

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

45 CFR Part 60

RIN 0906-AA57

National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting on Adverse and Negative Actions

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises existing regulations under sections 401 through 432 of the Health Care Quality Improvement Act of 1986, governing the National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners, to incorporate statutory requirements under section 1921 of the Social Security Act, as amended by section 5(b) of the Medicare and Medicaid Patient and Program Protection Act of 1987 (MMPPPA), and as amended by the Omnibus Budget Reconciliation Act of 1990 (OBRA).

The MMPPPA, along with certain additional provisions in the OBRA, was designed to protect program beneficiaries from unfit health care practitioners, and otherwise improve the anti-fraud provisions of Medicare and State health care programs. Section 1921, the statutory authority upon which this regulatory action is based, requires each State to adopt a system of reporting to the Secretary of Health and Human Services (the Secretary) certain adverse licensure actions taken against health care practitioners and health care entities licensed or otherwise authorized by a State (or a political subdivision thereof) to provide health care services. It also requires each State to report any negative actions or findings that a State licensing authority, peer review organization, or private accreditation entity has concluded against a health care practitioner or health care entity.

DATES: This rule is effective March 1, 2010.

FOR FURTHER INFORMATION CONTACT: Mr. Darryl Gray, Director, Division of Practitioner Data Banks, Bureau of Health Professions, Health Resources and Services Administration (HRSA), Parklawn Building, 5600 Fishers Lane, Room 8-103, Rockville, MD 20857; telephone number: (301) 443-2300.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Health Care Quality Improvement Act of 1986

The National Practitioner Data Bank (NPDB) was established by the Health Care Quality Improvement Act (HCQIA) of 1986, as amended (42 U.S.C. 11101 *et seq.*). The NPDB contains reports of adverse licensure actions against physicians and dentists (including revocations, suspensions, reprimands, censures, probations, and surrenders for quality of care purposes only); adverse clinical privilege actions against physicians and dentists; adverse professional society membership actions against physicians and dentists; Drug Enforcement Administration (DEA) adverse actions; Department of Health and Human Services (HHS), Office of the Inspector General (OIG) Medicare and Medicaid exclusions; and medical malpractice payments made for the benefit of any health care practitioner. Groups that have access to this information include hospitals, other health care entities that conduct peer review and provide health care services, State Medical or Dental Boards and other health care practitioner State boards. Individual practitioners can self-query. The reporting of information under the NPDB is limited to medical malpractice payers, State Medical and Dental Boards, DEA, HHS OIG, professional societies with formal peer review, and hospitals and other health care entities (such as health maintenance organizations).

B. Section 1921 of the Social Security Act

On March 21, 2006, the Health Resources and Services Administration published a proposed rule in the **Federal Register** (71 FR 14135) designed to implement section 1921 of the Social Security Act (herein referred to as section 1921), as amended by section 5(b) of the MMPPPA, and as amended by the OBRA. Section 1921 expands the scope of the NPDB. Section 1921 requires each State to adopt a system of reporting to the Secretary certain adverse licensure actions taken against health care practitioners and health care entities by any authority of the State responsible for the licensing of such practitioners or entities. It also requires each State to report any negative action or finding that a State licensing authority, a peer review organization, or a private accreditation entity has finalized against a health care practitioner or entity.

Groups that have access to this information include all organizations eligible to query the NPDB under the HCQIA (hospitals, other health care entities that conduct peer review and provide health care services, State Medical or Dental Boards and other health care practitioner State boards), other State licensing authorities, agencies administering Federal health care programs, including private entities administering such programs under contract, State agencies administering or supervising the administration of State health care programs, State Medicaid Fraud Control Units, and certain law enforcement agencies, and utilization and quality control peer review organizations (referred to as QIOs) as defined in Part B of title XI of the Social Security Act and appropriate entities with contracts under section 1154(a)(4)(C) of the Social Security Act. Individual health care practitioners and entities can self-query. The reporting of information under section 1921 is limited to State licensing and certification authorities, peer review organizations, and private accreditation entities. Section 1921 requires the Secretary to provide for the maximum appropriate coordination in the implementation of its reporting requirements with those of section 422 of the HCQIA.

C. Section 1128E of the Social Security Act

The reporting requirements of both section 422 of the HCQIA and section 1921 overlap with the requirements under section 1128E of the Social Security Act (herein referred to as section 1128E), as added by section 221(a) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191. Section 1128E directs the Secretary to establish and maintain a national health care fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions taken against health care providers, suppliers or practitioners. The statute requires the Secretary to avoid duplicating the reporting requirements established for the NPDB. This data bank is known as the Healthcare Integrity and Protection Data Bank (HIPDB). The HIPDB began collecting reports in November 1999 concerning actions taken on or after August 21, 1996.

D. Distinctions Between the NPDB and the HIPDB

Although section 422 of the HCQIA and sections 1921 and 1128E have overlapping components, they have unique elements, including differences

in types of reportable adverse actions as well as differences in types of individuals or entities with access to the information. For example, private-sector hospitals have access to information reported under the HCQIA and section 1921, but not under section 1128E. The two tables below illustrate the similarities and differences among the HCQIA, section 1921, and section 1128E. Table 1, Description of Statutory Provisions, summarizes the specific provisions of each of the three statutes.

Table 2, Description of Data Banks, compares the HIPDB with the NPDB (as expanded by section 1921).

Section 1921 expands State reporting of licensure actions taken against physicians and dentists to the NPDB. This expansion matches the State reporting requirements to the HIPDB under section 1128E. Currently, the HCQIA limits NPDB reporting by medical and dental licensing authorities only to those adverse actions related to professional competence or professional

conduct, but these authorities must report all actions to the HIPDB. The change will make the reporting of adverse actions by all State licensure and certification authorities nearly identical for both the NPDB and HIPDB. No current NPDB reporting requirements will be changed for hospitals, other health care entities, professional societies, DEA, HHS OIG, or medical malpractice payers.

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Table 1: Description of Statutory Provisions

HCQIA (NPDB)	SECTION 1921 (NPDB)	SECTION 1128E (HIPDB)
<p>WHO REPORTS?</p> <ul style="list-style-type: none"> ▪ Medical malpractice payers ▪ Boards of Medical/Dental Examiners ▪ Hospitals ▪ Other health care entities ▪ Professional societies with formal peer review ▪ DEA ▪ HHS OIG <p>WHAT INFORMATION IS AVAILABLE?</p> <ul style="list-style-type: none"> ▪ Medical malpractice payments ▪ Adverse licensure actions (physicians/dentist) <ul style="list-style-type: none"> -- revocation, suspension, reprimand, probation, surrender, censure ▪ Adverse clinical privileges actions (primarily physicians/dentists) • Adverse professional society membership (primarily physicians/dentists) • Adverse Actions against DEA Certification • Medicare Exclusions <p>WHO CAN QUERY?</p> <ul style="list-style-type: none"> ▪ Hospitals ▪ Other health care entities with formal peer review ▪ Professional societies with formal peer review ▪ Boards of Medical/Dental Examiners ▪ Other health care practitioners ▪ State licensing boards ▪ Plaintiff's attorney/<i>pro se</i> plaintiffs (limited circumstances) ▪ Health care practitioners (self-query) ▪ Researchers (statistical data only) 	<p>WHO REPORTS?</p> <ul style="list-style-type: none"> ▪ State medical, dental and other health care practitioner licensing boards ▪ State health care entity licensing boards ▪ Peer review organizations ▪ Private accreditation organizations <p>WHAT INFORMATION IS AVAILABLE?</p> <ul style="list-style-type: none"> ▪ Any adverse licensure actions (practitioners/entities) <ul style="list-style-type: none"> -- revocation, reprimand, censure, suspension, probation -- any dismissal or closure of the proceedings by reason of the practitioner or entity surrendering the license or leaving the State or jurisdiction -- any other loss of the license ▪ Any negative action or finding by a State licensing authority, peer review organization, or private accreditation organization concluded against a health care practitioner or entity <p>WHO CAN QUERY?</p> <ul style="list-style-type: none"> ▪ Hospitals and other health care entities (HCQIA) ▪ Professional societies with formal peer review ▪ State medical, dental and other health care practitioner/entity licensing boards ▪ Agencies administering Federal health care programs, or their contractors ▪ State agencies administering State health care programs ▪ Quality Improvement Organizations ▪ State Medicaid Fraud Control Units ▪ U.S. Comptroller General ▪ U.S. Attorney General and other law enforcement ▪ Health care practitioners/entities (self-query) ▪ Researchers (statistical data only) 	<p>WHO REPORTS?</p> <ul style="list-style-type: none"> ▪ Federal and State Government Agencies ▪ Health Plans <p>WHAT INFORMATION IS AVAILABLE?</p> <ul style="list-style-type: none"> ▪ Licensing and certification actions (practitioners, providers, and suppliers) <ul style="list-style-type: none"> revocation, reprimand, suspension (including length), censure, probation; any other loss of license, or right to apply for, or renew, a license of the provider, supplier, or practitioner, whether by voluntary surrender, non-renewability, or otherwise and; any other negative action or finding that is publicly available information ▪ Health care-related civil judgments (practitioners, providers, and suppliers) ▪ Health care-related criminal convictions (practitioners, providers, and suppliers) ▪ Exclusions from Federal or State health care programs (practitioners, providers, and suppliers) ▪ Other adjudicated actions or decisions (practitioners, providers, and suppliers) <p>WHO CAN QUERY?</p> <ul style="list-style-type: none"> ▪ Federal and State Government Agencies ▪ Health Plans ▪ Health care practitioners/providers/ suppliers (self-query) ▪ Researchers (statistical data only)

Table 2: Description of Data Banks

HIPDB (1128E)	Expanded NPDB (HCQIA and 1921)
<p>Who Reports?</p> <ul style="list-style-type: none"> ▪ Federal and State Government Agencies ▪ Health Plans <p>What Information is Available?</p> <ul style="list-style-type: none"> ▪ Licensing and certification actions (practitioners, providers, and suppliers) revocation, reprimand, suspension (including length), censure, probation voluntary surrender, any other negative action or finding by a Federal or State licensing or certification agency that is publicly available information ▪ Health care-related civil judgments (practitioners, providers, and suppliers) ▪ Health care-related criminal convictions (practitioners, providers and suppliers) ▪ Exclusions from Federal or State health care programs (practitioners, providers, and suppliers) ▪ Other adjudicated actions or decisions (practitioners, providers, and suppliers) <p>Who Can Query?</p> <ul style="list-style-type: none"> ▪ Federal and State Government Agencies ▪ Health Plans ▪ Health care practitioners/providers/ suppliers (self-query) ▪ Researchers (statistical data only) 	<p>Who Reports?</p> <ul style="list-style-type: none"> ▪ Medical malpractice payers ▪ State health care practitioner licensing and certification authorities (including medical and dental boards) ▪ Hospitals ▪ Other health care entities with formal peer review (HMOs, group practices, managed care organizations) ▪ Professional societies with formal peer review ▪ State entity licensing and certification authorities ▪ Peer review organizations ▪ Private accreditation organizations ▪ DEA ▪ HHS OIG <p>What Information is Available?</p> <ul style="list-style-type: none"> ▪ Medical malpractice payments (all health care practitioners) ▪ Any adverse licensure action (all practitioners or entities) <ul style="list-style-type: none"> -revocation, reprimand, censure, suspension, probation -any dismissal or closure of the proceedings by reason of the practitioner or entity surrendering the license or leaving the State or jurisdiction -any other loss of license ▪ Adverse clinical privileging actions ▪ Adverse professional society membership actions ▪ Any negative action or finding by a State licensing or certification authority ▪ Peer review organization negative actions or findings against a health care practitioner ▪ Private accreditation organization negative actions or findings against a health care or entity ▪ Adverse Actions against DEA Certification ▪ Medicare Exclusions <p>Who Can Query?</p> <ul style="list-style-type: none"> ▪ Hospitals ▪ Other health care entities, with formal peer review ▪ Professional societies with formal peer review ▪ State health care practitioner licensing and certification authorities (including medical and dental boards) ▪ State entity licensing and certification authorities* ▪ Agencies or contractors administering Federal health care programs* ▪ State agencies administering State health care programs* ▪ State Medicaid Fraud Control Units* ▪ U.S. Comptroller General* ▪ U.S. Attorney General and other law enforcement* ▪ Health care practitioners and entities (self query) ▪ Plaintiff's attorney/<i>pro se</i> plaintiffs (under limited circumstances)** ▪ Quality Improvement Organizations* ▪ Researchers (statistical data only) ▪ DEA ▪ HHS OIG <p>*eligible to receive only those reports authorized by section 1921. ** eligible to receive only those reports authorized by HCQIA</p>

E. Maximum Coordination Between the NPDB and the HIPDB

Section 1921 requires the Secretary to provide for the maximum appropriate coordination in the implementation of its reporting requirements with those of section 422 of the HCQIA. The Secretary is implementing these regulations in a manner to avoid the need for an entity that must report information to both the NPDB and the HIPDB to file two reports. We have made significant efforts to develop these regulations in a manner that minimizes the burden on reporters. Therefore, reporters responsible for reporting the final adverse actions to both the NPDB and HIPDB will be required only to submit one report per action, provided that reporting is made through the Department's Web-based system that will sort the appropriate actions into the HIPDB, the NPDB or both. The required adjustments to the reporting system are made easier because both Data Banks are operated through a consolidated electronic system. For consistency and clarity, we have made minor edits to the regulations. For example, we replaced references to "the Data Bank" with "the NPDB" throughout the regulations, and modified references to types of report subjects who may dispute the accuracy of a report to include health care entities.

