in the State in which the act or omission upon which the medical malpractice claim was based. Alternatively, NPDB reporters may elect to send an electronic version of the report to the appropriate State licensing board through the NPDB's <u>Electronic Report Forwarding service</u>, provided the State board has agreed to accept electronic notices of a payment.

Sanctions for Failing to Report to the NPDB

The OIG has the authority to impose civil money penalties in accordance with <u>Title IV</u>. Under the statute, any malpractice payer that fails to report medical malpractice payments in accordance with NPDB requirements is subject to a civil money penalty of up to \$11,000 for each such payment involved.

The civil money penalty provided for under Title IV is to be imposed in the same manner as other civil money penalties imposed pursuant to Section 1128A of the Social Security Act, 42 USC § 1320a-7a. Regulations governing civil money penalties under Section 1128A are set forth at 42 CFR Part 1003.

Table E-4 provides examples of whether medical malpractice payments must be reported to the NPDB.

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Table E-4: Determining if Medical Malpractice Payments Must be Reported				
Action	Reportable?			
A malpractice settlement or court judgment that includes a stipulation that the terms are kept confidential.	Yes			
A malpractice settlement is structured so that the claimant receives an annual sum for each year he or she is alive.	Yes Must report within 30 days of the initial payment stating the total amount awarded. The multiple payments should be explained in the narrative.			
A malpractice settlement that involves multiple practitioners that are named in the claim and named in the release.	Yes A separate report must be submitted for each practitioner.			
A payment made as the result of oral demands.	No			
A payment made by an individual out of personal funds.	No			
A medical malpractice payment made by a professional corporation or other business entity composed of a sole practitioner (who was named in the complaint and the settlement).	Yes			
A medical malpractice payment made solely for the benefit of a corporation such as a clinic, group practice, or hospital.	No			
A malpractice payment made for the benefit of a licensed resident or intern.	Yes			
A practitioner's fee refunded by an entity (including a solo incorporated practitioner) as the result of a written demand.	Yes			
A practitioner's fee refunded by the individual practitioner out of personal funds as the result of a written demand.	No			
A practitioner defendant released from a medical malpractice lawsuit as a condition of settlement.	Yes			
A practitioner defendant dismissed from a lawsuit, without condition, prior to settlement or judgment.	No			
A medical malpractice payment made for the benefit of a practitioner who settled out of court.	Yes			
An insurance company's reimbursement to a practitioner for a medical malpractice payment the practitioner made out of pocket to a patient as a result of a written complaint.	Yes			
A payment made for the benefit of an unlicensed medical resident.	No			
A payment made on behalf of an unlicensed student practitioner.	No			

Q&A: Reporting Medical Malpractice Payments

1. The authorized submitter for a medical malpractice payer found documentation of reportable payments that were not reported to the NPDB. What should the authorized submitter do?

The authorized submitter should submit reports on those payments to the NPDB.

2. Do medical malpractice payers have to report payments made for the benefit of a deceased practitioner?

Yes. Medical malpractice payers must submit reports of payments made for the benefit of <u>deceased practitioners</u> because fraudulent practitioners may seek to assume the identity of a deceased practitioner. One of the principal objectives of the NPDB is to restrict the ability of incompetent practitioners to move from State to State without disclosing their previous damaging or incompetent performance.

3. How should a payment be reported to the NPDB if a total amount has not been determined and the payer is making an initial partial payment?

Complete the MMPR screens according to the instructions in the <u>IQRS</u>. Note the amount of the first payment and, in the narrative section, explain that the total amount has not been determined and the first payment is a partial payment. When the final amount is determined, submit a Correction Report, update the "Total Amount Paid" section of the report, and explain the additional payment in the narrative section.

4. Should a payment exclusively for the benefit of a clinic, hospital, or other health care entity be reported?

No. Medical malpractice payments made solely for the <u>benefit of a clinic</u>, <u>hospital</u>, <u>or other health care entity</u> should not be reported to the NPDB. However, a payment made for the benefit of a professional corporation or business entity consisting only of a sole practitioner is reportable to the NPDB

5. What are the NPDB reporting requirements for self-insured employers who provide professional liability coverage for their employed health care practitioners?

Self-insured entities have the same reporting responsibilities as all other medical malpractice payers. Employers that are self-insured and provide their employees professional liability coverage must report medical malpractice payments they make for the benefit of their employees.

6. If a patient makes an oral demand for payment for damages, should the resulting payment be reported to the NPDB?

No. Only payments resulting from <u>written demands</u> must be reported to the NPDB. Even if the practitioner transmits the demand in writing to the medical malpractice payer, the payment should not be reported if the patient's only demand was oral. However, if a subsequent written claim or demand is received from the patient and then a payment is made by an entity (including a solo incorporated practitioner), that payment must be reported.

7. A patient made a written demand for a refund for services and, in response, the practitioner made the payment out of her personal funds. Should the payment be reported to the NPDB?

No. A refund made by an individual out of <u>personal funds</u> should not be reported to the NPDB. However, if the practitioner's malpractice insurer reimburses the practitioner for her out-of-pocket expenses, the insurer must report the payment.

8. Following an unsuccessful course of treatment, a patient and a practitioner enter into a State-sponsored voluntary series of discussions in an attempt to settle their disagreement before resorting to litigation. The discussions lead to the practitioner's insurance company making a money payment to the patient to settle the dispute. Should this money payment be reported to the NPDB?

It depends. If, during the course of discussions, the patient made a written complaint or written claim demanding a monetary payment for damages, the payment must be reported. If the complaint or claim for damages was never put in writing, the payment is not reportable.

9. If an individual practitioner is not named, identified, or described in a

medical malpractice claim or complaint, but the facility or practitioner group is named, should the payment be reported?

No, with one exception. If the named defendant is a sole practitioner identified as a "professional corporation," a payment made for the <u>professional corporation</u> must be reported for the practitioner.

10. A supervisory practitioner is named in an action based on the services of a subordinate practitioner, and payments are made for the benefit of the supervisor and the subordinate. How should the payments be reported to the NPDB?

Separate reports must be submitted for the <u>supervisory and subordinate</u> <u>practitioners</u>. The report on the supervisory practitioner should be submitted using the same malpractice claim description code used in the subordinate practitioner's payment report. The reporting entity should use the narrative description to explain that the supervisory practitioner was named based on the subordinate practitioner's services.

11. If a stipulation of settlement or court order requires that terms remain confidential, how does a medical malpractice insurer report the payment to the NPDB without violating the settlement agreement or court order?

<u>Confidential terms of a settlement or judgment</u> do not excuse an entity from the statutory requirement to report the payment to the NPDB or from providing a narrative describing the payment. The reporting entity should explain in the narrative section of the reporting format that the settlement or court order stipulates that the terms of the settlement are confidential.

12. If there is no medical malpractice payment and Loss Adjustment Expenses (LAEs) are paid in order to release or dismiss a health care practitioner from a medical malpractice lawsuit, should the LAEs be reported?

No. LAEs refer to expenses other than those in compensation of injuries, such as attorney fees, billable hours, expert witness fees, and deposition and transcript costs. If <u>LAEs</u> are not included in the medical malpractice payment, then they should not be reported to the NPDB. LAEs should be reported only if they are part of the total medical malpractice payment and, when reported, should be explained in the narrative description.

13. Does a medical malpractice payment have to exceed a certain dollar amount before it is reportable to the NPDB?

No. There is no minimum payment amount threshold. Medical malpractice payments of any amount that meet the reporting criteria should be reported to the NPDB.

14. A defendant health care practitioner agreed to settle a medical malpractice claim in exchange for being dismissed from a lawsuit. All parties involved in the lawsuit agreed to the condition. Should the resulting payment be reported to the NPDB?

Yes. Because the payment is the result of the condition that the defendant health care practitioner be dismissed from the lawsuit, the payment can only be construed as a payment for the benefit of the health care practitioner and must be reported to the NPDB.

15. A hospital and a health care practitioner were named in a medical malpractice claim. Further review revealed that the practitioner had never treated the plaintiff who filed the claim. The practitioner was dismissed from the lawsuit without condition. A settlement on behalf of the hospital was reached and a payment was made to the plaintiff to resolve the claim. The release stated that the defendant health care practitioner was dismissed from the lawsuit prior to settlement and the payment was being made on behalf of the hospital. Is this payment reportable to the NPDB?

No. Because the health care practitioner had been dismissed from the action independently of the settlement or release, the payment cannot be viewed as being made for the benefit of the health care practitioner. The payment made on behalf of the hospital should not be reported to the NPDB.

REPORTING ADVERSE CLINICAL PRIVILEGES ACTIONS

Hospitals and other health care entities must report adverse clinical privileges actions to the NPDB that meet NPDB reporting criteria – that is, any professional review action that adversely affects the clinical privileges of a physician or dentist for a period of more than 30 days *or* the acceptance of the surrender of clinical privileges, or any restriction of such privileges by a physician or dentist, (1) while the physician or dentist is under investigation by a health care entity relating to possible incompetence or improper professional conduct, or (2) in return for not conducting such an investigation or proceeding. Clinical privileges include

privileges, medical staff membership, and other circumstances (e.g., network participation and panel membership) in which a physician, dentist, or other health care practitioner is permitted to furnish medical care by a health care entity.

Adverse clinical privileges actions that *must* be reported to the NPDB are professional review actions – that is, they are based on a physician's or dentist's professional competence or professional conduct that adversely affects, or could adversely affect, the health or welfare of a patient. Generally, the entity that takes the clinical privileges action determines whether the physician's or dentist's professional competence or professional conduct adversely affects, or could adversely affect, the health or welfare of a patient. Hospitals and other health care entities *must* report clinical privileges actions taken against physicians and dentists when those actions meet the criteria for reportability.

In addition, hospitals and other health care entities *may* report – and are encouraged to report – clinical privileges actions taken against health care practitioners *other than* physicians and dentists when those clinical privileges actions are based on the practitioner's professional competence or professional conduct that adversely affects, or could adversely affect, the health or welfare of a patient.

<u>Definitions and examples</u> of these terms are provided in Chapter C: Subjects of Reports.

Table E-5 outlines	reporting	obligations	for adverse	clinical	privileges	actions.

Table E-5: Authority for Reporting Adverse Clinical Privileges Actions			
Law	Who Reports?	What is Reported?	Who is Reported?
Title IV	Hospitals Other health care entities with formal peer review	Certain clinical privileges actions related to professional competence or conduct	Physicians and dentists Other practitioners (optional)

Hospitals and other eligible health care entities must report:

- Professional review actions that adversely affect a physician's or dentist's clinical privileges for a period of more than 30 days
- Acceptance of a physician's or dentist's surrender or restriction of clinical privileges while under investigation for possible professional incompetence or improper professional conduct, or in return for not conducting such an

investigation or not taking a professional review action that otherwise would be required to be reported to the NPDB

Actions taken against a physician's or dentist's clinical privileges include reducing, restricting, suspending, revoking, or denying privileges, and also include a health care entity's decision not to renew a physician's or dentist's privileges if that decision was based on the practitioner's professional competence or professional conduct. Clinical privileges actions are reportable once they are made final by the health care entity. However, summary suspensions lasting more than 30 days are reportable *even if* they are not final.

Adverse clinical privileges actions should not be reported to the NPDB unless they adversely affect the practitioner's clinical privileges for a period longer than 30

days. Matters not related to the professional competence or professional conduct of a practitioner should not be reported to the NPDB. For example.

Adverse clinical privileges actions should not be reported to the NPDB unless they adversely affect the practitioner's clinical privileges for a period longer than 30 days.

adverse actions based primarily on a practitioner's advertising practices, fee structure, salary arrangement, affiliation with other associations or health care professionals, or other competitive acts intended to solicit or retain business are excluded from NPDB reporting requirements.

Hospitals and other health care entities also must report revisions to previously reported adverse clinical privileges actions. For more information, go to <u>Types of Reports</u> in this chapter.

Administrative Actions

Administrative actions that do not involve a professional review action should not be reported to the NPDB. For example: A hospital's bylaws require physicians to be board certified in their specialty. A physician's board certification expires and, as a result, the hospital automatically revokes the physician's clinical privileges through an administrative action. The revocation of clinical privileges was not a result of a professional review action and should not be reported to the NPDB.

Multiple Adverse Actions

If a single professional review action produces multiple clinical privileges actions (for example, a 12-month suspension followed by a 5-month mandatory consultation period requiring approval of a department chair before the exercise of

clinical privileges), only one report, reflecting the multiple actions taken, should be submitted to the NPDB. The reporting entity may select up to five Adverse Action Classification Codes on the reporting format to describe the actions taken. Reporting entities should use the narrative description to explain any additional adverse actions imposed.

A Revision-to-Action Report must be submitted when each of the multiple actions is lifted or otherwise changed. For the example in the previous paragraph:

- If the Initial Report clearly states that the suspension is to end after 12 months, and the mandatory consultation period is to end after 5 months, and if these penalties are not changed and are fully met by the practitioner, no additional reports should be submitted
- If, after the Initial Report is submitted, the suspension period is extended to 14 months or the mandatory consultation period is shortened to 4 months, a Revision-to-Action Report must be submitted when either change is imposed

If an adverse action against the clinical privileges of a practitioner is based on multiple grounds, only a single report should be submitted to the NPDB. However, all reasons for the action should be reported and explained in the narrative description. The reporting entity may select up to four Basis for Action Codes to indicate these multiple reasons. Additional reasons should be summarized in the narrative description.

Denials or Restrictions

Denials or restrictions of clinical privileges for more than 30 days that result from professional review actions relating to the practitioner's professional competence or professional conduct that adversely affects, or could adversely affect, the health or welfare of a patient must be reported to the NPDB. This includes denials of initial applications for clinical privileges. When used by the NPDB in the context of clinical privileges actions, a "restriction" is the result of a professional review action based on clinical competence or professional conduct that leads to the inability of a practitioner to exercise his or her own independent judgment in a professional setting.

Note that a denial of clinical privileges at appointment or reappointment that occurs solely because a practitioner does not meet a health care institution's established threshold criteria for that particular privilege should not be reported to the NPDB. Such denials are not deemed the result of a professional review action relating to the practitioner's professional competence or professional conduct but are considered decisions based on eligibility. In addition, if a hospital or other health care entity retroactively changes the threshold criteria for a particular clinical

privilege, a physician who does not meet the new criteria will lose previously granted clinical privileges. This loss of privileges should not be reported to the NPDB.

Examples of eligibility threshold criteria may include: (1) minimum professional liability coverage, (2) board certification, (3) geographic proximity to the hospital, and (4) performance of a minimum number of procedures prescribed for a particular clinical privilege.

Withdrawal of Applications

Voluntary withdrawal of an initial application for medical staff appointment or clinical privileges prior to a final professional review action generally should not be

A practitioner's awareness that an investigation is being conducted is not a requirement for filing a report with the NPDB.

reported to the NPDB. However, if a practitioner applies for renewal of a medical staff appointment or clinical privileges and

voluntarily withdraws that application while under investigation by the health care entity for possible professional incompetence or improper professional conduct, or in return for not conducting such an investigation or not taking a professional review action, then the withdrawal of application for renewal of clinical privileges must be reported to the NPDB. These actions must be reported regardless of whether the practitioner knew he or she was under investigation when the renewal application for medical staff appointment or clinical privileges was withdrawn. A practitioner's awareness that an investigation is being conducted is not a requirement for filing a report with the NPDB.

Nonrenewals

Nonrenewals of medical staff appointment or clinical privileges generally should not be reported to the NPDB. However, if the practitioner does not apply for renewal of medical staff appointment or clinical privileges while under investigation by the health care entity for possible professional incompetence or improper professional conduct, or in return for not conducting such an investigation or not taking a professional review action, the event is considered a surrender while under investigation and must be reported to the NPDB. These actions must be reported regardless of whether the practitioner was aware of the investigation at the time he or she failed to renew the staff appointment or clinical privileges. A practitioner's awareness that an investigation is being conducted is not a requirement for filing a report with the NPDB.

Investigations

Investigations should not be reported to the NPDB. However, a surrender of clinical privileges or failure to renew clinical privileges while under investigation or to avoid investigation must be reported.

NPDB interprets the word "investigation" expansively. It may look at a health care entity's bylaws and other documents for assistance in determining whether an investigation has started or is ongoing, but it retains the ultimate authority to determine whether an investigation exists. The NPDB considers an investigation to run from the start of an inquiry until a final decision on a clinical privileges action is reached. In other words, an investigation is not limited to a health care entity's gathering of facts or limited to the manner in which the term "investigation" is defined in a hospital's by-laws. An investigation begins as soon as the health care entity begins an inquiry and does not end until the health care entity's decisionmaking authority takes a final action or makes a decision to not further pursue the matter.

A *routine*, formal peer review process under which a health care entity evaluates, against clearly defined measures, the privilege-specific competence of *all* practitioners is *not* considered an investigation for the purposes of reporting to the NPDB. However, if a formal, targeted process is used when issues related to a *specific practitioner's* professional competence or conduct are identified, this *is* considered an investigation for the purposes of reporting to the NPDB.

A health care entity that submits a clinical privileges action based on surrender, restriction of, or failure to renew a physician's or dentist's privileges while under investigation should have evidence of an ongoing investigation at the time of surrender, or evidence of a plea bargain. The reporting entity should be able to produce evidence that an investigation was initiated prior to the surrender of clinical privileges by a practitioner. Examples of acceptable evidence may include minutes or excerpts from committee meetings, orders from hospital officials directing an investigation, or notices to practitioners of an investigation (although there is no requirement that the health care practitioner be notified or be aware of the investigation).

Guidelines for Investigations

- For NPDB reporting purposes, the term "investigation" is not controlled by how
 that term may be defined in a health care entity's bylaws or policies and
 procedures.
- The investigation must be focused on the practitioner in question.
- The investigation must concern the professional competence and/or professional conduct of the practitioner in question.

- To be considered an investigation for purposes of determining whether an activity is reportable, the activity generally should be the precursor to a professional review action.
- An investigation is considered ongoing until the health care entity's decisionmaking authority takes a final action or formally closes the investigation.
- A routine or general review of cases is *not* an investigation.
- A routine review of a particular practitioner is *not* an investigation.

Temporary Clinical Privileges

For the purpose of reporting to the NPDB, no distinction is made between temporary clinical privileges (including but not limited to emergency and disaster clinical privileges) and clinical privileges. If, however, temporary privileges are awarded to a physician or dentist for a specific amount of time, with no opportunity for renewal – and both the physician or dentist and the privileging party agree that the privileges are temporary – and the temporary privileges expire while the practitioner is under investigation, a report should *not* be submitted to the NPDB. In this scenario, there is no opportunity to renew the temporary clinical privileges, so the expiration of the temporary privileges while under investigation cannot be considered a nonrenewal or surrender of clinical privileges while under investigation.

Summary Suspensions

A summary suspension must be reported if it is

- In effect or imposed for more than 30 days
- Based on the professional competence or professional conduct of the physician, dentist, or other health care practitioner that adversely affects, or could adversely affect, the health or welfare of a patient, and
- The result of a professional review action taken by a hospital or other health care entity

In addition, summary suspensions that have not lasted more than 30 days but are expected to last more than 30 days, and that are otherwise reportable, may be reported to the NPDB. If the summary suspension ultimately does not last more than 30 days, it must be voided.

The NPDB treats summary suspensions differently from other professional review actions because the procedural rights of the practitioner are provided *following* the imposition of a suspension, rather than *preceding* it. A summary suspension is often imposed by an official (for instance, the chairman of a department) on behalf of the

hospital or health care entity for the purpose of protecting patients from imminent danger. Commonly, this action is then reviewed and

If a summary suspension is confirmed by a review body, the action is considered to have taken effect when it was first imposed by a hospital official.

confirmed by a hospital committee, such as a medical executive committee (MEC), as authorized by the medical staff bylaws or other official documents (e.g., rules and procedures, standard operating procedures). Summary suspensions are considered to be effective when they go into effect, even though they may be subject to review by some committee or body of the health care entity according to the entity's bylaws or other official documents.

For purposes of reporting a summary suspension to the NPDB, if the summary suspension is confirmed by the review body, the action is considered to have taken effect when it was first imposed by the hospital official. If a summary suspension is in effect for more than 30 days before an action is taken by the authorized hospital committee or body, it must be reported to the NPDB. If the authorized hospital committee or body does not confirm the initial action or takes a different professional review action, a Revision-to-Action Report must be submitted. If the authorized hospital committee or body vacates the summary suspension, the entity must void the previous report submitted to the NPDB.

If the summary suspension subsequently is modified or revised as part of a final decision by the governing board or similar body, the health care entity must then submit a Revision-to-Action Report to supplement the Initial Report submitted to the NPDB.

If the physician, dentist, or other health care practitioner surrenders his or her clinical privileges during a summary suspension, regardless of whether the suspension has been confirmed by a hospital review body, that action must be reported to the NPDB. The action must be reported because the practitioner is surrendering the privileges either while under investigation concerning professional conduct or professional competence that did or could affect the health or welfare of a patient, or in return for not conducting an investigation concerning the same.

This reporting policy for summary suspensions is in keeping with the purpose of the NPDB, which is to protect the public from the threat of incompetent practitioners continuing to practice without disclosure or discovery of previous damaging or incompetent performance.

An action must be reported to the NPDB based on whether it satisfies NPDB reporting requirements and not based on the name affixed to the action. A

An action must be reported to the NPDB based on whether it satisfies NPDB reporting requirements and not based on the name affixed to the action.

suspension or restriction, whether called immediate, summary, emergency, or precautionary, typically means that a serious question has been raised and must be

addressed quickly. Therefore, if a hospital or other health care entity suspects but has not confirmed a risk to an individual or individuals and imposes a suspension or restriction as immediate or precautionary, and the suspension remains in effect for more than 30 days, it must be reported to the NPDB.

Proctors

If, as a result of a professional review action related to professional competence or conduct, a proctor is assigned to a physician or dentist for a period of longer than 30 days, whether the action must be reported to the NPDB depends on the role of the proctor. If, for a period lasting more than 30 days, the physician or dentist cannot perform certain procedures without proctor approval or without the proctor being present and watching the physician or dentist, the action constitutes a restriction of clinical privileges and must be reported to the NPDB. However, if the proctor is not required to be present for or approve the procedures (for example, the proctoring consists of the proctor reviewing the physician's or dentist's records or procedures after they occur), the action is not considered a restriction of clinical privileges and should not be reported to the NPDB.

Residents and Interns

Residents and interns generally should not be subjects of adverse clinical privileges actions because they are trainees in graduate health professions education programs and are not granted clinical privileges within the meaning of NPDB regulations, but they are authorized by the sponsoring institution to perform clinical duties and responsibilities within the context of their graduate educational program. However, adverse clinical privileges actions based on events occurring outside the scope of a formal graduate educational program – for example moonlighting in the intensive care unit or emergency room – must be reported to the NPDB.

Confidentiality Laws Related to Drug and Alcohol Treatment

If a clinical privileges action is taken and the practitioner enters a drug or alcohol treatment or rehabilitation program as a result, the adverse action must be reported. This is true even if the treatment is a condition of probation. However, the fact that the practitioner entered a drug or alcohol treatment facility should not be reported.

Submitting a Copy of the Report to a State Licensing Board

A copy of the Report Verification Document that health care entities receive after a clinical privileges action report is processed successfully by the NPDB must be provided to the appropriate State licensing board in the State in which the health care entity is located. Alternatively, NPDB reporters may elect to send an electronic version of the report to the appropriate State licensing board through the NPDB's Electronic Report Forwarding service, provided the State board has agreed to accept electronic notices of an action.

Sanctions for Failing to Report to the NPDB

A hospital or other health care entity that has substantially failed to submit adverse clinical privileges reports can lose, for 3 years, the <u>immunity protections provided under Title IV</u> for professional review actions it takes against physicians and dentists based on their professional competence and professional conduct.

The Secretary of HHS will conduct an investigation if there is reason to believe that a health care entity has substantially failed to report required adverse actions. If the investigation reveals that the health care entity has not complied with NPDB regulations, the Secretary will provide the entity with written notice describing the noncompliance. This written notice provides the entity with the opportunity to correct the noncompliance and notifies it of its right to request a hearing.

A request for a hearing must contain a statement of the material factual issues in dispute to demonstrate cause for a hearing and must be submitted to HHS within 30 days of receipt of the notice of noncompliance. These issues must be both substantive and relevant. An example of a material factual issue in dispute is a health care entity refuting HHS's claim that the health care entity failed to meet reporting requirements.

A request for a hearing will be denied if it is untimely or lacks a statement of material factual issues in dispute, or if the statement is frivolous or inconsequential. Hearings are held in the Washington, DC, metropolitan area.

