AHLA

Highlights of the 2015 Databank Guidebook: Navigating the New NPDB

Member Briefing, June 2015

Sponsored by the NPDB Work Group of the Medical Staff, Credentialing, and Peer Review Practice Group. Co-sponsored by the Academic Medical Centers and Teaching Hospitals, Antitrust, Health Care Liability and Litigation, Hospitals and Health Systems, In-House Counsel, Labor and Employment, and Physician Organizations Practice Groups, the Accreditation, Certification, and Enrollment Affinity Group of the Regulation, Accreditation, and Payment Practice Group, and the Accountable Care Organization and Enterprise Risk Management Task Forces.

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Chapter A: Introduction and General Information

1. Background

In the introduction to the April 2015 Guidebook (2015 Guidebook), the Health Resources and Services Administration (HRSA) provides an overview of the organization of the new manual, and points out that it now encompasses mandated reporting under three separate federal statutes:

- The Health Care Quality Improvement Act's (HCQIA's) traditional National Practitioner Data Bank (NPDB or Data Bank) reporting;[1]
- The Medicare and Medicaid Patient and Program Protection Act's Mandatory State Licensure Sanction reporting (Social Security Act (SSA) Section 21); and[2]
- The Health Insurance Portability and Accountability Act's (HIPAA's) Healthcare Integrity and Protection Data Bank (HIPDB) reporting.[3]

Importantly, while the Draft Guidebook continued to use HIPDB's terminology, the 2015 Guidebook has completely eliminated that terminology, and NPDB now has completely subsumed the former HIPDB.

The 2015 Guidebook provides a history of the Data Bank, noting that the HCQIA established NPDB to (1) address the nationwide increasing occurrence of medical malpractice; (2) restrict the ability of incompetent physicians to move from state to state without disclosure/discovery of prior damaging or incompetent performance; (3) to ameliorate the threat of treble damages under the federal antitrust laws, which unreasonably discouraged physicians from participating in professional review actions;

[1] Title IV of the Health Care Quality Improvement Act of 1986 (HCQIA), P.L. 99-660, 42 U.S.C. § 11101 *et seq*.; implementing regulations, 45 C.F.R. Part 60.
[2] Section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987, P.L. 100-93, codified as Section 21 of the Social Security Act (SSA), 42 U.S.C. 1396r–2.
[3] Health Insurance Portability and Accountability Act of 1996, PL 104-191, Codified as Section 1128E of the SSA, 42 U.S.C. 1320a–7e.

and (4) provide incentives and protection for engaging in professional peer review. Originally, the data included only malpractice and adverse privileging actions taken against physicians and dentists. Subsequent laws expanded the information collected and disclosed by NPDB to include:

- Sanctions taken by state licensure authorities against health care practitioners and entities;
- "Any negative action or finding" by state licensing authorities, Peer Review Organizations (PROs), or private accrediting agencies; and
- HIPDB reports, which include final adverse actions taken by federal and state agencies and health plans against practitioners, providers, and suppliers (including licensure, certification, health care-related criminal convictions and civil judgments, exclusion from federal or state health care programs, and other adjudicated actions or decisions).

In 2010, Section 6402 of the Affordable Care Act (ACA) combined NPDB and HIPDB.

2. Laws Governing NPDB Operations

The 2015 Guidebook provides the following summary overview of the three relevant laws:

- The *HCQIA* was enacted 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/discovery of previous medical malpractice payment and adverse action history. Adverse actions include certain licensure, clinical privilege, and professional society membership actions, as well as U.S. Drug Enforcement Administration (DEA)/Controlled Dangerous Substance (CDS) actions and exclusions from participation in Medicare, Medicaid, and other federal health care programs;

- *SSA Section 21* was enacted to provide protection to beneficiaries of the Medicare and state health care programs from unfit practitioners. Information collected includes state licensure and certification actions against practitioners, entities, providers, and suppliers; negative actions or findings by PROs and private accrediting organizations; and final adverse actions taken by state agencies, including law enforcement agencies, state Medicaid Fraud Control Units (MFCUs), and state agencies administering or supervising state health care programs. Final adverse actions include exclusions from a state health care program, health care-related criminal convictions and civil judgments, and other adjudicated actions or decisions; and

- *HIPAA/HIPBD* was enacted to combat federal fraud and abuse, by collection and reporting of information regarding adverse actions taken by federal agencies and health plans against practitioners, providers, and suppliers, including 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.

These laws limit access of the information in NPDB to specific users and circumstances, the details of which are summarized in the individual chapters, below.

3. Interpretation of NPDB Information

The 2015 Guidebook explains that NPDB primarily is a flagging system that may alert users that a more comprehensive review of the qualifications or background of a health care practitioner, entity, 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, certification, licensure, or other decisions. It should not be used as the sole source of verification of professional credentials.

4. Civil Liability Protection

All three statutes provide immunity for reporting to NPDB unless such reports are made with actual knowledge that the information in the report is false. The HCQIA has additional immunity provisions to encourage and support professional review activity of physicians and dentists.

5. Confidentiality and Security

Information reported to NPDB is considered confidential and may not be disclosed except as specified in the HCQIA regulations. The 2015 Guidebook points out that NPDB has a comprehensive security system to protect against unauthorized access. The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) may impose Civil Monetary Penalties (CMPs) for violation of the HCQIA's confidentiality provisions. The regulations governing the administration of CMPs are available at 42 C.F.R. Part 1003.

NPDB information may be disclosed as follows:

- To others who are part of the same investigation or peer review process, as long as the information is used for the purposes for which it was provided;
- The subject of an NPDB report may obtain and share the report without restriction; and
- Statistical data that do not identify any individual or organization are available to the public for research purposes.

Chapter B: Eligible Entities

1. Eligible Entities

Each of the three federal statutes has different provisions regarding the entities that are eligible and/or required to query or report to NPDB. The 2015 Guidebook provides the following overview:

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

Under the HCQIA:

- A hospital;
- A health care entity that provides health care services and follows a formal peer review process;
- A professional society that follows a formal peer review process; or
- A board of medical examiners or other state licensing board.

Under SSA Section 21 or HIPAA/HIPDB:

- A hospital;
- A health care entity that provides health care services and follows a formal peer review process;
- A professional society that follows a formal peer review process;
- A health plan;
- A Quality Improvement Organization (QIO);
- A state licensing or certification authority;

- A state law enforcement agency;
- A state MFCU;
- A state agency administering or supervising the administration of a state health care program;
- An agency administering a federal health care program, including a private entity administering such a program under contract;
- A federal agency responsible for the licensing or certification of health care practitioners, providers, or suppliers; or
- A federal law enforcement agency or official.

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

Under the HCQIA:

- An entity that makes a malpractice payment;
- A hospital or other health care entity that takes an adverse clinical privileging action as a result of professional review;
- A professional society that takes an adverse membership action as a result of professional review;
- A board of medical examiners that takes an adverse action;
- DEA when it takes a CDS registration action; or
- OIG when it makes an exclusion from federal health care programs.

Under SSA Section 21 or HIPAA/HIPDB:

- A state licensing or certification authority;
- A PRO;
- A private accreditation organization that takes a negative action or finding against a health care entity, provider, or supplier;
- A state law enforcement agency;
- A federal or state prosecutor;
- A state MFCU;
- A state agency administering or supervising the administration of a state health care program;
- A federal government agency; or
- A health plan.

The 2015 Guidebook also notes that the U.S. Department of Defense (DOD), U.S. Department of Veteran Affairs, and certain agencies within HHS report to NPDB under a memorandum of understanding, as opposed to the 2015 Guidebook. It also is noted that *authorized agents* may do the querying and reporting for an entity.

2. Registering with NPDB

The 2015 Guidebook addresses the steps required to register to be a querying and reporting entity with NPDB,[4] and includes the responses to specific operational questions in a set of questions and answers (Q&As).

[4] *See* B-13-B-20.

Chapter C: Reporting Entities and Reported Health Care Practitioners

1. Merger of NPDB and HIPDB

The merger of NPDB and HIPDB expands the reporting entities and queriers to include federal and state law enforcement and related entities.

2. Expanded List of Licensed Health Care Practitioners

The 2015 Guidebook expands the list of licensed health care practitioners to include an extensive list of nurses and several other additional categories. The new description reflects the technological changes so that queries and self-queries now may be done online through links contained in the online version of the Guidebook.

3. Revised Q&As

The revised Q&As indicate that health care navigators, i.e., individuals whose positions were created by the ACA who facilitate the purpose of health care coverage via the federal and state exchanges, now are included as licensed health care practitioners and subject to Data Bank reports, which presumably will be pursuant to the integrity protections now included through SSA § 1921 and the HIPAA/HIPDB provisions. One Q&A indicates that unlicensed individuals posing as licensed individuals, i.e., imposters, should be reported even if they are not licensed. Finally, the expansion of the HIPAA/HIPDB provisions to include adverse criminal actions now will include providers and suppliers, as well as individuals.