II. Summary of the Proposed Rule

The proposed regulations published on March 21, 2006, were developed to revise existing NPDB regulations at 45 CFR part 60 by adding section 1921 requirements for reporting of specific data elements to and procedures for obtaining this information from the NPDB. Certain sections of the existing NPDB regulations are consistent with section 1921 requirements. Specifically, the following provisions apply to NPDB and the section 1921 component of NPDB: (1) The provisions in § 60.6, pertaining to reporting errors, omissions, and revisions to an action previously reported to the NPDB; (2) the confidentiality provisions in the redesignated § 60.15 (formerly § 60.13); and (3) the provisions in the redesignated § 60.16 (formerly § 60.14), regarding procedures for disputing the accuracy of information in the NPDB. The significant section 1921 additions are described below and are listed according to the sections of the regulations that they affect.

• § 60.3 *Definitions.*

In the proposed rule, we set forth definitions for the statutory terms "formal proceeding," "negative action or finding," "peer review organization,"

"private accreditation entity," "Quality Improvement Organization," and "voluntary surrender." Because of the statutory distinctions between peer review organizations and QIOs and differences in the missions of those organizations, we proposed to exclude QIOs from the definition of the term "peer review organization." We also proposed definitions for certain terms established in HIPDB regulations to enhance coordination between the NPDB and the HIPDB in areas where overlapping requirements exist. These terms are "affiliated or associated," "organization name," and "organization type."

• § 60.5 *When information must be reported.*

The proposed regulations sought to amend this section of the existing NPDB regulations by:

1. Revising the introductory text of this section to include references to the newly added §§ 60.9 and 60.10 and redesignated § 60.11;
2. Revising paragraph (b), "Licensure Actions (§ 60.8 and § 60.9)," to refer specifically to the State Board of Medical Examiners and to clarify the requirements made in new § 60.9;
3. Revising the reference to "§ 60.9" in the title and the third sentence of paragraph (d) to read "§ 60.11;" and
4. Adding a new paragraph, "Negative Action or Finding (§ 60.10)," to provide a new category of actions that are to be reported in accordance with section 1921.

• § 60.7 *Reporting medical malpractice payments.*

We revised paragraph (c) of this section to link the potential civil money penalty for each violation of the NPDB's confidentiality provisions to the amount set in 42 CFR 1003.103(c), which establishes the amount of a civil money penalty that may be imposed by the Inspector General for such a violation. Currently this section authorizes a civil money penalty of up to \$11,000 for each violation.

• § 60.8 *Reporting licensure actions taken by Boards of Medical Examiners.*

For consistency with reporting requirements for States in the newly proposed § 60.9, we proposed to revise paragraph (b)(10) of this section to require the reporting of the description of an action taken by a Board to include the duration of a non-permanent action.

• § 60.9 *Reporting licensure actions taken by States. (New)*

We proposed to redesignate the current § 60.9 as § 60.11, and add a new § 60.9 to implement the reporting requirements of section 1921. In proposed § 60.9, we addressed the reporting of licensure actions taken by

State licensing authorities resulting from a formal proceeding. We proposed to include any formal or official proceeding held before the authority, organization or entity taking the action to provide maximum flexibility.

Section 1921 specifically requires the reporting of a health care practitioner who, or entity that, voluntarily surrenders a license. Based on extensive discussions with various State licensing authorities, we have been advised that the voluntary surrender and non-renewal of licensure are used by Federal and State health care programs as a means to exclude questionable health care practitioners and entities from participation. These voluntary surrenders and non-renewal actions, if not reported to the NPDB, would result in allowing health care practitioners or entities to move from State-to-State without detection. We also recognize that many voluntary surrenders are not a result of the types of adverse actions that are intended for inclusion in the NPDB. Therefore, we proposed that voluntary surrenders and licensure non-renewals due to non-payment of licensure fees, changes to inactive status, and retirements be excluded from reporting to the NPDB unless they are taken in combination with a revocation, suspension, reprimand, censure, or probation, in which case they would be reportable.

We proposed defining the phrase "any negative action or finding" by a State licensing authority to mean any action or finding that is publicly available and rendered by a licensing or certification authority. The definition excluded administrative fines or citations, and corrective action plans, unless they are: (1) Connected to the delivery of health care services and (2) taken in conjunction with other licensure or certification actions.

Reportable actions, by statute, must be based on the result of formal proceedings. Thus, events unrelated to such proceedings would be excluded.

We also proposed a list of "mandatory" data elements, as well as other data elements that should be reported to the NPDB "if known."

• § 60.10 *Reporting negative actions or findings taken by peer review organizations or private accreditation entities. (New)*

We proposed to redesignate the current § 60.10 as § 60.12 and add a new § 60.10 to implement the reporting requirements of section 1921. Under this provision, each State is required to adopt a system of reporting to the NPDB any negative action or finding that a peer review organization or private accreditation entity has concluded

against a health care practitioner or health care entity (both as defined in § 60.3), respectively.

With respect to reporting by private accreditation entities, we proposed that private accreditation entities be required to report determinations of less than full accreditation that indicate a substantial risk to the safety of a patient or patients or quality of health care services.

We also proposed peer review organizations be required to report any recommendation to sanction a practitioner.

• § 60.13 *Requesting information from the NPDB. [Redesignated]*

Under the statute, section 1921 data would be released for the purpose of determining the fitness of an individual to provide health care services and to protect the health and safety of individuals receiving health care through programs administered by the requesting entities, as well as to protect the fiscal integrity of these programs. We proposed to redesignate the current § 60.11 as § 60.13 and revise the redesignated § 60.13, paragraph (a), entitled, "Who may request information and what information may be available," to clarify to whom information in the NPDB and section 1921 would be made available. Information reported under §§ 60.7, 60.8 and 60.11 is available only to those entities that have access to the information under the HCQIA (e.g., hospitals and other health care entities, and State licensing boards). Information reported under §§ 60.9 and 60.10 is available to organizations authorized to receive section 1921 information, which includes all organizations eligible to query the NPDB under the HCQIA and new organizations specified in section 1921 (e.g., Federal and State health care programs, law enforcement agencies, and QIOs).

• § 60.14 *Fees applicable to requests for information. [Redesignated]*

We proposed to redesignate the current § 60.12 as § 60.14 and to revise redesignated § 60.14. Section 1921 expands the scope of the NPDB by permitting additional entities to query regarding adverse licensure actions and certain other negative actions or findings. As provided in the annual HHS Appropriations Acts, the Department's authority for charging user fees (in addition to the basic authority) under section 427(b)(4) of the HCQIA applies to all requests for information from the NPDB and is set in amounts sufficient to cover the full costs of operating the NPDB. Additionally, we made technical changes to this section in order to comply with Office of Management and Budget (OMB) Circular A-25 governing the Federal

policy regarding fees assessed for government services.

• § 60.15 *Confidentiality of NPDB. [Redesignated]*

In accordance with 42 CFR 1003.103(c), the Department's OIG has raised the CMP for each violation of the NPDB's confidentiality provisions from up to \$10,000 to up to \$11,000. Therefore, we proposed to revise paragraph (b) to reflect this change.

III. Summary and Response to Public Comments

The proposed rule set forth a 60-day public comment period, ending May 22, 2006. HRSA received 33 public comments from State licensing authorities and their associations; associations representing physicians, dentists and other health care practitioners; associations representing health insurers; hospitals, other health care entities, and their associations; private accreditation organizations; private citizens; and private attorneys. Based on review of the statute and the assessment of public comments received, we believe the final regulations to implement section 1921 fully and adequately balance the Department's concerns with those expressed by the commenting public.

Set forth below is an overview of the various comments and recommendations received and our responses to those concerns. In the preamble of the proposed rule, we requested comments concerning two specific areas. The first area concerned QIOs and peer review organizations. We asked for comments related to our proposed exemption of QIOs from reporting under section 1921, the proposed definition of a peer review organization, potential reportable events by peer review organizations and their relationships with other entities, the public or private status of peer review organizations, and the types of practitioners and entities they review. The second area concerned private accreditation entities and any potential limitations on their abilities to report under section 1921. The comments addressing these specific issues are included in the appropriate sections of the regulations below. Section IV of this preamble sets forth a summary of the specific revisions and clarifications to be made to the final regulations as a result of those comments.

A. Section-by-Section Analysis of Issues

The National Practitioner Data Bank (§ 60.1)

Comment: We received several comments that addressed the

distinctions among the HCQIA, section 1921 and section 1128E. Commenters expressed difficulty understanding the specific reporting requirements, access to the information authorized by section 1921, and the additional changes that would occur under section 1921.

Response: The distinctions among the HCQIA, section 1921, and section 1128E are found in Table 1, Description of Statutory Provisions, in the preamble. Section 1921 will not increase the reporting burden on State licensing authorities because these entities currently report adverse actions to the NPDB and/or the HIPDB. Specifically, the HCQIA requires the reporting of licensure actions based on professional conduct or competence only against physicians and dentists, whereas sections 1921 and 1128E require the reporting of all licensure actions taken against all health care practitioners. Also, sections 1921 and 1128E require the reporting of adverse licensure actions taken against certain health care organizations. Existing NPDB reporting requirements for hospitals, other health care entities, professional societies, and medical malpractice payers are not affected by section 1921.

Entities that are eligible to query the NPDB will continue to query as they always have and will gain access to additional information under section 1921. New queriers, such as government health care programs and law enforcement agencies, that gain access to the NPDB through section 1921 eligibility (i.e., queriers who did not already have NPDB eligibility), will only have access to information reported under section 1921. These new queriers will not have access to the NPDB information reported under the HCQIA. Most of these new section 1921 queriers already have access to HIPDB information. Currently, private-sector hospitals do not have access to HIPDB information, which includes adverse licensure actions taken against health care practitioners other than physicians and dentists, as well as licensure actions taken against physicians and dentists that are not related to professional competence or conduct. Under section 1921, private-sector hospitals will have access to all licensure actions taken against health care practitioners, including physicians and dentists.

Applicability of These Regulations (§ 60.2)

Comment: We received several comments supporting the NPDB's expansion under section 1921, particularly with respect to collecting licensure actions on all health care practitioners. However, we also received

several comments expressing concern over NPDB's expansion under section 1921 to collect actions taken against health care entities. Citing the wording of the statute's first paragraph, which refers to peer review organizations and private accreditation entities reviewing the services provided by health care practitioners, one commenter questioned NPDB's authority to collect peer review and accreditation organization actions taken against health care entities. Other commenters questioned the authority of the NPDB to collect any type of action taken against health care entities because the NPDB was originally authorized to collect actions taken against health care practitioners only. These commenters also questioned the value of collecting reports on health care entities.

Response: In 1987, Congress authorized the Secretary to collect adverse actions taken by licensing agencies against health care practitioners and health care entities in the MMPPPA. In 1990, Congress expanded this requirement through OBRA to include reporting of negative actions and findings by peer review organizations, and private accreditation entities. The statute, as amended, requires the collection of information from formal proceedings "concluded against a health care practitioner or entity [emphasis added] by any authority of the State * * * responsible for the licensing of health care practitioners (or any peer review organization or private accreditation entity reviewing the services provided by health care practitioners) or entities."

Second, section 1921(a)(1)(D) of the Social Security Act requires the collection of "any negative action or finding by such authority, organization, or entity regarding the practitioner or entity." This language clearly indicates that the action taken by the licensing authority, peer review organization or private accreditation entity may be against a health care practitioner or health care entity.

Finally, private accreditation entities, which are not operated by a unit of State or Federal government, accredit health care facilities, not individuals. Therefore, while their work may include reviewing the services provided by health care practitioners, these entities ultimately make determinations about health care facilities' qualifications and their ability to provide quality health care.

While the statute clearly authorizes the Secretary to collect actions taken against health care practitioners and health care entities, the proposed rule limited reporting of peer review

organization actions or findings to those against health care practitioners only—not health care entities. We made this decision because it is our understanding that peer review organizations are primarily involved with evaluating the quality of patient care practices or services ordered or performed by health care practitioners. Peer review organizations under section 1921 would only be evaluating the performance of health care practitioners and not the specific performance of a health care facility. In addition, it is the health care facility that would be contracting with the peer review organization, so we do not believe the peer review organization would be in a position to recommend a sanction against the facility with which it contracts. Reporting by a peer review organization is limited to the discovery of practices by an individual physician, dentist or other practitioner that are so serious that they warrant a sanction recommendation by the peer review organization to the appropriate health care facility or other authority.

Comment: Several commenters stated that information required to be reported by section 1921 is not reflective of the quality of health care provided by health care practitioners. One commenter expressed concern over the professional and economic impact of having a report in the NPDB.

Response: Section 1921 does not limit reporting to only those actions judged by the reporting entity to be based on the quality of the health care services provided. The statute requires the reporting of specified actions that result from formal proceedings. The NPDB is a national repository of actions taken by mandated reporters. We understand that there may be a professional or economic impact as a result of an action taken against a health care practitioner who, or entity that, is reported to the NPDB. However, the NPDB is primarily an alert or flagging system. The information in the NPDB is intended to be used as a resource to assist authorized queriers in conducting an extensive independent investigation of the qualifications of a health care practitioner or entity. The NPDB is simply a conduit for information on actions taken and reported by authorized entities.

Comment: Two commenters stated that before the section 1921 regulations are implemented, HRSA should fully implement the recommendations from the Government Accountability Office's (GAO) 2000 report on the NPDB titled, "National Practitioner Data Bank: Major Improvements Are Needed to Enhance Data Bank's Reliability."

Response: The implementation of section 1921 is the final action needed

to fully implement the recommendations from the GAO's 2000 report. By the end of 2004, HRSA had satisfactorily addressed the GAO's recommendations with the exception of including the adverse licensure actions taken against nurses and other non-physicians healthcare practitioners.