If a request for a hearing is denied or if HHS determines that a health care entity has substantially failed to report information in accordance with NPDB requirements, the name of the entity will be published in the Federal Register, and the entity will lose the immunity provisions of Title IV with respect to professional review activities for a period of 3 years, commencing 30 days from the date of publication in the Federal Register.

Table E-6: Determining if Clinical Privileges Actions Must be Reported		
Action	Reportable?	
Based on assessment of professional competence, a proctor is assigned to a physician or dentist for a period of more than 30 days. The proctor must grant approval before the practitioner can perform procedures.	Yes	
Based on assessment of professional competence, a proctor is assigned to supervise a physician or dentist for a period of more than 30 days, but the proctor need not be present or grant approval before medical care is provided by the practitioner.	No	
Based on assessment of professional competence, a proctor is assigned to watch a physician's or dentist's procedures for a period of more than 30 days, and the proctor needs to be present or grant approval before medical care is provided by the practitioner.	Yes	
Practitioners who have recently been granted clinical privileges are routinely assigned a proctor for 60 days as required by hospital policy.	No	
A physician or dentist restricts or surrenders clinical privileges; the physician or dentist is under investigation related to professional competence or professional conduct.	Yes	
A physician or dentist restricts or surrenders clinical privileges for personal reasons; the physician or dentist is not under investigation related to professional competence or professional conduct.	No	
A physician or dentist restricts or surrenders clinical privileges in return for not conducting an investigation related to professional competence or professional conduct.	Yes	
A physician or dentist surrenders clinical privileges for personal reasons but is under investigation for professional competence or conduct.	Yes	
A physician or dentist is denied medical staff appointment or clinical privileges because the health care entity has too many specialists in the practitioner's discipline.	No	
A physician's or dentist's application for medical staff appointment is denied based on a professional review action related to professional competence or professional conduct.	Yes	
A physician's or dentist's request for clinical privileges is denied or restricted for more than 30 days based upon an assessment of clinical competence as defined by the hospital.	Yes	
A physician's or dentist's clinical privileges are suspended for reasons not related to professional competence or professional conduct.	No	

Q&A: Reporting Clinical Privileges Actions

1. If a physician's initial application for clinical privileges is denied or the privileges granted are more limited than those requested, must this be reported to the NPDB?

If the <u>denial or limitation of privileges</u> is the result of a professional review action and is related to the practitioner's professional competence or professional conduct, then the action must be reported to the NPDB. If the denial or limitation of privileges occurs solely because a practitioner does not meet a health care institution's established eligibility threshold criteria for that particular privilege (e.g., lacks the required number of clinical hours in a specialty), it should not be reported to the NPDB. The latter type of restriction or denial is not deemed the result of a professional review action relating to the practitioner's professional competence or professional conduct.

2. A hospital filed a report with the NPDB announcing the revocation of a practitioner's clinical privileges. The reporting hospital had established a system of professional review under its bylaws, and it also had an employment termination procedure. In this case, the hospital used the employment termination procedure, not the professional review process. The practitioner's privileges were revoked by the employment termination process, but no action was taken through the professional review process. The practitioner was not given a choice of which process (system of professional review or employment termination procedure) the hospital would use. Should the hospital have filed the report with the NPDB?

No. The termination was not a result of a professional review action and, therefore, was not reportable. It does not matter that the employment termination, which was a result of the hospital's employment termination process, automatically resulted in the end of the practitioner's clinical privileges. However, if the hospital had performed a professional review of the practitioner's clinical privileges and revoked the practitioner's privileges as a result of the review, the professional review action would have been reportable, even if the action started as an employment termination. In order to be reportable to the NPDB, adverse actions must be the result of professional review. Generally, the reporting entity decides when a professional review has occurred.

3. A physician applied for a medical staff appointment at a hospital but then withdrew the application before a final decision was made by the hospital's governing body. The physician was not being specifically investigated by

the hospital. Should the withdrawal of the application be reported to the NPDB?

No. Absent a particular investigation, the voluntary withdrawal of an application for medical staff appointment or clinical privileges should not be reported to the NPDB.

4. A physician member of a hospital medical staff applied for an expansion of clinical privileges. Although the physician met all threshold criteria established by the hospital for the expanded privileges, the physician's department head and the medical staff credentials committee recommended denial of the request for expanded clinical privileges based on their assessment that the physician did not have the clinical competence to perform the additional tests and procedures sought. The hospital's governing body reviewed the case, affirmed the findings and recommendations, and denied the physician's request for expanded clinical privileges for reasons relating to professional competence. Does the denial of a request for expanded clinical privileges have to be reported to the NPDB?

Yes. The action must be reported to the NPDB because the <u>denial of expanded</u> <u>privileges</u> was the result of a professional review action and adversely affected the clinical privileges of the physician for longer than 30 days.

5. A physician who applied for clinical privileges does not meet a health plan's threshold criteria for the privileges and withdraws the application. Is this reportable to the NPDB?

No. A health plan should not report the withdrawal of a physician's application for clinical privileges when the physician fails to meet the health plan's threshold requirements.

6. A physician's application for surgical privileges was denied because the physician is not board certified in the clinical specialty and subspecialty for which he applied. Must this action be reported to the NPDB?

No. The action should not be reported to the NPDB if the physician failed to meet the hospital's established threshold criteria applied to all medical staff or clinical privilege applicants. Examples of threshold criteria may include: (1) minimum professional liability coverage, (2) board certification, (3) geographic proximity to the hospital, and (4) performance of a minimum number of procedures prescribed for a particular clinical privilege.

7. A physician applied to a hospital for clinical privileges to perform cardiac procedures. The hospital requires that such applications be granted only if the applying physician has performed 50 cardiac procedures in the previous year. The applying physician has performed only 40 such procedures. The hospital denies the application based solely on the physician not having met its 50-procedure requirement. Should this denial be reported to the NPDB?

No. A denial of clinical privileges that occurs solely because a practitioner does not meet a health care institution's established threshold criteria for that particular privilege should not be reported to the NPDB. Such denials are not considered to be the result of a professional review action relating to the practitioner's professional competence or professional conduct but, rather, are considered to be decisions based on eligibility that are not reportable.

8. A physician applying for renewal of his hospital clinical privileges falsified his application by omitting information about an ongoing licensure investigation. The hospital took a professional review action to deny his renewal application, which the MEC considered to be related to the practitioner's professional conduct, even though there was no actual patient harm. Should this be reported to the NPDB?

It depends. A clinical privileges action must be reported to the NPDB if it is the result of a professional review action that relates to professional competence or conduct that adversely affects, or *could adversely affect*, the health or welfare of a patient and lasts for a period longer than 30 days. Whether an action <u>affects or could affect</u> patient health or welfare is generally a determination that must be made by the entity taking the action. If, in the opinion of the MEC, the practitioner's falsification of his application *could* adversely affect the health or welfare of a patient, and the action is the result of a professional review, the action must be reported to the NPDB.

9. When a physician surrenders medical staff privileges due to personal reasons, infirmity, or retirement, and such a surrender did not occur in order to avoid an investigation or during an investigation, should it be reported to the NPDB?

No. The surrender <u>should not be reported</u> to the NPDB because the physician did not surrender his clinical privileges while under investigation by a health care entity relating to possible professional incompetence or improper professional conduct, or in return for not conducting such an investigation.

However, if an investigation was under way when the physician surrendered his privileges, even if the physician was not aware of the investigation, the surrender would have to be reported even if the physician claimed he surrendered the privileges for unrelated personal reasons.

10. A health care entity terminated a physician's contract for causes relating to poor patient care, which in turn resulted in the loss of the practitioner's network participation. Should this be reported to the NPDB using one or two reports?

Depending on the circumstances, the health care entity may be required to submit two different reports. The loss of the practitioner's network participation that resulted from the termination of the contract for reasons relating to professional competence or professional conduct must be reported as a clinical privileges action only if it is considered to be a <u>professional review action</u> by the health care entity.

The termination of the practitioner's contract with the health care entity, in itself, does not meet NPDB reporting criteria for a clinical privileges action. However, if the contract termination meets the requirements of an "other adjudicated action or decision," the contract termination should be reported separately to the NPDB.

11. A preferred provider organization (PPO) investigated a member physician after receiving quality of care complaints from several plan participants. The physician was unaware of the investigation, but, during the investigation, he relinquished his panel membership for personal reasons. Is this reportable?

Yes. A health care entity must report a physician's surrender of panel membership (a form of clinical privileges) while under investigation. The reporting entity should be able to produce evidence that an investigation was initiated prior to the surrender, and the physician's awareness of the investigation is immaterial. In addition, in this situation, any termination of the physician's contract with the PPO must be reported to the NPDB separately if the action meets the definition of an "other adjudicated action or decision."

12. A hospital automatically revoked a physician's clinical privileges when the physician lost her license. Should this action be reported?

No. <u>Administrative actions</u> that do not involve a professional review action should not be reported to the NPDB. The revocation of clinical privileges is

automatic because the practitioner no longer holds a license. Regardless of the reason for the State medical board's licensure action, the hospital's revocation of privileges was not the result of a professional review action. Therefore, the hospital's action should not be reported to the NPDB.

13. A physician holds clinical privileges at First Hospital and Second Hospital. First Hospital suspends the physician's privileges. Second Hospital's rules provide that a suspension or termination of privileges at another hospital requires suspension or termination at Second Hospital. Consequently, once it learns of First Hospital's suspension of the physician's clinical privileges, Second Hospital also suspends the physician's privileges. Should Second Hospital report its action to the NPDB?

No. Second Hospital's suspension of the physician is an administrative action that does not involve a professional review action and, therefore, should not be reported.

14. A hospital suspended a physician's clinical privileges for 45 days for failing to complete medical records. Should this action be reported to the NPDB?

Such a suspension must be reported to the NPDB if the suspension is a result of a professional review action and the hospital determines that the failure to complete medical records is related to the physician's professional competence or conduct and adversely affects or could adversely affect a patient's health or welfare. If the suspension of the practitioner's clinical privileges is the result of an automatic or administrative action, and not the result of a professional review action, the suspension should *not* be reported to the NPDB.

15. A hospital imposed a 30-day suspension of privileges as a result of a professional review action based on a physician's professional competence. Should this be reported to the NPDB?

No. The action should not be reported because the adverse action taken by the professional review body was not imposed for *more than* 30 days. However, if this action had lasted longer than 30 days, it must be reported to the NPDB on the 31st day.

16. A physician held clinical privileges at a hospital entitling him to perform specific procedures. The head of the physician's medical department pointed out to the physician that the physician was no longer performing some of the procedures, and the department head suggested that the physician voluntarily relinquish those privileges. The physician agreed.

Should this voluntary relinquishment of privileges be reported to the NPDB?

No. The physician was not under investigation when the privileges were voluntarily relinquished, and consequently no reportable action occurred.

17. A hospital's chief of surgery summarily suspended a physician's privileges for outbursts of anger and throwing charts and instruments in an operating room. Should this action be reported to the NPDB?

The action must be reported if the <u>summary suspension</u> is in effect for longer than 30 days and the hospital considers the summary suspension to be a professional review action. Summary suspensions are considered to be final when they become professional review actions through a decision of the authorized hospital committee or body, according to bylaws or other official documents (e.g., rules and procedures, standard operating procedures). In this scenario, the chief of surgery could reasonably conclude that the physician's outbursts affect the orderly conduct of business in the hospital, which could pose an imminent threat to patient safety.

18. A hospital began an investigation of a physician on staff at the hospital for issues related to professional competence 4 weeks prior to the expiration of the physician's clinical privileges. The physician failed to renew the clinical privileges while the investigation was ongoing. Should this event be reported to the NPDB?

The physician's <u>failure to renew</u> clinical privileges is considered a surrender while under, or in return for not conducting, an investigation. This action must be reported to the NPDB regardless of whether the physician knew he was under investigation at the time he failed to renew his clinical privileges. A practitioner's awareness that an investigation is being conducted is not a requirement for reporting to the NPDB.

19. Should investigations be reported if they do not reach a conclusion?

No. <u>Investigations should not be reported</u> unless a physician or dentist surrenders or fails to renew clinical privileges, or if privileges are restricted while the practitioner is under investigation by a health care entity for possible incompetence or improper professional conduct, or in return for not conducting an investigation. In such cases, the surrender or restriction must be reported to the NPDB.

20. A physician is being investigated by a hospital for issues related to professional competence and resigns her clinical privileges. At the time of her resignation she states that she plans to move to a different State. Should the resignation be reported to the NPDB?

Yes. Since the physician resigned while under investigation for issues related to professional competence, the reason for the practitioner's resignation is irrelevant. The hospital must report this action.

21. A hospital is investigating a physician who holds clinical privileges at the hospital. Separately from the investigation, colleagues and friends of the physician – who are not hospital officials – caution the physician that he should take time off to resolve personal problems. The physician takes a leave of absence from the hospital for 45 days, and the hospital reports this to the NPDB as a resignation while under investigation. When the physician returns to the hospital and his clinical privileges are reinstated, the hospital's governing body determines that the physician engaged in no professional conduct that adversely affected or could have adversely affected the health or welfare of a patient, and it found no reason to fault the physician's professional competence. What action should the hospital take with respect to the NPDB?

The hospital is not required to take any additional action with respect to the NPDB. However, the NPDB encourages reporting entities in such situations to file a Revision-to-Action Report reflecting the reinstatement of clinical privileges in order to provide future queriers a more complete history of the situation.

22. For the purposes of reporting resignations to the NPDB, when is an investigation considered to be complete?

An investigation is considered ongoing until the body conducting the investigation, or other authorized body, takes a final action or formally closes the <u>investigation</u>.

23. The hospital where a physician held clinical privileges as a surgeon initiated an investigation and suspended her privileges after receiving a complaint against the surgeon from a patient. Two weeks later, the hospital offered the surgeon the option of returning to work if she agreed to certain restrictions on her privileges. The surgeon chose not to accept the offer and, instead, resigned her clinical privileges. However, after the surgeon resigned, the hospital submitted a report to the NPDB indicating the

surgeon resigned while under investigation. The surgeon contended that the investigation was over as evidenced by the hospital's offer to let her return to work. Is the surgeon correct?

No. An investigation is considered ongoing until the health care entity's decisionmaking authority takes a final action or formally closes the <u>investigation</u>. In this situation, the hospital had not taken a final action or formally closed the investigation. Therefore, for purposes of NPDB reporting, the investigation was still ongoing at the time of resignation.

24. After receiving multiple quality of care complaints about a physician, a hospital initiated an investigation. During the investigation, the physician resigned her clinical privileges at the hospital. Since there was no professional review action taken, should a report be submitted to the NPDB?

Yes. The <u>investigation</u> was triggered by an event involving professional competence and centered on the physician's performance outside the scope of a routine review. Since the physician resigned her clinical privileges while under investigation, a report must be submitted to the NPDB.

25. A physician on staff at a hospital resigned her clinical privileges during a routine review that applied to all practitioners holding clinical privileges. Should this be reported to the NPDB?

No. A routine review process under which a health care entity evaluates, against clearly defined measures, the privilege-specific competence of all practitioners is not considered an investigation for the purposes of reporting to the NPDB. Therefore, this resignation would not be considered a resignation while under investigation and should not be reported to the NPDB. If, as a result of the routine review, the health care entity decides to start a targeted investigation of a specific physician, and that physician resigns during the targeted investigation, the resignation would be considered a resignation while under investigation and should be reported to the NPDB.

26. After conducting a professional review of a surgeon's competence, a hospital assigned a surgical proctor for 60 days. The surgeon could not perform surgery without being granted approval by the surgical proctor. Is the hospital required to report this action to the NPDB?

Yes. Since the surgeon cannot practice surgery without approval from the <u>proctor</u>, this restriction of clinical privileges, for more than 30 days, must be reported to the NPDB.

27. A physician holding courtesy privileges in a hospital applied for and was granted full staff privileges. As a condition of staff privileges, the physician is required to be on-call in the emergency department for one weekend a month. Due to personal reasons, the physician told the hospital he would not be able to fulfill his emergency department commitment. The physician did not miss any on-call duties. The hospital and the physician eventually agreed to change his clinical privileges from full staff to courtesy (with no professional review of this matter). Should this be reported to the NPDB?

No. The change in clinical privileges should not be reported because it is not the result of a professional review action based on the physician's professional competence or conduct that affects or could adversely affect the health or welfare of a patient.

28. A health care entity took a clinical privileges action against a practitioner, but a court issued an injunction against the clinical privileges action before it was implemented. Should the action be reported to the NPDB?

No. An adverse action enjoined prior to implementation should not be reported. Clinical privileges actions must be reported only if they are in effect for more than 30 days. However, if the action has been in effect for more than 30 days and is then enjoined, the action should be reported as an Initial Report and the injunction should be reported separately as a Revision-to-Action Report.

29. A physician is denied panel membership because a peer review committee determined that the physician had too many malpractice settlements. Is this denial of membership reportable to the NPDB?

It depends. A reporting entity must report a physician's denial of panel membership based on too many malpractice settlements if the peer review committee determines that the malpractice settlements relate to the competence or conduct of the physician.

30. A managed care organization's (MCO's) peer review panel restricts a nurse practitioner's panel membership for 31 days because of concerns about his ability to perform certain procedures. May this be reported?

Yes. A health plan may elect to report the membership action to the NPDB

because adverse panel membership actions taken against health care practitioners other than physicians and dentists *may* be reported to the NPDB. Adverse panel membership actions taken against physicians and dentists *must* be reported.

31. During a hospital's routine chart audit, the hospital discovered that several physicians were "cutting and pasting" notes and/or lab results from one patient's electronic health record (EHR) to another patient's EHR. No patient harm actually occurred, but the hospital viewed these documentation practices as having the potential for patient harm. The hospital took a professional review action against each of the physicians involved, which resulted in the restriction of each of their clinical privileges for 60 days. Should these actions be reported to the NPDB?

Yes. A clinical privileges action must be reported to the NPDB if it is the result of a professional review action related to professional competence or conduct that adversely affects, or *could adversely affect*, the health or welfare of a patient and lasts for a period longer than 30 days. Whether an <u>action affects or could affect</u> patient health or welfare generally is a determination that must be made by the entity taking the action. In this case, the hospital viewed the documentation practices as having the potential for patient harm, so the restrictions must be reported.

32. An "impaired physician" member of a hospital's medical staff has been repeatedly encouraged to enter a rehabilitation program. The practitioner continues to disregard the hospital's advice and offers of assistance. If an authorized hospital official, such as the CEO or department chair, directs the practitioner to give up clinical privileges and enter a rehabilitation program or face investigation relating to possible professional competence or conduct, and the physician surrenders his privileges, must the surrender of clinical privileges be reported to the NPDB?

Yes. If the authorized hospital official directs the physician to surrender his or her clinical privileges or face investigation by the hospital for possible professional incompetence or improper professional conduct, the surrender must be reported to the NPDB. The surrender of clinical privileges in return for not conducting an investigation triggers a report to the NPDB, regardless of whether the practitioner is impaired.

33. If an "impaired practitioner" takes a leave of absence and enters a rehabilitation program, must it be reported?

The fact that an impaired practitioner voluntarily enters a rehabilitation program should not be reported to the NPDB if no professional review action was taken and the practitioner did not relinquish clinical privileges while under investigation or in return for not conducting an investigation.

If a professional review action is taken against an impaired physician's or dentist's clinical privileges (e.g., suspension of clinical privileges), and the physician or dentist is required to involuntarily enter a rehabilitation program, the suspension must be reported to the NPDB. The reporting entity should explain in the narrative that the practitioner's privileges were suspended for reasons related to professional competence and conduct. The fact that the practitioner entered a rehabilitation program should not be reported.

34. A physician who holds clinical privileges at a hospital tests positive for a nonprescribed drug. He enters into a treatment plan, but he continues to practice while gradually working to modify his addictive behavior. Is this reportable to the NPDB?

It depends. If there was a professional review action taken by the hospital that limits the physician's privileges while he seeks treatment, the restriction or limitation of clinical privileges must be reported to the NPDB. If there is no restriction or limitation, but the practitioner must be interviewed and screened periodically for a relapse, this would not be reportable to the NPDB.

35. Laws related to drug and alcohol treatment programs have confidentiality provisions. Won't a report concerning a practitioner in a treatment program violate those provisions?

No. Only the adverse actions affecting privileges must be reported to the NPDB; the fact that a practitioner entered a <u>treatment or rehabilitation program</u> should not be reported.

36. Must a hospital or other health care entity report adverse actions concerning the clinical privileges of medical and dental residents and interns?

The action is not reportable if it was taken within the scope of the <u>training</u> <u>program</u>. Since residents and interns are trainees in graduate health professions education programs, they are not granted clinical privileges per se but are authorized by the sponsoring institution to perform clinical duties and responsibilities within the context of their graduate educational program. However, a resident or intern may practice outside the scope of the formal

graduate education program – for example, moonlighting in the intensive care unit or emergency department. Adverse clinical privileges actions related to practice occurring outside the scope of a formal graduate educational program must be reported.

37. A hospital took a professional review action to revoke a nurse practitioner's clinical privileges for reasons related to professional conduct. Should this action be reported to the NPDB?

This action is not required to be reported but may be reported. Hospitals and other health care entities *must* report professional review actions based on reasons related to professional competence or professional conduct that adversely affect the clinical privileges (including network participation and panel membership) of physicians or dentists. Hospitals and other health care entities *may* report such clinical privileges actions when taken against health care practitioners other than physicians and dentists.

38. As a prerequisite for awarding laparoscopic appendectomy clinical privileges, a hospital's standard operating procedures require physicians to perform five procedures within 30 days under the supervision of a proctor. In one situation, a physician successfully completed four procedures, but no additional patients required a laparoscopic appendectomy within the 30-day time period. Consistent with the standard operating procedures, the hospital extended the time period for completing the remaining laparoscopic appendectomy. Should this be reported to the NPDB?

No. The assignment of the proctor and the extension of the time period beyond 30 days are part of the hospital's standard operating procedures and are not the result of a professional review action. The hospital has nothing to report to the NPDB.

39. An anesthesiologist is hired by the hospital's anesthesia group and receives temporary privileges while his application for clinical privileges is pending the formal review process. After the hospital receives several quality of care-related complaints about the anesthesiologist, the practitioner agrees to resign the temporary privileges and withdraw his application for full privileges in return for the hospital not investigating the complaints. Is this reportable?

Yes. The NPDB does not generally draw a distinction between adverse actions taken with respect to temporary or permanent privileges. Because the physician

surrendered his temporary clinical privileges in return for the hospital not conducting an investigation into issues related to professional competence or conduct, the surrender must be reported.

40. A hospital initiated an investigation related to the professional conduct of a physician who held time-limited, nonrenewable, temporary privileges at the hospital. During the investigation, the physician's temporary privileges expired and the hospital took no further action. Should this be reported?

No. Generally, the NPDB makes no distinction between adverse actions taken with respect to temporary or permanent privileges. However, in this case, there was no resignation of privileges while under investigation because the temporary privileges expired and the physician could not renew them. This is unlike the typical situation where regular privileges that could be renewed expire during an investigation. In a situation such as that, an action to not renew permanent clinical privileges while under investigation for issues related to professional competence or conduct is considered a resignation while under investigation and should be reported.

41. A hospital repeatedly reminded a physician to update his medical records in a timely manner. After there was no change in the physician's behavior, the hospital initiated an investigation, which revealed that the physician had more than 300 incomplete medical records. As a result, the hospital took a professional review action to suspend the physician's clinical privileges for 60 days, citing professional misconduct. Because there was no actual patient harm, should this be reported to the NPDB?

It depends. A clinical privileges action must be reported to the NPDB if it is the result of a professional review action related to professional competence or conduct that adversely affects, or *could adversely affect*, the health or welfare of a patient and lasts for a period longer than 30 days. Whether a practitioner's behavior affects or could affect patient health or welfare is a determination that generally must be made by the entity taking the action. If, in the opinion of the MEC, the physician's lack of attention to updating medical records in a timely manner *could* adversely affect the health or welfare of a patient, and the action is the result of a professional review, the action must be reported to the NPDB.

42. A hospital summarily suspended a physician's clinical privileges to allow sufficient time for allegations of gross negligence to be fully investigated. The day after the summary suspension was imposed, the physician requested an educational leave of absence. If the hospital grants the leave of absence, must the summary suspension be reported to the NPDB?

If the <u>summary suspension</u> is not lifted within 30 days, it must be reported to the NPDB, regardless of when the leave of absence begins or if it ever occurs.

REPORTING ADVERSE PROFESSIONAL SOCIETY MEMBERSHIP ACTIONS

Professional societies *must* report <u>professional review actions</u> based on reasons related to professional competence or professional conduct that adversely affect or may adversely affect the membership of a physician or dentist. Professional societies *may* report such adverse membership actions when taken against health care practitioners other than physicians and dentists.