Chapter D: Queries

1. Overview

Because the HCQIA has not been revised, the nature of the information regarding mandatory and self-queries also has not changed significantly. The merger of HIPDB into NPDB has expanded the purpose of the queries, and added new governmental entities eligible to query.

2. Revised Summary Table

The 2015 Guidebook creates a two-part Table D-1 that summarizes the eligible queries and the nature of the available information, categorized by source law (see discussion above).

3. New Sections

The 2015 Guidebook has added *new* explanations regarding the credentialing process, as follows:

3.1 Centralized Credentialing

Centralized credentialing requires that a multi-entity health system conducts its credentialing centrally, has a centralized peer review process, and has one final decision-making body. In such instances, the health system may query NPDB once and share the NPDB report among the different entities. However, if the health system's entities have their own separate decision-making bodies for credentialing, then each entity must query NPDB separately, even if the credentials verification process is centralized. Sharing NPDB reports in the latter situation is prohibited.

3.2 Credentials Verification Organization

A Credentials Verification Organization (CVO) is a centralized body that processes applications and conducts the verification process for multiple different entities. A CVO operating in a centralized credentialing environment should register once with NPDB as a single entity. In a non-centralized credentialing environment, each entity must register separately, and the CVO will register as an agent of each of those separate entities.

3.3 Delegated Credentialing

Delegated credentialing occurs when an entity, such as a preferred provider organization, delegates responsibility for the entire credentialing process to another entity, such as a hospital, and relies on the evaluation and decision making of that other entity. In such situations, the entity that has delegated its credentialing authority to another is not entitled to receive or access a practitioner's NPDB report from the entity that actually is conducting the credentialing. A hospital may not delegate its responsibility to query NPDB; the hospital's query must be submitted directly, or through an authorized agent.

3.4 Continuous Query

The 2015 Guidebook promotes the use of the Continuous Query, in which an entity enrolls all of its practitioners on an annual basis, and then is entitled to receive, initially, a complete and current NPDB report, and then going forward, each new NPDB report within 24 hours of its being filed with NPDB. This system avoids the necessity of a new, separate query every two years.

3.5 Historical Query Summaries

Historical query summaries permit inquirers to receive NPDB reports that existed at a particular point in time, but which may have subsequently been voided, corrected, or revised.

4. Q&As

The following points of interest are made in the Query Q&A section:[5]

4.1 Queries on Courtesy Staff with No Clinical Privileges

If a physician is on the medical staff, the hospital must query the Data Bank every two years, even if the physician does not maintain active clinical privileges. Physicians who are permitted access to medical library facilities, or continuing medical education programs, but who are *not* members of the medical staff, need not be credentialed or re-credentialed.

4.2 Self-Queries

A practitioner may self-query and share the NPDB report with any entity or individual. However, a hospital may not rely on a physician's self-query to satisfy its legal obligation to query the Data Bank.

4.3 Employment-Related Queries

NPDB queries are not just for credentialing. Hospitals and other prospective employers may use them in hiring decisions.

4.4 Sharing Prohibited Even with Consent

Even with a physician's consent, an entity may not share an NPDB report with another entity. Physicians who self-query, however, may share their own NPDB report with any

[5] *See* D-20.

person or entity (and employers often require physicians to self-query and provide the report as part of the employer's due diligence).[6]

Chapter E: Reports

1. Overview

The revised "Chapter E: Reports: Overview" clarifies the reporting obligations of eligible entities and the circumstances under which the various types of reports should be submitted. The majority of "new" material results from the incorporation of requirements for law enforcement and other government agencies reporting due to the combining of NPDB with HIPDB.

2. Terminology

As a threshold issue, actions must be reported based on whether they satisfy reporting requirements, and not based on the name the reporting entity gives them. For example, a suspension of clinical privileges is reportable if it meets reporting criteria (i.e., results from a professional review action that adversely affects the clinical privileges of the practitioner for more than 30 days), regardless of whether the suspension is labelled as "summary, immediate, emergency, precautionary, or any other term."[7]

3. Types of Reports

NPDB now has three report formats: Medical Malpractice Payment Report (for reporting medical malpractice payments); Judgment or Conviction Report (for reporting health care-related criminal convictions and civil judgments); and Adverse Action Report (AAR) (for reporting all other actions required to be submitted to NPDB). The following

[6] The no-sharing provisions seems potentially problematic. Information obtained in the peer review process should be confidential, by state law, because it remains within the peer review process. However, once information has been released from NPBD, it is unclear how it would remain confidential.

discussion is limited largely to the AAR format, which reporting hospitals will continue to use. Regardless of the format, however, there are four types of reports, and the 2015 Guidebook clarifies when the use of each type of report is appropriate.

3.1 Initial Report

The first report of an adverse action is considered the Initial Report. For certain actions, the reporting entity also must provide a copy of the report to the state licensing board which, in many cases, can be done online. When an Initial Report is filed, NPDB generates a Data Bank Control Number (DCN) of which the reporting entity should maintain a record for the purposes of submitting subsequent reports or seeking fee adjustments.

3.2 Correction Report

When an error or omission is identified in a submitted report, the reporting entity must submit a Correction Report as soon as possible. *The Correction Report, NPDB clarifies, replaces the previous erroneous report*. So, for example, if a hospital reports a clinical privilege action to NPDB in an Initial Report, but includes an incorrect address for the practitioner, the hospital must then submit a Correction Report that will replace the Initial Report.

3.3 Void Report

A Void Report withdraws a report in its entirety. A Void Report results in the removal of the report from the disclosable record of the subject of the report, although all reports remain in the NPDB database. A Void Report may be issued when: the report was submitted in error; the action was not reportable because it did not meet NPDB reporting requirements; or the action was overturned on appeal. When a Void Report is received, NPDB sends a notification to all queriers who received the previous version of

[7] *See* p. E-2.

the report within the past three years. This has not changed since the 2001 version of the Guidebook. *What has changed is what queriers are supposed to do with the prior report: previously, they were required to note that the report was voided. Pursuant to the new version of the 2015 Guidebook, queriers are "directed to destroy the prior report and any copies of it."*[8]

3.4 Revision-to-Action Report

A Revision-to-Action Report modifies an adverse action previously reported to NPDB. This is a more limited use of the report, which the 2001 version of the Guidebook described as being filed when an action "relating to and/or modifying" a previous adverse action was taken. A Revision-to-Action Report does not replace or void a previous AAR. Rather, it represents a separate report that pertains to a previous report *and* modifies it. The Guidebook includes several examples that illustrate when various reports are used:

- Example 1: A hospital files an Initial Report suspending a practitioner's clinical privileges for 90 days. The suspension is later reduced to 45 days. Under these circumstances, the hospital should file a Revision-to-Action Report because the action in the Initial Report has been modified. Because both reports were accurate when filed, a Correction Report should not be filed;

- Example 2: A state medical board reprimands a physician and mandates completion of five hours of Continuing Education Units (CEUs) within three months. The board submits an Initial Report that documents these requirements. When the physician fails to complete the CEUs and the board puts her license on probation until she completes them, the board must then submit a Revision-to-Action Report that

[8] *See* p. E-8. The directive to destroy voided reports may be problematic in cases that still are pending at the hospital level, or in litigation, and may conflict with other legal obligations the reporting entity may have. Destroying such reports may result in practical challenges, such as gaps in the records of practitioners raising questions for credentialing committees when applications are reviewed. Without the voided reports, the committee will need to search old committee minutes to determine, for example, why an applicant was previously denied medical staff membership.

documents the imposition of the probation. Because the second action *modified* the action in the Initial Report, a Correction Report should be filed; and

- Example 3: A state licensing board suspends a pharmacist's license for three months and requires additional training, which the board must approve, prior to the license being reinstated. The board files an Initial Report with this information. When the pharmacist returns to the board seeking approval of his choice of training, the board should *not* file a Revision-to-Action Report, even though it issues a formal order approving the training, because such an order relates to, but does not modify, the action described in the Initial Report. In addition, NPDB notes, the board's second order is not a reportable adverse action.

4. Narrative Descriptions

NPDB has doubled the number of characters—to 4000—that may be used to create a:

> detailed narrative describing the acts or omission of the subject of the report upon which the action is based so 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 on which the report is based.'[9]

Narrative descriptions are to be limited to statements of fact and may not include URLs/references to external websites or the proper names of or identifying information about any individuals except the subject of the report.[10] Individuals involved in the underlying circumstances may be characterized in terms of their relationship to the subject (e.g., the patient).[11]

Importantly, NPDB asserts the right to determine that a narrative description provides insufficient detail to place future queriers on notice of what the subject practitioner is

[9] *See* p. E-11.
[10] The Draft Guidebook included language allowing the name of the subject's attorney to be included as well, but that is not present in the official 2015 Guidebook.
[11] *See* p. E-12.

alleged to have done. Accordingly, ***at any time*** *after a report is submitted, NPDB may require the reporting entity to submit a Correction Report. Moreover, the Guidebook states that "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," with all the consequences attendant to such failure*.[12] The Guidebook does not specify what would precipitate such a determination, time frames within which the 2015 NPDB would make the determination, the form of the notice to the reporting entity, the applicable deadlines for responding with a Correction Report, or similar details. Without this information, reporting entities may be unprepared to respond adequately to such a determination by NPDB.