Definitions (§ 60.3)

Comment: We received two comments requesting clarification of current NPDB definitions. One commenter stated that the definition of the term "physician" should include doctors of podiatric medicine, and the other requested clarification of the term "health care entity" as used in these regulations.

Response: The terms "physician" and "health care entity" are defined under the HCQIA and are clarified in existing NPDB regulations in § 60.3. A doctor of podiatric medicine is not included in the term "physician," which is defined by statute as a doctor of medicine or osteopathy legally authorized to practice medicine or surgery by a State (or who, without authority, holds himself or herself out to be so authorized), but is considered a "health care practitioner." Section 1921 requires the Secretary to provide the maximum appropriate coordination with the HCQIA when implementing this statute. Therefore, we have an obligation to be consistent with existing definitions and are unable to make the requested change.

Throughout these regulations, we use the terms "health care practitioners, physicians, dentists and entities" to describe the full range of subjects of a section 1921 report. Our approach to describing section 1921 report subjects differs slightly from the statutory language of section 1921 "health care practitioners and entities." We adopted this approach because we relied on existing NPDB definitions. These existing definitions, however, do not work seamlessly with each section 1921 provision. The existing NPDB definition of "health care practitioner" specifically excludes physicians and dentists, which are defined separately. We, therefore, refer throughout these regulations to "health care practitioners, physicians, and dentists" to remedy this difference between the HCQIA and section 1921.

We use the current NPDB definition of "health care entity" to define the range of organizations that may be subjects of a report under section 1921. This definition, however, is used in the HCQIA to specify certain organizations that are authorized to report and receive information under the HCQIA. The current definition includes hospitals and other health care entities that provide health care services and

perform formal peer review activities for the purpose of furthering quality health care. The definition, however, also includes professional societies that conduct formal peer review activities for the purpose of furthering quality health care. We do not believe that professional societies fit the definition of subjects of section 1921 reports, and, for the following reasons, we do not intend to collect actions against professional societies under this statute. First, section 1921(a)(1)(A) through (C) requires the reporting of any adverse action taken by a licensing authority, any dismissals or closures of licensing proceedings, or any other loss of a license. To our knowledge, licensing authorities do not license, nor do they take licensure actions against, professional societies. Therefore, we do not expect any licensure reports on professional societies. Second, section 1921(a)(1)(D) requires the reporting of any negative action or finding by a licensing authority, peer review organization or private accreditation entity. Under section 1921, private accreditation entities, by definition, evaluate the quality of health care services provided by a health care entity, measure the health care entity's performance, assign that entity a level of accreditation, conduct periodic reviews of the quality of health care provided by the entity, and report to the NPDB certain final determinations that affect the entity's accreditation status. We are unaware of any professional societies that directly provide health care services and that would contract with a private accreditation entity to perform these defined functions. Current NPDB guidance defines a professional society as a membership association of physicians, dentists, or other health care practitioners that follows a formal peer review process for the purpose of furthering quality health care. Therefore, we do not believe that professional societies could be the subjects of private accreditation entity reports. Because only health care practitioners, physicians, and dentists will be the subjects of peer review organization reports, professional societies will not be the subjects of these section 1921 reports either.

1. Formal Proceeding

Comment: Three commenters expressed concern over the broad nature of the definition of formal proceeding. These commenters stated that the definition gives too much discretion and not enough guidance to reporting entities; does not differentiate between informal and formal proceedings; will generate large volumes of report

information with little value; and, will be difficult to enforce.

Response: While HRSA crafted the proposed definition of "formal proceeding" to allow the different types of reporters the maximum flexibility in determining the processes they will follow in conducting their proceedings, we agree that the current definition is too broad and should provide more guidance. As a result, we changed the definition of "formal proceeding" to include proceedings that are taken by entities or organizations that maintain defined rules, policies, or procedures for such proceedings. We believe this definition of "formal proceeding" provides reporters with enough information to be able to distinguish between informal and formal proceedings. In determining whether a process is formal, we are only concerned with the presence of defined rules, policies or procedures and not whether the rules, policies and procedures have been strictly adhered to. To the extent disputes arise regarding whether a process is formal (for instance during the Secretarial Review process), the NPDB will not generally examine whether the defined rules, policies or procedures have been followed.

Comment: Two commenters asked why the due process requirements for a "formal peer review process" under 42 U.S.C. 11112 do not apply to adverse actions reported under section 1921. We received other comments requesting that we include a due process provision in the "formal proceeding" definition. These commenters stated that the proposed definition does not ensure due process protections for health care practitioners reported under section 1921.

Response: The provision under 42 U.S.C. 11112 cited by several commenters refers to due process standards for professional review activities undertaken at a hospital or other health care entity. Hospital and other health care entity professional review activities must meet these standards if the entities wish to avail themselves of the Federal liability protections described in 42 U.S.C. 11111. These standards do not affect the NPDB reporting requirements. Therefore, it is consistent for these standards not to apply to section 1921 reporting requirements.

While the professional review provisions under 42 U.S.C. 11111 do not apply to section 1921, as several commenters noted, licensing agencies operating under State law must provide due process protections for those they regulate. Therefore, it is the formal

proceedings conducted by private accreditation and peer review organizations that appear to be of greatest concern. To address this concern, we have modified the definitions of "peer review organization" and "private accreditation entity" to include provisions regarding the presence of due process mechanisms. If a peer review organization or private accreditation entity does not make due process available, the entity does not meet the respective definition. As stated earlier, the NPDB is concerned only with the presence of due process mechanisms, *i.e.*, defined rules, policies or procedures and not whether the rules, policies and procedures have been strictly adhered to.

Comment: One commenter requested that HRSA modify the definition of formal proceeding to include proceedings "taken at the request of" a State licensing or certification authority, peer review organization or private accreditation entity.

Response: Section 1921 does not include the authority to collect actions taken or findings made by organizations or bodies other than those specified in the statute.

2. Negative Action or Finding

We received 20 comments concerning the definition of negative action or finding by a State licensing authority, peer review organization, or private accreditation entity. We organized these comments according to the reporting requirements of the three sections of the definition: private accreditation organization, peer review organization, and State licensing authority.

Comment: The majority of comments concerning negative actions or findings reported by private accreditation entities (*i.e.*, receipt of less than full accreditation from a private accreditation entity that indicates a substantial risk to patient safety and health care quality) suggested the elimination or limitation of the reporting requirement for private accreditation entities. Several commenters stated that the adoption of the proposed rule would have an adverse effect on health care quality because it would deter facilities from participating in accreditation programs, which are primarily voluntary. Two commenters compared the role of private accreditation organizations to that of QIOs and supported their exemption from reporting based on the same rationale used to exempt QIOs. Others, citing the dynamic nature of the accreditation process in which preliminary or conditional decisions can change quickly, recommended

narrowing the scope of reportable actions to include only final outcome determinations, such as a withdrawal or termination of accreditation status or a denial of accreditation status. One commenter requested that the actions be further limited to those actions due to an immediate threat or harm to patients, rather than the proposed "substantial risk to the safety of a patient or patients or quality of health care services." In addition, this commenter suggested the exclusion of actions based solely on administrative determinations.

Response: Unlike QIOs, which were not specifically named as reporters in section 1921, the statute clearly requires private accreditation entities to report. HRSA, however, agrees that the collaborative and continuous nature of the accreditation process could prove difficult for private accreditation organizations by creating a potential for the submission of multiple reports on a health care entity that is not fully compliant with the particular private accreditation organization standards for reasons other than a threat to patient safety. Therefore, we modified this part of the negative action or finding definition to require the reporting of final determinations of denial or termination of an accreditation status that indicates a risk to the safety of a patient(s) or quality of health care services. We believe limiting private accreditation organization reporting to these final actions would streamline the reporting process, would not have a negative impact on voluntary accreditation efforts, and would meet section 1921 reporting requirements.

By limiting reporting to those negative actions or findings that indicate a risk to patient safety or quality of health care services, we believe we have precluded the reporting of negative actions or findings based solely on administrative reasons. We disagree with the comment to modify the definition to reporting based on immediate threat or harm to a patient. This language is likely to result in uneven interpretation and reporting by accreditation entities and would severely limit reporting.

We also changed the definition to require reporting of those final determinations that are based on "a risk" to patient safety as opposed to "a substantial risk" to ensure more uniform understanding and reporting of these actions as well as more consistent enforcement of the reporting requirement.

Comment: With respect to negative actions or findings reported by private accreditation entities, one commenter expressed concern that reporting by private accreditation entities to the

NPDB would undermine physician self-governance by reporting physician infractions unrelated to medical competence.

Response: Under section 1921, private accreditation entities would only report final actions related to the accreditation of health care entities. Physicians, dentists, and other health care practitioners would not be subjects of these reports.

Comment: Nine organizations raised concerns about the requirement for peer review organizations to report any negative actions or findings to the NPDB under section 1921. Several commenters stated that requiring the peer review committee to report sanctions would have a chilling effect on the peer review process in a hospital. The commenters stated that the peer review conducted by a hospital or professional society peer review committee is a confidential process and that these committees should be exempt from reporting under section 1921. Another commenter stated that professional societies are not peer review organizations. One commenter stated that peer review organization reporting would not have an effect on the hospital peer review process.

Response: Section 1921 requires the reporting of "any negative action or finding" by a peer review organization. Therefore, it would be inappropriate to exclude the reporting of "any negative action or finding" by peer review organizations. For purposes of section 1921 reporting, the term "peer review organization" does not include the internal peer review committees of hospitals, professional societies, or other health care entities as defined in the current NPDB regulations. Peer review organizations are separate from the internal peer review committees of hospitals and professional societies. According to the definition, a peer review organization is an "organization" whose primary purpose is to evaluate the quality of patient care and services against objective criteria that define acceptable and adequate practice through an evaluation by a sufficient number of health care practitioners to ensure adequate peer review. This requires that the peer review organization be a stand-alone organization separate from a hospital or other health care entity.

Comment: Several commenters recommended limiting peer review organization reporting to recommended sanctions that indicate a substantial risk to patient safety or quality of care. Other commenters noted that State laws require peer review organizations to report more serious findings to State licensing agencies, making it likely that

the NPDB would already capture this information in a subsequent licensure action. One commenter stated that peer review organizations that contract with health care facilities do not recommend sanctions; they recommend improvements.

Response: We agree that peer review organizations identify and recommend opportunities for practitioner improvement and generally do not recommend sanctions. The health care entities themselves (e.g., their peer review committees or boards) would use this information to make the decision to sanction a health care practitioner. Further, we believe that a sanction recommended by a peer review organization would occur in extremely rare instances, likely when there is an immediate threat to patient health or safety. Consequently, we believe that we do not need to modify the negative action or finding definition as suggested by the commenter.

Comment: Several commenters requested that reportable actions be limited to final actions that are afforded due process. They stated that, since peer review organizations make recommendations for action and the recommendations may be acted upon by another agency or organization, peer review organizations should not be required to report.

Response: We agree that peer review organizations may make recommendations for another entity to take an action and do not take or enforce actions themselves. Therefore, they do not take final actions. The presence of a due process mechanism, however, is a hallmark of peer review organizations and private accreditation entities and can provide greater validity to the information reported. As stated earlier, we addressed this concern by modifying the definition of "peer review organization" to include provisions requiring the presence of due process mechanisms.

Comment: One commenter requested clarification of the term "sanction" as it relates to reporting sanctions recommended by peer review organizations.

Response: In the context of section 1921, a sanction is a recommendation by a peer review organization concerning a health care practitioner, physician or dentist that, if adopted by the hospital or health care entity, would negatively affect the status of that individual. For example, if a peer review organization make a recommendation that, if adopted, would adversely affect the clinical privileges of a physician, the recommended sanction would be reportable to the NPDB.

Comment: We received a wide range of comments concerning negative actions or findings taken by licensing and certification authorities (*i.e.*, any negative action or finding that is publicly available, excluding administrative fines or citations, and corrective action plans unless they are: (1) Connected to the delivery of health care services, and (2) taken in conjunction with other licensure or certification actions). Several commenters stated the definition was too broad and would generate a large volume of reports with little value. They recommended that the definition be limited to actions or findings based on patient safety and quality of care issues, or based on professional competence or conduct. Conversely, other commenters thought the definition was too restrictive, gave licensing bodies too much latitude in deciding what to report, and would exclude important information regarding a practitioner's fitness to practice. One of these commenters stated that licensing boards have a unique role in consumer protection and that HRSA should modify the definition to include any action taken by a licensing authority that finds a violation of a statute or regulation and is a matter of public record. Another commenter requested that we modify the definition so that administrative fines or citations and corrective action plans are reportable if they are either related to the delivery of health care services or taken with another reportable action.

Response: Section 1921 states that State licensing agencies must report "any negative action or finding" without any limitation other than the action or finding must result from a formal proceeding. We agree with commenters that further limiting reporting to negative actions or findings based on competence or conduct, or quality of care issues, would create a subjective standard that unnecessarily exempts important information and may lead to uneven interpretation and reporting by licensing agencies.

After consideration of comments suggesting that the proposed definition is too restrictive and describing the unique consumer protection role played by State boards, we modified the definition regarding the reporting of administrative fines or citations, and corrective action plans. This modification includes the collection of those actions or findings if they are either (1) related to the delivery of health care services or (2) taken with another reportable action. The definition in the proposed rule mandated that both requirements be

met. While we do not wish to collect administrative fines and citations, or corrective action plans that are imposed for reasons unrelated to health care delivery (such as a fine for failing to notify a board of an address change in a timely fashion), we believe that if such an action is related to the delivery of health care services by a health care practitioner, physician, dentist, or health care entity, it should be reported. Such an action or finding should not have to meet the additional requirement of being taken in conjunction with another action. This modification to the definition creates a slight difference with the HIPDB definition; however, we believe that this change is important to ensure that meaningful actions are not excluded from reporting.