Table E-7 outlines reporting obligations for professional society membership actions

Table E-7: Authority for Reporting Professional Society Membership Actions			
Law	Who Reports?	What is Reported?	Who is Reported?
Title IV	Professional societies with formal peer review	Certain professional society membership actions related to professional competence or conduct	Physicians and dentists Other practitioners (optional)

An action taken by a professional society that adversely affects or may adversely affect a physician's or dentist's membership must be reported to the NPDB when that action is taken in the course of professional review activity through a formal peer review process, provided the action is based on the member's professional competence or professional conduct that adversely affects, or could adversely affect, the health or welfare of a patient. The professional society that takes the adverse action generally determines whether the physician's or dentist's professional competence or professional conduct adversely affects, or could adversely affect, the health or welfare of a patient.

Matters *not* related to the professional competence or professional conduct of a physician or dentist should not be reported to the NPDB. For example, adverse actions against a practitioner based primarily on his or her advertising practices, fee structure, salary arrangement, affiliation with other associations or health care professionals, or other competitive acts intended to solicit or retain business are excluded from NPDB reporting requirements.

In addition, if censure, reprimand, or admonishment is the sole result of an adverse membership action, that action should not be reported to the NPDB.

Professional societies also must report revisions to previously reported adverse actions. For more information, go to <u>Types of Reports</u> in this chapter.

Table E-8 provides examples of whether specific professional society membership actions must be reported to the NPDB.

Table E-8: Determining if Professional Society Membership Actions Must be Reported		
Action	Reportable?	
A professional society denies membership to a physician after the society's peer review committee found that the physician had failed to obtain required informed consents for several patients.	Yes	
A professional society denies membership to a dentist who has had his wages garnished for not paying child support.	No	
A professional society terminates a dentist's membership for failure to pay the annual membership fee.	No	
A professional society's peer review committee took an action to suspend a physician's membership based on a State licensing board's action to place the physician's license on probation for reasons related to professional conduct that adversely affects, or could adversely affect, the health or welfare of a patient.	Yes	
A physician resigns a professional society membership or allows the membership to lapse while under a formal peer review investigation by the professional society, but before a final decision is rendered.	No	

Submitting a Copy of the Report to the State Licensing Board

A copy of the Report Verification Document that professional societies receive after a report is processed successfully by the NPDB must be provided to the appropriate State licensing board in the State in which the professional society is located. Alternatively, NPDB reporters may elect to send an electronic version of the report to the appropriate State licensing board through the NPDB's <u>Electronic Report Forwarding service</u>, provided the State board has agreed to accept electronic notices of an action.

Sanctions for Failing to Report to the NPDB

A professional society that has substantially failed to report adverse membership actions can lose, for 3 years, the <u>immunity protections</u> provided under Title IV for professional review actions it takes against physicians and dentists based on their

professional competence and professional conduct.

The Secretary of HHS will conduct an investigation if there is reason to believe that a professional society has substantially failed to report adverse membership actions taken as result of professional review activity. If the investigation reveals that the professional society has not complied with reporting requirements, HHS will inform the professional society of its noncompliance in writing. This written notice provides the professional society with the opportunity to correct the noncompliance and notifies it of its right to request a hearing.

A request for a hearing must contain a statement of the material factual issues in dispute to demonstrate cause for a hearing and must be submitted to HHS within 30 days of receipt of the notice of noncompliance. These issues must be both substantive and relevant. An example of a material factual issue in dispute is a professional society refuting HHS's claim that the professional society failed to meet reporting requirements.

A request for a hearing is denied if it is untimely or lacks a statement of material factual issues in dispute, or if the statement is frivolous or inconsequential. Hearings are held in the Washington, DC, metropolitan area.

If a request for a hearing is denied or if HHS determines that a professional society has substantially failed to report information in accordance with NPDB requirements, the name of the entity will be published in the Federal Register, and the professional society will lose the <u>immunity provisions under Title IV</u> with respect to professional review activities for a period of 3 years, commencing 30 days from the date of publication in the Federal Register.

Q&A: Reporting Professional Society Membership Actions

1. If a professional society denies membership to a physician, should it be reported to the NPDB?

It depends. The action must be reported to the NPDB if the denial of membership was based on a professional review action conducted through a formal peer review process and was based on an assessment of the physician's professional competence or professional conduct that adversely affected or could have adversely affected the health or welfare of a patient or patients. Denials based on the practitioner not meeting the established threshold criteria for membership are not reportable.

2. A professional society suspended the membership of a physician for reasons related to professional conduct. It reported this action to the

NPDB. Later, the professional society's peer review committee took a professional review action that resulted in the reinstatement of the physician's membership. Should the reinstatement be reported?

It depends. If the suspension was imposed with a fixed term and the physician was automatically reinstated at the end of the fixed term, no Revision-to-Action Report is required. Queriers can easily determine whether the suspension has been lifted by looking at the date and the term in the Initial Report. If the suspension had an indefinite term, or the physician was reinstated before the expiration of the fixed term, or if the physician was not reinstated when the fixed term expired, a Revision-to-Action Report must be filed.

3. A professional society takes a professional review action to terminate the membership of a psychologist for reasons related to professional conduct. Should this action be reported to the NPDB?

This action is not required to be reported, but it may be reported. Professional societies *must* report professional review actions based on reasons related to professional competence or professional conduct that adversely affect the membership of a physician or dentist and that adversely affect, or may adversely affect, the health or welfare of a patient. Professional societies *may* report such adverse membership actions when taken against health care practitioners other than physicians and dentists.

4. A professional society's ethics committee takes a professional review action to place a physician on probation for 60 days for falsifying a résumé. Should this action be reported to the NPDB?

It depends. Generally, if the professional society determines that falsifying the résumé is professional conduct that adversely affects, or could adversely affect, the health or welfare of a patient, the action must be reported to the NPDB.

5. A professional society expels a member physician because the physician was convicted of health care fraud. Should this expulsion be reported to the NPDB?

It depends. Professional societies must report professional review actions based on reasons related to professional competence or professional conduct that adversely affects the membership of a physician or dentist. Generally, the professional society determines whether the activity in question is related to professional competence or professional conduct that adversely affects the member's membership. The professional society must make that determination

in this case.

6. A professional society takes a professional review action against a member physician to revoke the physician's membership based on a finding that the physician provided expert witness testimony without conducting an evaluation, and that the physician provided a medical opinion that departed from the widely held standard of care. Should the membership revocation be reported to the NPDB?

It depends. The professional society took an adverse action against the membership of a physician in the course of a professional review action that was related to the member's professional competence or conduct. If the professional society determines that the member's professional competence or conduct adversely affects, or could adversely affect, the health or welfare of a patient, the action must be reported to the NPDB.

7. If, during the course of its peer review process, a professional society finds that a physician or dentist failed to provide adequate care, but the physician or dentist resigns the membership or fails to renew the membership as a result of this finding, should a report be submitted to the NPDB?

It depends. If the finding is not yet final and the physician or dentist resigns while the peer review process is still pending, then the action is not reportable. However, once negative findings are finalized, whether or not the physician or dentist resigns or allows the membership to lapse, a report is required.

REPORTING STATE LICENSURE AND CERTIFICATION ACTIONS

State licensing and certification authorities must report to the NPDB certain actions (referred to as State licensure and certification actions) taken against health care practitioners, entities, providers, or suppliers. The term State licensing and certification authorities includes, but is not limited to, any authority of a State or of a political subdivision that is responsible for the licensing or certification of health care practitioners (or of any peer review organization or private accreditation entity reviewing the services provided by health care practitioners), health care entities, providers, or suppliers. The actions to be reported must be as a result of <u>formal proceedings</u>.

Actions that must be reported include:

- Any adverse action taken by the State licensing or certification authority as a
 result of a formal proceeding, including: revocation or suspension of a license,
 certification agreement, or contract for participation in a Government health
 care program; reprimand; censure; or probation.
- Any dismissal or closure of a formal proceeding because the health care practitioner, entity, provider, or supplier surrendered the license, certification agreement, or contract for participation in a Government health care program, or because the subject of the proceeding left the State or jurisdiction.
- Any other loss of license or loss of certification agreement or contract for participation in a Government health care program, or the right to apply for, or renew, a license or certification agreement or contract of the health care practitioner, entity, provider or supplier, whether by operation of law, voluntary surrender, nonrenewal (excluding nonrenewals due to nonpayment of fees, retirement, or change to inactive status), or otherwise.
- Any negative action or finding by the State licensing or certification authority that, under the State's law, is publicly available information, including, but not limited to, limitations on the scope of practice, liquidations, injunctions, and forfeitures. This definition also includes final adverse actions rendered by a State licensing or certification authority such as exclusions, revocations, or suspension of license or certification that occur in conjunction with settlements in which no finding of liability has been made (although such a settlement itself is not reportable). This definition excludes administrative fines or citations and corrective action plans and other personnel actions, unless:
 - o the underlying activity is connected to the delivery of health care services, *or*
 - o the action is taken in conjunction with other adverse licensure or certification actions, such as revocation, suspension, censure, reprimand, probation, or surrender.

When a license, agreement, or contract is suspended, the length of the suspension must be reported also.

State licensing and certification authorities also must report any revisions to a previously reported licensing or certification action, such as a reinstatement of a suspended license, and whether an action is on appeal. For more information, go to Types of Reports in this chapter.

An action must be reported to the NPDB based on whether it satisfies NPDB reporting requirements and <u>not based on the name</u> affixed to the action by the reporting entity.

Table E-9 outlines reporting obligations for State licensure and certification actions.

Table E-9: Authority for Reporting State Licensure and Certification Actions			
Law	Who Reports?	What is Reported?	Who is Reported?
Title IV	State medical and dental boards	Certain adverse licensure actions related to professional competence or conduct (Medical and dental boards that meet their reporting requirements for Section 1921, below, will also meet their requirements to report under Title IV)	Physicians and dentists
Section 1921	State licensing and certification authorities	State licensure and certification actions	Practitioners, entities, providers, and suppliers

Formal Proceeding

State licensing and certification actions reported pursuant to Section 1921 must be the result of formal proceedings. In this context, a formal proceeding is one that is conducted by a State licensing or certification authority that maintains defined rules, policies, or procedures for such a proceeding. The definition of formal proceedings is written broadly to include formal hearings as well as other processes that follow defined rules, policies, or procedures. In determining whether a process meets this definition, the NPDB is only concerned with the presence of defined rules, policies, or procedures and not whether the rules, policies, or procedures have been strictly adhered to.

Certification

In the NPDB regulations, the term "certification" has two distinct meanings. First, the term is related to licensure, because licensure includes certification and other forms of authorization to provide health care services. Based on State laws and requirements, States may "license," "certify," or "register" certain types of health care practitioners, entities, providers, or suppliers.

Second, the term also is used to refer to certification of a health care practitioner, entity, provider, or supplier to participate in a Government health care program. In this context, certification includes certification agreements and contracts for participation in a Government health care program.

Administrative Fines and Formal Money Penalties

State licensing and certification authorities must report to the NPDB all money penalties and administrative fines that are adverse actions resulting from a formal proceeding (e.g., formal disciplinary actions) against health care practitioners, entities, providers, and suppliers.

However, fines that are considered administrative or technical in nature must be reported to the NPDB only if they meet the NPDB definition of negative actions or findings. First, these types of administrative fines must be publicly available information. In addition, administrative fines reported as negative actions or findings must be either:

- Connected to the delivery of health care services, or
- Taken in conjunction with other adverse licensure or certification actions, such as revocation, suspension, censure, reprimand, probation, or surrender.

Generally, each reporting entity determines whether the action is connected to the delivery of health care services.

An action must be reported to the NPDB based on whether it satisfies NPDB reporting requirements and not based on the name affixed to the action.

Publicly Available Information

Publicly available information means that information is accessible to the interested public, and this can occur in a variety of ways, including, but not limited to, phone, writing, electronic media (e.g., website or portal), or other media available for general distribution to any member of the public.

Stayed Actions

A licensure or certification action imposed with a stay should not be reported to the NPDB as long as the entire action is stayed. In instances where only part of the action is stayed, the part of the action that is not stayed must be reported. For example, if a practitioner's license is placed on probation for 6 months, but 4 months of the probation are stayed, the remaining 2 months of the probation must be reported to the NPDB.

In addition, if a stayed action is accompanied by another reportable action, the reportable action that accompanied the stayed action must be reported. For example, a practitioner's license is suspended for 6 months, the suspension is stayed, and the practitioner is placed on probation with terms and conditions for 1 year. The suspension should not be reported to the NPDB because it was stayed, but

the probation must be reported to the NPDB.

Summary or Emergency Suspensions and Other Nonfinal Actions

The requirements for reporting State licensure and certification actions are not limited to final actions. Interim or nonfinal adverse actions taken by a State licensing or certification authority also must be reported to the NPDB. Examples of such actions include a State licensing board's summary or emergency suspension of a license, or a health care practitioner's voluntary agreement to refrain from practice pending completion of a State licensing board investigation. Once a final action is taken that supersedes or modifies the initial action, the State licensing or certification authority must submit a Revision-to-Action Report.

Denials of Initial and Renewal Applications

State licensing and certification authorities must report to the NPDB denials of initial and renewal applications for licensure or certification for health care

practitioners, entities, providers, or suppliers if they are adverse actions resulting from formal proceedings. For example, if, after a

State licensing or certification authorities should not report cases in which a health care practitioner, entity, provider, or supplier simply does not meet the threshold criteria for licensure or certification.

formal proceeding, a State licensing board denies a practitioner's initial licensure application because the applicant misrepresented credentials, that action is reportable.

However, State licensing or certification authorities should not report cases in which a health care practitioner, entity, provider, or supplier simply does not meet the threshold criteria for licensure or certification. For example, if a State licensing board determines that an applicant failed to meet the education requirements or failed to pass a required exam and denies the applicant's license, the State licensing board should not report that action.

Withdrawals of Initial and Renewal Applications While Under Investigation, and Failure to Renew While Under Investigation

Investigations should not be reported to the NPDB. However, withdrawal of a renewal application for licensure or certification, or failure to renew, while the State licensure or certification authority is investigating the applicant is reportable. In addition, an applicant's withdrawal, for any reason, of an initial application for licensure or certification is not reportable, even if the applicant is under investigation.

The NPDB interprets the word "investigation" expansively, although the investigation must be focused on a specific individual or entity. For example, if a State licensing board routinely runs a criminal background check on all applicants for license renewal, that is not considered an investigation. If, as a result of the routine check, the board decides to further examine a specific applicant's record, that examination is considered an investigation. The NPDB retains the ultimate authority to determine whether an investigation exists.

The NPDB considers an investigation to run from the start of an inquiry until a final decision is reached. In other words, an investigation is not limited to a State licensure or certification authority's gathering of facts or by the manner in which the State licensing or certification authority defines the term "investigation." An investigation begins as soon as the State licensure or certification authority begins a nonroutine inquiry and does not end until the authority's decisionmaking body takes a final action or makes a decision not to further pursue the matter.

A licensure or certification authority that submits a report based on a withdrawal of a renewal application while the applicant is under investigation should have evidence of an ongoing investigation at the time of withdrawal. Examples of acceptable evidence may include minutes or excerpts from committee meetings, orders from licensing or certification officials directing an investigation, or notices to renewal applicants of an investigation. (The licensure or certification authority must be able to show that the practitioner was notified of the investigation, although actual knowledge of the investigation on the part of the practitioner is not required.)

Guidelines for Investigations

- For NPDB reporting purposes, the term "investigation" is not controlled by how that term may be defined by a licensing or certification authority's policies and procedures.
- A routine review of a particular practitioner is *not* an investigation.
- The investigation must be focused on the practitioner in question.
- To be considered an investigation for purposes of determining whether an activity is reportable, the activity generally should be the precursor to a licensure or certification action.
- An investigation is considered ongoing until the licensing or certification authority's decisionmaking authority takes a final action or formally closes the investigation.

Voluntary Surrenders

State licensing and certification authorities are required to report voluntary surrenders of a license or certification agreement or contract for participation in a

Government health care program by a health care practitioner, entity, provider, or supplier. NPDB regulations define a <u>voluntary surrender</u> of a license or certification as "a surrender made after a notification of investigation or a formal official request by a Federal or State licensing or certification authority for a health care practitioner, health care entity, provider, or supplier to surrender the license or certification (including certification agreements or contracts for participation in Federal or State health care programs). The definition also includes those instances where a health care practitioner, health care entity, provider, or supplier voluntarily surrenders a license or certification (including program participation agreements or contracts) in exchange for a decision by the licensing or certification authority to cease an investigation or similar proceeding, or in return for not conducting an investigation or proceeding, or in lieu of a disciplinary action."

The voluntary relinquishment of a practitioner's license for personal reasons such as retirement or illness is not reportable to the NPDB if no other action or investigation is in progress. Only the surrender of the license, while under investigation or in return for not conducting an investigation, is reportable.

Consent Agreement

Any State licensure or certification action that meets NPDB reporting requirements must be reported, regardless of whether the action was imposed through board order, consent agreement, or other method. Thus, even if a consent agreement contains a provision stating that the State licensing agrees not to report a practitioner to the NPDB, the provision is immaterial and the consent agreement remains reportable. It is the action itself, rather than the method by which the action was taken, that determines whether the action must be reported. For example, if a State licensing board issues a reprimand through a consent agreement, the reprimand is reportable.

Confidentiality Laws Related to Drug and Alcohol Treatment

If a licensure or certification action is taken and the practitioner enters a treatment or rehabilitation program as a result, the adverse action must be reported. This is true even if the treatment is a condition of probation. However, the fact that the practitioner entered a drug or alcohol treatment facility should not be reported.

If a practitioner (or other reportable individual) voluntarily enters a treatment or rehabilitation program at the direction or suggestion of a licensing or certification authority (initiated either by the board or the practitioner) and no action is taken, a report should not be submitted to the NPDB.

Table E-10 provides guidance on when State licensure and certification actions

must be reported to the NPDB. Table E-11 describes which reporting format should be used for reporting State licensing and certification actions.

Nurse Licensure Compact

The NPDB's Nurse Multi-State Privilege Adverse Action Classification Codes were developed to allow the reporting of actions taken against a nurse's privilege to practice under the Nurse Licensure Compact (NLC). The State that issues the license to practice (the nurse's home State or State of residency) should use the State Licensure Actions - Adverse Action Classification Codes for Individual Subjects to report an action it takes against the nurse's license. If the remote State (the State that did not issue the license) takes an action against the nurse's Multi-State Privilege to Practice, it also should submit a separate report of that action using the Nurse Multi-State Privilege Adverse Action Classification Codes. Both the Nurse Multi-State Privilege Adverse Action Classification Codes and the State Licensure Adverse Action Classification Codes are included under the State Licensure Action category.

Sanctions for Failing to Report

If HHS determines that a State licensing or certification authority has substantially failed to report information required to be reported to the NPDB, the name of the entity will be published and made publicly available.

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Table E-10: Determining if State Licensure and Certification Actions Must be Reported, Part 1		
Action	Reportable?	
A formal adverse action to deny an application for licensure or certification (initial or renewal).	Yes	
A State licensing board did not grant a license to an applicant who failed to pass the required licensure exam.	No	
The withdrawal of an initial application for licensure or certification while under investigation.	No	
The withdrawal, while under investigation, of an application to renew a licensure or certification.	Yes	
An applicant for an initial State license or for a State license renewal does not meet threshold licensing criteria and withdraws the application.	No	
A psychologist decides to withdraw a licensure application; the psychologist was not under investigation nor did he withdraw the application to avoid an investigation.	No	
The non-renewal of a license while under investigation or to avoid an investigation, if the licensee has the option to renew.	Yes	
A physical therapist decides, for personal reasons, to no longer practice physical therapy and to change her license to inactive status.	No	
The voluntary relinquishment of a practitioner's license due to retirement.	No	
A practitioner's surrender of a license in lieu of a disciplinary action.	Yes	
In lieu of taking a disciplinary action, a State licensing board issues a consent order in which a practitioner agrees not to re-apply for a license in the future.	Yes	
A State licensing authority censures a health care supplier based on the supplier's failure to report a licensure disciplinary action taken by another licensing authority.	Yes	
A State licensing board imposes, through an order that is not publicly available, monitoring that does not constitute a restriction on the license of a health care practitioner, entity, provider, or supplier for a specific period of time.	No	
A civil money penalty imposed by a State licensing or certification authority that is an adverse action resulting from a formal proceeding (e.g., a formal disciplinary action).	Yes	
A State licensing board imposes an administrative fine that is not a formal adverse action but is publicly available information and is related to the delivery of health care services.	Yes	

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Table E-10: Determining if State Licensure and Certification Actions Must be Reported, Part 2		
Action	Reportable?	
An administrative fine imposed for late payment of a licensure application renewal fee; this action is not a formal adverse action, and the State licensing board does not consider the fine to be connected to the delivery of health care, nor was it taken in conjunction with any other adverse licensure or certification action.	No	
An administrative fine, taken as a result of a formal proceeding, that is considered to be an adverse action.	Yes	
A licensure or certification action that is imposed with a "stay"; the entire action was stayed.	No	
A summary or emergency suspension of a health care practitioner's license, of any length, and any subsequent revision to the action.	Yes	
A corrective action plan that is imposed in conjunction with a reprimand.	Yes	
A State licensing or certification action that otherwise must be reported to the NPDB and is part of a consent agreement or settlement.	Yes	
A reinstatement of a practitioner's license after a previously reported indefinite suspension of the license.	Yes	
A cease and desist order, citation, or letter issued by a State licensing board against an unlicensed individual who holds himself or herself out to be licensed or otherwise authorized by the State to provide health care services.	Yes	
A finding entered into a State's nurse aide registry concerning abuse, neglect, or mistreatment of residents, or misappropriation of their property, which disqualifies the nurse aide from employment in the State's skilled nursing facilities.	Yes	
Based on findings that a nursing facility violated Medicare and Medicaid participation requirements, a State survey and certification agency imposes a formal money penalty and requires on-site monitoring.	Yes	
A State Medicaid agency's termination of a health care provider's contract, for repeated noncompliance with participation requirements, for participation in the State's Medicaid program.	Yes	

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Table E-11: Selecting the Appropriate NPDB Reporting Format for State Licensure and Certification Actions		
Type of Action	NPDB Reporting Format	
Actions taken with respect to licensure, certification, registration, or other authorization by the State to provide health care services	State Licensure Action category on the Adverse Action Report format	
Actions taken with respect to certification agreements or contracts for participation in Government health care programs	Government Administrative Action category on the Adverse Action Report format	

Q&A: Reporting State Licensure and Certification Actions

1. How should a State licensing or certification authority report actions when they are changed by court order?

The State licensing or certification authority should report the initial adverse action; the authority should then report the judicial decision as either a <u>revision</u> to action or <u>void</u>. For example, if a State licensing board revoked a physician's license and a judicial appeal resulted in the court modifying the discipline to probation for one year, then the board would be required to report both its initial revocation (as an Initial Report) and the court-ordered revision to probation (as a Revision-to-Action Report). If a court overturns a board's order, the board should void the Initial Report.

2. How should a negative finding in a State nurse aide registry be reported to the NPDB?

State licensing and certification authorities are required to report any negative action or finding by the State licensing or certification authority that is publicly available information, including findings in a State nurse aide registry. Nurse aide registry findings should be reported to the NPDB as Government Administrative Actions using the Adverse Action Classification Code "Employment Disqualification Based on Finding in State Nurse Aide Registry."

However, if a State licensing or certification authority is authorized by State law (e.g., a State practice act or a State title act) to regulate nurse aides, and takes a licensure or certification action against a nurse aide's certification or authorization to practice, that action should be reported to the NPDB as a State Licensure Action. In these instances, depending on the State's law, if a State licensing or certification authority takes a related nurse aide registry finding, the State licensing or certification authority may submit a single State Licensure

Action report that documents both the action and registry finding. The reporting entity may select up to five Adverse Action Classification Codes and use the narrative description field when describing multiple actions taken.

3. When reporting a reprimand by a State licensing board, what Length of Action should the board enter in the report?

The board should select "Indefinite" for the Length of Action when reporting a reprimand to the NPDB.

4. Should a State licensing or certification authority report a suspension when the suspension has been fully stayed prior to implementation?

No. Licensure and certification actions that are imposed with a <u>stay</u> should not be reported to the NPDB. However, any reportable action that accompanies a stayed action must be reported.

5. If, as a result of a formal proceeding, a State licensing board suspends a practitioner's license for 1 year, but stays 3 months of the suspension, how should it be reported?

The State licensing board must report the 9-month suspension (1-year suspension, minus the 3-month stayed suspension). The <u>stayed</u> portion of the suspension should not be reported to the NPDB.

6. A State licensing board submitted a report to the NPDB 6 months ago, after the board placed a practitioner's license on probation. Three months ago, the board reinstated the license in full. The report in the NPDB still indicates that the license is on probation. Because the status of the licensure action has changed, should the board update the information in the NPDB?