5. Q&A: Submitting Reports

The Q&A section clarifies some issues and muddies others:

5.1 Permanent Record

Information reported to NPDB is "maintained permanently unless it is corrected or voided from the system." "When the reporting entity *voids* a report, the report is removed from the *disclosable record* of the subject of the report,"[13] but maintained permanently in the non-disclosable record of the subject of the report.

5.2 Redaction

Reporting entities may disclose copies of a report to the subject of the report *without* redaction. (The Draft Guidebook permitted disclosure but required redaction of certain information.)

[12] *Id.*
[13] Emphasis added.

5.3 Affiliated or Associated

The term “affiliated or associated” means any professional or business relationship, including an employment relationship.

5.4 Reporting Licensure Reinstatement

A Revision-to-Action Report is the correct report to be filed when a license is reinstated, but need not be filed if the original report indicates a date certain for automatic reinstatement. Likewise, if a penalty is changed after the original report is filed, a Revision-to-Action Report should be filed specifying the date and nature of the change.

5.5 Notice of Appeal

When a physician appeals an action that has been reported to NPDB (e.g., licensure suspension), then the entity whose action was appealed must file a Notice of Appeal with NPDB. However, a different entity that took action based on the original action (e.g., hospital suspending privileges based on licensure suspension) is not required to file a Notice of Appeal merely because the licensure action was appealed.

6. Reporting Medical Malpractice Payments

The 2015 Guidebook section on medical malpractice payments makes very few substantive changes compared to the 2001 Guidebook, and even those changes, while substantive, are not dramatic additions or deletions.

Before considering the headings of the 2015 Guidebook, please note that two headings from 2001 have been deleted: the heading “Trigger Date for Reporting,” that appears at the beginning of the 2001 section on malpractice payments and the entire paragraph underneath it, have been deleted in the 2015 Guidebook. The 2001 heading, “Deceased

Practitioners," has been deleted in the malpractice section and now appears in the Overview section.[14] *The subject also is addressed in the malpractice reporting Q&A.*[15]

6.1 Interpretation of Medical Malpractice Information

This section is significantly shorter in the 2015 Guidebook as the result of the deletion of two pages of instructions for completing the narrative field and five examples from the "Harvard Risk Management Foundation Sample Claims Descriptions." The remaining text is unchanged, stating that the report of a medical malpractice payment is not construed as a presumption that medical malpractice has occurred.

6.2 Payments by Individuals

The core of the Payment by Individuals section is unchanged: individual practitioners who make payments from their own funds, for their own benefit, are not required to report, even where there is a written claim and the payment is in satisfaction of that claim.

New for 2015 is a paragraph[16] *with two additions. First, the 2015 Guidebook makes clear that (1) there is no de minimis exception for a payment; and (2) payments made, resulting from professional peer review proceedings, "may" need to be reported.* Second, "Peer review committees . . . should consider notifying practitioners of reporting obligations before a payment is made." This addition is included with no context or explanation; it is unclear how this would arise in practice.

6.3 Identifying Practitioners

This provision reflects a lowered standard of precision for identification of practitioners on whose behalf payments are made. In the 2001 version, the requirement was that a

[14] *See* E-6.
[15] *See* E-26.
[16] *See* E-17-18.

practitioner must be identified by name, except for the special case in which state law provides that a practitioner does not have to be named in the release if sufficiently identifiable. Under the 2015 Guidebook, that practitioner must be "named, identified, or otherwise described . . ." whether by title or role in a procedure. As long as the clinical role or function can be identified in the claim and the release, the payment on behalf of that practitioner is reportable.

6.4 Written Complaint or Claim

This is a new heading, added for emphasis, that addresses what constitutes a "written complaint or claim" triggering a reporting obligation. The 2001 provision stated: "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." The 2015 Guidebook broadens the definition of a "writing" with the following caveat: "The NPDB interprets this requirement to include any form of writing, including pre-litigation written communications." Moreover, the 2015 Guidebook states that it is "the NPDB, not any other entity, [that] determines whether a written claim has occurred for purposes of filing a report." In other words, an entity's own conclusion that a particular writing did not trigger a reporting obligation is not binding on NPDB.

6.5 Confidential Terms of a Settlement or Judgment

This new heading, and new guidance, states that confidentiality provisions, as a condition of a settlement or payment, do not alter the requirement to report the payment to NPDB. However, when filing an NPDB report a reporting entity may indicate in the narrative field that the order or settlement agreement stipulates the confidentiality of specific terms.

6.6 Residents and Interns

The 2015 Guidebook expanded the 2001 section on residents and interns with the addition of a paragraph of guidance for the reporting of supervisory practitioners. Under this new guidance, if a supervisory practitioner is named based on the actions of a subordinate, separate reports must be filed for each practitioner, with the same claim description code used for each, but with the reporting entity making clear in the narrative that the supervisory practitioner was named solely based on the subordinate practitioner's activities.

6.7 Offshore Payers

The 2013 Draft NPDB Guidebook carried over from the 2001 Guidebook a brief discussion regarding U.S. agents for foreign companies being subject to service of process. The 2015 Guidebook eliminated that discussion, leaving only the single sentence: "A medical malpractice payment made by an offshore medical malpractice insurer must be reported to the NPDB." This revision is only a deletion of commentary on service of process; it otherwise makes no substantive change.

6.8 Reporting of Medical Malpractice Payments by Authorized Agents

This provision is unchanged substantively, but the 2015 Guidebook does delete a paragraph that provided instructions on designating and registering authorized agents. That instruction is provided elsewhere. It remains that the organization that makes a medical malpractice payment is responsible for making the NPDB report, but it may do so through an authorized agent.

6.9 Submitting a Copy of the Report to the State Licensing Board

This is a new heading for 2015, although the (now deleted) 2001 heading "Trigger Date for Reporting" contained a provision requiring that, for any action reportable to NPDB, a report be sent concurrently to the state's licensing authority. This requirement is met

either by sending a copy of the Report Verification Document to the state authority, or by having NPDB send an electronic copy directly through its Electronic Report Forwarding service.

6.10 Sanctions for Failing to Report to NPDB

This is new as a discrete heading for 2015, but the identical content was included at E-27 in the 2001 Guidebook. It references OIG's authority to impose CMPs of up to $11,000 for each payment not reported to NPDB.

6.11 Unchanged Provisions

Many provisions in the malpractice reporting section are substantively unchanged from the 2001 version, including:

- Payments for Corporations and Hospitals;
- Dismissal of a Defendant from a Lawsuit;
- Insurance Policies that Cover More than One Practitioner;
- One Payment for More than One Practitioner (this provision is unchanged);
- Practitioner Fee Refunds;
- Waiver of Debt (included under the "Practitioner Fee Refunds" heading in the 2001 Guidebook);
- Loss Adjustment Expenses;
- High-Low Agreements;
- Payments by Multiple Payers;
- Subrogation-Type Payments;

- Structured Settlements; and
- Payments Made Prior to Settlement (some text deleted but not substantively different).

6.12 Table of Reportable Payments

Table E-4, at page E-25 of the 2015 Guidebook, carries over the eight scenarios as to reportability of payments from the similar Table E-2 in the 2001 Guidebook and adds four new ones:

- A payment for the benefit of a practitioner who settles out of court must be reported;
- 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 must be reported;
- A payment made *for the benefit of* an unlicensed medical resident is *not* reportable; and
- A payment made *on behalf of* an unlicensed student practitioner is *not* reportable.

The only other change for Table E-4 is in the example described in the 2001 Guidebook as: "Payments made for the benefit of a corporation such as a clinic, group practice or hospital are not currently reportable." In the 2015 Guidebook, the language is more restrictive, reading: "A medical malpractice payment made *solely* for the benefit of a corporation such as a clinic, group practice, or hospital" is not reportable.[17]

[17] Emphasis added.

6.13 Changes to the Q&A Section

Briefly, the changes in the Q&A section for medical malpractice payments are: (1) in the location of the Q&A materials; (2) the deletion of one question from 2001; and (3) the addition of one question in 2015.

The 2001 Guidebook has no formal Q&A text within the "Reporting Medical Malpractice Payments" section. The Q&A text is included after the other sections, such that one reading only the section of the Guidebook on medical malpractice reporting might not know that those resources are included later, toward the end of Chapter E. In the 2015 version, the Q&As relevant to medical malpractice reporting appear within the body of that section of the chapter.

The 2001 Guidebook contains, within the Q&A section, 14 Q&As for medical malpractice payments. Twelve of those carried over to the 2015 Guidebook; the two deleted Q&As focus on whether a written claim must be directed to the subject practitioner (no) and whether payments on behalf of residents, interns, and students are reportable (no, unless the practitioner is licensed). The others are substantively unchanged.