We disagree that the definition gives licensing authorities too much latitude in deciding which actions to report, as they are currently required to report any negative action or finding that is publicly available, with the previously stated exceptions for administrative fines or citations, and corrective action plans. These fines, citations and corrective action plans are limited to those related to health care delivery to ensure that they are meaningful to queriers. It is for this same reason we disagree with the proposal to require reporting of all violations of statute or regulation that are a matter of public record. In addition, we are obligated to try to maintain consistency with HIPDB reporting requirements, and this proposed definition would create a substantial difference between section 1921 and HIPDB State licensure reporting requirements.

In addition to this change in the definition, HRSA is making a minor grammatical change to the definition. In the proposed definition, we misplaced a comma. That comma should have appeared after "administrative fines or citations," rather than between those two terms. In the final rule, we moved the comma to its intended place.

Comment: One commenter stated that HRSA should limit reporting of licensure actions to final actions.

Response: We disagree with this comment. HRSA's interaction with State licensure authorities revealed that, within the operation of State licensure authorities, there are instances when temporary actions, *i.e.*, summary or emergency limitation or restriction on license, are necessary to prevent imminent danger to the public. Temporary actions are treated differently than other actions in that procedural rights of the practitioner are provided following the action, rather than preceding it. Further, HRSA opines

that the reporting of temporary actions is in keeping with the purpose of the NPDB, which is to protect the public from the threat of incompetent practitioners continuing to practice without disclosure or discovery of previous damaging or incompetent performance. In addition, the statute does not limit licensure actions to those that are final actions. Currently, licensure actions reported to the NPDB are not limited to final actions.

Comment: One commenter expressed concern about whether the negative action or finding definition would require licensing authorities to report the referral of a practitioner for impairment monitoring or participation in a diversion program. The commenter stated that HRSA should either withdraw the definition or clarify that such referrals are "corrective actions," and agreed with another commenter that corrective actions should only be reported when taken with another reportable action.

Response: Current policy guidance for reporting NPDB and HIPDB licensing and certification actions specifically excludes reporting of agreements that impose monitoring of a practitioner for a specific period of time, unless such monitoring constitutes a restriction of the practitioner's license or is considered to be a reprimand. Since we do not believe that the referral of a practitioner for impairment monitoring or participation in a diversion program are adverse actions under the statute and therefore not reportable, we will continue this policy under section 1921. It is up to each licensing authority to determine whether the actions they take are "corrective actions," which, based on the definition change mentioned previously, are reportable if they are publicly available and are either related to the delivery of health care services or taken in conjunctions with another reportable action.

Comment: One commenter recommended expanding the definition to include negative actions "taken at the request of" a licensing or certification authority.

Response: Section 1921 does not include the authority to collect actions taken or findings made by organizations or bodies other than those specified in the statute.

Comment: Two commenters requested that HRSA specify what types of negative actions or findings, particularly what types of administrative penalties, should be reported under the definition of negative action or finding.

Response: The type of reportable negative action or finding by a State licensing authority includes any action

or finding that is publicly available and rendered by a licensing or certification authority. Administrative fines or citations, and corrective action plans, are excluded unless they are: (1) Connected to the delivery of health care services or (2) taken in conjunction with other licensure or certification actions.

Reportable actions, by statute, must be based on the result of formal proceedings and events unrelated to such proceedings would be excluded. The types of negative actions or findings likely will vary from State-to-State.

Comment: With respect to all negative actions or findings reported under section 1921, one commenter requested that the Secretary limit all reportable negative actions and findings to those that last longer than 30 days. Such a restriction exists for clinical privileges actions reported to the NPDB under the HCQIA.

Response: Under the HCQIA, only adverse actions against clinical privileges are limited to actions that last more than 30 days. This limitation does not apply to the other reportable actions under the NPDB. Consequently, section 1921 does not limit the reporting of negative actions or findings to any particular time period. To place a 30-day restriction is not consistent with the statute and current NPDB and HIPDB reporting requirements for licensure and other actions.

3. Organization Name

Comment: One commenter requested that HRSA clarify the nature of the employment organization relative to information that must be reported in § 60.9. The commenter asked whether HRSA intended to collect the name of the employer at the time of the act or omission that led to the reported action.

Response: This information is collected currently by both the NPDB and the HIPDB, and the intent is to collect the name of the employer of the physician, dentist, or other health care practitioner at the time of the act or omission that led to the reported action.

4. Peer Review Organization

Comment: In response to our request for comments concerning peer review organizations, including the exemption of QIOs from reporting under section 1921, four commenters responded that QIOs should be exempt from the reporting requirements of section 1921(a)(1) based on the rationale provided in the NPRM. One commenter stated that if QIOs are, in fact, peer review organizations, they should not be exempted from reporting. The commenter, however, agreed that the rationale to exempt QIOs from reporting

was reasonable. One commenter responded that QIOs should not be exempted from reporting, stating that if private accreditation organizations are required to report, then QIOs should be required to report as well.

Response: Section 1921 does not specifically include QIOs in the peer review organization definition. Section 1921(a)(1) refers to reporting of proceedings by “any peer review organization.” Yet, section 1921(b)(4), when discussing who may have access to information, refers to “utilization and quality control peer review organizations described in Part B of Title XI * * *” (currently referred to as QIOs). This indicates that the earlier reference to “any peer review organization” does not refer to “utilization and quality control peer review organizations” as described in Part B of title XI.

With respect to linking QIO reporting to private accreditation entity reporting, we disagree with this contention. Section 1921 specifically requires that private accreditation entities report to the NPDB. The statute does not specifically require QIO reporting. In addition, the reporting of QIO sanction recommendations to the NPDB will significantly interfere with the critical mission of the QIO program, which focuses on maintaining collaborative relationships with providers and practitioners to improve the quality of health care services delivered to Medicare beneficiaries. Private accreditation entities do not have this specific mission.

Based on these reasons and in light of the support for the QIO exclusion from this definition in the proposed rule, we have decided to maintain this exclusion in the final rule.

Comment: Two commenters stated that the definition of “peer review organization” should be amended to include language assuring that peer review organizations reporting to the NPDB are those that provide due process to their physician participants and that a physician has had ample opportunity to appeal the peer review organization’s findings. Additional provisions such as these would provide at least minimal assurance of the quality of information considered and the fairness of the fact-finding process.

Response: We concur with these comments and have added language regarding the presence of due process to the definition. As stated earlier, while the professional review provisions under 42 U.S.C. 11111 do not apply to section 1921, as several commenters noted, licensing agencies operating under State law must provide due

process protections for those they regulate. Therefore, it is the formal proceedings conducted by peer review organizations and private accreditation that are of the greatest concern.

To address this concern, we have modified the definitions of “peer review organization” and “private accreditation entity” to include provisions regarding the presence of due process mechanisms. If a peer review organization or private accreditation entity does not make due process available to practitioners and entities, respectively, the entity does not meet the definition.

For purposes of reporting, the NPDB is only concerned with the presence of a due process mechanism and not whether due process has been strictly adhered to. To the extent disputes arise regarding whether due process has been provided (for instance during the Secretarial Review process), the NPDB will not generally examine whether the due process rules of any particular entity have been followed or the extent to which particular practitioners had access to such mechanisms.

Comment: We received comments requesting that patient safety organizations (PSOs), as defined by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), and programs that are operated by payers (e.g., pay-for-performance or value-based purchasing programs), be excluded from the definition of peer review organizations. One commenter stated that the proposed rule was inconsistent with the Patient Safety Act and would hamper patient safety organization activities.

Response: We do not feel that the rule is inconsistent with the Patient Safety Act nor will it hamper PSO activities. We do not believe that a specific exclusion from the definition of peer review organizations is necessary since we do not expect PSOs to take any reportable actions under this regulation. The only actions that a peer review organization must report to the NPDB are recommendations to sanction a health care practitioner, physician or dentist. By contrast, PSOs, defined in section 921(4) of the Public Health Service Act (42 U.S.C. 299b–21(4)), in order to properly carry out their mandatory patient safety activities in accordance with the Patient Safety Act, are to use data and reports they develop to “encourage a culture of safety,” which is understood to mean using the data they receive and develop into reports to create an environment in which errors and close calls will be readily reported by providers and thoroughly discussed

without fear of penalty or an increased risk of liability. Accordingly, it would be inconsistent with PSO commitments made to the Secretary pursuant to section 924(a) and 921(5) of the Public Health Service Act to make sanction recommendations regarding providers and therefore there would be no crossover with this regulation mandating peer review organization reporting responsibilities with the separate and distinct objectives and responsibilities of PSOs, as set forth in the Patient Safety Act.

We also do not feel that an exception is appropriate for programs that are operated by payers. QIOs were excluded from the definition of peer review organization because of the statutory distinctions between peer review organizations and QIOs in section 1921 and differences in the missions of those organizations. There is no similar statutory distinction between peer review organizations and programs that are operated by payers in section 1921 and we do not feel that the mission of programs operated by payers justify such an exclusion as with QIOs.

5. Private Accreditation Entity

Comment: We received two comments requesting clarification of this definition. One of these commenters asked HRSA to confirm that organizations that accredit educational programs do not meet the requirements of the "private accreditation entity." The other commenter requested that organizations that accredit mammography screening facilities be exempted because a Federal accreditation program currently exists to regulate this type of accrediting organization.

Response: The definition of the term "private accreditation entity" includes only those organizations that meet the requirements of the definition. Private accreditation entities are only required to report actions concerning health care entities. If a private accreditation entity accredits organizations other than those that meet the definition of the term "health care entity," such as purely educational programs, then any actions taken against those organizations would not be reportable.

Reporting information to another government agency instead of the NPDB does not fulfill an entity's obligations under section 1921. Section 1921 does not provide an exclusion from reporting to the NPDB for organizations that may report to other government agencies.

Comment: One commenter stated that at least a dozen organizations would meet the definition of a private accreditation entity and requested that

HRSA ensure these organizations comply equally with section 1921 reporting requirements.

Response: HRSA agrees with the commenter and expects entities that are required to report to the NPDB will do so in accordance with section 1921 requirements. In addition, HRSA will monitor compliance with these reporting requirements as it does currently with NPDB and HIPDB reporting requirements.

6. Voluntary Surrender

Comment: We received several comments concerning the voluntary surrender of a license and a notice of an investigation. These commenters raised concerns regarding the nexus between a notice of investigation and a subsequent voluntary license surrender to imply either wrongdoing or negligence. One commenter recommended that "notification of investigation" be stricken from the definition of voluntary surrender.

Response: The NPDB is primarily a flagging system intended to facilitate a comprehensive review of the credentials of a health care practitioner, physician, dentist or entity. An NPDB reported action serves to alert users that a careful review of the past actions of a health care practitioner, physician, dentist or entity may be prudent. NPDB information is intended to be used in combination with information from other sources, which is consistent with the prevailing credential verification and professional review standards within the healthcare delivery industry.

We disagree with the comment requesting that voluntary surrenders after notification of an investigation be excluded from the voluntary surrender definition. In an effort to ease the reporting burden and to make the information contained in both the HIPDB and NPDB as useful as possible for queriers, HRSA has attempted to make the reporting requirements under the HIPDB and NPDB as uniform as possible. The definition of voluntary surrender is based on the definition currently used in the HIPDB. In addition, reporting voluntary surrenders after notification of investigation eliminates a loophole in which a health care practitioner, physician, or dentist surrenders his or her license to avoid possible disciplinary proceedings and a subsequent report to the Data Banks. If these voluntary surrenders are not reported to the NPDB, health care practitioners, with potentially questionable histories, would be able to move from state-to-state without detection. Therefore, HRSA has

maintained the "notification of investigation" language in the final rule.

It is important to note that the definition of the term "voluntary surrender" applies only to State licensing actions reported under section 1921 and does not apply to actions reported under the HCQIA. To avoid confusion among entities that report surrenders under the HCQIA, such as hospitals reporting surrenders of clinical privileges, we have modified this term as it appears in § 60.3 of the regulations, from "voluntary surrender" to "voluntary surrender of license."

Comment: We received several comments supporting the exclusion of non-disciplinary voluntary surrenders from the proposed rule. One commenter requested that the reporting requirement for exclusion of late license renewals be more plainly stated.

Response: A State licensing authority's determination that a health care practitioner, physician, or dentist or entity has voluntarily surrendered his, her or its license because of non-payment or belated payment of renewal fees would not be reportable unless the surrender occurred after a notification of investigation, was done in exchange for a decision by the licensing authority to cease an investigation, or otherwise satisfies the requirements of the voluntary surrender definition. We attempted to maintain consistency with the HIPDB definition of "voluntary surrender" and the HIPDB exclusion of non-renewals for non-payment of fees. While there are some slight differences in language between the two regulations, we view these two definitions as containing the same requirements.

Comment: One commenter requested clarification that a voluntary surrender of a license will not preclude a State licensing authority from continuing or initiating a disciplinary action.

Response: A State's reporting obligations under section 1921 have no impact on the State's authority to continue or curtail disciplinary action, which is dependent upon the State's rules.

Comment: We received several comments recommending that HRSA clarify the differences between "involuntary surrenders" and "voluntary surrenders." One commenter suggested that HRSA establish a clear distinction between truly voluntary license surrenders, involuntary license surrenders and license revocations, with separate definitions and reporting categories for each. The commenter urged HRSA to make mandatory reporting of information on all voluntary or involuntary surrenders and

non-renewals of licenses, including those occasioned by non-payment of licensure fees, a change to inactive status, or due to retirement.