Yes. Entities that submit an <u>Initial Report</u> to the NPDB also must report any subsequent revision to the underlying action. The State licensing board, therefore, is required to submit a <u>Revision-to-Action Report</u> after reinstating the license. If, however, the initial action to place the license on probation included an automatic reinstatement of the license that was indicated on the Initial Report, the board is not required to submit a Revision-to-Action Report.

7. A board of medical examiners initiated an investigation related to a physician's professional conduct. Two weeks later, the physician allowed his license to expire. Since the physician's license lapsed prior to any proposed agreement or board decision, must the lapse be reported to the

NPDB?

Yes. A <u>nonrenewal of a license while under or to avoid an investigation</u> must be reported to the NPDB.

8. How should an action taken against a nurse who is licensed in one State but authorized to practice in another State under the Nurse Licensure Compact (NLC) be reported to the NPDB?

The Nurse Multi-State Privilege Adverse Action Classification Codes were developed to allow the reporting of actions taken against a nurse's privilege to practice under the NLC. The State that issues the license to practice (the nurse's home State or State of residency) should use the State Licensure Adverse Action Classification Codes to report an action it takes against the nurse's license. If the remote State (the State that did not issue the license) takes an action against the nurse's Multi-State Privilege to Practice, it should submit a separate report of that action using the Nurse Multi-State Privilege Adverse Action Classification Codes.

9. A State licensing board issued a formal cease and desist order to an unlicensed practitioner who held herself out to be a licensed psychotherapist. Should the action be reported to the NPDB?

Yes. NPDB regulations define a health care practitioner as "an individual who is licensed or otherwise authorized by a State to provide health care services (or any individual who, without authority, holds himself or herself out to be so licensed or authorized)." Therefore, State licensure and certification actions taken against unlicensed individuals that result from a formal proceeding must be reported to the NPDB. When reporting an action against an unlicensed individual, select "No License" on the licensure information screen and select the field of licensure claimed by the individual for the Occupation/Field of Licensure category.

10. A State Medicaid agency terminated the contract for participation of one of its Medicaid MCOs after holding formal hearings and determining that the MCO had not maintained a sufficient network of providers to meet the State's access and quality requirements. Should the State agency report this action to the NPDB?

Yes. Any adverse action taken against a health care practitioner, entity, provider, or supplier by a licensing or certification authority of the State as a result of a formal proceeding, including revocations or suspensions of a

certification agreement or contract for participation in a Government health care program, <u>must be reported</u> to the NPDB. This termination of the MCO's contract for participation in the State's Medicaid program should be reported to the NPDB as a Government Administrative action on the Adverse Action Report format.

11. A State Medicaid agency excluded a pharmacy from the State's Medicaid program for submitting false claims. Is this action reportable?

Yes. The exclusion of health care practitioners, providers, or suppliers from participation in Federal or State health care programs must be reported to the NPDB. However, exclusions are distinct from licensure and certification actions and should be reported to the NPDB as Exclusion or Debarment actions on the Adverse Action Report format. For more information, see the section in this chapter on Reporting Exclusions from Participation in Federal or State Health Care Programs.

12. A physician voluntarily terminated a contract to participate in a State health care program after the State initiated an investigation into allegations that the physician had billed for services not provided. Should this action be reported to the NPDB?

Yes. The surrender of a license or certification agreement or contract for participation in a Government health care program, made after a notification of an <u>investigation or a formal official request</u> by a State licensing or certification authority for a health care practitioner, entity, provider, or supplier to surrender a license or certification (including certification agreements or contracts for participation in Government health care programs), must be reported to the NPDB.

13. If a State licensing or certification authority takes an action that is later expunged, should the State licensing or certification authority report the expungement?

An expungement removes the practitioner's public record but does not vacate or change the action. Therefore, if the reporting entity itself expunges a record, or if the reporting entity learns that one of its records has been expunged, it should file a Revision-to-Action Report with the NPDB, to note that an expungement has occurred. An expunged record is not a reason to void a report.

14. A State medical board suspended a physician's license and, as a result of the same incident, the State pharmacy board revoked the Controlled

Dangerous Substance (CDS) registrations of both the physician and a pharmacy that filled many of the physician's prescriptions. All actions were taken as a result of formal proceedings. How should these actions be reported to the NPDB?

<u>Three separate reports must be submitted to the NPDB.</u> The State medical board must report the suspension of the physician's license. The pharmacy board must report the revocation of the physician's CDS registration and, separately, the revocation of the pharmacy's CDS registration.

15. If a State licensing or certification authority issues a letter of concern, should it be reported to the NPDB?

It depends. If, under the State's law, the letter of concern is a publicly available <u>negative action or finding</u>, it must be reported to the NPDB. If, under the State's law, the letter of concern does not meet the definition of a publicly available negative action or finding, it should not be reported.

16. As a result of a formal proceeding, a State licensing or certification authority reprimanded a practitioner. In addition, the authority imposed a publicly available, technical, administrative fine, which is not an adverse action, in the amount of \$500. Should this administrative fine be reported to the NPDB?

Yes. State licensing or certification authorities must report <u>administrative fines</u> (i.e., fines that are administrative or technical in nature) if they are publicly available information and if they are either connected to the delivery of health care services *or* taken in conjunction with other adverse licensure or certification actions. The scenario described provides insufficient information to determine if the fine was connected to the delivery of health care services. However, because the fine was taken in conjunction with another adverse licensure or certification action (the reprimand), the fine, along with the reprimand, must be reported.

17. A State licensing board is required to report any publicly available negative actions or findings. If a State licensing board does not publish its actions on the board's website, but publishes them in a publicly available monthly newsletter, does the board still have to report the actions to the NPDB?

Yes. Publicly available information means that information is accessible to the interested public and can occur in a variety of ways, including, but not limited

to, phone, writing, electronic media (e.g., website or portal), or other media available for general distribution to any member of the public.

18. During an interview with a practitioner, a State licensing board discovers that the practitioner failed to disclose prior substance abuse on a licensure application. As a result, the State board required the practitioner to complete 5 hours of continuing education pertaining to professional ethics. Should this action be reported to the NPDB?

It depends. If, based on the State's laws, the imposition of the continuing education requirement is a publicly available <u>negative action or finding</u>, the action must be reported to the NPDB. If, under State law, the action does not meet the definition of a publicly available negative action or finding, it should not be reported.

19. When should administrative fines be reported to the NPDB?

Two types of <u>administrative fines</u> must be reported to the NPDB. First, administrative fines that are adverse actions taken as a result of a formal proceeding must be reported.

Second, fines that are not adverse actions and are considered administrative or technical in nature must be reported only if they meet the NPDB definition of negative action or finding. These types of administrative fines must be publicly available information. In addition, administrative fines reported as <u>negative</u> actions or findings must be either:

- Connected to the delivery of health care services, or
- Taken in conjunction with other adverse licensure or certification actions, such as revocation, suspension, censure, reprimand, probation, or surrender.

20. If, as a result of a formal proceeding, a State dental board suspends a dentist's permit to administer anesthesia, should the action be reported to the NPDB?

Yes. State licensing and certification authorities must report to the NPDB certain actions (referred to as State licensure and certification actions) taken against health care practitioners, entities, providers, or suppliers. Licensure includes certification and other forms of authorization to provide health care services. Because the anesthesia permit authorizes the dentist to administer anesthesia, any licensure or certification actions taken against the anesthesia permit must be reported.

21. If a State board denies an application to a practitioner who did not have the required number of practicum hours, should the action be reported?

No. A board should not report cases in which a health care practitioner, entity, provider, or supplier simply does not meet the <u>threshold criteria for licensure</u>.

22. A State agency responsible for licensing skilled nursing facilities suspended a facility's license after substantiating several serious quality of care complaints against the facility. Is this reportable to the NPDB?

Yes. State licensing and certification authorities must report adverse actions resulting from a formal proceeding, such as revocation or suspension of a license, taken against a health care practitioner, entity, provider, or supplier.

23. A State licensing and certification authority suspended the license of a durable medical equipment supplier for selling defective intravenous supplies. Is this reportable to the NPDB?

Yes. State licensing and certification authorities must report any adverse action resulting from a formal proceeding, such as revocation or suspension of a license, taken against a health care practitioner, entity, provider, or supplier.

REPORTING FEDERAL LICENSURE AND CERTIFICATION ACTIONS

Federal licensing and certification agencies must report final adverse licensure and certification actions taken against health care practitioners, providers, or suppliers, regardless of whether the final adverse action is the subject of a pending appeal. Such final adverse actions include:

- Formal or official actions such as revocation or suspension of a license, certification agreement, or contract for participation in Government health care programs; reprimand; censure; or probation
- Any dismissal or closure of the proceedings because the health care practitioner, provider, or supplier surrendered a license, certification agreement, or contract for participation in Government health care programs, or left the State or jurisdiction
- Any other loss of the license, certification agreement, or contract for
 participation in Government health care programs, or the right to apply for, or
 renew, a license, certification agreement, or contract of the health care
 practitioner, provider, or supplier, whether by operation of law, voluntary

surrender, nonrenewal (excluding nonrenewals due to nonpayment of fees, retirement, or change to inactive status), or otherwise

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- Any other negative action or finding by a Federal licensing or certification agency that is publicly available information, including but not limited to limitations on the scope of practice, liquidations, injunctions, and forfeitures. This definition also includes final adverse actions rendered by a Federal licensing or certification agency such as exclusions, revocations, or suspension of license or certification that occur in conjunction with settlements in which no finding of liability has been made (although such a settlement itself is not reportable). This definition excludes administrative fines or citations, corrective action plans, and other personnel actions, unless:
 - o the underlying action is connected to the delivery of health care services, or
 - o the action is taken in conjunction with other adverse licensure or certification actions, such as revocation, suspension, censure, reprimand, probation, or surrender

When a license, agreement, or contract is suspended, the length of the suspension must be reported also.

Federal licensing and certification agencies also must report any revisions to a previously reported licensing or certification action, such as a reinstatement of a suspended license, and whether an action is on appeal. For more information, go to Types of Reports in this chapter.

Settlements in which no findings or admissions of liability have been made are statutorily excluded from being reported. However, actions that occur in conjunction with settlements in which no findings of liability have been made and that otherwise meet NPDB reporting requirements must be reported.

Table E-12 outlines reporting obligations for Federal licensure and certification actions.

Table E-12: Authority for Reporting Federal Licensure and Certification Actions			
Law	Who Reports?	What is Reported?	Who is Reported?
Title IV	DEA	DEA controlled-substance registration actions*	Practitioners
Section 1128E	Federal agencies	Federal licensure and certification actions (including DEA actions)	Practitioners, providers, and suppliers

^{*} This information is reported to the NPDB under Title IV based on a Federal memorandum of understanding.

Certification

In the NPDB regulations, the term "certification" has two distinct meanings. First, the term is related to licensure, because licensure includes certification and other forms of authorization to provide health care services. This term can apply to agencies that "license," "certify," or "register" certain types of health care practitioners, entities, providers, or suppliers.

Second, the term "certification" also is used to refer to certification of a health care practitioner, provider, or supplier to participate in a government health care program. In this context, certification includes certification agreements and contracts for participation in a Government health care program.

Administrative Fines and Formal Money Penalties

Federal licensing and certification agencies must report to the NPDB all money penalties and administrative fines that are formal or official actions (e.g., formal disciplinary actions) against health care practitioners, providers, or suppliers.

However, fines that are considered administrative or technical in nature must be reported to the NPDB only if they meet the NPDB definition of negative actions or findings. First, these types of administrative fines must be publicly available information. In addition, administrative fines reported as negative actions or findings must be either:

- Connected to the delivery of health care services, or
- Taken in conjunction with other adverse licensure or certification actions, such as revocation, suspension, censure, reprimand, probation, or surrender.

Generally, each reporting entity determines whether its action is connected to the delivery of health care services.

An action must be reported to the NPDB based on whether it satisfies NPDB reporting requirements and not based on the name affixed to the action.

Publicly Available Information

Publicly available information means that information is accessible to the interested public. This can occur in a variety of ways, including, but not limited to, phone, writing, electronic media (e.g., website or portal), or other media available for general distribution to any member of the public.

Stayed Actions

A licensure or certification action imposed with a stay should not be reported to the

NPDB as long as the entire action is stayed. When only part of the action is stayed, the part of the action that is not stayed must be reported. In addition, if a stayed action is accompanied by another reportable action, the reportable action that accompanied the stayed action must be reported.

Denials of Initial and Renewal Applications

Federal licensing and certification agencies must report to the NPDB denials of initial and renewal applications for licensure or certification for health care practitioners, providers, or suppliers if the denials are formal or official final adverse actions. For example, if a Federal licensing agency takes a final action to deny a practitioner's initial licensure application because the practitioner misrepresented information on the application, that action is reportable.

Federal licensing or certification agencies should not report cases in which the agency denies the licensure or certification only because a health care practitioner, provider, or supplier does not meet the threshold criteria for licensure or certification.

Withdrawals of Initial and Renewal Application While Under Investigation, and Failure to Renew While Under Investigation

Investigations should not be reported to the NPDB. However, withdrawal of a renewal application for licensure or certification, while the Federal licensure or certification authority is investigating the applicant, is reportable. In addition, an applicant's withdrawal, for any reason, of an initial application for licensure or certification is not reportable, even if the applicant is under investigation.

The NPDB interprets the word "investigation" expansively, although the investigation must be focused on a specific individual or entity. For example, if a Federal licensing board routinely runs a criminal background check on all applicants for license renewal, that is not considered an investigation. If, as a result of the routine check, the board decides to further examine a specific applicant's record, that examination is considered an investigation. The NPDB retains the ultimate authority to determine whether an investigation exists.

The NPDB considers an investigation to run from the start of an inquiry until a final decision is reached. In other words, an investigation is not limited to a Federal licensure or certification authority's gathering of facts or by the manner in which the Federal licensing or certification authority defines the term "investigation." An investigation begins as soon as the Federal licensure or certification authority begins a nonroutine inquiry and does not end until the authority's decisionmaking body takes a final action or makes a decision not to further pursue the matter.

A licensure or certification authority that submits a report based on a withdrawal of a renewal application while the applicant is under investigation should have evidence of an ongoing investigation at the time of withdrawal. Examples of acceptable evidence may include minutes or excerpts from committee meetings, orders from licensing or certification officials directing an investigation, or notices to renewal applicants of an investigation. (The licensure or certification authority must be able to show that the practitioner was notified of the investigation, although actual knowledge of the investigation on the part of the practitioner is not required.)

Guidelines for Investigations

- For NPDB reporting purposes, the term "investigation" is not controlled by how that term may be defined by a licensing or certification authority's policies and procedures.
- A routine review of a particular practitioner is *not* an investigation.
- The investigation must be focused on the practitioner in question.
- To be considered an investigation for purposes of determining whether an activity is reportable, the activity generally should be the precursor to a licensure or certification action.
- An investigation is considered ongoing until the licensing or certification authority's decisionmaking authority takes a final action or formally closes the investigation.

Voluntary Surrenders

Federal licensing and certification agencies are required to report voluntary surrenders of a license, certification agreement, or contract for participation in a Government health care program by a health care practitioner, provider, or supplier. NPDB regulations define a <u>voluntary surrender</u> of a license or certification as "a

surrender made after a notification of investigation or a formal official request by a Federal or State licensing or certification authority for a health care practitioner, health

The voluntary relinquishment of a license for personal reasons such as retirement or illness is not reportable to the NPDB if no other action or investigation is in progress.

care entity, provider, or supplier to surrender the license or certification (including certification agreements or contracts for participation in Federal or state health care programs). The definition also includes those instances where a health care practitioner, health care entity, provider, or supplier voluntarily surrenders a license or certification (including program participation agreements or contracts) in exchange for a decision by the licensing or certification authority to cease an investigation or similar proceeding, or in return for not conducting an investigation

or proceeding, or in lieu of a disciplinary action."

The voluntary relinquishment of a license for personal reasons such as retirement or illness is not reportable to the NPDB if no other action or investigation is in progress. Only the surrender of the license while under investigation, or in return for not conducting an investigation, is reportable.

Confidentiality Laws Related To Drug and Alcohol Treatment

If a licensure or certification action is taken and the practitioner enters a treatment or rehabilitation program as a result, the adverse action must be reported. This is true even if the treatment is a condition of probation. However, the fact that the health care practitioner entered a drug or alcohol treatment facility should not be reported.

If a health care practitioner (or other reportable individual) voluntarily enters a treatment or rehabilitation program at the direction or suggestion of a licensing or certification agency, a report should not be submitted to the NPDB.

Sanctions for Failing to Report

If HHS determines that a Federal licensing or certification agency has substantially failed to report information required to be reported to the NPDB, the name of the entity will be published and made publicly available.

Table E-13 provides guidance on when Federal licensure or certification actions must be reported to the NPDB. Table E-14 describes which reporting format should be used for reports on Federal licensure and certification actions.

Q&A: Reporting Federal Licensure or Certification Actions

1. A physician's application to renew his DEA registration to prescribe controlled substances was denied because he provided false information on the application. Should this action be reported to the NPDB?

Yes. Federal licensing and certification agencies must report a formal denial of a health care practitioner's, provider's, or supplier's renewal application for licensure or certification. NPDB regulations require the reporting of <u>any loss of a license</u> or loss of a certification agreement or contract for participation in a government health care program, or the right to apply for, or renew, a license or certification agreement or contract of a health care practitioner, provider, or supplier, whether by operation of law, voluntary surrender, nonrenewal (excluding nonrenewals due to nonpayment of fees, retirement, or change to inactive status), or otherwise.

2. If a laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificate is revoked, should the action be reported to the NPDB?

Yes. Federal licensing and certification agencies must report formal or official final adverse actions such as revocations or suspensions of a license, certification agreement, or contract for participation in a Government health care program; reprimands; censures; or probations taken against a health care practitioner, provider, or supplier. These actions must be reported regardless of whether the final adverse action is the subject of a pending appeal.

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Table E-13: Determining if Federal Licensure or Certification Actions Must be Reported		
Action	Reportable?	
A formal, final action to deny an application for licensure or certification (initial or renewal).	Yes	
A Federal licensing authority did not grant a license to an applicant who did not meet the agency's threshold criteria for licensure.	No	
The withdrawal of an initial application for licensure or certification while under investigation.	No	
The withdrawal, while under investigation, of an application to renew a license or certification.	Yes	
The applicant for an initial Federal license does not meet the threshold licensing criteria and withdraws the application.	No	
A health care practitioner withdraws an application for Federal licensure or certification; the practitioner was not under investigation, nor did he withdraw the application to avoid an investigation.	No	
A practitioner surrenders a Federal license or certification in lieu of a disciplinary action.	Yes	
Through an order that is not publicly available, a Federal certification authority imposes monitoring for a specific period of time that does not constitute a restriction on the certification of a health care supplier.	No	
An action imposed by a Federal licensing or certification agency with a "stay"; the entire action was stayed.	No	
Any money penalty imposed by a Federal licensing or certification agency that is a formal or official final adverse action.	Yes	
A Federal licensing or certification agency imposes an administrative fine that is not a formal or official action but is publicly available information and is related to the delivery of health care services.	Yes	
An administrative fine imposed against a health care provider for late payment of an application renewal fee; the action is not a formal or official action, and the agency does not consider the fine to be connected to health care delivery, nor was it taken in conjunction with another adverse licensure or certification action.	No	
A formal or official action to impose an administrative fine.	Yes	
A Federal licensing or certification agency terminates a health care provider's contract for participation in a Federal health care program due to repeated noncompliance with participation requirements.	Yes	
A voluntary relinquishment or termination, without cause, of a health care provider's contract to participate in a Government health care program; the provider was not under investigation at the time and did not voluntarily terminate the contract to avoid an investigation.	No	
A reinstatement of a practitioner's previously reported indefinite suspension of a Federal license or certificate.	Yes	

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Table E-14: Selecting the Appropriate NPDB Reporting Format for Federal Licensure and Certification Actions			
Type of Action	NPDB Reporting Format		
Actions taken with respect to licensure, certification, registration, or other authorization to provide health care services	Federal Licensure Action category on the Adverse Action Report format		
Actions taken with respect to certification agreements or contracts for participation in Government health care programs	Government Administrative Action category on the Adverse Action Report format		

3. A skilled nursing facility's contract to participate in a Federal health care program (e.g., Medicare provider agreement) is formally terminated for cause. Should this action be reported to the NPDB?

Yes. Federal licensing and certification agencies must report formal or official final actions – such as revocations or suspensions of a license, certification agreement, or contract for participation in a Government health care program – taken against health care practitioners, providers, or suppliers.

4. A clinic terminates its contract to participate in a Federal health care program for business-related reasons. No investigation or other action was pending. Should this action be reported to the NPDB?

No. Federal licensing and certification agencies should only report those voluntary surrenders (including voluntary terminations) of a license, certification agreement, or contract for participation in a Government health care program specified in NPDB regulations. As long as the clinic did not voluntarily terminate its contract while under investigation, in exchange for a decision by the licensing or certification agency to cease an investigation or similar proceeding, in return for not conducting an investigation or proceeding, or in lieu of a disciplinary action, this action should not be reported.

REPORTING PEER REVIEW ORGANIZATION NEGATIVE ACTIONS OR FINDINGS

Peer review organizations are required to report to the NPDB certain <u>negative</u> <u>actions or findings</u>. These negative actions or findings are defined in NPDB regulations as any recommendation by a peer review organization to sanction a health care practitioner. The health care practitioner must be licensed or otherwise authorized by the State to provide health care services. The actions taken must be a result of formal proceedings.

Peer review organizations also must report any revisions to a previously reported negative action or finding. For more information, go to <u>Types of Reports</u> in this chapter.

Various types of organizations, including but not limited to patient safety organizations and peer review consultants, may provide information, including recommendations, to hospitals and other health care entities. Unless these organizations meet the definition of a <u>peer review organization</u>, these organizations do not report their recommendations to the NPDB as peer review organizations.

Table E-15 outlines reporting obligations for peer review organizations.

Table E-15: Authority for Reporting Peer Review Organization Negative Actions or Findings			
Law	Who Reports?	What is Reported?	Who is Reported?
Section 1921	Peer review organizations	Negative actions or findings by peer review organizations	Practitioners

Submitting a Copy of the Report to the State Licensing or Certification Authority

A copy of the Report Verification Document, which peer review organizations receive after a report is successfully processed by the NPDB, must be provided to the appropriate State licensing or certification authority.

Table E-16: Determining if Peer Review Organization Negative Actions or Findings Must be Reported		
Action	Reportable?	
After an evaluation of a hospital's surgical services, a peer review organization formally recommends that the hospital temporarily suspend a surgeon's clinical privileges pending further investigation of the surgeon's professional competence.	Yes	
A peer review organization, under contract with a hospital to conduct a review of several departments, reports a list of findings and overall recommendations on ways the hospital could improve quality of care; the peer review organization makes no recommendations to sanction a practitioner.	No	
A hospital contracts with an independent organization for assistance in conducting a peer review of a practitioner. The independent organization, which does not conduct formal proceedings for physicians reviewed, provides a report with recommendations to the hospital's peer review committee for consideration.	No	
A hospital's peer review committee makes an initial recommendation to impose a 15-day suspension of a physician's clinical privileges.	No	
A peer review organization, under contract with a hospital to conduct a medical review of several departments, makes a formal recommendation that the hospital sanction one of its physicians based on evidence of patient abuse.	Yes	

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Q&A: Reporting Peer Review Organization Negative Actions or Findings

1. A hospital contracted with a peer review organization to conduct a review of several departments within the hospital. As a result, the peer review organization provided the hospital findings and overall recommendations on ways the hospital could improve quality of care. Should this be reported to the NPDB?

No. Peer review organizations that meet the NPDB's regulatory definition are required to report to the NPDB any recommendations to sanction a health care practitioner. They should not report recommendations or findings regarding health care entities, providers, or suppliers, nor should they report recommendations regarding practitioners that do not involve sanctions.

2. As part of an evaluation of a hospital's maternity services, a peer review organization found the quality of care provided by one of the hospital's physicians poor enough that it formally recommended that the hospital

place the physician on probation and assign him a proctor for all procedures. Should the peer review organization report this recommendation, even if the organization does not know whether the hospital subsequently took the recommended action?

Yes. Peer review organizations must report any recommendation to sanction a health care practitioner, as long as the recommendation was a result of a formal proceeding and otherwise meets NPDB reporting requirements. A recommendation to place the physician on probation and assign him a proctor would meet this reporting requirement, regardless of the hospital's actions.

3. A hospital peer review committee reviewed several patient complaints concerning the quality of care provided by a surgeon who had privileges at the hospital. The committee made a recommendation to censure the surgeon and require that he complete a mandatory 5-day course in effective communication. Should the action be reported to the NPDB?