The 2015 Guidebook answers four new questions:

- Whether a report is required for a payment resulting from voluntary settlement discussions undertaken before litigation (if there was a written claim, the payment is reportable);
- There is no minimum payment threshold, i.e., no *de minimis* amount *not* subject to reporting;
- A settlement paid in exchange for dismissal from a lawsuit is reportable; and
- If a practitioner, due to a lack of evidence of fault, is dismissed prior to a settlement, a payment to a co-defendant is not reportable as to the dismissed practitioner.

7. Reporting Adverse Clinical Privileges Actions

7.1 Overview

A major emphasis in the 2015 Guidebook is the reporting of adverse clinical privileges actions. The 2015 Guidebook immediately focuses on the necessity for health care entities to report adverse actions against clinical privileges that meet the NPDB reporting criteria, and has been amended to explain that the criteria for reporting adverse clinical privileges actions include *both* of the following:

- Professional review actions that adversely affect a physician's or dentist's clinical privileges for a period of more than 30 days; and
- 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.

Thus, a restriction or suspension of clinical privileges initiated by a health care entity must be reported after 30 days. *However, a restriction or voluntary relinquishment of clinical privileges initiated by the physician or dentist while under investigation is to be reported immediately.*[18]

The 2015 Guidebook continues to define adverse clinical privileges actions that require reports as those "based on a physician's or dentist's professional competence or professional conduct that adversely affects, or could adversely affect, the heath or welfare of a patient."[19] With regard to other health care practitioners, health care entities "*may*" report adverse clinical privileges actions that are based on the same criteria.[20]

[18] *See* E-29-30; *see also* E-42 at Q&A No. 9; E-43 at Q&A No. 11; E-44 at Q&A No. 16; E-46 at Q&A No. 20.
[19] E-30.
[20] *Id*. (emphasis in original).

Amendments to the 2015 Guidebook underscore that adverse clinical privileges actions are reportable once they are final but that summary suspensions are reportable after 30 days "even if" they are not final.[21] However, matters not related to the professional competence or professional conduct of a practitioner should not be reported to NPDB.[22]

7.2 Administrative Actions

Administrative actions that do not involve a professional review action should *not* be reported to NPDB.[23] For example, loss of privileges due to termination of a contract or because a physician's board certification expires causing automatic revocation is not reportable, even if the underlying reasons for the termination relate to quality of care, since the revocation was not the result of a professional review action.[24] Likewise, where suspension of privileges from a first hospital results in the physician's automatic suspension at a second hospital, the second hospital's suspension is considered an "administrative" action that does not have to be reported.[25]

7.3 Multiple Adverse Actions

If a single professional review action produces multiple clinical privileges actions, only one report is necessary. *However, the 2015 Guidebook has been amended to clarify that the single report should reflect the multiple actions taken.*[26] *Further, while Revision-to-Action Reports continue to be required after each of the multiple actions is lifted, the Guidebook now clarifies that no additional report is necessary if the Initial Report clearly states when the respective penalties will be lifted.*[27] *Any modifications to the penalties, however, must be reported through a Revision-to-Action Report.*[28]

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[21] *See* E-31.
[22] *Id*.
[23] *See* E-31; *see also* E-48 at Q&A No. 27 (emphasis added).
[24] *See* E-40 at Q&A No. 2; E-41 at Q&A No. 6; E-43 at Q&A No. 10.
[25] *See* E-44 at Q&A No. 13.
[26] *See* E-31-32.
[27] *See* E-32.
[28] *Id*.

7.4 Denials or Restrictions

The 2015 Guidebook has been amended to include the denial of initial applications as being reportable, if the denial is based on professional conduct or competence that adversely affects, or could adversely affect, the health or welfare of patients, but not if it is based on a failure to meet threshold credentialing criteria.[29] Also, it underscores that a "restriction" in the context of clinical privileges actions must be 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."[30]

7.5 Withdrawal of Applications

The 2015 Guidebook confirms that the withdrawal of an initial application before a professional review action has been taken is not a reportable event. However, the withdrawal of an application for renewal of appointment or privileges while the practitioner is under investigation is reportable regardless of whether the practitioner knew she was under investigation at the time she withdrew the application.[31]

7.6 Nonrenewals

Nonrenewals of medical staff appointment or clinical privileges generally are not reportable. However, if the practitioner fails to renew while under investigation, it must be reported. Again, the practitioner's awareness of the investigation does not affect the necessity to report.[32]

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[29] *See* E-32.
[30] *Id*.
[31] *See* E-33.
[32] *See* E-33; *see also* E-45 at Q&A No. 18.

7.7 Investigations

The 2015 Guidebook adopts a broad interpretation of "investigation."[33] If a formal, targeted process is used, related to a specific practitioner's professional competence or conduct, this is considered an investigation for the purposes of reporting to NPDB. A focused professional practice evaluation can be considered an investigation if based on concerns that a physician conduct or practice has or could adversely affect patients. However, a routine peer review process under which a health care entity evaluates, against clearly defined measures, the privilege-specific competence of *all* practitioners (e.g., a quality review of the department of surgery) is not considered an investigation for the purposes of reporting to NPDB.[34] Pursuant to the 2015 Guidebook, an investigation begins as soon as the health care entity begins an inquiry and does not end until the health care entity's decision-making authority takes a final action or makes a decision to not further pursue the matter.[35] Further, a practitioner's awareness that an investigation is being conducted is not a requirement for reporting to NPDB.

7.8 Temporary Clinical Privileges

Provided there is no opportunity to renew, expiration of temporary privileges is not reportable regardless of whether an investigation is pending.[36] *Here, the key change has been to include language that specifies that "both the physician or dentist and the privileging party agree that the privileges are temporary" for the expiration of the temporary privileges to not be reportable.*[37] Otherwise, temporary privileges are treated like any other privileges for reporting purposes.

[33] *See* E-34.
[34] *Id*.; *see also* E-47 at Q&A No. 25.
[35] *See* E-45 at Q&A No. 19.
[36] E-35.
[37] *Id*.; *see also* E-52 at Q&A No. 40.

7.9 Summary Suspensions

The 2015 Guidebook has been amended to note that reports may be filed with NPDB prior to the completion of 30 days for a summary suspension that is expected to last more than 30 days.[38] Should the summary suspension not last more than 30 days, this report must be voided.[39] Also, the 2015 Guidebook notes that summary suspensions are considered to be in effect regardless of whether they are subject to some review by some committee or body of the health care entity under the respective bylaws.[40] The Guidebook provides that a suspension 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.[41]

7.10 Proctors

Here, the distinction between whether proctoring must be reported to NPDB depends on whether the physician or dentist, for more than 30 days, cannot perform certain procedures without proctor approval.[42] *If* the proctor is not required to be present *or* provide approval, the action should not be reported.[43] For example, if the proctor is responsible for reviewing the records after the procedure occurs, a report should not be made.[44] Routine proctoring for new privileges that is not based on clinical competence or conduct that adversely affects, or could adversely affect, the health or welfare of patients is not reportable, even if the proctor must be present.

[38] *See* E-35.
[39] *Id*.
[40] *See* E-36.
[41] *See* E-37.
[42] *See* E-37.
[43] *Id*.; *see also* E-47-48 at Q&A No. 26.
[44] *Id*.

7.11 Residents and Interns

The 2015 Guidebook clarifies that residents and interns are not granted clinical privileges "within the meaning of NPDB regulations."[45] Thus, adverse clinical privileges actions are reportable regarding residents and interns only if they are based on "events occurring outside the scope of a formal graduate education program," for example, while "moonlighting."[46]

7.12 *Confidentiality Laws Related to Drug and Alcohol Treatment*

Notwithstanding state confidentiality laws as applied to drug and alcohol treatment programs, the fact that an adverse professional review action may require a physician to undergo drug or alcohol treatment does not negate the hospital's obligation to report the adverse professional review action itself. However, entities are cautioned that, while the adverse professional action is reportable (e.g., a period of probation), the fact that a practitioner has entered into a voluntary treatment program should not be reported.[47] If a physician takes a voluntary leave of absence for drug or alcohol rehabilitation with no adverse action taken against him, that is not reportable.[48]

7.13 Submitting a Copy of the Report to a State Licensing Board

A health care entity must provide a copy of verification of a clinical privileges report from NPDB to the appropriate state licensing board "in the State in which the health care entity is located."[49] Note, though, that some state boards may have agreed to accept an electronic copy of the report from NPDB.[50]

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[45] *See* E-37.
[46] *Id*.; *see also* E-50-51 at Q&A No. 36.
[47] *See* E-37; *see also* E-49 at Q&A No. 32.
[48] *See* E-49-50 at Q&A Nos. 33-35.
[49] *See* E-38.
[50] *Id*.