Response: We disagree with these comments. Section 1921 and section 1128E both require reporting of any loss of license, including a loss for the reason of a voluntary surrender. During the public comment period for the section 1128E proposed rule, we received public comments concerning this same definition of voluntary surrender. Commenters, particularly licensing authorities, expressed concern regarding the volume of reports that would have to be submitted if all surrenders of license—including those due to retirement or non-payment of fees—were reportable and the value of these non-disciplinary related surrenders to queriers. At that time, it was determined that voluntary surrenders for reasons such as retirement and non-payment of licensure renewal fees would provide little value to Data Bank users and that such actions would not be collected. Distinctions between voluntary and involuntary surrenders have not been an issue for those reporting such actions to the HIPDB, and we do not think such distinctions are warranted at this time. To ensure consistency between section 1921 and HIPDB reporting requirements, we will maintain this definition of voluntary surrender for both Data Banks.

Comment: One commenter expressed concern about a potential conflict between the reporting of a negative action or finding that under State law is publicly available information and a “voluntary surrender after a notification of investigation or a formal official request” to surrender the license. The commenter believed that many reportable voluntary surrenders may be based on non-public investigative information and, therefore, not reportable. The commenter requested clarification of the definition of a reportable voluntary surrender to include surrenders regardless of whether they are based upon a notification of investigation, or request, or agreement that is publicly available.

Response: We believe there is no conflict between reporting a negative action or finding that is publicly available and a voluntary surrender that is based on information that is not publicly available. Voluntary surrenders are reportable even if the underlying reasons for the surrender are not public information. However, voluntary surrenders relating to retirement, non-payment of licensure renewal fees, and change to inactive status, if there is not

an investigation in progress, are not reportable.

We did not receive any comments on the definitions of the terms “affiliated or associated,” “organization type,” or “Quality Improvement Organization.”

How Information Must Be Reported (§ 60.4)

Comment: We received several comments supporting the integration of the electronic reporting and querying system for the NPDB and the HIPDB, which enables reporting entities to submit a single adverse action to both Data Banks, as appropriate. One commenter, however, questioned the need for two systems if all of the information is automatically sent to both with a single query or report submission.

Response: The NPDB and the HIPDB are separate and distinct repositories, with different types of reportable actions contained in each, as well as different sets of authorized queriers. However, this distinction notwithstanding, the NPDB and the HIPDB form one integrated system. Within this integrated system, an action reportable to both the NPDB, including section 1921 and the HIPDB, will only need to be reported once. The system will subsequently store the report according to the appropriate statutory authority. Additionally, an eligible querier that is registered to have access to information under both Data Banks can query for information through a single request.

When Information Must Be Reported (§ 60.5)

Comment: One commenter stated the 15-day timeframe to report to a State is not a reasonable amount of time for reporting information. We also received comments expressing concern over the need to report to individual States rather than directly to the NPDB.

Response: We feel that the 15-day timeframe is a reasonable amount of time for reporting information. Currently, health care entities have 15 days to report actions to the Data Banks. This procedure has been in place since the implementation of the NPDB and we have not received notice of any concerns from users. Consequently, we feel it is appropriate to use this timeframe with section 1921. Further, since the development of electronic reporting technology, entities now submit reports directly to the NPDB using the Data Bank’s electronic reporting system. The Data Banks’ electronic reporting system enables reporting entities to satisfy reporting obligations to State licensing authorities

by automatically providing a copy of the report for submission via mail or fax to the appropriate State Board.

Comment: One commenter requested clarification of the penalties for failure to report to the NPDB.

Response: Current regulations specify the penalties for failing to report information to the NPDB under the HCQIA. For State licensing authorities that fail to report licensing actions, § 60.8 (c) states that “[i]f, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board has failed to submit a report as required by this section, the Secretary will designate another qualified entity for the reporting of information under § 60.9” (redesignated as § 60.11). There are no additional penalties specified under section 1921 for failure to report.

Reporting Errors, Omissions, and Revisions (§ 60.6)

Comment: One commenter questioned how HRSA would handle reports on hospital subjects that changed ownership or discontinued operation or services. The commenter suggested that HRSA should specify how a report would be updated when the information is no longer meaningful given a change in hospital circumstances.

Response: The Data Banks provide several methods to update identifying information. If the subject of a report determines that reported information concerning the subject is no longer accurate, the subject should first contact the reporting entity to request that the entity submit a correction report with the updated information. Also, the subject may provide more current information, such as a name change, to the Data Banks. In addition, the subject may submit a subject statement for the report. This statement could note the change in ownership or other change in status since the report was filed. However, reporting entities are responsible for ensuring the accuracy of the information contained in any report they submit.

Reporting Licensure Actions Taken by Boards of Medical Examiners (§ 60.8)

Comment: Two commenters requested that §§ 60.8 and 60.9 of the NPDB regulations be revised to include other health care practitioners in addition to physicians and dentists. These commenters requested that adverse clinical privileges actions taken against other health care practitioners be made mandatory instead of voluntary. One commenter stated that the current regulations do not adequately protect consumers and health care facilities

from health care practitioners who have had actions taken against their licenses or clinical privileges.

Response: As indicated in the proposed rule, the current regulations governing the NPDB, which are not expanded or modified by section 1921, are not subject to review and comment. Consequently, neither the reporting requirements for licensure actions taken by Boards of Medical Examiners under § 60.8 nor the reporting requirements for clinical privileges under § 60.9 (redesignated as § 60.11) are not expanded or modified by section 1921 and, therefore, are not subject to review and comment. The reporting requirement of the new § 60.9 (as added by section 1921) requires the reporting of adverse licensure actions taken against health care practitioners, physicians, dentists, and entities (health care facilities). This revision to the NPDB enhances consumer protection and patient safety.

Reporting Licensure Actions Taken by States (§ 60.9)

Comment: Two commenters requested information about the types of licensure actions to be reported to the NPDB and the HIPDB. One commenter asked whether data elements used for reporting to the NPDB and the HIPDB will have the same definitions and whether the NPDB and HIPDB will use the same violation and action codes for reporting. Another asked for examples of the new types of licensure actions to be collected by the NPDB and also requested that nominal or ministerial acts or omissions not be reported.

Response: State licensing authorities will use the same reporting formats, data element definitions, and code lists they currently use for reporting licensure actions to the HIPDB for reporting section 1921 licensure actions. Examples of NPDB licensure actions that will be reportable under section 1921 that are not currently reportable under the HCQIA include formal or official actions, such as revocations, suspensions and reprimands that are not based solely on professional competence or conduct. Under section 1921, the NPDB also will collect publicly available negative actions or findings, including fines or citations for reasons related to the delivery of health care services or taken with another action. HRSA will provide additional examples of reportable actions in forthcoming policy guidance.

In keeping with our commitment to maintain consistency between NPDB and HIPDB reporting formats, we are changing the status of the data element "Amount of Monetary Penalty" from "if

known" to "mandatory" when the reported action consists of a monetary penalty. This field is mandatory on the HIPDB reporting format for monetary penalties reported by State licensing agencies and was inadvertently listed as "if known" in the proposed rule.

We disagree with the suggestion to exclude actions that are based on "nominal or ministerial acts or omissions." Implementing this suggestion would likely lead to uneven interpretation among States and create a discrepancy between section 1921 and HIPDB definitions. We have limited the reporting of certain types of negative actions or findings, such as administrative fines or citations, and corrective action plans, to those either based on the delivery of health care services or taken with another action. We believe these limitations would ensure that meaningful actions are reported, which appears to be the commenter's goal, while maintaining as much consistency as possible with the HIPDB.

Comment: Concerning information reported on all subjects, one commenter expressed uncertainty over the purpose of collecting the narrative description of acts or omissions. The commenter noted that, for purposes of flagging individuals for additional scrutiny, a narrative is not needed, and that it was not practical for use in research.

Response: As specified in both the HCQIA and 1128E, "a description of the acts or omissions or other reasons for the action" is information that must be reported to the NPDB and the HIPDB. In instances in which the statute clearly defines a requirement, HRSA does not have the authority to make any modifications. In order to maintain consistency between the NPDB and section 1921, we have retained the narrative description on the reporting format for section 1921. In addition, we believe a narrative description adds value to a flagging system. The narrative description is critical to understanding the reasons for and importance of a particular action for subsequent reviewers of the report as well as the subject of the report, who has a right to challenge the accuracy of the report.

Comment: One commenter urged HRSA to include, within the scope of the proposed regulations, a requirement for mandatory reporting of prescribing psychologists, including a specific NPDB data reporting category.

Response: To the extent that prescribing psychologists meet the definition of a "health care practitioner," they are subject to reports under section 1921.

Comment: One commenter questioned whether a State licensing authority can take an action against a practitioner's license when the action is based on another State licensing authority determination.

Response: Section 1921 does not supersede the ability of a State to take an action against a practitioner or entity. States may take actions for any reason permitted in their own laws and regulations.

Reporting Negative Actions or Findings Taken by Peer Review Organizations or Private Accreditation Entities (§ 60.10)

Comment: One commenter requested that the Secretary limit accreditation report content to the information collected during the accreditation process so that accreditation entities can avoid costly software changes. Another commenter noted that certain accreditation entities post accreditation status on their Web sites, making additional reporting unnecessary.

Response: HRSA disagrees with these comments. We continue to believe the data elements selected for inclusion under section 1921 are essential for users to properly identify entities that are subjects of reports in the Data Bank and to understand the nature of the actions taken against them. We believe the required information should be available from information contained in existing records compiled during the review process. The NPDB makes available an electronic reporting format that can be completed online at the Data Banks' secure Web-based reporting site. A reporting entity that makes information available in other public formats has not met its statutory reporting obligations under section 1921.

Comment: Several commenters expressed concern about the reporting process. One commenter stated that it is unclear what specifically must be reported since the proposed rule includes discretionary and mandatory data elements (§ 60.9).

Response: The mandatory data elements are listed in § 60.9(b). The electronic system will not accept a report that does not include these data elements. Data elements to be reported "if known" are listed in § 60.9(c). The inclusion of these data elements enhances the matching process between a query and a reported subject and provides additional information to aid users' understanding of the reported incident.

Comment: One commenter requested that the Secretary modify the regulations to require private accreditation entities to report their

negative actions or findings to all State agencies responsible for licensing hospitals and health care entities.

Response: Adopting such a reporting requirement for private accreditation entities is unnecessary and would be overly burdensome. Queriers, including State licensing authorities, will have access to negative actions and findings reported by accreditation entities through the NPDB, which is a national repository.

Comment: Two commenters expressed concern about the reporting of a narrative description of the act or omission upon which the reported action was based. The commenters requested that HRSA provide detailed guidance on the type of information to be included in this narrative description.

Response: A narrative description of the act(s) or omission(s) should contain sufficient specificity to allow a knowledgeable Data Bank querier to clearly understand what led to the reported action or finding and the seriousness of the act(s) or omission(s). Narrative information also should be supported by written documentation, such as official findings, orders or minutes. HRSA has provided examples of acceptable narrative descriptions on the NPDB Web site (*npdb-hipdb@hrsa.gov*), along with guidance on how to write an acceptable narrative description and will continue to provide information as needed.

Comment: One commenter expressed concern that the proposed § 60.10 does not include the requirement that the reported action must be the result of formal proceedings (as defined in § 60.3) and requested that this omission be corrected in the final rule.

Response: The requirement that an action must be the result of a formal proceeding was omitted in error and has been included in the final rule.

Comment: One commenter asked whether a hospital would be required to report its own accreditation recommendations.

Response: Section 1921 does not require hospitals or other health care entities to self-report accreditation recommendations. In general, only the entity that takes a reportable action or finding must report the action or finding to the NPDB. The subject of the reportable action does not report the action.

Requesting Information From the NPDB (§ 60.13) [Redesignated]

Comment: Several commenters questioned whether a hospital is authorized to query on nurses and other health care practitioners who are

employed by the hospital. They believed the proposed rule only authorizes hospitals to query on individuals on the medical staff or those who hold clinical privileges. Another commenter questioned whether hospitals had access to section 1921 information at all.

Response: Section 1921 information is available to hospitals. Section 1921(b)(6) of the Social Security Act states that this information is available to "hospitals and other health care entities * * * with respect to physicians or other licensed health care practitioners that have entered into, or may be entering into, an employment or affiliation relationship with, or have applied for clinical privileges or appointments to the medical staff of, such hospitals or other health care entities * * *" The other licensed health care practitioners include individuals in professions such as nursing and physical therapy.

Comment: Several commenters expressed concern that private accreditation entities are not authorized to query and receive section 1921 information, which would support their evaluations of a health care entity's performance. Other commenters supported public access to NPDB information.

Response: The Secretary is not authorized to provide private accreditation entities, other organizations, or the general public access to NPDB information.

Comment: We received several comments questioning the range of law enforcement agencies permitted to query the NPDB under the proposed rule. In particular, commenters questioned the inclusion in the proposed rule of certain law enforcement agencies, such as the Nuclear Regulatory Commission and the U.S. Chief of Postal Inspector, not specifically included in the statute. One commenter noted that law enforcement access to section 1921 information would deter participation in quality and risk management procedures. We also received comments requesting that subjects of reports be informed when law enforcement agencies receive a copy of their report, and that law enforcement agencies should be required to state the purpose of their query and not use the NPDB to circumvent standard criminal investigative procedures.