No. A hospital peer review committee does not meet the definition of a <u>peer review organization</u>, so this recommendation does not qualify as a peer review organization action. In addition, the recommendation is not a reportable <u>clinical privileges</u> action.

4. A hospital contracted with an organization to conduct a peer review of a specialist practitioner who held privileges at the hospital. The organization recommended that the practitioner be suspended. Should this be reported to the NPDB?

It depends. If the contracted organization meets the NPDB's definition of a peer review organization, including having due process mechanisms available to the practitioner, the organization should report its recommendation to the NPDB. If the organization does not meet the definition of a peer review organization, the organization should not submit a report.

REPORTING PRIVATE ACCREDITATION ORGANIZATION NEGATIVE ACTIONS OR FINDINGS

Private accreditation organizations are required to report to the NPDB certain negative actions or findings against health care entities, providers, and suppliers. These negative actions or findings are defined in NPDB regulations as a final determination of denial or termination of an accreditation status that indicates a risk to the safety of a patient, or patients, or quality of health care services. The actions taken must be as a result of <u>formal proceedings</u>. The health care entity, provider, or

supplier must be licensed or otherwise authorized by the State to provide health care services.

Private accreditation organizations also must report any revisions to a previously reported negative action or finding. For more information, go to <u>Types of Reports</u> in this chapter.

Table E-17 outlines reporting obligations for private accreditation organizations.

Table E-17: Authority for Reporting Private Accreditation Organization Negative Actions or Findings			
Law	Who Reports?	What is Reported?	Who is Reported?
Section 1921	Private accreditation organizations	Negative actions or findings by private accreditation organizations	Entities, providers, and suppliers

Table E-18 provides guidance on when private accreditation organization negative actions or findings must be reported to the NPDB.

Table E-18: Determining if Private Accreditation Organiz	ation
Negative Actions or Findings Must Be Reported	

Action	Reportable?
A private accreditation organization's final denial of accreditation to an ambulatory surgery center after finding the facility was noncompliant across a range of standards, including several serious clinical deficiencies that posed a risk to patient safety.	Yes
A private accreditation organization's issuance of a provisional or preliminary accreditation to a skilled nursing facility.	No
A private accreditation organization's preliminary denial of accreditation status; this action is not final.	No
A private accreditation organization's termination of a health care supplier's accreditation for noncompliance with significant policies and procedures required by the accreditation standards related to patient health and safety.	Yes
A deferral of a determination regarding an accreditation status.	No
Accreditation with a follow-up survey due to noncompliance with specific standards.	No

Submitting a Copy of the Report to the State Licensing or Certification Authority

A copy of the Report Verification Document, which private accreditation organizations receive after a report is successfully processed by the NPDB, must be provided to the appropriate State licensing or certification authority.

Q&A: Reporting Private Accreditation Organizations Negative Actions or Findings

1. A private accreditation organization issued a skilled nursing facility a provisional accreditation because the facility did not meet a number of standards related to staff training and quality of care. The facility was required to submit a corrective action plan for all standards that were either not met or only partially met. Should this action be reported?

No. Private accreditation organizations are only required to report to the NPDB a final determination of denial or termination of an accreditation status that indicates a risk to the safety of a patient or patients or quality of health care services. The issuance of provisional accreditation should not be reported.

2. A private accreditation organization terminated a skilled nursing facility's accreditation after the private accreditation organization found the facility to be noncompliant across a range of standards, including several serious clinical deficiencies. Should this action be reported to the NPDB?

Yes. A final determination of denial or termination of a health care entity's, provider's, or supplier's accreditation status from a private accreditation organization that indicates a risk to the safety of a patient, or patients, or quality of health care services must be reported to the NPDB.

3. A private accreditation organization awarded a hospital seeking accreditation the status of "accreditation with a follow-up survey." The hospital was required to address deficiencies identified during the accreditation survey within 90 days. Should this action be reported to the NPDB?

No. A private accreditation organization must report to the NPDB only final determinations of denial or termination of an accreditation status that indicates a risk to the safety of a patient, or patients, or quality of health care services. This was neither a final denial nor termination.

REPORTING EXCLUSIONS FROM PARTICIPATION IN FEDERAL OR STATE HEALTH CARE PROGRAMS

Federal agencies, <u>State law enforcement agencies</u>, <u>State Medicaid fraud control units</u>, and <u>State agencies administering or supervising the administration of a State health care program</u> must report health care practitioners, providers, or suppliers excluded from participating in Federal or State health care programs. With respect to the reporting of exclusions by the specified State agencies, only the State agency that takes the action to exclude a health care practitioner, provider, or supplier is responsible for reporting that action to the NPDB.

The term <u>"exclusion"</u> means a temporary or permanent debarment of an individual or entity from participation in any Federal or State health-related program, such that items or services furnished by the individual or entity will not be reimbursed under any Federal or State health-related program. <u>Federal health care programs</u> and <u>State health care programs</u> are limited to those defined in the Social Security Act.

The OIG and other Federal agencies, State law enforcement agencies, State Medicaid fraud control units, and State agencies administering or supervising the administration of a State health care program also must report any revisions to previously reported exclusions, such as reinstatements, and whether an action is on appeal. For more information, go to Types of Reports in this chapter.

With respect to these types of actions, settlements in which no findings or admissions of liability have been made are statutorily excluded from being reported. However, exclusions that occur in conjunction with settlements in which no finding of liability has been made and that otherwise meet NPDB reporting requirements must be reported.

Table E-19 outlines reporting obligations for exclusions from participation in Federal or State health care programs. Table E-20 provides guidance on when exclusions from Federal or State health care programs must be reported.

Sanctions for Failing to Report

If HHS determines that a Federal agency, a State law enforcement agency, a State Medicaid fraud control unit, or a State agency administering or supervising the administration of a State health care program has substantially failed to report information required to be reported to the NPDB, the name of the entity will be published and made publicly available.

Q&A: Reporting Exclusions from Federal and State Health Care Programs

1. Does an exclusion from participation in a Federal or State health care program have to be in effect for a certain amount of time before it must be reported to the NPDB?

No. All exclusions of health care practitioners, providers, or suppliers from participation in a Federal or State health care program must be reported to the NPDB within 30 days of the date the action was taken, regardless of the duration of the exclusion.

from	Table E-19: Authority for Reporting Exclusions from Participation in Federal or State Health Care Programs			
Law	Who Reports?	What is Reported?	Who is Reported?	
Title IV	OIG*	Exclusions from participation in Medicare, Medicaid, and other Federal health care programs*	Practitioners	
Section 1921	State law enforcement agencies** State Medicaid fraud control units** State agencies administering or supervising the administration of a State health care program**	Exclusions from participation in a State health care program	Practitioners, providers, and suppliers	
Section 1128E	Federal agencies	Exclusions from participation in a Federal health care program	Practitioners, providers, and suppliers	

^{*} This information is reported to the NPDB under Title IV based on a memorandum of understanding.

^{**} NPDB regulations define "State law or fraud enforcement agency" as including but not limited to these entities.

Table E-20: Determining if Exclusions from Federal or State Health Care Programs Must be Reported		
Action	Reportable?	
A practitioner is excluded from a State Medicaid program after pleading guilty to filing false claims.	Yes	
A company that does not meet the definition of a health care practitioner, provider, or supplier is excluded from a Federal health care program.	No	
A physician is indefinitely excluded from a State Medicaid program because her State medical license was suspended.	Yes	

2. The OIG pursued civil money penalties and exclusion against a physician because the physician and his medical practice allegedly billed Medicare improperly. The physician and his medical practice agreed to settle the case. The settlement did not include findings or admissions of liability, but the physician agreed to pay \$100,000 for allegedly violating the Civil Money Penalties Law and agreed to be excluded from Medicare, Medicaid, and other Federal health care programs for 3 years. Should the civil money penalty or the exclusion, or both, be reported to the NPDB?

The payment should not be reported because it was part of a <u>settlement</u> in which no findings or admissions of liability were made. <u>Section 1128E</u> specifically excludes from NPDB reporting any settlement that does not include an admission of liability. However, the exclusion must be reported. Exclusions that occur in conjunction with settlements in which no finding of liability has been made and that otherwise meet NPDB reporting requirements must be reported.

If the settlement had included an admission of liability, it would have been reportable under 45 CFR §60.16 as an "other adjudicated action or decision." As defined in NPDB regulations, the settlement would have been a "formal or official final action[s]" that "include[d] the availability of a due process mechanism" and was "based on acts or omissions that affect or could affect the payment, provision, or delivery of a health care item or service."

3. A physician was indefinitely excluded from a State Medicaid program because her medical license was suspended in another State. Should this exclusion be reported?

Yes. Health care practitioners, providers, or suppliers that are excluded from a

Federal or State health care program must be reported to the NPDB. In addition, the State licensing authority that suspended the physician's license must report that action to the NPDB.

4. The OIG pursued civil money penalties and exclusion from Medicare, Medicaid, and other Federal health care programs against a physician because of allegations that the physician and his medical practice improperly billed Medicare. The physician appealed the decision to impose a civil money penalty and exclusion to the HHS Departmental Appeals Board. The administrative law judge assigned to the case found in favor of the OIG and upheld the imposition of the civil money penalty and exclusion against the physician. Should these actions be reported as an "other adjudicated action or decision," as an exclusion, or both?

Both. The civil money penalty should be reported as an "other adjudicated action or decision" because it is a formal or official action taken against a health care practitioner by a Federal agency, includes the availability of a due process mechanism, and was based on acts or omissions that affect or could affect the payment of health care services. The exclusion should be reported as an exclusion because the physician was excluded from participation in a Federal health care program by a Federal agency.

5. The owner of a medical supply company was found not guilty of violating the False Claims Act in regard to fraudulent Medicare claims, but the OIG excluded the company from participating in the Medicare program. Should the exclusion be reported to the NPDB?

Yes. Health care practitioners, providers, or suppliers who are excluded from a Federal or State health care program must be reported to the NPDB. Thus, even though the owner of the medical supply company was found not guilty of False Claim Act violations, the OIG must report the company's exclusion from the Medicare program.

REPORTING FEDERAL OR STATE HEALTH CARE-RELATED CRIMINAL CONVICTIONS

Health care-related criminal convictions that must be reported to the NPDB include criminal convictions, injunctions, and nolo contendere/no contest pleas related to the delivery of health care items or services.

Table E-21 outlines obligations for reporting Federal or State health care-related criminal convictions

Tak	Table E-21: Authority for Reporting Criminal Convictions			
Law	Who Reports?	What is Reported?	Who is Reported?	
Section 1921	State prosecutors	Health care-related criminal convictions in State court	Practitioners, providers, and suppliers	
Section 1128E	Federal prosecutors	Health care-related criminal convictions in Federal or State court	Practitioners, providers, and suppliers	

Federal, State, and local prosecutors must report <u>criminal convictions</u> against health care practitioners, providers, or suppliers related to the delivery of health care items or services, regardless of whether the conviction is the subject of a pending appeal. For NPDB purposes, a criminal conviction includes:

- A judgment or conviction that has been entered against an individual or entity in a Federal, State, or local court, regardless of whether an appeal is pending or the conviction or other record relating to criminal conduct has been expunged
- A finding of guilt against an individual or entity that is made in a Federal, State, or local court
- A plea of guilty or nolo contendere by an individual or entity that has been accepted by a Federal, State, or local court
- When an individual or entity has entered into participation in a first offender, deferred adjudication, or other arrangement or program where conviction has been withheld

Settlements in which no findings or admissions of liability have been made are statutorily excluded from being reported. However, actions that occur in conjunction with settlements in which no finding of liability has been made and that otherwise meet NPDB reporting requirements must be reported.

In addition to reporting initial health care-related criminal convictions, Federal and State prosecutors also must report any revisions to previously reported actions, including when an action is on appeal. For more information, go to <u>Types of Reports</u> in this chapter.

Nolo Contendere/No Contest Plea

Federal and State prosecutors and investigative agencies must report nolo contendere/no contest pleas by health care practitioners, providers, or suppliers related to the delivery of a health care item or service. A plea of nolo contendere has the same effect as a plea of guilty as far as the criminal sentence is concerned, but it may not be considered as an admission of guilt for any other purpose.

Injunctions

Federal and State prosecutors and investigative agencies must report injunctions against health care practitioners, providers, or suppliers related to the delivery of a health care item or service.

First Offender, Deferred Adjudication, or Other Arrangement or Program Where Conviction Has Been Withheld

Federal and State prosecutors and investigative agencies must report a health care practitioner, provider, or supplier that has entered into participation in a first offender, deferred adjudication, or other arrangement or program where a conviction related to the delivery of a health care item or service has been withheld.

Sanctions for Failing to Report to the NPDB

If HHS determines that Federal or State prosecutors have substantially failed to report information required to be reported to the NPDB, the name of the government agency will be published and made publicly available.

Table E-22 provides guidance on when Federal and State health care-related criminal convictions must be reported to the NPDB.

Q&A: Reporting Federal or State Health Care-Related Criminal Convictions

1. If a health care practitioner is convicted of a health care-related offense, a report must be submitted to the NPDB within 30 days. Does the 30 days begin when the individual is convicted or when the individual is sentenced?

The report must be submitted within 30 calendar days of the date of the conviction. Federal, State, and local prosecutors must report criminal convictions in Federal and State court against health care practitioners, providers, or suppliers related to the delivery of health care items or services. These convictions must be reported regardless of whether the conviction is the subject of a pending appeal.

2. A health plan's CEO is convicted of embezzlement from the health plan and is sentenced to 4 years in prison. Should this be reported to the NPDB?

Yes. The described action is a criminal conviction related to the delivery of a health care item or service and therefore must be reported. The conviction must be reported because the CEO of a health plan meets the definition of a health care supplier.

3. A health care practitioner pleaded nolo contendere to fraud related to a claim he made on his homeowner's insurance. Should this be reported to the NPDB?

No. The practitioner's nolo contendere plea should not be reported because it is not related to the delivery of a health care item or service.

4. A physician accepted small sums of money for making referrals to a specialist. The offense resulted in a deferred conviction, under which the physician must satisfy a 2-year probationary period before the conviction is dropped. Should this be reported to the NPDB?

Yes. For NPDB purposes, a health care-related criminal conviction includes those cases in which an individual or entity agrees to participate in a <u>first</u> offender, deferred adjudication, or other program in order to avoid conviction.

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Table E-22: Determining if Federal or State Health Care-Related Criminal Convictions Must be Reported			
Action	Reportable?		
A deferred adjudication for health care fraud in which the practitioner agrees to a 6-month probationary period and 4 months of community service in exchange for dismissing the case if the probation and community service are successfully completed.	Yes		
The CEO of a health plan, who is a licensed physician, is convicted of embezzlement from the health plan and is sentenced to 4 years in prison.	Yes		
A registered nurse is convicted of shoplifting.	No		
A nurse's aide is convicted of abusing patients in a nursing home and is sentenced to 2 years in State prison.	Yes		
Two owners/operators of two separate ambulance companies are sentenced for their part in a Medicaid fraud scheme; each is sentenced to 12 months and 1 day incarceration, to be followed by a 3-year supervised probation, and each is ordered to pay \$2,000 in restitution.	Yes		
A dentist files several false claims under her homeowner's insurance policy and is convicted of insurance fraud.	No		
A man is sentenced for conspiracy to submit false Medicare claims in connection with his two durable medical equipment companies and his medical diagnostics company. His sentence includes a 21-month incarceration, payment of \$1 million in restitution, and a 3-year supervised release.	Yes		
A physician pleads nolo contendere to charges that she billed the Medicare program for services that were not medically necessary.	Yes		
A health care provider pleads nolo contendere to insurance fraud not related to health care.	No		
A practitioner pleads nolo contendere to shoplifting in a department store.	No		
A hospital pleads nolo contendere to illegally paying physicians in exchange for referring patients to the hospital.	Yes		
A practitioner has been harassing his ex-wife, who successfully seeks an injunction against him.	No		
A court issues an injunction against a residential nursing facility to cease and desist using intimidation against the facility's residents to keep them from relocating.	Yes		
A State court enjoins a company that owns a chain of diagnostic laboratories to stop discriminatory employment practices.	No		

5. A chiropractor accepted kickbacks from a medical supply company in exchange for patient referrals. Both the chiropractor and the medical supply company were convicted and each was sentenced to a fine of \$20,000. Should both convictions be reported in one report?

No. Two reports must be submitted. The chiropractor and the medical supply company should each be reported separately for their criminal convictions related to the delivery of health care items or services.

6. The U.S. Department of Justice (DOJ) pursued a criminal health care fraud case against a physician for billing for services that were not provided as claimed. The physician pleaded guilty to health care fraud. In addition, the OIG excluded the physician from participating in Federal health care programs due to his criminal conviction of an offense related to fraud in connection with the delivery of a health care item or service. How should this be reported to the NPDB?

The criminal conviction of the health care practitioner is related to the delivery of a health care item or service and, therefore, the DOJ should report this as a criminal conviction. The OIG must separately report the exclusion. Exclusions from participation in a Federal or State health care program should be reported as an <u>exclusion</u>.

7. A State court imposed an injunction on a medical equipment supplier to prevent the supplier from selling certain medical devices that may be faulty. The supplier plans to appeal the decision. Should the reporting entity wait until after the appeal to make a determination about submitting a report to the NPDB?

No. The injunction must be reported to the NPDB within 30 days of the date the court imposes it. If an appeal is filed prior to the submission of the report, the reporter must indicate on the Initial Report that the matter is on appeal. If, after the appeal, the injunction is lifted, the reporting entity must submit a Revision-to-Action Report.

REPORTING HEALTH CARE-RELATED CIVIL JUDGMENTS

Federal and State attorneys and health plans must report civil judgments related to the delivery of a health care item or service against health care practitioners, providers, or suppliers, regardless of whether the civil judgment is the subject of a pending appeal. NPDB regulations define <u>civil judgment</u> as "a court-ordered action rendered in a Federal or State court proceeding, other than a criminal proceeding.

This reporting requirement does not include consent judgments that have been agreed upon and entered to provide security for civil settlements in which there was no finding or admission of liability." Settlements in which no findings of liability have been made are statutorily excluded from being reported. However, actions that occur in conjunction with settlements in which no findings of liability have been made and that otherwise meet NPDB reporting requirements must be reported.

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Additionally, actions made with respect to <u>medical malpractice claims</u> should not be reported as civil judgments, but any payment made for the benefit of a health care practitioner in settlement of a medical malpractice claim or judgment must be reported to the NPDB by the medical malpractice payer.

Table E-23 outlines reporting obligations for health care-related civil ju	aomente
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Table E-23: Authority for Reporting Civil Judgments			
Law	Who Reports?	What is Reported?	Who is Reported?
Section 1921	State attorneys	Health care-related civil judgments in State court	Practitioners, providers, and suppliers
Section 1128E	Federal attorneys Health plans	Health care-related civil judgments in Federal or State court	Practitioners, providers, and suppliers

Table E-24 provides guidance on when health care-related civil judgments must be reported to the NPDB.

If a Government agency is party to a multi-claimant civil judgment (that is, more than one party has been awarded an amount because of the civil judgment), it must assume the responsibility for reporting the entire action, including all amounts awarded to all the claimants, both public and private. When a Government agency is not a party, but there are multiple health plans as claimants, the health plan that receives the largest award is responsible for reporting the total action for all parties. If more than one health plan receives the largest award, the plans receiving the largest award must work out among themselves which health plan will report to the NPDB for all parties, making sure that one – but only one – report is filed.

In addition to reporting initial health care-related civil judgments, Federal and State attorneys and all health plans also must report any revisions to previously reported actions, including that an action is on appeal. For more information, go to Types of Reports in this chapter.

Table E-24: Determining if Health Care-Related Civil Judgments Must Be Reported			
Action	Reportable?		
A judgment is entered against a clinical laboratory, resulting in a \$10,000 award for fraudulent billing and misleading marketing in a suit brought by health insurers and health care payers.	Yes		
A judgment imposes a \$40,000 fine on a medical supplies company for hiring discrimination.	No		
A judgment against a nursing home imposes a \$50,000 fine for neglect and for failure to adequately clean patients' rooms.	Yes		
A judgment against an ambulance company results in a \$30,000 fine for filing false claims and receiving payments for ambulance transportation in cases that were not medically necessary and for patients whose ambulatory status did not require such transportation.	Yes		
A judgment is entered against a practitioner stemming from an automobile accident not related to the delivery of a health care item or service.	No		

Sanctions for Failing to Report to the NPDB

If HHS determines that a Federal or State attorney has substantially failed to report information required to be reported to the NPDB, the name of the government agency will be published and made publicly available.

Any health plan that fails to report information on an adverse action required to be reported to the NPDB will be subject to a civil money penalty of up to \$25,000 for each such adverse action not reported. Such penalty will be imposed and collected in the same manner as civil money penalties under Section 1128A(a) of the Social Security Act.

Q&A: Reporting Civil Judgments

1. A health plan won a civil judgment against a clinical laboratory for submitting false claims. Two other health plans were party to the suit and received larger awards. Should all three health plans submit reports to the NPDB?

No. With respect to reporting health care-related civil judgments to the NPDB, when there are multiple health plans as claimants and a Government agency is not party to the suit, the <u>health plan that receives the largest award</u> is responsible for reporting the total action for all parties.

2. The DOJ pursued a civil False Claims Act case against a physician for billing for services that were not provided as claimed. The physician agreed to pay \$35,000 to settle False Claims Act liability. The OIG participated in the settlement and waived its exclusion authority in exchange for an integrity agreement with the physician. In the settlement, the physician neither admitted nor denied liability. Should anything be reported to the NPDB?

No. Settlements in which no findings or admissions of liability have been made are not reportable to the NPDB. Because the physician agreed to a payment as part of a settlement, without admitting liability, the DOJ should not report this settlement and payment. In addition, the OIG should not report either its waiver of its exclusion authority or the integrity agreement. The waiver of exclusion authority is not required to be reported, and the integrity agreement is part of the settlement in which no findings or admissions of liability were made.

3. A health plan won a civil judgment against a durable medical equipment supply company for submitting false claims, but the durable medical equipment supply company has indicated its intent to appeal the decision. Should a decision to report this action to the NPDB be withheld until after the outcome of the appeal is known?

No. The health plan should report the civil judgment at the time of the ruling. When the appeal is filed, the health plan should submit a <u>Notice of Appeal</u>.

4. A nurse practitioner was involved in an automobile accident with a delivery van before arriving at the local health clinic where she worked. The nurse practitioner was found liable for damages in a civil lawsuit. Is the judgment against the nurse practitioner reportable to the NPDB?

No. This judgment is not reportable because the judgment was due to the automobile accident and was not related to the delivery of a health care item or service.

5. In a State civil case, the court fined a professional staffing agency that supplied nurses, therapists, and other licensed health care personnel to hospitals and home health agencies \$150,000 and required the agency to pay \$325,000 in restitution to a group of local providers for overcharges during a 4-year period. Is this fine reportable to the NPDB?

The civil judgment against the staffing agency relates to the delivery of health

care items or services and is reportable if the staffing agency meets the definition of a health care provider or supplier.

REPORTING OTHER ADJUDICATED ACTIONS OR DECISIONS

Federal agencies, <u>State law enforcement agencies</u>, <u>State Medicaid fraud control units</u>, <u>State agencies administering or supervising the administration of a State health care program</u>, and <u>health plans</u> must report other adjudicated actions or decisions against health care practitioners, providers, and suppliers (regardless of whether the action or decision is subject to a pending appeal). Among the specified State agencies, only the State agency that takes an adjudicated action or decision against a health care practitioner, provider, or supplier is responsible for reporting that action to the NPDB.

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Table E-25: Authority for Reporting Other Adjudicated Actions or Decisions			
Law	Who Reports?	What is Reported?	Who is Reported?
Section 1921	State law enforcement agencies* State Medicaid fraud control units* State agencies administering or supervising the administration of a State health care program*	Other adjudicated actions or decisions	Practitioners, providers, and suppliers
Section 1128E	Federal agencies Health plan	Other adjudicated actions or decisions	Practitioners, providers, and suppliers

^{*} NPDB regulations define "State law or fraud enforcement agency" as including but not limited to these entities.

The term "other adjudicated actions or decisions" means:

- Formal or official final actions taken against a health care practitioner, provider, or supplier by a Federal agency, State law enforcement agency, State Medicaid fraud control unit, State agency administering or supervising the administration of a State health care program, or health plan;
- That include the availability of a due process mechanism; and

• That are based on acts or omissions that affect or could affect the payment, provision, or delivery of a health care item or service.