7.14 Sanctions for Failing to Report to NPDB

The 2015 Guidebook reiterates that loss of "the immunity protections provided under Title IV" for three years is a possible sanction for failing to report adverse clinical privileges actions.[51] It also provides for notification and opportunity to request a hearing in the event the Secretary of HHS determines that a health care entity has not complied with NPDB regulations. However, the notice also must afford the entity an opportunity to correct the noncompliance.[52]

8. Reporting Adverse Professional Society Membership Actions

The 2015 Guidebook states that professional societies must report professional review actions based on reasons related to professional competence or professional conduct even if it only "may adversely affect" the membership of the physician or dentist.[53] Where the suspension of the membership of a physician relates to professional conduct and the physician is reinstated, a Revision-to-Action Report would not be necessary if the suspension was for a fixed term that provided for automatic reinstatement.[54] However, an adverse membership action should not be reported to NPDB if censure, reprimand, or admonishment is the only result.[55] A report does have to be submitted where a physician resigns membership while under a formal peer review investigation if no final decision has been rendered.[56] Further, reports are permissive with regard to practitioners other than physicians and dentists.[57]

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[51] *See* E-38.
[52] *Id*.
[53] *See* E-53; E-55 at Q&A No. 1.
[54] *See* E-55-56 at Q&A No. 2.
[55] *Id*.
[56] *See* E-54; *see also* E-57 at Q&A No. 7.
[57] *See* E-56 at Q&A No. 3.

8.1 Submitting a Copy of the Report to a State Licensing Board

As with reports from health care entities, a professional society must provide a copy of the NPDB Report Verification Document to the appropriate state licensing board in the state in which the professional society is located.[58]

8.2 Sanctions for Failing to Report to NPDB

A professional society that "has substantially failed to report adverse membership actions" also is subject to losing the immunity protections provided under Title IV for three years.[59] As with health care entities, a professional society also will be provided with notification and an opportunity to request a hearing, and to correct the noncompliance, in the event the Secretary of HHS determines that it has not complied with reporting requirements.[60]

9. Reporting State Licensure and Certification Actions

9.1 Overview

This is an area of substantial augmentation. The 2001 Guidebook contained less than two pages of guidance for reporting state licensure actions, and only three Q&As. For 2015, the Guidebook contains ten pages of single-spaced text and 23 Q&As. Most of the additional material reflects the merger of the Section 1921 (HIPDB) requirements with the Title IV (NPDB) requirements. That merger, required by Section 6403 of the ACA, took effect on May 6, 2013, at which time HIPDB ceased to exist. For this section, therefore, the state licensure reporting provisions of the 2015 Guidebook must be compared primarily to the 2000 HIPDB Guidebook rather than the 2001 NPDB Guidebook. That task is complicated by the complete change in formatting for 2015.

[58] *See* E-54.
[59] *See* E-54.
[60] *See* E-55.

The 2015 Guidebook breaks out seven discrete headings (discussed below) that are commingled in the 2000 HIPDB Guidebook.

Readers should be aware that direct comparisons of sections of the 2015 Guidebook to either the 2001 NPDB or the 2000 HIPDB Guidebooks is not available.

9.2 Reportable Actions

The following state licensure and certification actions are reportable:

- Any adverse action taken by a state licensing or certification authority as a result of a *formal* procedure;
- Any dismissal or closure of a formal proceeding because the practitioner, entity, provider, or supplier either surrendered the license or certification, or left the jurisdiction;
- Any other loss of license or certification or contract, or the right to apply for such;
- Any negative action or finding by the state licensing or certification authority that is publicly available information, including final actions taken in conjunction with settlements where there was no finding of liability. Administrative fines, citations, and corrective action plans are not reportable unless either (1) the underlying activity is connected to the delivery of health care services; or (2) the action is taken in conjunction with other adverse licensure or certification actions; and
- Any revisions to a previously reported action.

Here, as elsewhere, the 2015 Guidebook underscores that the nature of the action, not the name affixed to the action, triggers the reporting obligation.

9.3 Formal Procedure

State licensing and certification actions must result from formal proceedings. Note, however, that NPDB is not concerned with the extent to which formal proceeding provisions were followed, but rather with whether such rules, procedures, or policies existed.[61]

9.4 Certification

The term *certification* has two meanings in the 2015 Guidebook, referring to (1) forms of authorization to provide services; and (2) certification to participate in a government health care program (wherein the term may encompass agreements or contracts to participate in the government program).

9.5 Administrative Fines and Money Penalties

All administrative fines and money penalties that are adverse actions resulting from a formal proceeding against practitioners, entities, providers, or suppliers must be reported if they are: (1) publicly available information; and (2) either connected to the delivery of health care services or taken in conjunction with some other adverse licensure or certification action. Fines that are considered technical or administrative are not reportable.

9.6 Publicly Available Information

Publicly available information is broadly defined as “information accessible to the interested public [in a variety of ways or media] available for distribution to any member of the public.”

[61] *See* E-59.

9.7 Stayed Actions

An action imposed with a stay does not have to be reported if the entire action is stayed, but any portion of the action not stayed must be reported. Where another reportable action accompanies a stayed action, the reportable action only is reported. For example, where terms of probation are imposed in conjunction with a fully stayed suspension, the suspension should not be reported, only the probation.

9.8 Summary or Emergency Suspensions

Interim or non-final actions by the state must be reported to NPDB. When a final decision is made, the state must submit a Revision-to-Action Report.

9.9 Denials of Initial and Renewal Applications

A state's denial of an initial or renewal application is reportable if it is the result of a formal proceeding. State authorities should not report cases in which the applicant does not meet threshold criteria.

9.10 Withdrawals of Applications While Under Investigation

As with hospital privileges, while the withdrawal of a renewal application and the failure to file a renewal application while under investigation are reportable, the withdrawal of an *initial* application is not reportable even if withdrawn while the applicant is under investigation. However, different from the rules regarding reporting of hospital privileges, a withdrawal while under investigation is not reportable unless that state can show that the practitioner was notified of the investigation, and can demonstrate documentary evidence of an ongoing investigation at the time of the withdrawal.

9.11 Voluntary Surrenders

The text must be read carefully, as it begins by saying that voluntary surrenders must be reported, but then defines "voluntary surrender" as "a surrender made after notification of an investigation, or a formal official request . . . for surrender." Significantly, and as with withdrawals above, the practitioner must have been notified that an investigation is underway. The 2015 Guidebook subsequently states: "voluntary *relinquishment* of a practitioner's license for personal reasons" is not reportable if no investigation is underway. This definitional distinction between "surrender" and "relinquishment" is not new—it was present in the 2000 HIPDB Guidebook as well as the 2001 NPDB Guidebook.

9.12 Consent Agreement

Any action that meets NPDB reporting requirements must be reported, without regard to whether the action was taken upon stipulation or by mutual consent. This section notes that an agreement that includes terms that the action will not be reported to NPDB is "immaterial" and the action nevertheless must be reported. *In other words, parties and their counsel may not negotiate, stipulate, or contract around the reporting requirement.*

9.13 Confidentiality Laws Related to Drug and Alcohol Treatment

If the state takes a licensure action that results in a practitioner entering a treatment or rehabilitation program, the licensure action should be reported, but "the fact that a practitioner enters a drug or alcohol treatment facility should not be reported." For example, if a practitioner is placed on probation while undergoing a treatment program, the probation should be reported but not the fact that the physician has entered a treatment program.

9.14 Nurse Licensure Compact

This section provides coding instructions for the two reporting formats associated with nurse compact licenses. If a state that issued the primary license takes an action, that action should be reported using the Adverse Action Classification Codes for Individual Subjects. If the remote state takes the action, it should be reported using the Nurse Multi-State Privilege Adverse Action Classification Codes.

9.15 Sanctions for Failing to Report

This information was included in the 2000 HIPDB Guidebook. The only sanction is that the name of the entity or state *substantially* failing to report will be published and made publicly available. While there is no definition for "substantially," the usual regulatory use of the term includes some provision for notice and opportunity to correct.

9.16 Examples and Q&A

Table E-10 provides 26 examples of actions that may or may not be subject to reporting followed by 23 Q&As. Most are self-evident, but the following are highlights of five that raise some new issue or concern:

- *When reporting a reprimand by a state licensing board, what length of time should the board enter in the report?* The guidance is to select "indefinite." Practitioners' counsel may have concerns that a reprimand does not have duration; it is an event on the opposite end of the spectrum from commendation. (Q.3);
- *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 NPDB?* The answer is an unqualified yes. However, as the 2015 Guidebook makes clear, the decision not to renew the license while under investigation is reportable *only if* the practitioner has been notified that an investigation is underway. *See* E-62: "The licensure or certification authority must

be able to show that the practitioner was notified . . . .” Boards relying only on the answer to this question inadvertently may overreport. (Note that Q.12 poses this same problem in the context of a physician’s termination of a contract.) (Q.7); and

- *If a state licensing or certification authority issues a letter of concern, should it be reported to NPDB?* The letter should be reported if it meets that state’s definition of a “publicly available negative action or finding.” In states with no definition of “publicly available negative action or finding,” counsel for the boards should address this proactively. (Note that Q.18 poses this same problem in the context of a requirement for continuing education in ethics.) (Q.15).

10. Reporting Federal Licensure and Certification Actions

This section is new to the NPDB Guidebook but carried over from the HIPDB Guidebook in most respects.