Response: Section 1921(b) of the Social Security Act authorizes the Secretary to release information collected under the statute to "the Attorney General and such other law enforcement officials as the Secretary deems appropriate." The list provided in the proposed rule of agencies authorized

to receive section 1921 information under these provisions is not considered to be exhaustive. Each of the listed agencies, however, meets the qualifications described in the statute. For example, the U.S. Chief of Postal Inspector and State law enforcement agencies play a major role in investigating health care fraud and abuse in government health care programs. The Nuclear Regulatory Commission enforces regulations governing the medical use of nuclear materials and also licenses physicians, clinical laboratories and hospitals to possess and use nuclear byproduct materials. These agencies will not have access to professional review actions or medical malpractice information in the NPDB, but only section 1921 reports, so we do not believe their access should have any impact on quality and risk management activities.

Currently, all NPDB and HIPDB queriers are required to provide a reason for their information request on a particular subject. Also, the system records the name of each querying entity that has requested and received a copy of a report, information that is available to the subject of that report upon request, with the exception of queries submitted by law enforcement agencies to the HIPDB. Consistent with what was done with the HIPDB, HRSA will be seeking an exemption to protect from release law enforcement queries for section 1921 information. This is necessary in order to protect the confidentiality and integrity of investigations by law enforcement.

Confidentiality of National Practitioner Data Bank Information (§ 60.15)

Comment: One commenter expressed concern that NPDB information may be misused or misinterpreted. The commenter stated that punishment for improper access to or use of NPDB information should be greater than the penalties for failing to report mandatory actions. Other commenters expressed concern that information may be stored in the wrong Data Bank and requested assurances that Data Bank information is secure.

Response: Information reported to the NPDB is considered confidential and access to and use of the information is restricted. As stated in § 60.15, "persons who, and entities which, receive information from the NPDB either directly or from another party must use it solely with respect to the purpose for which it was provided." Both improper use of and access to the NPDB may result in a CMP of up to \$11,000 for each violation.

The NPDB and the HIPDB are required by statute to coordinate reporting and querying. Reported information is and will continue to be contained only in the legally authorized Data Bank(s) as determined by report content. Additionally, when the Data Banks receive a query on a subject, the system searches for and releases information stored in the NPDB and the HIPDB based on the querying entity's statutory authority to access that information. Eligible entities that register with the Data Banks must certify their authority as a reporter and querier under each of the relevant statutes governing the Data Banks. Authorized users interact with the Data Banks over a secure Web-based server that uses the latest technology, along with various implementation measures, to provide a secure environment for querying, reporting, and data storage. Some of these security features include firewall protection and encryption of transmitted data to prevent unauthorized access, as well as the use of unique passwords for data entry and retrieval. The system security plan is reviewed and updated annually to address changes in guidance or industry standards needed to continue providing secrecy and privacy for the system. In addition, every three years the NPDB–HIPDB is required under the Federal Information System Management Act (FISMA) to conduct and renew the system's Certification and Accreditation (C&A). The C&A process involves convening a panel of information technology professionals who conduct a security risk assessment, security test and evaluation, technical vulnerability assessment, and a Continuity of Operation Plan (COOP) exercise.

How To Dispute the Accuracy of National Practitioner Data Bank Information (§ 60.16)

Comment: Several commenters raised concerns that the proposed regulations did not include provisions for practitioners to rebut information in NPDB reports. Other commenters expressed concern over subjects' due process rights and requested that the Secretary provide health care practitioners meaningful opportunities to dispute the accuracy of claims reported to the NPDB and require the removal of inaccurate reports. One of the commenters stated that a subject who discovered incorrect or inaccurate information in the NPDB should have a right to require the NPDB or the reporting entity to correct the error.

Response: The NPDB currently has in place multiple levels of safeguards to

protect and ensure the accuracy of a report. Subjects may dispute the accuracy of information provided in reports to the NPDB. These safeguards will not change under section 1921.

Comment: One commenter stated that additional protections for health care practitioners other than physicians and dentists should be in place, such that an opportunity to dispute the accuracy of their information reported to the NPDB should be guaranteed before the information is submitted to the NPDB.

Response: The NPDB's safeguards to protect and ensure the accuracy of reports apply equally to all types of practitioners. All subjects of a report are treated equally and fairly by the Data Banks once a report is submitted. We do not have the statutory authority to review the merits of adverse actions taken by reporting entities. We can only review (1) if the report is legally required or permitted to be filed, and (2) if the report accurately depicts the action taken and the reporter's basis for the action. Although we understand the comment, the statute is clear that the Data Bank's responsibility is to receive and disclose information expeditiously and in accordance with statute.

B. Other Issues Raised

1. Implementation Schedule

Comment: We received two comments regarding the requirement to report all actions occurring since the enactment of section 1921. These commenters expressed concern about the extra burden State licensing agencies would face by having to report information dating back fifteen years and questioned the accuracy and availability of such information across States. One commenter questioned whether subjects of reports dating back to 1992 would have access to information to enable them to dispute reported actions, if necessary. One commenter requested that HRSA only require the reporting of actions taken on or after the publication date of the regulations.

Response: In § 60.5, the NPDB regulations state that information must be submitted beginning with actions occurring on or after January 1, 1992. However, while we recognize the commenters' concerns, we strongly encourage each reporter to submit actions occurring on or after January 1, 1992. To assist in reducing the burden on State licensing agencies, we will offer State agencies two options for submitting legacy HIPDB reports (August 21, 1996, forward) to the NPDB. One option is, with the States' permission, for HRSA to provide copies to the NPDB of all actions previously

reported to the HIPDB that fall under the section 1921 requirements. The second option is for the State agencies to resubmit all legacy HIPDB reports (August 21, 1996, forward) to the NPDB under section 1921. We also recognize the report subjects' concerns regarding their ability to dispute reports of actions taken more than a decade ago. However, the dispute resolution process (Secretarial review) is available to determine whether an action is reportable under applicable law and regulations. The process also determines whether the report accurately describes the reporter's action and reasons for the action as stated in the reporter's decision documents or in a public record, such as board orders.

2. Immunity Provisions of the HCQIA

Comment: One commenter recommended extending the immunity from liability protections (under 42 U.S.C. 11111) to all individuals reporting information concerning a health care practitioner, physician, dentist or entity under section 1921.

Response: Part A of Title IV (42 U.S.C. 11111) provides that the professional review bodies of hospitals and other health care entities, and persons serving on or otherwise assisting such bodies, are offered, in certain circumstances, immunity from private damages in civil suits under Federal or State law. It does not apply to reporting licensure actions or medical malpractice payments under the HCQIA, nor does it apply to section 1921 reporting. HRSA is unable to extend this immunity without a statutory amendment.

3. Paperwork Reduction Act Statement

Comment: One commenter expressed concern that section 1921 would create an increased burden on State licensing and certification agencies.

Response: Section 1921 does not create a new reporting burden for State licensing authorities. State licensure reporting requirements under section 1921 are essentially identical to those already being reported under the HIPDB. Because of the Data Banks' integrated reporting and querying system, State licensing agencies will only need to submit a licensing action once. The system will subsequently store the report according to statutory requirements in the NPDB, the HIPDB or both.

Comment: One commenter stated that peer review organizations do not have substantial resources and that the section 1921 reporting requirement would be burdensome.

Response: Information required to be reported by peer review organizations

should be minimal. We have received comments noting that peer review organizations generally recommend areas of improvement and do not recommend sanctions (the only type of reportable event for these organizations). Therefore, we believe their reporting requirements will not be overly burdensome.

Comment: One commenter stated that the proposed rule did not account for additional staff time responding to a greater volume of telephone calls resulting from increased access to reported State licensure discipline information.

Response: The licensing actions to be reported to the NPDB under section 1921 have already been or are required to be reported to the HIPDB. It is for this reason that we do not believe the volume of telephone calls resulting from these reports would constitute an added burden to State licensing boards.

Comment: One commenter recommended that HRSA amend the proposed rule to allow State licensing agencies and private accreditation entities that contract with and report to other Federal agencies to determine among themselves which agency will report to the NPDB, to further reduce reporting burden. This commenter expressed concern that section 1921 would alter its existing reporting relationship with another Federal agency.

Response: Statutes governing the NPDB and the HIPDB specifically state who must report and what must be reported to each Data Bank. A State licensing authority that takes a reportable action must report the action to the NPDB and/or the HIPDB. The statute will not alter existing reporting relationships between agencies or between agencies and their contractors.

IV. Summary of Revisions in the Final Rule

Based on our review and response to the array of public comments, and on the discretionary authority given to the Department under the statute, we have made the revisions to the proposed regulations outlined below. We believe these revisions will allow the NPDB to collect and disseminate information under section 1921 in an effective and efficient manner.

Section 60.2

- We are modifying the proposed change to the first sentence in § 60.2 to read “State licensing or certification authorities, peer review organizations, and private accreditation entities that take negative actions or findings against

health care practitioners, physicians, dentists, or entities.”

Section 60.3

- We are revising the definition of the term “formal proceeding” to read as follows: *Formal Proceeding* means a proceeding held before a State licensing or certification authority, peer review organization, or private accreditation entity that maintains defined rules, policies, or procedures for such a proceeding.

- We are modifying language in the definition of the term “negative action or finding” to limit the scope of actions or findings reported by private accreditation organizations. The sentence “Receipt of less than full accreditation from a private accreditation entity that indicates a substantial risk to the safety of a patient(s) or quality of health care services and includes, but is not limited to, denial of accreditation or non-accreditation;” is replaced by “A final determination of denial or termination of an accreditation status from a private accreditation entity that indicates a risk to the safety of a patient(s) or quality of health care services.”

- To ensure clarity of the range of reportable subjects, we are modifying the definition of the term “negative action or finding” to replace the sentence “Any recommendation by a peer review organization to sanction a practitioner.” to read: “Any recommendation by a peer review organization to sanction a health care practitioner, physician, or dentist.”

- We are revising the following sentence in the definition of the term “negative action or finding:” “This definition excludes administrative fines, or citations and corrective action plans, unless they are: (1) Connected to the delivery of health care services, and (2) taken in conjunction with other licensure or certification actions such as revocation, suspension, censure, reprimand, probation, or surrender.” In this sentence, we are replacing the “and” in between “connected to the delivery of health care services” and “taken in conjunction with other licensure * * *” with an “or.” Also in this sentence, we are deleting the “,” in “administrative fines, or citations” and adding a “,” after “citations” and before “and corrective action plans.”

- After the first sentence in the definition of the term “peer review organization,” we are adding a requirement that to qualify as a peer review organization for purposes of this rule, an organization must have due process mechanisms. This sentence reads: “The organization has due

process mechanisms available to health care practitioners, physicians, and dentists.” We also are changing the term “health care practitioners” in the first sentence to read “health care practitioners, physicians, or dentists.”

- We are adding a fourth element in the proposed definition of “private accreditation entity” to include an entity that “Has due process mechanisms available to health care entities.” We are also deleting the “and” at the end of the statement “Measures a health care entity’s performance based on a set of standards and assigns a level of accreditation;” and deleting the period at the end of the statement “Conducts ongoing assessments and periodic reviews of the quality of health care provided by a health care entity” and replacing it with “and.”

- For clarification purposes, we are changing the term “Voluntary surrender” to “Voluntary surrender of license.” Also, in the first and second sentences of the definition, we are changing the phrase “a health care practitioner or entity” to read “a health care practitioner, physician, dentist, or entity.”

Section 60.9

- In § 60.9(a), we are changing the phrase “a health care practitioner or entity (both as defined in § 60.3)” to read “a health care practitioner, physician, dentist, or entity (as defined in § 60.3).”

- In § 60.9(a)(2) through § 60.9(a)(4), we are changing the phrase “practitioner or entity” to read “health care practitioner, physician, dentist, or entity.”

- In § 60.9(a)(3) we are replacing the word “nonpayment” with “non-payment.”

- We are changing the phrase “health care practitioner” in §§ 60.9(b)(1), 60.9(b)(2), 60.9(c)(1), and § 60.9(c)(2) to read “health care practitioner, physician, or dentist.”

- We are deleting § 60.9(c)(4)(ii), the requirement to report the amount of any monetary penalty resulting from the reported action “if known,” and adding that requirement to § 60.9(b)(4)(iii). This change makes the reporting of this data element mandatory instead of discretionary.

Section 60.10

- We are adding a third sentence to § 60.10(a) to state that the actions taken must be as a result of formal proceedings (as defined in § 60.3).

- In section § 60.10(a), we are changing the phrase “health care practitioner or health care entity” to read “health care practitioner, physician, dentist, or entity.”

Section 60.13

- To clarify the range of subjects that may be queried on, we are changing the phrase “individual health care practitioner or entity” in the first sentence of paragraph (a)(2) of § 60.13 to read: “individual health care practitioner, physician, dentist, or entity.”

- We are changing the phrase “licensing health care practitioners and entities” in § 60.13(a)(2)(ii) to read “licensing health care practitioners, physicians, dentists, and entities.”

- In 60.13(a)(2)(iv), we capitalized the phrase “Medicaid Fraud Control Units.”

Section 60.14

- In § 60.14(a), we are changing the sentence “The amount of such fees will be sufficient to recover the full costs of operating the NPDB” to read “The amount of such fees will be sufficient to cover the full costs of operating the NPDB.” We are changing the word “recover” to read “cover” for clarification.

V. Regulatory Impact Statement

A. Regulatory Analysis

OMB has reviewed this final rule in accordance with the provisions of Executive Order 12866 and the Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601–612), and the Small Business Regulatory Enforcement Act of 1996, Public Law 104–121, which amended the RFA, and has determined that it does not meet the criteria for an economically significant regulatory action. In accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, we have determined that this rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of \$110 million or more, and that a full analysis under the Act is not required.