A hallmark of any valid adjudicated action or decision is the availability of a due process mechanism. The fact that the subject elects not to use the due process mechanism provided by the authority bringing the action is immaterial, as long as such a process is available to the subject before the adjudicated action or decision is made final. In general, if an adjudicated action or decision follows an agency's established administrative procedures (which ensure that due process is available to the subject of the final adverse action), it would qualify as a reportable action under this definition. For health plans that are not government entities, an action taken following adequate notice and the opportunity for a hearing that meets the standards of due process set out in <u>Title IV</u> also would qualify as a reportable action under this definition.

The definition of "other adjudicated action or decision" *specifically excludes* the following:

- Clinical privileges actions and similar paneling decisions made by health plans
- Overpayment determinations and denial of claims determinations
- Business or administrative decisions taken by health plans that result in contract terminations unrelated to health care fraud, abuse, or quality of care (e.g., a practitioner's contract is terminated because the practitioner no longer practices at a facility in the health plan's network; a health plan terminates all provider contracts in a certain geographic area because it ceases business operations in that area)

Settlements in which no findings or admissions of liability have been made are statutorily excluded from being reported. However, actions that occur in conjunction with settlements in which no findings of liability have been made and that otherwise meet NPDB reporting requirements must be reported.

Actions with respect to medical malpractice claims should not be reported in this category.

Federal agencies, State law enforcement agencies, State Medicaid fraud control units, State agencies administering or supervising the administration of a State health care program, and health plans also must report any revisions to a previously reported other adjudicated action or decision, including whether the action is on appeal. For more information, go to Types of Reports in this chapter.

Table E-26 provides guidance on when other adjudicated actions or decisions must be reported to the NPDB. Table E-27 describes which reporting format should be

used for reporting other adjudicated actions or decisions to the NPDB.

Table E-26: Determining if Other Adjudicated Actions or Decisions Must be Reported to the NPDB			
Action	Reportable?		
A health plan's termination of a practitioner's contract based on poor patient care, after the practitioner was afforded due process.	Yes		
A health plan's personnel-related suspension of a practitioner for violating infection control procedures, after the practitioner declined to avail himself of the due process mechanism.	Yes		
A Federal agency's reduction of a practitioner's pay for failure to appropriately supervise the delivery of health care services, after the practitioner exhausted her due process rights.	Yes		
An overpayment determination against a practitioner made by a Federal or State health care program, its contractor, or a health plan.	No		
A denial of claim determination against a practitioner made by a Federal agency.	No		
A health plan's decision to terminate a contract with a physician based on business or administrative reasons (e.g., the physician is retiring).	No		

Table E-27: Selecting the Appropriate NPDB Reporting Format for Other Adjudicated Actions or Decisions		
Type of Action	NPDB Reporting Format	
Other adjudicated actions or decisions taken by a Government agency	Government Administrative Action on the Adverse Action Report format	
Other adjudicated actions or decisions taken by a health plan	Health Plan Action on the Adverse Action Report format	

Other Adjudicated Actions or Decisions Taken in Conjunction with Clinical Privileges Actions

Certain Federal and State agencies and health plans that are required to report other adjudicated actions or decisions also may be required to report clinical privileges actions if those actions meet NPDB reporting requirements. However, because the definition of other adjudicated actions or decisions specifically excludes <u>clinical privileges</u>, if an entity takes both a clinical privileges action and another adjudicated action or decision, the entity must report them separately.

For example, if a health plan takes a network participation action that meets the NPDB reporting requirements for an adverse clinical privileges action in conjunction with a contract termination that meets the definition of an "other adjudicated action or decision," each action must be reported separately. When submitting these actions to the NPDB, the health plan must submit two reports: the health plan must report the network participation action as a Clinical Privileges Action on the NPDB's Adverse Action Report format; in addition, it must report the contract termination (which is another adjudicated action or decision) as a Health Plan Action on the Adverse Action Report format.

Sanctions for Failing to Report to the NPDB

If HHS determines that a Federal agency, a State law enforcement agency, a State Medicaid fraud control unit, or a State agency administering or supervising the administration of a State health care program has substantially failed to report information required to be reported to the NPDB, the name of the entity will be published and made publicly available.

Any health plan that fails to report information on an adverse action required to be reported to the NPDB will be subject to a civil money penalty of up to \$25,000 for each such adverse action not reported. Such penalty will be imposed and collected in the same manner as civil money penalties under Section 1128A(a) of the Social Security Act.

Q&A: Reporting Other Adjudicated Actions or Decisions

1. A Federal hospital terminated the employment of one of its nurses after an investigation determined that the nurse had physically and verbally abused several patients. The nurse was afforded due process. Should this action be reported to the NPDB?

Yes. Federal agencies must report other adjudicated actions or decisions to the NPDB. The Federal hospital meets the definition of a Federal agency, and the employment termination meets the definition of another adjudicated action or decision. Other adjudicated actions or decisions must be formal or official final actions taken against a health care practitioner, provider, or supplier that are related to the delivery of a health care item or service and include the availability of a due process mechanism.

2. A health plan terminated contracts with several psychologists in its network because the plan determined it already had too many psychologists in that geographic area. Should this action be reported to the NPDB?

No. While health plans are required to report actions that meet the definition of an "other adjudicated action or decision," that definition specifically excludes business or administrative decisions by health plans that result in contract terminations unrelated to health care fraud, or abuse, or quality of care issues. The contract terminations taken by this health plan were based on the health plan's <u>business decisions</u> regarding its network and were not related to health care fraud, or abuse, or the quality of health care delivered by the practitioners involved

3. A health maintenance organization (HMO) terminated the contract of one of its physicians for sexually harassing a nurse. The HMO also took a professional review action to revoke the physician's network participation. The HMO's standard operating procedures require that practitioners be afforded due process when contract actions are taken for cause. The standard operating procedures also require a committee of peers to make all network participation determinations. What should be reported to the NPDB?

The HMO must submit two separate reports to the NPDB. The contract termination must be reported to the NPDB because it meets the definition of an "other adjudicated action or decision." The HMO should report the contract termination as a Health Plan Action on the NPDB's Adverse Action Report format. The HMO also should separately report the revocation of network participation to the NPDB because it is a professional review action based on the physician's professional competence or conduct. This action should be reported as a Clinical Privileges Action on the Adverse Action Report format. NPDB governing laws and regulations require that clinical privileges actions (including network participation) and other adjudicated actions or decisions be reported to the NPDB separately.

4. A health care entity terminated a physician's contract for causes relating to poor patient care, which in turn resulted in loss of the practitioner's network participation. Should this be reported to the NPDB using one or two reports?

Depending on the circumstances, the health care entity may be required to submit two different reports. The loss of the practitioner's network participation that resulted from the termination of the contract for reasons relating to professional competence or professional conduct must be reported as a clinical privileges action only if it is considered to be a <u>professional review action</u> by the health care entity.

The termination of the practitioner's contract with the health care entity, in itself, does not meet NPDB reporting criteria for a clinical privileges action. However, if the contract termination meets the definition of an "other adjudicated action or decision," the contract termination should be reported separately to the NPDB.

5. After an investigation and formal hearing, a State hospital suspended without pay one of its physician employees after discovering that the physician had misrepresented his credentials on his employment application. Is this reportable?

Yes. Certain State agencies, including State agencies administering State health care programs, must report other adjudicated actions or decisions to the NPDB. Other adjudicated actions or decisions are formal or official final actions taken against a health care practitioner, provider, or supplier that are related to the delivery of a health care item or service and that include the availability of a due process mechanism.

6. A health plan determines that a pharmacy had been improperly substituting generic compounds for certain prescribed brand-name drugs and terminates the pharmacy's contract. While reaching its decision, the health plan employed the due process safeguards it had set in place. Is the termination reportable?

Yes. The action taken by the health plan is a reportable adjudicated action because it was taken against a health care practitioner, provider, or supplier, included the availability of due process, and was related to the delivery of health care items or services.

7. After he disclosed conduct to the OIG as part of a settlement agreement, a physician agreed to pay \$30,000 for allegedly violating the Civil Monetary Penalties Law. The physician disclosed that he employed an individual who he knew or should have known was excluded from participation in Federal health care programs. The settlement did not involve a finding or admission of liability. Should this be reported to the NPDB as an other adjudicated action or decision?

No. <u>Settlements in which no findings or admissions of liability have been made</u> are statutorily excluded from being reported to the NPDB. Therefore, the OIG should not report the payment made as part of a settlement in which there was no finding of liability. However, if the OIG had taken an action in conjunction with this settlement and that action otherwise met NPDB reporting

requirements (e.g., an exclusion from participation in Federal health care programs), that action must be reported.

8. The OIG pursued civil money penalties against a hospital for allegedly failing to provide an appropriate medical screening examination and stabilizing treatment. The patient was told to go home and follow orders from his primary care provider. Two days later, the patient went to another hospital's emergency department, was admitted to the intensive care unit, and then died due to H1N1 influenza. The first hospital agreed to pay \$25,000 to settle its liability for civil money penalties under the Emergency Medical Treatment and Active Labor Act. The settlement did not include any findings or admission of liability by the hospital. Should this action be reported?

No. Settlements in which no findings or admissions of liability have been made are statutorily excluded from being reported to the NPDB. Therefore, the OIG should not report the payment made as part of a settlement in which there was no finding of liability. However, if the OIG had taken an action in conjunction with this settlement, and the action otherwise met NPDB reporting requirements (e.g., an exclusion from participation in Federal health care programs), that action must be reported.

9. The OIG pursued civil money penalties against a physician because the physician and his medical practice allegedly billed Medicare improperly. The physician appealed the decision to impose a civil money penalty to the HHS Departmental Appeals Board. The administrative law judge assigned to the case found in favor of the OIG and upheld the imposition of the civil money penalty against the physician. Should these money penalties be reported?

Yes, the civil money penalties should be reported as <u>other adjudicated actions</u> or <u>decisions</u> because they are formal or official actions taken against a health care practitioner by a Federal agency that include the availability of a due process mechanism and were based on acts or omissions that affect or could affect the payment of health care services.

CHAPTER F: SUBJECT STATEMENTS AND THE DISPUTE PROCESS

OVERVIEW

The NPDB is an information clearinghouse created by Congress with the primary goals of improving health care quality, protecting the public, and reducing health care fraud and abuse in the United States. The NPDB collects information on medical malpractice payments and certain adverse actions and discloses that information to eligible entities to facilitate comprehensive reviews of the credentials of health care practitioners, entities, providers, and suppliers. These payments and actions are required to be reported to the NPDB under Title IV of Public Law 99-660, the Health Care Quality Improvement Act of 1986; Section 1921 of the Social Security Act; Section 1128E of the Social Security Act; and their implementing regulations found at 45 CFR Part 60.

The NPDB is committed to maintaining accurate information and ensuring that subjects of reports are informed when a report concerning them is submitted to the NPDB. This chapter describes the process by which the NPDB notifies subjects of reports and avenues available to subjects who may not agree with the content of a report, including adding a subject statement, disputing the report, and entering the report into Dispute Resolution.

NOTIFICATION OF A REPORT

When the NPDB receives a <u>report</u>, the NPDB processes it as submitted by the reporting entity. The contents of a report are determined by the reporting entity and not by the NPDB. The report format, including all mandatory information, must be completed successfully before a report can be generated. Reporting entities are responsible for the accuracy of the information they report and are required to certify that the report is accurate. After entering the report, the reporting entity receives a Report Verification Document, which instructs the entity to review the information to ensure its accuracy. Only the reporting entity may submit changes or corrections to a report.

When the NPDB processes a report, the NPDB notifies the subject of the report. The notification provides instructions for obtaining an official copy of the report through the Report Response Service on the NPDB website.

Even though the subject of a report may not change the content of the report with which the subject disagrees, the subject may add a statement to the report or dispute the report.

Reviewing a Report

The subject of a report submitted to the NPDB should review the report for accuracy, including the description of the reported event and identifiers such as name, date of birth, current address, etc.

If the report contains information that inaccurately identifies the subject of the report (e.g., date of birth, State license number), the subject of the report should contact the reporting entity, identified in Section A of the report, and request that the reporting entity correct the inaccurate identification information by submitting a Correction Report.

Incorrect Address

The NPDB notifies the subject of a report, at the address provided by the reporting entity, that the report has been submitted. If the subject of a report receives a report with an incorrect address, the subject of a report may update the home or work address, or both, in records maintained by the NPDB. However, this update does not change the subject of a report's address as reflected in the actual NPDB report. Future correspondence from the NPDB will be sent to the most current address of record the NPDB has. Only the entity that originally submitted the report can modify or correct information provided in the report. The subject of a report should contact the entity identified in Section A of the report and request that it make the address correction.

Subjects of reports may update their addresses using the <u>Report Response Service</u> on the NPDB website.

SUBJECT STATEMENTS

The subject of a report may add a <u>Subject Statement</u> to the report at any time. Subject Statements *must not* include information that may identify individuals – including patients, colleagues, and others – such as names, addresses, or phone numbers, because that information is considered confidential; however, Subject Statements may characterize individuals in terms of their relationships (e.g., the patient, the attending physician). In addition, a Subject Statement should not include links (URLs) to websites. Confidential information and coarse language are removed from Subject Statements before they are released to queriers.

Once processed, the Subject Statement becomes part of the report and remains with the report unless the subject of a report edits or removes it. The Subject Statement is sent to the reporting entity and all queriers who received a copy of the report within the past 3 years, and it will be included with the report when the report is released to future queriers. A subject of a report may modify or remove a Subject Statement

at any time through the Report Response Service.

If the reporting entity changes or corrects a report, the subject of the report will be notified of the change to the report by mail. If the report contains a Subject Statement, even though the report is corrected, the Subject Statement will remain unchanged. The subject of the report may then update or remove the Subject Statement by going to the Report Response Service on the NPDB website.

DISPUTE PROCESS

Procedures for a health care practitioner, entity, provider, or supplier to dispute the accuracy of information reported to the NPDB are described in the NPDB regulations and outlined below. The dispute process involves two separate procedures. To dispute a report, you first enter it into Dispute Status. If, in addition, you would like the NPDB to review the accuracy of the report, you may request Dispute Resolution.

Entering the Report into Dispute Status

At any time, the subject of a report or a designated representative may dispute the report and enter the report into <u>Dispute Status</u> to disagree with either the factual accuracy of the report or whether the report was submitted in accordance with NPDB reporting requirements, including the eligibility of the entity to report the information to the NPDB

Entering the report into Dispute Status does not trigger a review of the report by the NPDB. Before the NPDB can review the report for factual accuracy or whether it was submitted in accordance with NPDB reporting requirements, the subject of the report must request that the report be elevated to <u>Dispute Resolution</u>.

When a report is entered into Dispute Status by the subject of the report, the NPDB sends a notification of the dispute to the reporting entity and all queriers who received the report within the past 3 years. The notification will be included with the report when it is released to future queriers.

Once the report has been entered into Dispute Status, the subject of a report may:

- Take no further action the report will remain in the NPDB with a dispute notation; no additional action will be taken by the NPDB
- Withdraw the report from Dispute Status the dispute notation will be deleted from the report
- Request that the report be elevated to Dispute Resolution

If the report is changed by the reporting entity, the subject of the report is notified,

and the Dispute Status notation attached to the report is removed. If the subject believes that the new version of the report is factually inaccurate or was not submitted in accordance with the NPDB reporting requirements, the subject of a report may re-enter the report into Dispute Status.

Prerequisites for Dispute Resolution

The subject of a report may request that a report be elevated to Dispute Resolution after all the following prerequisites have been met and documented:

- The subject of the report has entered the report into Dispute Status
- The subject has waited 60 days after entering the report into Dispute Status, during which the subject has attempted to contact the reporting entity to resolve the issues raised by the report
- The subject has verified this effort; proof of a lack of success need not be more than a copy of correspondence to the reporting entity and the reporting entity's response, if any

Note: After the subject of the report enters the report into Dispute Status, and during the 60 days the subject of the report is attempting to resolve the dispute with the reporting entity, the reporting entity may tell the subject of the report in writing that it refuses to correct or void the report. If the subject of the report receives such written communication, the subject may ask the NPDB to elevate the report immediately to Dispute Resolution, without waiting the full 60 days. The subject should contact the NPDB Customer Service Center for further instructions and be prepared to provide documentation demonstrating the reporting entity's refusal to correct or void the report.

If the subject of a report has not first attempted to resolve the concerns regarding the report's accuracy with the reporting entity and met the other conditions outlined above, the NPDB will return the request to elevate the report to Dispute Resolution and remind the subject of the requirements. The report will remain in Dispute Status and the subject of the report must again request that the report be elevated if the subject wishes to pursue Dispute Resolution.

Dispute Resolution

The regulations governing the NPDB give the Secretary of Health and Human Services the authority to review, at the request of the subject of a report, the accuracy of NPDB reports. This authority has been delegated by the Secretary to the Division of Practitioner Data Bank (DPDB) of the Health Resources and Services Administration. Reports that have been elevated to Dispute Resolution are reviewed in the order in which they are received.

Dispute Resolution Limitations

The subject of a report may dispute only:

- Whether a report was submitted in accordance with <u>NPDB reporting</u>
 requirements, including the eligibility of the reporting entity to report the
 information to the NPDB, and/or
- The factual accuracy of the information

For additional information on reporting, see <u>Chapter E: Reports</u>.

The Dispute Resolution process does *not* include reviewing:

- The underlying reasons for the report, such as the merits of a medical malpractice claim or the appropriateness of, or basis for, other types of reports
- The extent to which entities followed due process procedures; due process issues must be resolved between the subject and the reporting entity

Late reporting does not constitute grounds for disputing a report. Although eligible entities must report medical malpractice payments and other reportable actions to the NPDB within 30 calendar days of the date the action was taken or the payment was made, an entity's failure to do so does not preclude the NPDB from collecting such a report beyond the 30-day time frame. Issues of timely reporting are handled through the NPDB's compliance program.

Responsibilities of Subjects of Disputed Reports

Subjects of reports who request that a report be elevated to Dispute Resolution should be prepared to:

- Succinctly describe the issues in dispute and the facts as understood by the subject of the report. Electronic submission with supporting documentation is encouraged, although paper submissions may be sent to the <u>same address</u> that is used for requests for reconsideration of decisions. These comments and points of dispute are separate and distinct from and do not replace the Subject Statement that may have been submitted previously. These comments and points of dispute are used for Dispute Resolution purposes only and will not be disclosed as part of the report.
- Submit documentation substantiating the points of dispute and showing that the report is inaccurate or not submitted in accordance with NPDB reporting requirements. The documentation must relate directly to the facts in dispute and substantially clarify the issues at hand. Subjects of reports may submit all relevant documentation, bearing in mind the criteria concerning pertinent documentation set forth in Table F-1. The subject of the report is encouraged to provide all pertinent documentation at one time that substantiates the subject's

position and to show how each document relates to the points of dispute. The NPDB will request more information if it is necessary for a proper resolution of the matter.

• Submit proof of an unsuccessful attempt to resolve the disagreement with the reporting entity (e.g., a copy of an email message or letter sent to the reporting entity and the response, if any).

Table F-1 illustrates the kinds of documentation that are considered pertinent and those that generally are unrelated to a dispute of an NPDB report.

Table F-1: Pertinent and Unrelated Documentation	
Pertinent Documentation	Unrelated Documentation
Originals or copies of: • For a Medical Malpractice Payment Report, the written claim and settlement or release document • For a Judgment or Conviction Report, a court judgment • For a State licensure Adverse Action Report, the State licensing board's findings of fact and conclusions of law • For a clinical privileges Adverse Action Report, the final report of the hearing panel	 Originals or copies of: Medical journal articles and newspaper clippings Letters of recommendation or praise Copies of awards or certificates of meritorious achievement Second professional opinions of the underlying reason for the action taken Examples of similar actions taken by other entities or health care practitioners Résumés or curricula vitae Diagnostic images Photographs

Responsibilities of Reporters and Subjects in Dispute Resolution

During the review process, the entity that submitted the report may receive a request from the NPDB to provide additional information and supporting documentation pertaining to the accuracy of the report. A response is required, and failure to respond, or an inadequate response, may constitute a failure to meet NPDB reporting requirements.

In addition, subjects of reports in the review process also have an obligation to cooperate with the NPDB. A subject's failure to cooperate may result in the Dispute Resolution process being suspended or dismissed.

Dispute Resolution Decisions

There are three possible outcomes as a result of a Dispute Resolution, although a Dispute Resolution may result in multiple outcomes when several issues are disputed by the subject of the report:

• The report is accurate as submitted: The report is found to be factually accurate

as submitted to the NPDB by the reporting entity, as evidenced by the record compiled during Dispute Resolution, and/or the report is found to be submitted in accordance with the NPDB reporting requirements.

- The report is inaccurate as submitted: The report is found to be factually inaccurate as submitted to the NPDB by the reporting entity, as evidenced by the record compiled during Dispute Resolution, and/or the report is found to be not submitted in accordance with the reporting requirements.
- The dispute is found to be outside the scope of Dispute Resolution.

If a Report is Accurate as Submitted

If a report is found to be *accurate as submitted*, it remains in the NPDB. A letter explaining this decision will address the issues raised by the subject. A decision letter is sent to the subject of the report, with a copy to the reporting entity. All queriers who received notification of the dispute and have received the report within the 3 years before the Dispute Resolution decision receive a copy of the disputed report with a summary of the decision; they do not receive a copy of the decision letter.

If a Report is Inaccurate as Submitted

If a report is found to be *inaccurate as submitted*, the reporting entity is asked to determine whether it agrees with the assessment, based on the record compiled during the Dispute Resolution, that the report is inaccurate.

If the reporting entity agrees with the assessment, the reporting entity corrects the inaccurate information in the report. When the NPDB processes a <u>Correction</u> Report, the NPDB provides the reporting entity with a Report Verification Document. In addition, the NPDB sends a notification to the subject of the report

If a report is found to be inaccurate as submitted, the reporting entity is asked to determine whether it agrees with the assessment.

and a copy to all queriers who received the previous version of the report within the past 3 years. The corrected report remains in the NPDB.

If the reporting entity does not agree with the assessment, it is asked to explain its rationale in writing and provide additional documentation. The DPDB reassesses the accuracy of the report. The subject of the report also may submit documentation in response to the reporting entity's reply.

If the reporting entity does not submit additional documentation that substantiates the report and fails to correct the report, the DPDB corrects the report consistent with the record compiled during Dispute Resolution, and the report remains in the NPDB. A letter explaining the decision will address the issues raised by the subject. The decision letter is sent to the subject of the report, with a copy to the reporting

entity. All queriers who received notification of the dispute and received the report within the 3 years before the Dispute Resolution decision receive a corrected copy of the disputed report with a summary of the decision; they do not receive a copy of the decision letter.

If the reporting entity submits additional documentation that substantiates the report, and the report is found to be accurate as submitted, it remains in the NPDB. (See <u>If a Report is Accurate as Submitted</u>.)

Corrected reports are removed from Dispute Resolution unless additional Dispute Resolution review is sought by the subject of the report. Following the correction, if the subject of the report disagrees with the accuracy of the corrected report, the subject of the report can request that the report be re-elevated for review. The subject of the report may update the report's Dispute Resolution Statement but is not required to submit additional documentation or contact the reporting entity again.

If a report is found to *not meet the NPDB reporting requirements*, the reporting entity is asked to determine whether it agrees with the assessment, based on the record compiled during the Dispute Resolution, that the report should be voided.

If the reporting entity agrees with the assessment, the reporting entity voids the report. When the reporting entity <u>voids a report</u>, it is removed from the disclosable

record of the subject of the report. When the NPDB processes a Void, the NPDB provides the reporting entity with a Report Void Confirmation. The NPDB also sends a notification to the subject of the report and to all queriers who received the previous version

If a report is found to have not been submitted in accordance with reporting requirements, the reporting entity is asked to determine whether it agrees that the report should be voided.

of the report within the past 3 years. All queriers who received the previous version of the report within the past 3 years are advised to destroy the report and any copies of it.

If the reporting entity does not agree with the assessment, it is asked to explain its rationale in writing and provide documentation. The information and documentation is used by the DPDB to reassess the accuracy of the report.

If the reporting entity does not submit documentation that substantiates the report and fails to void the report, the DPDB voids the report. A decision letter is sent to the subject of the report with a copy to the reporting entity. All queriers who received notification of the dispute and received the report within the 3 years before

the Dispute Resolution decision receive a summary of the decision; they do not receive a copy of the decision letter. All queriers who received the previous version of the report within the past 3 years are advised to destroy the report and any copies of it

If the reporting entity submits documentation that substantiates the report and the report is found to be accurate as submitted, it remains in the NPDB. (See <u>If a Report is Accurate as Submitted.</u>)

Outside the Scope of Dispute Resolution

If the issues in dispute are found to be *outside of the scope of review*, the NPDB adds an entry to that effect to the report, and the dispute notification is removed from the report. A decision letter is sent to the subject of the report, with a copy to the reporting entity. All queriers who received notification of the dispute and received the report within the 3 years before the Dispute Resolution decision receive a copy of the disputed report with a summary of the decision; they do not receive a copy of the decision letter.