10.1 Licensure

Federal licensing and certification agencies must report four categories of final adverse licensure actions, regardless of whether the action is the subject of an appeal. Three of these were in the 2000 HIPDB Guidebook.

10.1.1 Formal or official actions against a license, certification agreement, or contract, including revocation, suspension, reprimand, censure, and probation.

10.1.2 Dismissal or closure of proceedings because the practitioner, provider, or supplier either surrendered a license, certification agreement, or contract, or left the jurisdiction. This provision, not included in the HIPDB Guidebook, is new in the 2015 Guidebook.

10.1.3 Any other loss of, or loss of the right to apply for, a license, certification agreement, or contract for participation in government health care programs.

This catch-all category, while broad, does not include nonrenewals due to retirement, change to inactive status, or nonpayment of fees.

10.1.4 Any other negative action or finding that is publicly available information. While this provision was included in the HIPDB Guidebook, there appears to be an expansion of the scope of reports, or at the least, a lack of clarity about whether reprimands are reportable.

10.1.5 The HIPDB Guidebook stated that a settlement agreement that imposes monitoring is considered to be a reprimand, and is *not* reportable.[62] In contrast, the 2015 Guidebook specifically identifies settlements that include reprimands as reportable.[63]

As with state agency actions, federal agencies do not report settlements in which no finding of liability has been made, but any action that occurs in conjunction with those settlements must be reported if the concurrent action standing alone would meet NPDB reporting requirements.

10.2 Certification

As with the section on state agency reports, the term “certification” has two possible meanings. It may refer to certification in the sense of licensure, or in the sense of approval to participate in a government health care program.

10.3 Administrative Fines and Formal Money Penalties

Money penalties or fines that are the result of official action must be reported, with the limitation that fines are administrative or technical in nature if they (1) meet the NPDB definition of negative actions or findings; (2) are publicly available information; and (3) are either connected to the delivery of health care services or taken in conjunction with other adverse licensure or certification actions. The 2015 Guidebook explicitly warns

[62] *See* HIPDB Guidebook (archived) at E-10.
[63] *See* E-74

that an action is reportable based on whether the action meets NPDB definitions, not the name affixed to that action by the entity, but the same paragraph states that the state reporting entities generally are free to decide whether that action is connected to the delivery of health care services.

10.4 Stayed Actions

Stayed actions are not reportable as long as the entire action is stayed. *This is somewhat revised from the HIPDB Guidebook, which stated that a licensure disciplinary action that is imposed with a "stay" pending completion of specific programs or actions is not reportable.*

10.5 Denials of Initial and Renewal Applications

Denials of initial or renewal actions are reportable only if the denial is the result of a formal or official final adverse action. Denials for failure to meet threshold criteria are not reportable.[64]

10.6 Withdrawal of Initial and Renewal Applications While Under Investigation

(New section). Although investigations in themselves are not reportable, withdrawal of a *renewal* application while the applicant is under investigation is reportable. In contrast, withdrawal of an *initial* application while under investigation is not reportable. The section also notes that the NPDB definition of "investigation" is expansive: "An investigation begins as soon as the [entity] begins a non-routine inquiry and does not end until the authority's decision-making body takes a final action or makes a decision not to pursue the matter."

As with the requirements for state agency reporting, federal agencies must have documentary evidence of an ongoing investigation at the time of withdrawal, and the

[64] Although the HIPDB Guidebook had no section with this heading, the content was addressed in examples of reportable and non-reportable actions.

reporting entity must be able to demonstrate that the practitioner was notified of the investigation. This stands in contrast to the explicit statement that, for reporting medical staff matters, a practitioner who withdraws an application while under investigation need *not* have been notified of the investigation. NPDB does not explain or address the inconsistency.

Four guidelines for investigations are presented:

1. NPDB determines the existence of an investigation, not the definitions in a licensing or certification authority's policies or procedures;

2. An investigation must be focused on the practitioner in question, but a routine review of a particular practitioner is not an investigation;

3. To be considered an investigation, the activity generally should be a precursor to a licensing or certification activity; and

4. An investigation remains ongoing until there is a final action to resolve or close the matter.

10.7 Voluntary Surrenders

The text seems to make a distinction between the terms "surrender" and "relinquishment." The voluntary *relinquishment* of a license for personal reasons is not reportable, but the voluntary *surrender* of a license while under investigation, or to avoid an investigation, must be reported. "Voluntary surrender" is defined as "a surrender made after a notification of investigation or a formal official request . . . to surrender the license or certification . . . ." Note the requirement that the practitioner have been notified of the investigation is inconsistent with the reporting rule for medical staff actions.

10.8 Confidentiality Rules Relating to Drug and Alcohol Treatment

This section states that:

> 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.

The Guidebook specifies further that 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 NPDB.

10.9 Sanctions for Failure to Report

The sanction for an agency that has "substantially failed" to report is publishing the federal agency's name and its failure to report in some way that is publicly available. *This is expanded compared with the same provision in the HIPDB Guidebook, which notes only that the agency's name would be published. Public availability has been added*.

11. Reporting PRO Negative Actions or Findings

11.1 Overview

The 2015 Guidebook addresses the requirement that PROs, as defined by 45 C.F.R. § 60.3, report to NPDB certain negative actions or findings. PROs include organizations 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

that define acceptable and adequate practice. PROs must provide due process mechanisms to health care practitioners. PROs do not include utilization and quality control peer review organizations (QIOs) and other organizations funded by the Centers for Medicare & Medicaid Services to support the QIO program and must be separate from hospitals and other health care entities. The 2015 Guidebook recognizes that various organizations, including patient safety organizations and peer review consultants, may provide information, including recommendations, to hospitals and other health care entities. Unless these organizations meet the above definition of PRO, they may not report their recommendations to NPDB as PROs.

11.2 Table of PRO Reportable Actions/Findings

Table E-16 provides an overview of when negative actions or findings by a PRO are reportable. The 2015 Guidebook also includes an additional example of findings that are not reportable. Specifically, when a hospital contracts with an independent organization for assistance in reviewing a practitioner, but the organization does not conduct formal proceedings for the physician reviewed, the reviewing organization's report and recommendations are not reportable to NPDB. The Q&A for Reporting PRO Negative Actions or Findings also includes an additional example of an action that may be reportable which was not in the earlier Draft Guidebook. *Specifically, when a hospital contracts with an organization to conduct peer review of a specialist practitioner who held privileges at the hospital, and the organization recommends the practitioner be suspended, the recommendation should be reported only if the contracted organization meets NPDB's definition of PRO*.

11.3 Reporting Private Accreditation Organization Negative Actions or Findings

The 2015 Guidebook addresses the requirement that private accreditation organizations report to NPDB certain negative actions or findings (defined in NPDB regulations) against health care entities, providers, and suppliers. This section of the 2015 Guidebook does not substantively differ from the Draft Guidebook.

11.4 Reporting Exclusions from Participation in Federal or State Health Care Programs

The 2015 Guidebook includes significantly expanded guidance on reporting exclusions from participation in federal or state health care programs as compared to the 2001 Guidebook. Federal agencies, state law enforcement agencies, state MFCUs, and state agencies administering or supervising the administration of a state health care program are required to report health care practitioners, providers, or suppliers excluded from participating in federal or state health care programs. The 2015 Guidebook addresses the intersection between exclusions and settlements in more depth than the Draft Guidebook. Specifically, in a circumstance where a settlement does not include findings or admissions of liability, but a practitioner agrees to pay a CMP and to be excluded from Medicare, Medicaid, and other federal health programs, the 2015 Guidebook explains that the payment should not be reported but the exclusion should. Section 1128E specifically excludes from NPDB reporting any settlement that does not include an admission of liability. (In contrast, where a similar settlement includes an admission of liability, it is reportable under 45 C.F.R. § 60.16 as another adjudicated action or decision.) The Q&A examples in the 2015 Guidebook also provide an additional example not found in the Draft Guidebook that clarifies that even when a health care practitioner or other covered party is found not guilty of False Claims Act violations, if the health care practitioner is excluded from a federal or state health care program, the exclusion nevertheless must be reported to NPDB.

11.5 Reporting Federal or State Health Care-Related Criminal Convictions

The 2015 Guidebook outlines the requirement that federal and state prosecutors report health care-related criminal convictions to NPDB, including injunctions, and nolo contendere/no contest pleas related to the delivery of health care items or services. If HHS determines that prosecutors have substantially failed to report as required, the name of the government agency will be published and made publicly available. Table E-

22 provides additional examples of when health care-related criminal convictions are reportable, including:

- A CEO, who is a licensed physician, is convicted of embezzlement from a health plan; and
- An individual is sentenced for conspiracy to submit false Medicare claims in connection with two durable medical equipment companies and his medical diagnostics company.