1. Executive Order 12866

HRSA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: having an annual effect on the economy of \$100 million, adversely

affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. Regulations are also considered a significant regulatory action if it raises novel legal or policy issues.

The Office of Information and Regulatory Affairs (OIRA) has designated this final rule a significant regulatory action under the Executive Order since it raises novel legal and policy issues under section 3(f)(4) of the Executive Order. OIRA concludes, however, that this rule does not meet the significance threshold of \$100 million effect on the economy in any one year under section 3(f)(1).

Consistent with section 1921, these regulations identify certain data elements for reporting that are mandatory and specify other discretionary data elements for reporting. Many of the mandatory and discretionary data elements set forth in this final rule are already collected and maintained on a routine basis for a variety of purposes by reporting entities, and should not result in additional costs or in new and significant burdens. After consulting with State representatives, we understand that States routinely collect and maintain much of this information. Many licensing boards routinely collect and report much of this information to national organizations such as the National Council of State Boards of Nursing, Federation of Chiropractic Licensing Boards, American Association of State Social Work Boards, Federation of State Medical Boards and the Association of State and Provincial Psychology Boards. In addition, State Survey and Certification agencies are required to report adverse information to CMS regarding certain health care entities. Moreover, this information is reported to the HIPDB under section 1128E. Actions that are reported under section 1128E will only need to be reported once; the NPDB–HIPDB system will automatically route these reports to both Data Banks. Further, private accreditation entities maintain information on Internet Web sites regarding health care entities that have undergone the accreditation survey process and their ensuing accreditation status. We are unaware of any peer review organizations that make available specific information relating to their reviews on their organization’s Web sites.

Since we recognize that some classes of reporters may not collect or maintain the full array of data elements contemplated for inclusion into the NPDB (e.g., other name(s) used or a DEA registration number), we are classifying

certain data elements to be reported “if known.” We do not intend to impose new or added burdens on reporters and are proposing to give reporters the option of omitting certain data elements that they do not maintain or to which they do not have access.

2. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HRSA to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Further, in accordance with the RFA, if a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. Therefore, we have defined small entities as peer review organizations, private accreditation entities and local health care practitioner and entity licensing boards; individuals and States are not included in this definition of small entities. We have determined that both the burden and costs associated with reporting to the NPDB will be minimal. According to leading private accreditation entities, (e.g., the Joint Commission, National Committee for Quality Assurance, Utilization Review Accreditation Commission and Commission on Accreditation of Rehabilitation Facilities), accreditation entities take approximately 11 negative findings or actions per year against health care entities. Based on a review of public comments, we estimate the potential volume of reporting by peer review organizations to be minimal. Most commenters that addressed the volume of such reports, while not providing specific estimates, stated that peer review organizations would rarely make the types of recommendations that would be reportable under these regulations. On this basis, we have determined that the data collection process will not have a significant impact on local government agencies, peer review organizations, private accreditation entities, and that this rule will not have a major effect on the economy or on Federal or State expenditures.

We estimate that the costs to entities that must report to the NPDB under section 1921 and those that opt to query under section 1921 will not approach the threshold of a major rule. In the burden estimate table which follows, the total cost of the section 1921 to users

is less than \$300,000 annually. This cost estimate does not include the cost of queries which the entity may file. The major reason for the low cost is that the majority of categories of reporters and potential queriers are already interacting with the NPDB and/or the HIPDB. These users are already familiar with the operation and procedures of the Data Banks. For instance, the State licensing authorities are currently reporting to the NPDB and/or the HIPDB. Reports required under section 1921 will be the same as those currently being made to the HIPDB, and filing one report, in almost all cases, will meet the reporting obligation for the NPDB, HIPDB and section 1921 of the enhanced NPDB. Hospitals and other health care entities are currently querying the NPDB regarding physicians and dentists, for these entities there would only be a small increase in administrative costs if they began to query on other hospital personnel such as nurses. Thus, the Secretary certifies that these regulations will not have a significant impact on a substantial number of small entities.

3. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4) requires that agencies assess anticipated costs and benefits for any rulemaking that may result in an annual expenditure of \$110 million or more by State, local, or tribal governments, or the private sector. In accordance with the UMRA, we have determined that the only costs are those related to the ability to transmit the information electronically (e.g., Internet service) and additional staff hours

needed to transmit information (which we believe will not be significant). We estimate an initial start-up cost of approximately \$500 per private accreditation entity. For this reason, we have determined that this rule does not impose any mandates on State, local or tribal government or the private sector that will result in an annual expenditure of \$110 million or more, and that a full analysis under the UMRA is not necessary.

4. Executive Order 13132

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has Federalism implications. In reviewing this final rule under the threshold criteria of Executive Order 13132, we have determined that this rule will not significantly affect the rights, roles, and responsibilities of State or local governments because the actions that are to be reported under section 1921 are already being reported to the HIPDB under 1128E.

B. Paperwork Reduction Act of 1995

The NPDB regulations contain information collection requirements that have been approved by OMB under the Paperwork Reduction Act of 1995 (PRA) and assigned control number 0915-0126.

This final rule also contains information collection requirements. As required by the PRA [44 U.S.C. 3507(d)], we have submitted a copy of this final rule to OMB for its review of these information collection requirements.

Collection of Information: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners.

Description: Information collected under §§ 60.9 and 60.10 of this final rule would be used by authorized parties, specified in the final rule, to determine the fitness of individuals to provide health care services, to protect the health and safety of individuals receiving health care through programs administered by the requesting agencies, and to protect the fiscal integrity of these programs. Information collected under §§ 60.6 and 60.16 would be used to correct reports submitted to the NPDB. Information collected under § 60.13 would be used to disseminate reports to individuals and entities eligible to query the NPDB.

Description of Respondents: State government authorities responsible for licensing health care practitioners, physicians, dentists, and health care entities, peer review organizations, and private accreditation entities reviewing the services of a health care practitioner, physician, dentist, or entity.

Estimated Annual Reporting: We estimate that the public reporting burden for the final rule is 10,429.48 hours. Each State is required to adopt a system of reporting to the Secretary certain adverse licensure actions taken against health care practitioners, physicians, dentists, and health care entities, and any other negative actions or findings by a State licensing authority, peer review organization, or private accreditation entity. The estimated annual reporting and querying burden is as follows:

Section No.	Number of respondents	Frequency of response	Number of responses	Hours per response	Burden hours	Hourly cost	Total cost
Errors and Omissions 60.6 (a) ¹	23	1	23	15 min	5.75	\$25	\$144
Revisions to Actions 60.6 (b) ¹	7	1	7	30 min	3.5	25	88
Licensure Actions 60.9 ²	0	0	0	0	0	0	0
Adverse Action 60.10 Private Accreditation Entities ³	11	1	11	45 min	8.25	25	206
Adverse Action 60.10 Peer Review Organizations ³	25	2	50	45 min	37.50	25	938
Queries: Agencies administering Federal health care programs 60.13 (a)(2)(i) ⁴	10	26	260	5 min	21.66	25	542
Queries: State Licensing Authorities 60.13(a)(2)(ii) ⁴	0	0	0	0	0	0	0
Queries: State Agencies 60.13 (a)(2)(iii) ⁴	51	20	1020	5 min	85	25	2,125
Queries: State Medicaid 60.13 (a)(2)(iv) ⁴	51	20	1020	5 min	85	25	2,125
Queries: Law Enforcement 60.13 (a)(2)(v) ⁴	262	1	262	5 min	21.83	25	546
Queries: QIOs 60.13 (a)(2)(vi) ⁴	51	5	255	5 min	21.25	25	531
Queries: Hospitals and other health care entities 60.13 (a)(2)(vii) ⁴	10,930	11	120,230	5 min	10,019.16	25	250,479
Self-Query 60.11(a)(2) ⁵	0	0	0	0	0	0	0
Entity Registration 60.3 ⁶	50	1	50	60 min	50	25	1,250
Entity Update 60.3 ⁶	25	1	25	5 min	2.08	25	52
Initial Request for Dispute of Report 60.16(b) ⁷	18	1	18	15 min	4.5	45	203

Section No.	Number of respondents	Frequency of response	Number of responses	Hours per response	Burden hours	Hourly cost	Total cost
Practitioner Requests for Secretarial Review 60.16(b) ⁷ .	3	1	3	8 hours	24	200	4,800
Subject Statements 60.16(b) ⁷	40	1	40	60 min	40	100	4,000
Total	11,557	123,183	10,429.48	268,029

¹ Although OMB has previously approved the burden under the HCQIA for the reporting of errors and omissions to information previously reported to the NPDB, section 1921 will expand the scope of the NPDB to include all health care practitioners and health care entities. However, licensure actions reported to the NPDB regarding health care practitioners, physicians, dentists, and health care entities are already reported to the HIPDB and, thus, were previously calculated in the burden estimates for the HIPDB. Therefore, the burden for correcting or revising NPDB licensure actions is not included in this regulation. Section 60.6 requires individuals and entities that report information to the NPDB to ensure the accuracy of the information. If there are any errors or omissions to the reports previously submitted to the NPDB, the individual or entity that submitted the report to the NPDB is responsible for making the necessary correction or revision to the original report. If there is any revision to the action, the individual or entity that submitted the original report to the NPDB is responsible for reporting the revision. Based upon corrections and revisions made under the HCQIA, we estimate that a total of 23 respondents will need to correct their reports each year and that a total of 7 respondents will need to revise actions originally reported each year. Based on experience with the NPDB, a correction is expected to take 15 minutes to complete and submit. A revision is expected to take somewhat longer (30 minutes) because it involves completing a portion of a new report form rather than just correcting the individual items that are in error. The costs associated with preparing corrections and revisions are estimated at \$25 per hour.

² Since § 60.9 requires each State to adopt a system of reporting to the NPDB disciplinary licensure actions, the various licensing boards within each State will be required to report such actions directly to the State licensing authorities. These same licensing boards already are responsible for reporting such actions to the HIPDB. Therefore, we calculate the annual reporting burden for State licensing boards under the HIPDB and not this regulation. As a result, the reporting burden for State licensing boards is not included in this regulation. We estimate that, under the HIPDB regulations, 40,400 reports will be submitted to both the NPDB and the HIPDB each year, for an average of 187 reports per State licensing authority and 22 reports per State licensing board. The costs associated with preparing licensure reports are estimated at \$25 per hour. The cost estimates for this burden are associated with the HIPDB.

³ Section 1921 requires each State to adopt a system of reporting to the NPDB any negative action or finding concluded against health care practitioners, physicians, dentists, and health care entities by a State licensing authority, peer review organization, or private accreditation entity. The negative actions or findings taken by State licensing authorities are already required to be reported to the HIPDB and were included in the HIPDB regulations. This regulation, therefore, includes the burden estimates only for those negative actions or findings taken by peer review organizations and private accreditation entities. We anticipate that there may be 25 peer review organizations that meet the definition proposed in this NPRM. Comments on the proposed rule indicate that peer review organizations will not often take the type of action or finding required to be reported in this regulation. Therefore, we estimate that on average these organizations would, at most, report a finding 2 times a year to the NPDB. We estimate that, under § 60.10, there will be approximately 11 private accreditation entities reporting on an average 2 times each during the year to the NPDB for a total of 50 reports. We have identified 11 organizations that meet the definition of a private accreditation entity. We believe that these entities will report an average of 11 actions per year. This estimation is based on changes in the final rule that limits reportable actions to final terminations and denials of accreditation. Based on experience with the NPDB, we estimate that it will take a peer review organization or a private accreditation entity 45 minutes to complete and submit an initial report. The costs associated with preparing reports are estimated at \$25 per hour.

⁴ Although OMB has previously approved the burden under the HCQIA for querying the NPDB, section 1921 authorizes additional entities, such as State Medicaid Fraud Control Units, Quality Improvement Organizations, and certain law enforcement officials to query the NPDB for disciplinary licensure actions, and other negative actions or findings concluded against health care practitioners, physicians, dentists, and health care entities. Based on current NPDB querying patterns, we estimate an approximate total of 123,183 new (section 1921—only) queries per year on health care practitioners, physicians, dentists, and health care entities. The costs associated with preparing these queries are estimated at \$25 per hour. This estimate excludes queries by State licensing authorities. State licensing boards that license health care practitioners already have access to NPDB information. Additionally, State licensing authorities that license health care practitioners and entities currently have access to the HIPDB, which not only contains the new types of licensing reports collected under section 1921, but also contains a range of other types of adverse actions. Because of the low volume of queries currently submitted by these authorities, we do not anticipate an increase in queries as a result of section 1921 implementation. All queries under section 1921 are voluntary.

⁵ Currently, self queries by health care practitioners are automatically submitted to both the NPDB and the HIPDB, and we anticipate the same policy will be in effect for health care entities when section 1921 is implemented. Therefore, self queries submitted to the NPDB by health care practitioners, physicians, dentists, and health care entities already are included in HIPDB burden estimates and are not included in this regulation. Since the burden and costs for preparation of self queries is contained in HIPDB no additional cost estimates are required by the implementation of section 1921. All self-querying is voluntary.

⁶ To access the NPDB, entities are required to certify that they meet section 1921 reporting and/or querying requirements. Consequently, an eligible entity must complete and submit an *Entity Registration Form* to the NPDB. Data collected on this form provides the NPDB with essential information concerning the entity (e.g., name, address, and entity type). Eligible entities (e.g., State licensing agencies, hospitals, or managed care organizations) that have access to the HCQIA, section 1921 and section 1128E information will only be required to register once. We estimate that an additional 50 entities will register with the NPDB each year for the next 3 years for a total of 150 entities. We estimate that it will take an entity 60 minutes to complete and submit the *Entity Registration Form* to the NPDB. The costs associated with preparing the registration and entity verification documents are estimated at \$25 per hour.