Tables F-2 and F-3 provide graphical representations of the Dispute Resolution process.

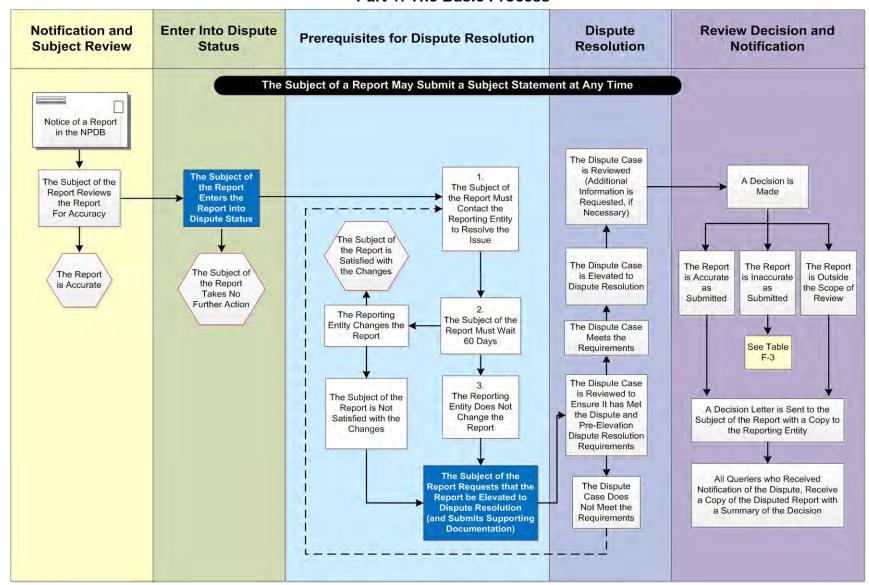


Table F-2: Pre-Elevation and Elevation to Dispute Resolution
Part 1: The Basic Process

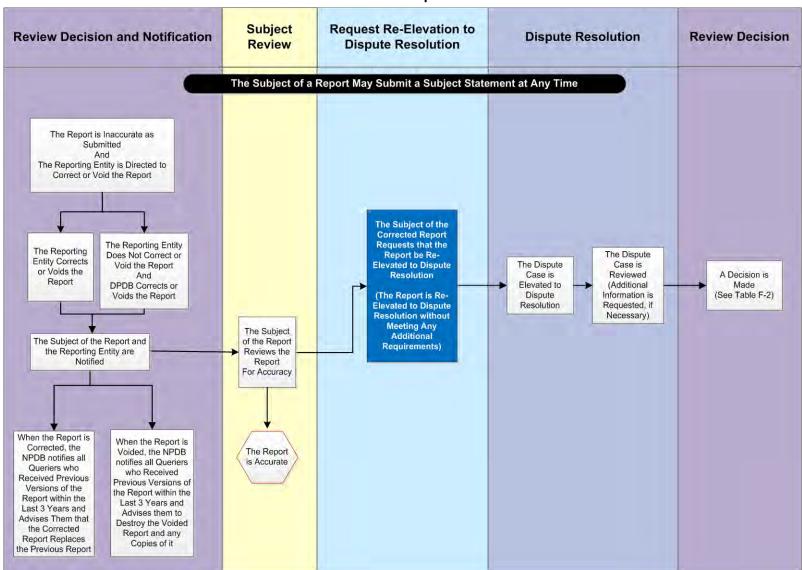


Table F-3: Re-Elevation to Dispute Resolution
Part 2: The Review Decision is the Report is Inaccurate as Submitted

Reconsideration of a Dispute Resolution Decision

Subjects of reports may request reconsideration of Dispute Resolution decisions. Subjects of reports should be specific about any new information that was unavailable to them at the time of the review, as well as the issue(s) they believe were inappropriately considered during the review. Either the previous decision will be affirmed or a revised final decision will be issued.

The subject of a report must submit a written request for reconsideration and documentation to support any new information to the NPDB to one of the following addresses:

Standard Mail	Overnight Mail
National Practitioner Data Bank ATTN: Dispute Resolution P.O. Box 10832 Chantilly, VA 20153-0832	National Practitioner Data Bank ATTN: Dispute Resolution 4094 Majestic Lane PMB-332 Fairfax, VA 22033

Subject of the Report is Deceased

The legal representative of a deceased individual's estate may dispute an NPDB report on behalf of the subject of the report. To dispute a report, the representative must provide documentation that he or she has been appointed the legal representative of the estate. Acceptable documentation includes a photocopy of the authenticated will or other legal document that indicates the legal representative as executor of the will or trust. The NPDB Customer Service Center can help the legal representative begin this process.

EXAMPLES OF DISPUTE RESOLUTION

The following examples assume that the subject of the report entered the report into Dispute Status, made a request to elevate the report to Dispute Resolution, and met the other prerequisites for having the report elevated.

The Report is Accurate as Submitted

1. A Medical Malpractice Payment Report (MMPR) was submitted to the NPDB naming a licensed medical resident as the subject of the report. The resident claimed that the report was improperly submitted because she was still in training at the time of the incident.

Outcome: The report was submitted in accordance with NPDB reporting

requirements based on the definition of <u>health care practitioner</u>: "an individual who is licensed or otherwise authorized by the state to provide health care services (or any individual who, without authority holds himself or herself out to be so licensed or authorized)." Whether the health care practitioner is in training is irrelevant when reporting medical malpractice payments. The report was found to be accurate as submitted.

2. A provider was named as the subject of a report on a health care-related criminal conviction. The provider argued that he was not convicted of a crime because he had pleaded nolo contendere to an allegation of submitting false claims to a health plan.

Response: The report was submitted in accordance with NPDB reporting requirements based on the definition of <u>criminal conviction</u>, which includes a nolo contendere plea. The report was found to be accurate as submitted.

3. A State licensure action report was submitted to the NPDB naming an ambulance service as the subject. The ambulance service was reprimanded for "failing to assure that critical patient care equipment has spare batteries or an alternative power source." The ambulance service claimed that it had run out of batteries only once but the narrative implied that this was an ongoing problem.

Response: The narrative was reviewed against the materials provided by the State licensing board and the report was found to be accurate as submitted.

4. A hospital reported a clinical privileges action to the NPDB indicating that a surgeon resigned while under investigation. The surgeon objected, saying she did not know she was under investigation. She insisted that an investigation was never mentioned to her and there is no mention of investigations in the hospital bylaws. For these reasons, she said, the report should be removed from the NPDB.

Response: A hospital must submit a report to the NPDB when a physician or dentist resigns his or her clinical privileges while under investigation, regardless of whether the health care practitioner is aware of the investigation. The hospital provided documentation of an ongoing investigation at the time the surgeon resigned her clinical privileges. Therefore, the report was found to be accurate as submitted.

The Report is Inaccurate as Submitted

1. A report of a State licensure action taken against a chiropractor was

submitted to the NPDB. The chiropractor claimed the narrative was misleading because it cited "patient harm" but the State licensing board's finding was "inappropriate communication." The chiropractor requested that the description be changed.

Outcome: The narrative was reviewed against the findings submitted by the State licensing board and was found not to accurately reflect the board's findings of fact and conclusion of law. The reporting entity was directed to change the narrative.

2. A report of a summary suspension of clinical privileges was submitted to the NPDB. The subject of the report, a physician, argued that the report was illegally submitted because the suspension was less than 30 days. Specifically, the hospital reported the suspension of the physician's clinical privileges on the 10th day of an indefinite suspension. As part of the suspension, the physician was required to undergo a psychiatric evaluation. The physician completed the required action on the 20th day of the suspension. The psychiatric evaluation was unremarkable, and clinical privileges were immediately restored. The hospital did not void the report from the NPDB.

Outcome: The reporting entity was directed to void the report because only clinical privileges actions in effect or imposed for more than 30 days may be reported to the NPDB, and the summary suspension the reporting entity took lasted only 20 days. When a summary suspension of clinical privileges is indefinite in length, it should not be reported until it has been in effect for more than 30 days. However, once the action has been in effect for more than 30 days, it must be reported.

3. A hospital submitted a report to the NPDB regarding a physician's summary suspension of clinical privileges based on professional competence. The suspension lasted 28 days. The hospital took no subsequent action. The physician resigned a year later while still under investigation by the hospital for the same professional competence issue. The hospital submitted a second report related to the physician's resignation while under investigation.

After the second report was submitted, the physician disputed both reports. The physician argued that the first report was not submitted in accordance with the NPDB reporting requirements because the length of the suspension was less than 30 days and that the second report also was submitted illegally because it was based on the same issue that had

previously been illegally reported to the NPDB.

Outcome: The reporting entity was directed to void the first report because the <u>summary suspension</u> was neither in effect nor imposed for more than 30 days, as required for clinical privileges actions submitted to the NPDB. The second report was found to be accurate as submitted because the physician had resigned while <u>under investigation</u> for issues related to professional competence.

4. A hospital reported a clinical privileges action stating that a surgeon had exhibited improper and unprofessional conduct. The physician argued that the report did not adequately describe his conduct, which he described as essential to saving the life of a patient.

Outcome: The narrative was found to be factually insufficient and the hospital was asked to correct it. When the hospital failed to correct the narrative, the NPDB corrected the narrative consistent with the record compiled during Dispute Resolution. The corrected narrative indicated that the surgeon had to be restrained by the police after he became upset because he had to wait for an operating room. The surgeon had insisted that a trauma patient needed immediate attention. Two other surgeons, however, had determined that the patient's injuries were not life threatening. As a result, a nurse refused to let the surgeon operate.

5. A physician was completing his surgical residency and applied for board certification in surgery at the same time he applied for surgical privileges at a hospital. The hospital denied his application for surgical privileges when it received notice that that the physician was not awarded board certification, a threshold eligibility criteria for privileges at that hospital. The hospital reported the action to the NPDB, and the physician disputed the report.

Outcome: The denial of surgical privileges solely because a physician does not meet the hospital's established threshold eligibility criteria should not be reported to the NPDB. Such denials are not a result of a professional review action relating to the practitioner's professional competence or conduct. The hospital was directed to void the report.

The Issues in Dispute are Outside the Scope of Dispute Resolution

1. A health care practitioner was the subject of a clinical privileges action report. He alleged that the health care entity, during professional review, denied him due process. He claimed the reviewers ignored the testimony of medical experts and other witnesses called to prove various points that he

believed were important to his defense.

Outcome: The issue raised by the subject of the report (i.e., whether due process was afforded the subject of the report) was found to be outside the scope of review because it did not concern the report's factual accuracy or whether the report was submitted in accordance with NPDB reporting requirements.

2. A physician objected to an NPDB report because she did not think she was responsible for the incident that resulted in the restriction of her clinical privileges. She stated that she had only seen the patient once.

Outcome: The issues raised in the dispute were found to be outside the scope of review because they addressed the basis for the clinical privileges action. The number of times a patient is seen by a health care practitioner or whether the health care practitioner accepts responsibility for the incident is irrelevant to reporting a clinical privileges action.

3. A health care practitioner argued against an MMPR, saying that he was not given the opportunity for a court hearing because his insurance company settled the claim without his knowledge.

Outcome: The issues raised by the health care practitioner were found to be outside the scope of review. Whether the health care practitioner agreed to a settlement is irrelevant to the requirement for submitting an MMPR.

4. After a State licensing board submitted charges against him, a social worker entered into a consent order with the board, agreeing that his license would be suspended for 60 days, and the subsequent State licensure action was reported to the NPDB. The practitioner claimed that he never had a formal proceeding as defined in NPDB regulations: "a proceeding held before a state licensing or certification authority, peer review organization, or private accreditation entity that maintains defined rules, policies, or procedures for such a proceeding."

Outcome: The issue regarding the lack of a formal proceeding was found to be outside the scope of review. The consent order the practitioner provided clearly stated that the social worker had an opportunity to consult legal counsel and, by signing the consent order, he agreed to forego the formal hearing process with the State licensing board. The board provided documentation showing that the activities surrounding the charge and consent order were activities held under a formal proceeding with defined rules, policies, and procedures to conduct such

activities. By not availing himself of the formal hearing, the social worker cannot claim that a formal proceeding was not used.

Q&A: SUBJECT STATEMENTS AND THE DISPUTE PROCESS

1. If the subject of a report enters the report into Dispute Status, will it automatically be elevated to Dispute Resolution after 60 days?

No. The subject of the report must request that the report be elevated to <u>Dispute Resolution</u> and submit the required documentation. Once the report has been entered into Dispute Status, the subject of the report must wait 60 days (or a lesser time if the subject obtains written proof from the reporting entity that the reporting entity will not change or void the report as requested by the subject) before requesting that the report be elevated to Dispute Resolution. During that time, the subject of the report must attempt to contact the reporting entity to attempt to resolve the dispute.

2. If the subject of a report makes a request to elevate a report to Dispute Resolution, does he or she have to add a Subject Statement?

No. <u>Subjects of reports</u> do not have to add a Subject Statement. However, subjects of reports are required to state clearly and briefly in writing, in a Dispute Resolution Statement, which facts in the report are in dispute. In addition, subjects of reports must submit documentation substantiating that the reporting entity's information is inaccurate or that the report was not submitted in accordance with NPDB reporting requirements. The documentation must relate directly to the facts in dispute and substantially clarify the issues in dispute. More information will be requested if it is necessary for a proper resolution of the matter. Subjects of reports also must submit proof of an unsuccessful attempt to resolve the disagreement with the reporting entity.

3. Must subjects of reports enter a report into Dispute Status in order to add a Subject Statement to the report?

No. Subjects of reports may add a <u>Subject Statement</u> to a report independently of the dispute process.

4. A subject of a report is attempting to resolve a dispute with a State licensing board that submitted a report concerning him, and it is taking a long time. Must the issue be resolved within a certain time?

No. There is no established time frame for resolving a dispute with the reporting entity. However, if the subject of the report decides to request elevation of the report to <u>Dispute Resolution</u>, the subject of the report must enter the report into Dispute Status and wait 60 days before asking the NPDB to elevate the report. During that time, the subject of the report must attempt to contact the reporting entity to attempt to resolve the issues. The subject of the report also must be able to provide documentation of an unsuccessful attempt to resolve the issues with the reporting entity (e.g., copy of an email message or letter sent to the reporting entity and the response, if any). If, before the end of 60 days, the subject of the report obtains written documentation that the reporting entity will not change or void the report, the subject may request that the NPDB elevate the dispute immediately.

5. The subject of a report entered a report into Dispute Status 3 months ago and never heard back from the NPDB. Why not?

Entering a report into Dispute Status simply notifies the reporting entity, queriers who received the report in the past 3 years, and future queriers that the subject of the report disagrees with the factual accuracy of the report or whether it was submitted in accordance with the NPDB reporting requirements. The NPDB does not contact the subject of a report that is in Dispute Status. Once the report is in Dispute Status, the subject of the report may request that the NPDB elevate the report to Dispute Resolution. To do this, the subject of the report must wait up to 60 days after the report has been entered into Dispute Status. During that time, the subject of the report must attempt to contact the reporting entity to allow both parties an opportunity to resolve the issues. If before the end of 60 days the subject of the report obtains written documentation that the reporting entity will not change or void the report, the subject may request that the NPDB elevate the report immediately. The NPDB will contact the subject of the report when elevation to Dispute Resolution has been requested.

CHAPTER G: FEES

OVERVIEW

The NPDB is an information clearinghouse created by Congress with the primary goals of improving health care quality, protecting the public, and reducing health care fraud and abuse in the United States. The NPDB collects information on medical malpractice payments and certain adverse actions and discloses that information to eligible entities to facilitate comprehensive review of the credentials of health care practitioners, entities, providers, and suppliers. These payments and actions are required to be reported to the NPDB under Title IV of Public Law 99-660, the Health Care Quality Improvement Act of 1986; Section 1921 of the Social Security Act; Section 1128E of the Social Security Act; and their implementing regulations found at 45 CFR Part 60.

QUERY FEES

Eligible Entity Query Fees

<u>Fees</u> are charged for all queries submitted to the NPDB. By Federal law, the NPDB must recover the full costs of operations. The NPDB does not receive annual Congressional appropriations; it is self-supporting through user fees.

For all queries except Self-Queries, there are two payment mechanisms. Queriers are charged individually for each One-Time (Traditional) Query submitted and are charged on a subscription basis for Continuous Query enrollments.

The act of submitting a query to the NPDB is considered an agreement to pay the associated fee for the service. This includes queries that are processed by the NPDB (regardless of whether there is information on file concerning the subject of the query) and queries that are rejected because they are improperly submitted or lack information. Query fees are charged based on the date the query is received at the NPDB. Query fees are subject to change; any change to fees is announced by the Secretary of Health and Human Services in the Federal Register.

Self-Query Fees

An individual or organization may submit a Self-Query at any time using the <u>Self-Query service</u>. A <u>fee</u> is charged per Self-Query and for any additional copies of the query response requested.

METHOD OF PAYMENT

The NPDB accepts query fee payments by credit card (VISA, MasterCard, Discover, and American Express), bank debit card (with a VISA or MasterCard logo), or preauthorized Electronic Funds Transfer (EFT). However, individual and organizational Self-Query fees must be paid by credit or debit card. Eligible entities may choose to pay by credit or debit card or preauthorized EFT. The NPDB does not accept personal checks, money orders, or cash.

Credit or Debit Card

Eligible entities and self-queriers choosing to pay by credit or debit card are not required to make advance arrangements with the NPDB to use their cards.

- An eligible entity making a One-Time Query or Continuous Query should enter the credit or debit card number and expiration date on the appropriate screen when querying (after <u>signing in</u> to the Integrated Querying and Reporting Service [IQRS], go to the Options menu).
- Self-queriers who process their requests entirely online through the Express
 Self-Query service should use their own credit or debit card while online; selfqueriers who do not use the Express Self-Query service should enter a credit or
 debit card number and expiration date in the appropriate fields of the SelfQuery application, either electronically before printing or in writing after
 printing the application, before submitting the printed application.

An eligible entity's administrator has the option to <u>securely store</u> the eligible entity's credit or debit card information to prevent having to enter it each time a new query is being submitted. In addition, the administrator can assign users to the credit or debit card for query processing. The administrator can assign multiple credit or debit cards if he or she chooses to do so.

EFT

Eligible entities choosing to pay by EFT must submit an Electronic Funds Transfer Authorization form before EFT payments can be processed. To obtain this form, go to the <u>sign in screen</u>, then to the Administrator Options menu, and select Authorize Electronic Funds Transfer.

Entities must provide:

- Their financial institution's routing number, account number, and the type of account (checking or savings); and
- A copy of a voided check or a financial institution's confirmation letter.

In addition, the entity's certifying official must sign the form in ink.

The EFT form, with the original ink signature, must be mailed to the address printed on the form to establish an EFT account. Once the completed form and required documentation have been received, the NPDB will establish electronic communications with the eligible entity's financial institution. This process takes approximately 5 business days. The eligible entity will be notified via NPDB Correspondence when the EFT account has been activated. NPDB Correspondence is accessible through the IQRS sign-in screen under the Options menu.

Once an eligible entity receives verification that the EFT account has been activated, the entity may pay query fees using its EFT account. Query charges will be deducted automatically from the eligible entity's designated EFT account. The eligible entity does not need to enter EFT account information when creating a query; it only needs to select the EFT payment option.

Eligible entities are responsible for ensuring that adequate funds are present in their accounts when queries are submitted for processing in order to avoid interruption and potential termination of NPDB services. If an eligible entity's EFT information changes, the eligible entity is responsible for notifying the NPDB by submitting a revised Electronic Funds Transfer Authorization form (select Authorize Electronic Funds Transfer from the Administrator Options menu to access the form).

AUTHORIZED AGENTS

Eligible entities may elect to use <u>authorized agents</u> to query and/or report to the NPDB on their behalf. An eligible entity may choose to have the query charge assessed either to its preauthorized EFT account or its agent's preauthorized EFT account. Another option is for the eligible entity to pay for the query using its own credit or debit card, or for the authorized agent to use its credit or debit card.

When an eligible entity designates an <u>authorized agent</u> to query on its behalf, the eligible entity ultimately is responsible for the payment of query fees incurred by its authorized agent. This includes any outstanding balances for unpaid queries. Written agreements with authorized agents should include procedures for the payment of query fees.

BILLING HISTORY

Eligible entities and agents may view query charges on the <u>Billing History screen</u> within the IQRS. This screen provides the most current information available for entities and authorized agents to better reconcile query charges as they appear on their financial institution's statements.

Eligible entities and agents will receive a Charge Receipt for each query processed, which may be viewed on the Billing History screen. The receipt, along with the information on the Billing History screen, can be used by entities for accounting purposes. Charges are referenced by the bill date and Data Bank Control Number (DCN) of each transaction.

<u>Self-queriers</u> may access receipts on the Self-Query Status screen after logging into the Self-Query application on the NPDB website.

ACCOUNT DISCREPANCIES

The NPDB collects outstanding query fee balances. The NPDB will ask the eligible entity or self-querier to complete an <u>Account Balance Transfer Request</u> form to authorize settlement of any outstanding balance. The NPDB has the duty and legal authority to collect all amounts owed to it. It may do so without prior approval from the customer; this authority does not expire.

RECONCILIATION OF STATEMENTS

Reconciliation of billing statements must be done through your financial institution. However, if you have questions or believe that you were charged incorrectly by the NPDB, contact the <u>Customer Service Center</u> as soon as possible for assistance. You will receive information about putting your request in writing. Your questions or disputes concerning charges must be received no later than 60 days from the date the query was submitted.

CREDITS AND DEBITS

The NPDB will issue credits when:

- A fee is incorrectly assessed, or
- The NPDB is responsible for a data processing error

The NPDB issues debits when:

- A credit is mistakenly applied to an account, or
- An original charge is not paid

Requests for credits should be made within 60 days of the query submission. An eligible entity that suspects that a bill is incorrect, or that needs more information about a transaction, should contact the NPDB Customer Service Center as soon as possible but no later than 60 days after the query submission on which the error or problem appeared. All of the following information must be provided:

- Your name
- A description of the error and explanation of why you believe there is an error
- The dollar amount of the suspected error
- Your entity's and/or authorized agent's Data Bank Identification Number (DBID)
- The DCN
- Your telephone number
- Your signature for NPDB records
- A copy of your bill
- Your fax number

BANKRUPTCY

Eligible entities are responsible for <u>notifying the NPDB</u> in writing of bankruptcy and must include all of the following information:

- The entity's DBID
- The entity's name
- The entity's address
- The type of bankruptcy Chapter 7, Chapter 9, Chapter 11, State liquidation, etc.

If your organization is undergoing bankruptcy, and you have an outstanding NPDB balance pending collection, the outstanding balance is still collectable until final resolution of the bankruptcy. Failure to make payments to the NPDB can result in termination of your ability to query the NPDB, even if your organization is required by law to do so.

Q&A: FEES

1. How does an eligible entity request a credit from the NPDB?

The eligible entity may request a <u>credit</u> by submitting the details of the issue and supporting documentation in writing to the <u>NPDB Customer Service</u> <u>Center</u>.

2. A hospital's administrator charged queries to the hospital's credit card and now can't figure out the bill from the credit card company. Does the NPDB reconcile credit card mistakes?

The NPDB cannot <u>reconcile a credit card billing statement</u>. Reconciliation of billing statements must be done through the entity's financial institution. However, if the hospital's administrator has questions or believes that the entity

was charged incorrectly by the NPDB, the administrator should contact the <u>Customer Service Center</u> as soon as possible for assistance. The administrator will receive information about putting information in writing. Questions or disputes must be received no later than 60 days from the date the query was submitted.

3. What should an administrator do if the eligible entity's credit card payment was rejected?

The NPDB does not authorize or deny credit card payments; the NPDB submits the payment information to the entity's financial institution for authorization. Before contacting the NPDB, the administrator should contact the entity's financial institution to determine the reason for the rejection. If the administrator still has questions, he or she may contact the NPDB Customer Service Center.

4. An eligible entity's EFT account is on hold. What should it do?

If an EFT account is on hold, the eligible entity should first contact its financial institution to research the problem. If, after resolving the issues with its financial institution, the eligible entity is unable to access its EFT account, the administrator should contact the NPDB Customer Service Center.

5. Will the NPDB Customer Service Center provide eligible entities with the balance of their EFT accounts?

The NPDB does not maintain balances on EFT accounts; eligible entities should contact their financial institution for questions regarding balance information.

6. Why can't eligible entities see the reference number on their billing statements?

The NPDB transmits the reference numbers to the eligible entity's financial institution to assist eligible entities with reconciling their statements. However, it is up to the financial institution to post the information on the eligible entity's billing statement. Eligible entities should contact their financial institution for additional information.