11.6 Reporting Health Care-Related Civil Judgments

Similar to criminal convictions, the 2015 Guidebook sets forth the obligation of federal and state attorneys and health plans to report civil judgments (as defined by NPDB regulations) 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. Some highlights are as follows:

- Where there are multiple health plan claimants, the plan that receives the largest award generally is responsible for reporting the total action for all parties. If more than one plan receives the largest award, however, the plans receiving the largest award must work out among themselves which health plan will report to NPDB for all parties: only one report is to be filed;
- Table E-24 provides examples to help determine if health care-related civil judgments must be reported;
- The Q&A section also provides two new factual scenarios. One demonstrates that a civil lawsuit arising out of an automobile accident is not reportable, even if a health care provider is a party to the suit, because the case is not related to the delivery of a health care item or service; and
- In contrast, in a state civil case where the court fines a professional staffing agency that supplied licensed health care personnel to hospital and health care agencies,

the judgment is reportable if the staffing agency meets the definition of “health care provider or supplier” because the case relates to the delivery of health care.

11.7 Reporting Other Adjudicated Actions or Decisions

Another new section in the Draft and 2015 Guidebook explains the obligation of federal agencies, state law enforcement agencies, state MFCUs, state agencies administering or supervising the administration of a state health care plan, and health plans to report “other adjudicated actions or decisions” against health care practitioners, providers, and suppliers (regardless of whether the action or decision is the subject of a pending appeal). Some highlights are as follows:

- Only the state agency that takes an adjudicated action is responsible for reporting the action to NPDB;
- Table E-25 outlines reporting obligations for other adjudicated actions or decisions;
- The term “other adjudicated actions or decisions” is defined in detail, and it necessarily includes a due process mechanism. The term specifically excludes clinical privilege actions and similar paneling decisions made by health plans, overpayment determinations and denial of claims determinations, and business or administrative decisions taken by health plans that result in contract terminations unrelated to health care fraud, abuse, or quality of care; and
- Table E-26 provides guidance on when other adjudicated actions or decisions must be reported to NPDB, and Table E-27 describes which reporting format should be used for reporting these matters.

The 2015 Guidebook Q&A section on Reporting Other Adjudicated Actions or Decisions adds new examples not included in the Draft Guidebook.

- One of these scenarios involves a situation where a health care entity terminated a physician’s contract for causes relating to poor patient care, and this in turn resulted

in the loss of the practitioner's network participation. Depending on the circumstances, the health care entity may be required to submit two different reports. The loss of the practitioner's network participation due to the termination of the contract for reasons relating to professional competence or conduct must be reported as a clinical privileges action if it is considered to be a professional review action by the health care entity. Separately, the termination of the practitioner's contract with the health care entity by itself, generally is not reportable. However, if the contract termination satisfies the definition of an "other adjudicated action or decision," then the contract termination also should be separately reported to NPDB; and

- The other new examples in this section review the requirement to report when a state hospital suspends without pay a physician who is discovered to have falsified his credentials on his employment application as well as when a health plan terminates a pharmacy's contract because it is determined to have been improperly substituting generic compounds for prescribed brand-name drugs.

Chapter F: Subject Statements and the Dispute Process

1. Overview

This section, which reviews the purpose of NPDB and reinforces its commitment to accuracy, is new in the Draft and Final, and does not appear in the 2001 Guidebook. The first paragraph appears to be verbatim from the 2007 *Factsheet on the Dispute Process* (2007 Factsheet). Notably, this section omits the recommendation in the 2007 Factsheet that reporters obtain subject approval prior to submitting a report.

2. Notification of a Report

The first paragraph of the 2015 Guidebook expands and clarifies, in logical order, the second and subsequent paragraphs of the 2001 Guidebook. The second and third

paragraphs in the 2015 Guidebook clarify that NPDB officially notifies the subject of a report, with instructions for obtaining an official copy of the report. The third paragraph reiterates that the subject may not change the content of the report, but may add a statement or dispute the report. *The 2015 Guidebook omits the language in the 2001 Guidebook that "the NPDB is prohibited by law from modifying information submitted in the reports."*

2.1 Reviewing a Report

This section recommends that a subject of a report review the entire report for accuracy, and that if the subject detects inaccuracies in her identifying information, the subject should notify the reporter, and request a Correction Report. Disputes about the substantive information in the report are addressed in a separate section, discussed below. The 2001 Guidebook also separated these issues.

2.2 Incorrect Address

This section notes that the subject's address in the report will not be changed when the subject updates her address in records maintained by NPDB, and reiterates the 2001 Guidebook statement that only the reporter can modify/correct information provided in the report, omitting the "prohibited by law" clause from the 2001 Guidebook. There is a new hyperlink provided, entitled, "Report Response Service," which the subject can utilize to update address information on the NPDB website.

3. Subject Statements

There are five major changes from the 2001 Guidebook with regard to subject statements:

- In paragraph four, the 2001 Guidebook linked the ability of a subject to submit a statement to the reporter's declination to change the report—thus apparently requiring the subject to attempt to resolve the issue first with the reporter. The 2015

Guidebook, in the opening line of this section, clarifies that the subject may add a subject statement to the report at any time;

- The 2001 Guidebook provided that the subject statement is part of the specific report the statement addresses; therefore, if the reporter amends the report, the attached subject statement is removed, and the subject must file a new subject statement that tracks the new DCN assigned to the amended report. The 2015 Guidebook clarifies that the subject statement becomes part of the report and remains with the report, even if the report is amended, unless the subject edits or removes it;

- The 2001 Guidebook provided specific character limitations for subject statements. The 2015 Guidebook removed these parameters and added a hyperlink entitled, "Subject Statement." The link expands the character limitation in the 2001 Guidebook from 2000 to 4000;

- The 2001 Guidebook provided that notification of the "dispute" is sent to all queriers who received the report and is included with the report when the report is released to future queriers. The 2015 Guidebook limits this to past queriers who received a copy of the report *within the past three years*, and includes all future queriers; and

- The 2001 Guidebook provided that statements *cannot* include any names, addresses, or phone numbers, including those of patients. The 2015 Guidebook states that statements "*must not*" (italicized in original) include the aforementioned information about patients, colleagues, and others, and adds that statements may characterize individuals in terms of their relationships (e.g., the patient, the attending physician). Unlike the 2001 Guidebook, the 2015 Guidebook also points out that statements should not include URLs, and that confidential information and coarse language are removed from statements before release to queriers.

4. Dispute Process

The Dispute Process section adds to and significantly reorganizes the comparable information in the 2001 Guidebook. The prefatory sentences point out the regulatory

bases for dispute of the accuracy of information reported, with a link to the Code of Federal Regulations, and clarify that the process involves two separate procedures: entering the report into Dispute Status and requesting Dispute Resolution (DR).

4.1 Entering the Report into Dispute Status

In addition to, or in lieu of, filing a subject statement, a subject who wishes to formally dispute a report, must affirmatively enter the report into Dispute Status (link provided) stating her disagreement with either: (1) the factual inaccuracy of the report; or (2) whether the report was properly submitted, including eligibility of the reporting entity. The key substantive difference with the 2001 Guidebook is that, in 2001, the subject was explicitly required to file a subject statement *and* a Dispute Initiation form, whereas in the 2015 Guidebook, the subject *may* provide a statement with initiation of dispute, *but is not required to do so*. (Q&A 3).

4.2 Request for Dispute Resolution

Entering the report into Dispute Status does not trigger a review of the report by NPDB. NPDB will not review a dispute until the subject requests elevation to DR (link provided). Once Dispute Status is entered by the subject, NPDB notifies the reporting entity and all queriers who received the report within the past three years, and future queriers.

4.3 Dispute Procedures

Once in Dispute Status, the subject may:

- Do nothing, and the “dispute” notation remains on the report, with no further action by NPDB, other than to send the notice of the dispute to past (within three years) and future queriers);
- Withdraw from Dispute Status, and notation is deleted from the report; or
- Request that the report be elevated to DR (link provided).

4.4 Revision by Reporting Entity

If the reporting entity changes the report, the subject is notified and the Dispute Status notation is removed. If the subject believes the revised report is factually inaccurate or not submitted according to NPDB reporting requirements, the subject may re-enter the revised report into Dispute Status. This is consistent with the 2001 Guidebook.

4.5 Prerequisites for Dispute Resolution

All of the following must be met and documented for the matter to enter the DR phase:

- The subject has entered the matter into Dispute Status;
- The subject has waited 60 days after entering the report into Dispute Status, during which the subject has attempted to notify the reporter to resolve issues. Note: if the reporter responds negatively in writing in less than 60 days, the subject may request elevation without waiting the full 60 days by contacting the NPDB Customer Service Center (link provided). The 2001 Guidebook required the subject to wait 30 days from the date of initiating discussions with the reporter before requesting Secretarial Review; and
- The subject can verify this effort with correspondence documentation, including the reporter's response, if any.

If the above requirements are not met, NPDB will return the subject's request, with a reminder of the prerequisites, and the report will remain in Dispute Status, pending request for elevation once prerequisites are met. These are consistent with 2001 Guidebook requirements for requesting Secretarial Review.

4.6 Review by DPDB

The 2001 Guidebook referred to this step as “Secretarial Review”; the 2015 Guidebook, in the prefatory sentences, explains that the Secretary of HHS has delegated this authority to HRSA’s Division of Practitioner Data Bank (DPDB). DPDB reviews DR matters in the order in which received. The requirements are generally consistent with 2001 requirements for Secretarial Review, although expanded explanations and descriptive tables appear in the 2015 Guidebook.

4.6.1 Limitations

Subjects’ disputes are limited to (1) whether a report was submitted in accordance with NPDB reporting requirements (link provided), including reporter’s eligibility to report; and/or (2) the factual accuracy of the information.

4.6.2 Exclusions

The DR process does not include reviewing (1) 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; and (2) the extent to which entities followed due process procedures, as those issues must be resolved between the subject and the reporting entity. This section specifies that late reporting does not constitute grounds for disputing a report, and the NPDB’s Compliance Program handles reporters with issues of timely reporting.[65]

[65] At the Educational Conference on April 7, 2015, at which the 2015 NPDB Guidebook was rolled out, DPDB representatives emphasized that DPDB’s current enforcement position is that providers will not be sanctioned for the submission of late reports, because, at this time, DPDB is more concerned that the reports, even if late, be submitted and posted.

4.6.3 Responsibilities of Subjects of Disputed Reports

Subjects requesting elevation to DR must be prepared to:

- Succinctly describe the issues in dispute and the facts, with supporting documentation. Electronic submission is preferred. These comments are separate and distinct from the subject statement, are used for DR purposes only, and will not be disclosed to queriers as part of the report;
- Submit documentation substantiating the points of dispute, showing that the report is inaccurate or that it was not submitted in accordance with NPDB reporting requirements. Subjects are encouraged to provide all substantiating documentation at one time, using Table F-1 as guidance for determining what is/is not pertinent. Subjects should show how each document relates to the points of dispute. NPDB will request more information if necessary for proper resolution. Note: Table F-1 provides specific examples of pertinent and unrelated documentation that are not present in the 2001 Guidebook; and
- Submit proof of an unsuccessful attempt to resolve the issue with the reporter (i.e., emails, letters) and reporter's response, if any.

4.6.4 Responsibilities of Reporters and Subjects in Dispute Resolution

During the review, reporters may receive requests from NPDB to provide additional information pertaining to the accuracy of the report. Failure to respond, or an inadequate response, may constitute a failure to meet NPDB reporting requirements. A subject's failure to cooperate may result in suspension or dismissal of the review process.

4.6.5 Dispute Resolution Decisions

There are three possible outcomes as a result of a DR, although multiple outcomes are possible when a subject disputes several issues: (Tables F-2 and F-3 provide graphic representations of the DR process.)

- *Accurate as Submitted*. The report is factually accurate as submitted and/or submitted in accordance with reporting requirements. The report remains in NPDB. A decision letter is sent to the subject, with a copy to the reporter. All queriers who received notification of the dispute and received the report within three years before the decision receive a copy of the disputed report with a summary of the decision—they do not receive the letter;

- *Inaccurate as Submitted*. The report is factually inaccurate as submitted and/or not submitted in accordance with reporting requirements. The reporter is asked whether it agrees with the decision, based on the record compiled during the process;

- If the reporter *agrees* with the DPDB determination, the reporter corrects the inaccurate report, and when NPDB processes a Correction Report (link provided), NPDB provides the reporter with a Report Verification Document, notifies the subject of the report, and copies all queriers who received the previous version of the report within the past three years;

- If the reporter *does not agree*, it explains its rationale in writing and provides additional documentation, and DPDB reassesses the accuracy of the report. The subject also may submit documentation responsive to the reporter's reply. If the report is found to be accurate as submitted, it remains in NPDB;

- If the reporter does not submit additional substantiating documentation, and fails to correct the report, DPDB corrects the report consistent with the record compiled during DR, and the report remains in NPDB. A decision letter explaining the decision will address the issues raised by the subject, and will be sent to the subject, with a copy to the reporter. Queriers who were notified of the dispute and received the

report within three years before the decision receive a corrected copy of the disputed report with a summary of the decision—they do not receive a copy of the letter;

- Corrected reports are removed from DR, unless the subject seeks additional review. If the subject disagrees with corrected report, the subject may request re-elevation for review and update the report's DR Statement, but is not required to submit documentation or contact the reporter again;

- *Submitted Contrary to Reporting Requirements*. If a Data Bank report is found to *not* meet NPDB reporting requirements, the reporter is asked to determine whether it agrees with the assessment that the report should be voided;

- If the reporter agrees with the assessment, the reporter voids the report, and it is removed from the disclosable record of the subject. When NPDB processes and provides the reporter with a Report Void Confirmation, it sends notice to the subject and to all queriers who received the previous version of the report within the past three years. All queriers who received the previous version of the report within the past three years are advised to destroy the report and any copies;

- If the reporter does not agree with the assessment, it is asked to explain its rationale in writing and provide documentation, for the DPDB's reassessment of the accuracy of the report. If DPDB finds the report to be accurate as submitted, based on the submitted documentation, it remains in NPDB;

- If the reporter does not submit substantiating documentation and fails to void the report, DPDB voids the report. A decision letter is sent to the subject, with a copy to the reporter. All queriers who received notification of the dispute and received the report within the three years before the DR decision receive a summary of the decision—they do not receive a copy of the letter. All queriers who received the previous version of the report within the past three years are advised to destroy the report and any copies; and

- *Disputed Issues are Outside the Scope of Review*. If the issues in dispute are found to be outside of the scope of review, 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, with a copy to the reporter. All queriers who received notification of the dispute and received the report within the three years before the DR decision receive a copy of the disputed report with a summary of the decision—they do not receive a copy of the decision letter.

4.6.6 Reconsideration of a Dispute Resolution Decision

A subject wishing to request reconsideration of a DR decision must submit a written request specifying any new information, the issue(s) the subject believes were inappropriately considered during the review, and supporting documentation to NPDB at one of the addresses listed below, depending on whether standard mail or overnight mail is used. Either the previous decision will be affirmed, or a revised final decision will be issued.

4.6.7 Subject of the Report Is Deceased

The legal representative of a deceased individual's estate may dispute a report by providing documentation of legal representative status and contacting the NPDB Customer Service Center (link provided) to begin the process.

5. Examples of Dispute Resolution

The examples provided in the 2015 Guidebook assume that the subject entered the report into Dispute Status, requested elevation to DR, and met the prerequisites for elevation. The examples illustrate the application of the rules by NPDB in various DR scenarios. The following points are emphasized:

- The DR process is not a forum for challenging the clinical (or other) basis for which a peer review action was taken, or the adequacy of the "due process" provided, but only whether the report accurately recites the actions taken and the basis of those actions. (Exs. 1 and 2); and

- The subject does not have to be aware of an investigation to be reported for resignation while under investigation (Ex. 4).

6. Q&A

This section helps clarify application of the rules to specific situations. For example, several questions relate to the DR process and emphasize that the subject must take affirmative action to elevate a disputed report into DR, and that the submission of a subject statement is not a condition precedent to elevation.

Chapter G: Fees

NPDB must be self-supporting through user fees. Currently, except for self-queries, there are two charging mechanisms: One-Time (Traditional) Query for each subject search (currently $3 each) or Continuous Query enrollments, in which an entity is charged on a subscription basis for each practitioner listed (currently $3 for each name per year).

NPDB has somewhat enhanced methodologies to make paying easier. American Express has been added to the list of credit cards accepted. More importantly, eligible entities now can securely store their credit or debit card information—multiple cards if they so choose—so they do not have to enter the information each time a new query is submitted.

NPDB also seems to be taking a stronger stance toward payment and payment issues:

- NPDB explicitly states that it can terminate a bankrupt entity's ability to query NPDB for failure to pay NPDB, even if the organization is required by law to make such queries;[66]
- To receive credit for an improperly assessed fee, an entity must include certain information, including the DCN assigned to the query; and

[66] *See* G-5.

- The Q&A section repeatedly refers eligible entities to their financial institutions for problems with rejected credit cards, figuring out the credit card bill, Electronic Funds Transfer (EFT) accounts on hold, EFT balances, and the information—or lack thereof—on credit card billing statements.[67]

Chapter H: Information Sources

The following contact information is provided:

NPDB Customer Service Center

Email address: help@npdb.hrsa.gov

Phone: 800-767-7632 (800-SOS-NPDB)

TTD: 703-802-9395

Outside the U.S.: 703-802-9380

Mailing Addresses

Standard

National Practitioner Data Bank

P.O. Box 10832

Chantilly, VA 20153-0832

Overnight

National Practitioner Data Bank

[67] *See* G-5, 6.

4094 Majestic Lane

PMB-332

Fairfax, VA 22033

Aggregate Research Data

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

Division of Practitioner Data Bank

Policy and Disputes Resolution Branch Chief

5600 Fishers Lane, Mail Stop 11SWH03

Rockville, MD 20857

Email address: npdbpolicy@hrsa.gov

Federal Employer Identification Number (EIN)

Health Resources and Service Administration

U.S. Department of Health and Human Services

5600 Fishers Lane, Mail Stop 11SWH03

Rockville, MD 20857

EIN: 52-082-1668