CHAPTER H: INFORMATION SOURCES

NPDB CUSTOMER SERVICE CENTER

For additional assistance, contact the NPDB Customer Service Center.

NPDB Customer Service Center

Email address: help@npdb.hrsa.gov Phone: 800-767-6732 (800-SOS-NPDB)

TTD: 703-378-3919

Outside the U.S.: 703-802-9380

Open: Mon.-Thurs., 8:30 a.m. to 6:00 p.m. (Eastern Time)

Fri., 8:30 a.m. to 5:30 p.m. (Eastern Time)

Closed: Federal holidays

NPDB ADDRESSES

General Information

Requests for general information about the NPDB and Dispute Resolution materials should be sent to one of the following addresses.

Standard Mail	Overnight Mail
National Practitioner Data Bank P.O. Box 10832 Chantilly, VA 20153-0832	National Practitioner Data Bank 4094 Majestic Lane PMB-332 Fairfax, VA 22033

Aggregate Research Data

Requests for <u>aggregated research data</u> should be sent to the following postal address or email address. There may be a charge for some data requests.

Division of Practitioner Data Bank Attn: Research 5600 Fishers Lane, Mail Stop 11SWH03 Rockville, MD 20857

Email Address:

dpdbdatarequests@hrsa.gov

Interpretation of NPDB Statutes and Regulations

Matters that deal specifically with the interpretation of statutory and regulatory authority should be directed to the following address.

Division of Practitioner Data Bank Policy and Disputes Branch Chief 5600 Fishers Lane, Mail Stop 11SWH03 Rockville, MD 20857

Email Address: npdbpolicy@hrsa.gov

FEDERAL EMPLOYER IDENTIFICATION NUMBER

The Federal Employer Identification Number (EIN), also known as a Federal Tax Identification Number, is used to identify a business entity. The name, address, and EIN for the NPDB are provided below.

Health Resources and Services Administration U.S. Department of Health and Human Services 5600 Fishers Lane, Mail Stop 11SWH03 Rockville, MD 20857

EIN: 52-082-1668

APPENDIX A: GLOSSARY

This glossary contains terms that relate to the NPDB, and the definitions apply only to their usage in conjunction with the NPDB and its policies and procedures. Please refer to the appropriate sections of this Guidebook for policy guidance.

Α

Administrator — A registered entity's administrator gives authority to individuals in each organization to manage NPDB activities. In particular, the administrator is responsible for creating and maintaining user accounts for all individuals in the organization who query or report.

Adverse Action Report — The report format used to submit actions, other than medical malpractice payments and convictions and judgments, taken against a health care practitioner, entity, provider, or supplier.

Affiliated or Associated — Defined in NPDB regulations as "health care entities with which a subject of a final adverse action has a business or professional relationship. This includes, but is not limited to, organizations, associations, corporations, or partnerships. This also includes a professional corporation or other business entity composed of a single individual."

Authorized Agent — An individual or organization that an eligible entity designates to query and/or report to the NPDB on its behalf.

Authorized Submitter — An individual empowered by an eligible entity to submit reports or queries to the NPDB. The authorized submitter certifies the legitimacy of information in a query or report submitted to the NPDB.

Authorized User — See *Authorized Submitter*.

В

Basis for Action Codes — A list of reasons for taking an adverse action and the corresponding codes used on reports submitted to the NPDB.

Board of Medical Examiners — Defined in NPDB regulations as "a body or subdivision of such body which is designated by a state for the purpose of licensing, monitoring, and disciplining physicians or dentists. This term includes a Board of Osteopathic Examiners or its subdivision, a Board of Dentistry or its subdivision, or an equivalent body as determined by the state. Where the Secretary, pursuant to section 423(c)(2) of the HCQIA (42 U.S.C. 11112(c)), has designated an alternate

entity to carry out the reporting activities of § 60.12 of this part due to a Board's failure to comply with § 60.8 of this part, the term Board of Medical Examiners or Board refers to this alternate entity." See also *State Licensing Board*, *State Licensing or Certification Authority*, and *State Medical or Dental Board*.

\mathbf{C}

Certification — The term "certification" has two distinct meanings.

- First, the term is related to licensure, because licensure includes certification and other forms of authorization to provide health care services. Based on State laws and requirements, States may "license," "certify," or "register" certain types of health care practitioners, entities, providers, or suppliers.
- Second, the term also is used to refer to certification of a health care practitioner, entity, provider, or supplier to participate in a Government health care program. In this context, certification includes certification agreements and contracts for participation in a Government health care program.

Certifying Official — An individual selected and empowered by an eligible entity to certify the legitimacy of registration for participation in the NPDB.

Clinical Privileges — Defined in NPDB regulations as "the authorization by a health care entity to a health care practitioner for the provision of health care services, including privileges and membership on the medical staff." The term "medical staff" also includes network participation and panel membership.

Continuous Query — An NPDB query service that notifies subscribing entities, within one business day, of the receipt of a new or updated NPDB report that names any of their enrolled practitioners as subjects.

Correction Report — Corrects an error or omission in a previously submitted report by replacing the current version of the report.

Criminal Conviction — For NPDB purposes, a criminal conviction includes:

- A judgment of conviction that has been entered against an individual or entity in a Federal, State or local court, regardless of whether an appeal is pending or the conviction or other record relating to criminal conduct has been expunged
- A finding of guilt against an individual or entity that is made in a Federal, State, or local court
- A plea of guilty or nolo contendere by an individual or entity that has been accepted by a Federal, State, or local court, and
- When an individual or entity has entered into participation in a first offender, deferred adjudication, or other arrangement or program where conviction has been withheld

D

Data Bank Control Number (DCN) — The identification number assigned by the NPDB that is used to identify each query and report.

Data Bank Identification Number (DBID) — A unique, 15-digit identification number assigned to eligible entities and authorized agents when they register with the NPDB.

Dentist — Defined in NPDB regulations as "a doctor of dental surgery, doctor of dental medicine, or the equivalent who is legally authorized to practice dentistry by a state (or who, without authority, holds himself or herself out to be so authorized)."

Department of Health and Human Services — The Federal department charged by Congress with administering, or delegating the administration of, the NPDB.

Dispute Process — The procedures by which a health care practitioner, entity, provider, or supplier can dispute the accuracy of information reported to the NPDB.

Draft Report — A report in progress that is temporarily electronically stored in the NPDB without being submitted to the NPDB for processing.

Drug Enforcement Administration (DEA) — The Federal agency that registers physicians, dentists, and other health care practitioners to dispense controlled substances and assigns them DEA numbers. DEA is a Federal law enforcement agency within the Department of Justice.

<u>E</u>

Electronic Report Forwarding Service — An NPDB service that forwards NPDB reports to State licensing boards if both the reporting entity and the board agree to participate in the service. The reporting entity remains responsible for ensuring that necessary reports are forwarded to appropriate State boards.

Eligible Entity — An entity that is authorized to query and/or report to the NPDB under the provisions of Title IV of Public Law 99-660, the Health Care Quality Improvement Act of 1986; Section 1921 of the Social Security Act; Section 1128E of the Social Security Act; or as specified in 45 CFR Part 60.

Exclusion — Defined in NPDB regulations as "a temporary or permanent debarment of an individual or entity from participation in any Federal or State health-related program, in accordance with which items or services furnished by such person or entity will not be reimbursed under any Federal or State health-related program."

F

Formal Peer Review Process — Defined in NPDB regulations as "the conduct of professional review activities through formally adopted written procedures which provide for adequate notice and an opportunity for a hearing."

Formal Proceeding — Defined in NPDB regulations as "a proceeding held before a state licensing or certification authority, peer review organization, or private accreditation entity that maintains defined rules, policies, or procedures for such a proceeding."

<u>H</u>

Health Care Entity — Defined in NPDB regulations as

- "(1) A hospital;
- "(2) An entity that provides health care services, and engages in professional review activity through a formal peer review process for the purpose of furthering quality health care, or a committee of that entity; or
- "(3) A professional society or a committee or agent thereof, including those at the national, state, or local level, of health care practitioners that engages in professional review activity through a formal peer review process, for the purpose of furthering quality health care.
- "(4) For purposes of paragraph (2) of this definition, an entity includes: a health maintenance organization which is licensed by a state or determined to be qualified as such by the Department of Health and Human Services; and any group or prepaid medical or dental practice which meets the criteria of paragraph (2)."

See also *Hospital* and *Professional Society*.

Health Care Practitioner, Licensed Health Care Practitioner, Licensed Practitioner, or Practitioner — Defined in NPDB regulations as "an individual who is licensed or otherwise authorized by a state to provide health care services (or any individual who, without authority, holds himself or herself out to be so licensed or authorized)."

Health Care Provider — Defined in NPDB regulations as "a provider of services as defined in section 1861(u) of the Social Security Act; any organization (including a health maintenance organization, preferred provider organization or group medical practice) that provides health care services and follows a formal peer review process for the purpose of furthering quality health care, and any other organization that, directly or through contracts, provides health care services."

Health Care Supplier — Defined in NPDB regulations as "a provider of medical and other health care services as described in section 1861(s) of the Social Security Act; or any individual or entity, other than a provider, who furnishes, whether directly or indirectly, or provides access to, health care services, supplies, items, or ancillary services (including, but not limited to, durable medical equipment suppliers, manufacturers of health care items, pharmaceutical suppliers and manufacturers, health record services [such as medical, dental, and patient records], health data suppliers, and billing and transportation service suppliers). The term also includes any individual or entity under contract to provide such supplies, items, or ancillary services; health plans as defined in this section (including employers that are self-insured); and health insurance producers (including but not limited to agents, brokers, solicitors, consultants, and reinsurance intermediaries)."

Health Plan — Defined in NPDB regulations as "a plan, program or organization that provides health benefits, whether directly, through insurance, reimbursement or otherwise, and includes but is not limited to:

- "(1) A policy of health insurance;
- "(2) A contract of a service benefit organization;
- "(3) A membership agreement with a health maintenance organization or other prepaid health plan;
- "(4) A plan, program, agreement, or other mechanism established, maintained, or made available by a self-insured employer or group of self-insured employers, a health care practitioner, provider, or supplier group, third-party administrator, integrated health care delivery system, employee welfare association, public service group or organization or professional association;
- "(5) An insurance company, insurance service, or insurance organization that is licensed to engage in the business of selling health care insurance in a state and which is subject to state law which regulates health insurance; and
- "(6) An organization that provides benefit plans whose coverage is limited to outpatient prescription drugs."

High-Low Agreement — A contractual agreement between a plaintiff and a defendant's insurer that defines the parameters of a payment the plaintiff may receive after a trial or arbitration proceeding.

Hospital — Defined in NPDB regulations as "an entity described in <u>paragraphs (1)</u> and (7) of Section 1861(e) of the Social Security Act." See also *Health Care Entity*.

ı

Initial Report — The first report of a payment or action submitted to and

processed by the NPDB.

Integrated Querying and Reporting Service — An electronic, Internet-based system for querying and reporting to the NPDB.

<u>J</u>

Judgment or Conviction Report — The report format used to report Federal or State health care-related criminal convictions and civil judgments.

<u>L</u>

Licensed Health Care Practitioner, Licensed Practitioner, Health Care Practitioner or Practitioner — See Health Care Practitioner, Licensed Health Care Practitioner, or Practitioner.

Locum Tenens Practitioner — A health care practitioner who fills a position for another health care practitioner on a temporary basis.

Loss Adjustment Expense — An expense other than those in compensation of injuries, such as attorney fees, billable hours, copying costs, expert witness fees, and deposition and transcript costs.

M

Medical Malpractice Action or Claim — Defined in NPDB regulations as "a written complaint or claim demanding payment based on a health care practitioner's provision of or failure to provide health care services, and includes the filing of a cause of action based on the law of tort, brought in any state or federal court or other adjudicative body." See also *Medical Malpractice Payment*.

Medical Malpractice Payer — An entity that makes a medical malpractice payment through an insurance policy or otherwise for the benefit of a health care practitioner in settlement of, or in satisfaction in whole or in part of, a claim or judgment against that practitioner.

Medical Malpractice Payment — A monetary exchange as a result of a settlement or judgment of a written complaint or claim demanding payment based on a health care practitioner's provision of or failure to provide health care services; the written complaint or claim may include, but is not limited to, the filing of a cause of action, based on the law of tort, brought in any State or Federal court or other adjudicative body. See also *Medical Malpractice Action or Claim*.

Medical Malpractice Payment Report — The format used by medical

malpractice payers to report to the NPDB a medical malpractice payment made for the benefit of a health care practitioner.

Ν

National Practitioner Data Bank —A confidential information clearinghouse created by Congress with the primary goals of improving health care quality, protecting the public, and reducing health care fraud and abuse in the United States.

Negative Actions or Findings by a Federal or State licensing or certification authority, peer review organization, or private accreditation entity — Defined in NPDB regulations as

- "(1) A final determination of denial or termination of an accreditation status from a private accreditation entity that indicates a risk to the safety of a patient(s) or quality of health care services;
- "(2) Any recommendation by a peer review organization to sanction a health care practitioner; or
- "(3) Any negative action or finding that, under the state's law, is publicly available information and is rendered by a licensing or certification authority, including but not limited to, limitations on the scope of practice, liquidations, injunctions, and forfeitures. This definition also includes final adverse actions rendered by a Federal or state licensing or certification authority, such as exclusions, revocations, or suspension of license or certification, that occur in conjunction with settlements in which no finding of liability has been made (although such a settlement itself is not reportable under the statute). This definition excludes administrative fines or citations and corrective action plans and other personnel actions, unless they are:
 - "(i) Connected to the delivery of health care services; or
 - "(ii) Taken in conjunction with other adverse licensure or certification actions such as revocation, suspension, censure, reprimand, probation, or surrender."

Notice of Appeal — A report notifying the NPDB that a subject has formally appealed a previously reported adverse action. A notice of appeal is separate and distinct from a subject's dispute of an NPDB report.

NPDB Customer Service Center — Provides information and support to NPDB users. Questions may be directed to information specialists at the Customer Service Center by email at help@npdb.hrsa.gov or by phone at 800-767-6732 (800-SOS-NPDB) The TDD number is 703-378-3919. The number to call from outside the United States is 703-802-9380.

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Office of Inspector General — An agency of the Department of Health and Human Services that performs several functions in connection with the NPDB, including:

- Exercising delegated authority to impose civil money penalties on those who violate the confidentiality provisions of Title IV
- Imposing civil money penalties on medical malpractice payers that fail to report payments to the NPDB
- Reporting to the NPDB exclusions from Federal health care programs and related civil money penalties, and
- Along with other Federal Inspectors General, querying the NPDB as a law enforcement agency

Other Adjudicated Actions or Decisions — Defined in NPDB regulations as "formal or official final actions taken against a health care practitioner, provider, or supplier by a Federal government agency, a state law or fraud enforcement agency, or a health plan, which include the availability of a due process mechanism, and are based on acts or omissions that affect or could affect the payment, provision, or delivery of a health care item or service."

This definition excludes:

- Clinical privileging actions taken by Federal agencies or State law and fraud enforcement agencies, and similar paneling decisions made by health plans
- Overpayment determinations made by Federal or State government programs, their contractors, or health plans
- Denial of claims determinations made by Federal agencies, State law or fraud enforcement agencies, or health plans, and
- Business or administrative decisions taken by health plans that result in contract terminations unrelated to health care fraud, or abuse, or quality of care (e.g., when a practitioner's contract is terminated because the practitioner no longer practices at a facility in the health plan's network, or a health plan terminates all provider contracts in a certain geographic area because it ceases business operations in that area)

For health plans that are not government entities, an action taken following adequate notice and the opportunity for a hearing that meets the standards of due process set out in Title IV also would qualify as a reportable action.

<u>P</u>

Peer Review Organization — Defined in NPDB regulations as "an organization

with the primary purpose of evaluating the quality of patient care practices or services ordered or performed by health care practitioners measured against objective criteria which define acceptable and adequate practice through an evaluation by a sufficient number of health care practitioners in such an area to ensure adequate peer review. The organization has due process mechanisms available to health care practitioners. This definition excludes utilization and quality control peer review organizations described in Part B of Title XI of the Social Security Act (referred to as QIOs) and other organizations funded by the Centers for Medicare & Medicaid Services (CMS) to support the QIO program."

Physician — Defined in NPDB regulations as "a doctor of medicine or osteopathy legally authorized to practice medicine or surgery by a state (or who, without authority, holds himself or herself out to be so authorized)."

Practitioner, Health Care Practitioner, Licensed Practitioner, or Licensed Health Care Practitioner — See *Health Care Practitioner, Licensed Health Care Practitioner, or Practitioner.*

Private Accreditation Entity or Organization —Defined in NPDB regulations as "an entity or organization that:

- "(1) Evaluates and seeks to improve the quality of health care provided by a health care entity, provider, or supplier;
- "(2) Measures a health care entity's, provider's, or supplier's performance based on a set of standards and assigns a level of accreditation;
- "(3) Conducts ongoing assessments and periodic reviews of the quality of health care provided by a health care entity, provider, or supplier; and
- "(4) Has due process mechanisms available to health care entities, providers, or suppliers."

Professional Review Action —Defined in NPDB regulations as "an action or recommendation of a health care entity:

- "(1) Taken in the course of professional review activity;
- "(2) Based on the professional competence or professional conduct of an individual health care practitioner which affects or could affect adversely the health or welfare of a patient or patients; and
- "(3) Which adversely affects or may adversely affect the clinical privileges or membership in a professional society of the health care practitioner.
- "(4) This term excludes actions which are primarily based on:
 - "(i) The health care practitioner's association, or lack of association, with a professional society or association;
 - "(ii) The health care practitioner's fees or the health care practitioner's advertising or engaging in other competitive acts intended to solicit

or retain business;

- "(iii) The health care practitioner's participation in prepaid group health plans, salaried employment, or any other manner of delivering health services whether on a fee-for-service or other basis;
- "(iv) A health care practitioner's association with, supervision of, delegation of authority to, support for, training of, or participation in a private group practice with, a member or members of a particular class of health care practitioner or professional; or
- "(v) Any other matter that does not relate to the competence or professional conduct of a health care practitioner."

Professional Review Activity — Defined in NPDB regulations as "an activity of a health care entity with respect to an individual health care practitioner

- "(1) To determine whether the health care practitioner may have clinical privileges with respect to, or membership in, the entity;
- "(2) To determine the scope or conditions of such privileges or membership; or
- "(3) To change or modify such privileges or membership."

Professional Society — A membership association of health care practitioners at the national, State, or local level that follows a formal peer review process for the purpose of furthering quality health care. Managed care organizations are not considered professional societies. See also *Health Care Entity*.

Q

Quality Improvement Organization — Defined in NPDB regulations as "a utilization and quality control peer review organization (as defined in Part B of Title XI of the Social Security Act) that:

- "(1)(i) Is composed of a substantial number of the licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area and who are representative of the practicing physicians in the area, designated by the Secretary under Section 1153, with respect to which the entity shall perform services under this part, or
 - "(ii) Has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area to assure that adequate peer review of the services provided by the various medical specialties and subspecialties can be assured;
- "(2) Is able, in the judgment of the Secretary, to perform review functions required under Section 1154 in a manner consistent with the efficient and effective administration of this part and to perform reviews of the pattern of quality of care in an area of medical practice where actual performance

- is measured against objective criteria which define acceptable and adequate practice; and
- "(3) Has at least one individual who is a representative of consumers on its governing body."

Query — A request for information submitted to the NPDB.

Querying and Reporting XML Service — An Extensible Markup Language (XML) reporting and querying interface. QRXS is an electronic submission service for high-volume queriers or reporters who wish to interface their data processing systems with the NPDB.

R

Report — A report of an adverse action or medical malpractice payment submitted to the NPDB. NPDB information is reported on one of three report formats: Medical Malpractice Payment Report, Adverse Action Report, or Judgment or Conviction Report.

Revision-to-Action Report — A report of an action relating to and modifying an adverse action previously reported to the NPDB. A Revision-to-Action Report does *not* replace a previously reported adverse action but, rather, is treated as a separate action that pertains to the previous action.

<u>S</u>

Secretary — Defined in NPDB regulations as "the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated."

Section 1128E – Section 1128E of the Social Security Act. Enacted as Section 221(a) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191. One of the three enabling statutes underlying the NPDB.

Section 1921 – Section 1921 of the Social Security Act. Enacted as Section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93. One of the three enabling statutes underlying the NPDB.

Self-Query — A health care practitioner's, entity's, provider's, or supplier's request for information about himself, herself, or itself contained in the NPDB.

State — Defined in NPDB regulations as "the fifty states, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands."

State Agency Administering or Supervising the Administration of a State Health Care Program — State agencies that administer (as well as those that provide payment for services) or supervise the administration of a State health care program, as defined in Section 1128(h) of the Social Security Act. These entities also are included in the definition of a State law or fraud enforcement agency because they have a role in investigating and preventing health care fraud and abuse and take certain final adverse actions consistent with that role. See also *State Law or Fraud Enforcement Agency*.

State Law Enforcement Agency — See *State Law or Fraud Enforcement Agency*.

State Law or Fraud Enforcement Agency — Defined in NPDB regulations as "includes, but is not limited to:

- "(1) A state law enforcement agency;
- "(2) A state Medicaid fraud control unit (as defined in section 1903(q) of the Social Security Act); and
- "(3) A state agency administering (including those providing payment for services) or supervising the administration of a state health care program (as defined in Section 1128(h) of the Social Security Act.)"

See also State Agency Administering or Supervising the Administration of a State Health Care Program.

State Licensing Board — A generic term used to refer to State medical and dental boards, as well as those bodies responsible for licensing, certifying, or otherwise authorizing physicians, dentists, or other health care practitioners to provide health care services. See also *Board of Medical Examiners*, *State Licensing or Certification Authority*, and *State Medical or Dental Board*.

State Licensing or Certification Agency —Defined in NPDB regulations as "includes, but is not limited to, any authority of a state (or of a political subdivision thereof) responsible for the licensing or certification of health care practitioners (or any peer review organization or private accreditation entity reviewing the services provided by health care practitioners), health care entities, providers, or suppliers. Examples of such state agencies include Departments of Professional Regulation, Health, Social Services (including State Survey and Certification and Medicaid Single State agencies), Commerce, and Insurance." See also *Board of Medical Examiners*, *Peer Review Organization*, *Private Accreditation Entity or Organization*, *State Licensing or Certification Authority*, *State Licensing Board*, and *State Medical or Dental Board*.

State Licensing or Certification Authority — A State Government body that
 Licenses, certifies, registers, or otherwise authorizes health care practitioners,

entities, providers, or suppliers to provide health care services; and/or

• Certifies physicians, dentists, other health care practitioners, entities, providers, or suppliers for participation in a Federal or State health care program.

Examples of such State agencies include departments of professional regulation, health, social services (including State survey and certification and Medicaid single State agencies), commerce, and insurance. See also *Board of Medical Examiners*, *State Licensing Board*, and *State Medical or Dental Board*.

State Medicaid Fraud Control Unit — Defined in Section 1903(q) of the Social Security Act. These entities also are included in the definition of a State law or fraud enforcement agency. See *State Law or Fraud Enforcement Agency*.

State Medical or Dental Board — A board of medical examiners. See also *Board of Medical Examiners, State Licensing Board*, and *State Licensing or Certification Authority*.

T

Title IV — Title IV of the Health Care Quality Improvement Act of 1986, Public Law 99-660. One of the three enabling statutes underlying the NPDB.

<u>V</u>

Void Report — A report format used to withdraw a report in its entirety. Also called a Void.

APPENDIX B: ACRONYM GUIDE

ACO Accountable Care Organization

CDS Controlled Dangerous Substance

CEU Continuing Education Unit

CFR Code of Federal Regulations

CLIA Clinical Laboratory Improvement Amendments

CMS Centers for Medicare & Medicaid Services

CVO Credentials Verification Organization

DBID Data Bank Identification Number

DCN Data Bank Control Number

DEA Drug Enforcement Administration

DOD Department of Defense

DOJ Department of Justice

DPDB Division of Practitioner Data Bank

DVA Department of Veterans Affairs

EFT Electronic Funds Transfer

EHR Electronic Health Record

HCQIA Health Care Quality Improvement Act of 1986

HHS Department of Health and Human Services

HIPDB Healthcare Integrity and Protection Data Bank

HMO Health Maintenance Organization

IQRS Integrated Querying and Reporting Service

LAE Loss Adjustment Expense

MCO Managed Care Organization

NPDB Guidebook

Appendix B: Acronym Guide

MEC Medical Executive Committee

MMPR Medical Malpractice Payment Report

NLC Nurse Licensure Compact

NPDB National Practitioner Data Bank

OIG Department of Health and Human Services, Office of Inspector General

PCMH Patient-Centered Medical Home

PPO Preferred Provider Organization

QIO Quality Improvement Organization

QRXS Querying and Reporting XML Service