If there are any changes in the entity's name, address, telephone number, entity type designation, or query and/or report point of contact, the entity representative must update the information on the *Entity Registration Update Form* and submit it to the NPDB. Of these 150 new registrants, we estimate that approximately 25 entities will need to update their organization's information each year. The costs associated with preparing the registration and entity verification documents are estimated at \$25 per hour.

⁷ OMB has previously approved the burden under the HCQIA for disputing the factual accuracy of information in a report and requesting Secretarial review of the disputed report. Based on experience with the NPDB, we estimate that an additional 18 reports will be entered into the "disputed status." We estimate that it will take a health care practitioner, physician, dentist, or health care entity 15 minutes to notify the NPDB to enter the report into "disputed status." The costs associated with preparing an initial dispute request is estimated at approximately \$45 per hour. Of the 18 disputed reports, we estimate that only 3 will be forwarded to the Secretary for review. We estimate that it will take a health care practitioner, physician, dentist, or entity 8 hours to describe, in writing, which facts are in dispute and to gather supporting documentation related to the dispute. Based on experience with the NPDB and HIPDB, we estimate the costs associated with preparing a request for Secretarial review at approximately \$200 per hour. In addition, a health care practitioner, physician, or dentist who, or a health care entity that, is the subject of a report may submit a 2,000-character statement at any time after the NPDB has received the report. We estimate that an additional 40 practitioners and entities will submit statements to the NPDB. Based on previous experience, we estimate that each statement will take approximately 60 minutes to prepare. The cost estimate for preparation of statements is \$100 per hour.

⁸ The costs presented in this table have been estimated based on whole hours. The cost estimates are for response preparation and do not cover the costs per query (user fee), which will be assessed for each name submitted to the NPDB. The per hour cost estimates have been developed by using operational reports of organizations utilizing the NPDB and HIPDB.

List of Subjects in 45 CFR Part 60

Claims, Fraud, Health, Health maintenance organizations (HMOs), Health professions, Hospitals, Insurance companies, Malpractice, Reporting and recordkeeping requirements.

Dated: September 9, 2009.

Mary K. Wakefield,

Administrator, Health Resources and Services Administration.

Dated: September 14, 2009.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

For the reasons set forth in the preamble, the Health Resources and Services Administration amends 45 CFR part 60 as set forth below:

PART 60—NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS

1. The authority citation for 45 CFR part 60 is revised to read as follows:

Authority: 42 U.S.C. 11101–11152; 42 U.S.C. 1396r–2.

Subpart A—General Provisions

2. Section 60.1 is revised to read as follows:

§ 60.1 The National Practitioner Data Bank.

The Health Care Quality Improvement Act of 1986, as amended (HCQIA), title IV of Public Law 99–660 (42 U.S.C. 11101 et seq.), authorizes the Secretary to establish (either directly or by contract) a National Practitioner Data Bank (NPDB) to collect and release certain information relating to the professional competence and conduct of physicians, dentists and other health care practitioners. Section 1921 of the Social Security Act (42 U.S.C. 1396r–2) (section 1921) requires each State to adopt a system of reporting to the Secretary adverse licensure actions taken against health care practitioners and entities. Section 1921 also requires States to report any negative action or finding which a State licensing authority, peer review organization, or private accreditation entity has concluded against a health care practitioner or entity. This information will be collected and released to authorized parties by the NPDB. The regulations in this part set forth the reporting and disclosure requirements for the NPDB.

§ 60.2 [Amended]

3. Section 60.2 is amended by adding the phrase “State licensing authorities;” after the phrase “Boards of Medical

Examiners;” in the first sentence and by adding “State licensing or certification authorities, peer review organizations, and private accreditation entities that take negative actions or findings against health care practitioners, physicians, dentists, or entities;” after the phrase “professional review actions;” in the first sentence; and by removing the phrase “National Practitioner Data Bank,” wherever it appears, and adding the term “NPDB” in its place.

4. Section 60.3 is amended by removing the reference to “§ 60.9” in the third sentence of the definition of “Board of Medical Examiners” and adding “§ 60.11” in its place, and by adding the following definitions: “Affiliated or associated,” “Formal proceeding,” “Negative action or finding,” “Organization name,” “Organization type,” “Peer review organization,” “Private accreditation entity,” “Quality Improvement Organization,” and “Voluntary surrender of license” in alphabetical order to read as follows:

§ 60.3 Definitions.

* * * * *

Affiliated or associated refers to health care entities with which a subject of a final adverse action has a business or professional relationship. This includes, but is not limited to, organizations, associations, corporations, or partnerships. This also includes a professional corporation or other business entity composed of a single individual.

* * * * *

Formal proceeding means a proceeding held before a State licensing or certification authority, peer review organization, or private accreditation entity that maintains defined rules, policies, or procedures for such a proceeding.

* * * * *

Negative action or finding by a State licensing authority, peer review organization, or private accreditation entity means:

(a) A final determination of denial or termination of an accreditation status from a private accreditation entity that indicates a risk to the safety of a patient(s) or quality of health care services;

(b) Any recommendation by a peer review organization to sanction a health care practitioner, physician, or dentist; or

(c) Any negative action or finding that under the State’s law is publicly available information and is rendered by a licensing or certification authority, including, but not limited to, limitations

on the scope of practice, liquidations, injunctions and forfeitures. This definition excludes administrative fines or citations, and corrective action plans, unless they are:

(1) Connected to the delivery of health care services, or

(2) Taken in conjunction with other licensure or certification actions such as revocation, suspension, censure, reprimand, probation, or surrender.

Organization name means the subject’s business or employer at the time the underlying acts occurred. If more than one business or employer is applicable, the one most closely related to the underlying acts should be reported as the “organization name,” with the others being reported as “affiliated or associated health care entities.”

Organization type means a description of the nature of that business or employer.

Peer review organization means an organization with the primary purpose of evaluating the quality of patient care practices or services ordered or performed by health care practitioners, physicians, or dentists measured against objective criteria which define acceptable and adequate practice through an evaluation by a sufficient number of health practitioners in such an area to ensure adequate peer review. The organization has due process mechanisms available to health care practitioners, physicians, and dentists. This definition excludes utilization and quality control peer review organizations described in Part B of Title XI of the Social Security Act (referred to as QIOs) and other organizations funded by the Centers for Medicare and Medicaid Services (CMS) to support the QIO program.

* * * * *

Private accreditation entity means an entity or organization that:

(a) Evaluates and seeks to improve the quality of health care provided by a health care entity;

(b) Measures a health care entity’s performance based on a set of standards and assigns a level of accreditation;

(c) Conducts ongoing assessments and periodic reviews of the quality of health care provided by a health care entity; and

(d) Has due process mechanisms available to health care entities.

* * * * *

Quality Improvement Organization means a utilization and quality control peer review organization (as defined in part B of title XI of the Social Security Act) that:

(a)(1) Is composed of a substantial number of the licensed doctors of

medicine and osteopathy engaged in the practice of medicine or surgery in the area and who are representative of the practicing physicians in the area, designated by the Secretary under section 1153, with respect to which the entity shall perform services under this part, or

(2) Has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area to assure that adequate peer review of the services provided by the various medical specialties and subspecialties can be assured;

(b) Is able, in the judgment of the Secretary, to perform review functions required under section 1154 in a manner consistent with the efficient and effective administration of this part and to perform reviews of the pattern of quality of care in an area of medical practice where actual performance is measured against objective criteria which define acceptable and adequate practice; and

(c) Has at least one individual who is a representative of consumers on its governing body.

* * * * *

Voluntary surrender of license means a surrender made after a notification of investigation or a formal official request by a State licensing authority for a health care practitioner, physician, dentist, or entity to surrender a license. The definition also includes those instances where a health care practitioner, physician, dentist, or entity voluntarily surrenders a license in exchange for a decision by the licensing authority to cease an investigation or similar proceeding, or in return for not conducting an investigation or proceeding, or in lieu of a disciplinary action.

■ 5. Subpart B is revised as set forth below:

Subpart B—Reporting of Information

60.4 How information must be reported.

60.5 When information must be reported.

60.6 Reporting errors, omissions, and revisions.

60.7 Reporting medical malpractice payments.

60.8 Reporting licensure actions taken by Boards of Medical Examiners.

60.9 Reporting licensure actions taken by States.

60.10 Reporting negative actions or findings taken by peer review organizations or private accreditation entities.

60.11 Reporting adverse actions on clinical privileges.

Subpart B—Reporting of Information

§ 60.4 How information must be reported.

Information must be reported to the NPDB or to a Board of Medical Examiners as required under §§ 60.7, 60.8, and 60.11 in such form and manner as the Secretary may prescribe.

§ 60.5 When information must be reported.

Information required under §§ 60.7, 60.8, and 60.11 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after September 1, 1990, and information required under §§ 60.9 and 60.10 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after January 1, 1992, as follows:

(a) *Malpractice Payments (§ 60.7)*. Persons or entities must submit information to the NPDB within 30 days from the date that a payment, as described in § 60.7, is made. If required under § 60.7, this information must be submitted simultaneously to the appropriate State licensing board.

(b) *Licensure Actions (§ 60.8 and § 60.9)*. The Board of Medical Examiners or other licensing or certifying authority of a State must submit information within 30 days from the date the licensure action was taken.

(c) *Negative Action or Finding (§ 60.10)*. Peer review organizations, or private accreditation entities must report any negative actions or findings to the State within 15 days from the date the action was taken or the finding was made. Each State, through the adopted system of reporting, must submit to the NPDB the information received from the peer review organization or private accreditation entity within 15 days from the date on which it received this information.

(d) *Adverse Actions (§ 60.11)*. A health care entity must report an adverse action to the Board within 15 days from the date the adverse action was taken. The Board must submit the information received from a health care entity within 15 days from the date on which it received this information. If required under § 60.11, this information must be submitted by the Board simultaneously to the appropriate State licensing board in the State in which the health care entity is located, if the Board is not such licensing Board.

§ 60.6 Reporting errors, omissions, and revisions.

(a) Persons and entities are responsible for the accuracy of information which they report to the NPDB. If errors or omissions are found

after information has been reported, the person or entity which reported it must send an addition or correction to the NPDB or, in the case of reports made under § 60.11, to the Board of Medical Examiners, as soon as possible.

(b) An individual or entity which reports information on licensure, negative actions or findings or clinical privileges under §§ 60.8, 60.9, 60.10, or 60.11 must also report any revision of the action originally reported. Revisions include reversal of a professional review action or reinstatement of a license. Revisions are subject to the same time constraints and procedures of §§ 60.5, 60.8, 60.9, 60.10, and 60.11, as applicable to the original action which was reported.

(Approved by the Office of Management and Budget under control number 0915-0126)

§ 60.7 Reporting medical malpractice payments.

(a) *Who must report*. Each entity, including an insurance company, which makes a payment under an insurance policy, self-insurance, or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement of or in satisfaction in whole or in part of a claim or a judgment against such physician, dentist, or other health care practitioner for medical malpractice, must report information as set forth in paragraph (b) of this section to the NPDB and to the appropriate State licensing board(s) in the State in which the act or omission upon which the medical malpractice claim was based. For purposes of this section, the waiver of an outstanding debt is not construed as a “payment” and is not required to be reported.

(b) *What information must be reported*. Entities described in paragraph (a) of this section must report the following information:

(1) With respect to the physician, dentist or other health care practitioner for whose benefit the payment is made—

(i) Name,
(ii) Work address,
(iii) Home address, if known,
(iv) Social Security Number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note),

(v) Date of birth,
(vi) Name of each professional school attended and year of graduation,

(vii) For each professional license: the license number, the field of licensure, and the name of the State or Territory in which the license is held,

(viii) Drug Enforcement Administration registration number, if known,

(ix) Name of each hospital with which he or she is affiliated, if known;

(2) With respect to the reporting entity—

(i) Name and address of the entity making the payment,

(ii) Name, title, and telephone number of the responsible official submitting the report on behalf of the entity, and

(iii) Relationship of the reporting entity to the physician, dentist, or other health care practitioner for whose benefit the payment is made;

(3) With respect to the judgment or settlement resulting in the payment—

(i) Where an action or claim has been filed with an adjudicative body, identification of the adjudicative body and the case number,

(ii) Date or dates on which the act(s) or omission(s) which gave rise to the action or claim occurred,

(iii) Date of judgment or settlement,

(iv) Amount paid, date of payment, and whether payment is for a judgment or a settlement,

(v) Description and amount of judgment or settlement and any conditions attached thereto, including terms of payment,

(vi) A description of the acts or omissions and injuries or illnesses upon which the action or claim was based,

(vii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary, and

(viii) Other information as required by the Secretary from time to time after publication in the **Federal Register** and after an opportunity for public comment.

(c) *Sanctions.* Any entity that fails to report information on a payment required to be reported under this section is subject to a civil money penalty not to exceed the amount specified at 42 CFR 1003.103(c).

(d) *Interpretation of information.* A payment in settlement of a medical malpractice action or claim shall not be construed as creating a presumption that medical malpractice has occurred.

(Approved by the Office of Management and Budget under control number 0915-0126)

§ 60.8 Reporting licensure actions taken by Boards of Medical Examiners.

(a) *What actions must be reported.* Each Board of Medical Examiners must report to the NPDB any action based on reasons relating to a physician's or dentist's professional competence or professional conduct:

(1) Which revokes or suspends (or otherwise restricts) a physician's or dentist's license,

(2) Which censures, reprimands, or places on probation a physician or dentist, or

(3) Under which a physician's or dentist's license is surrendered.

(b) *Information that must be reported.*

The Board must report the following information for each action:

(1) The physician's or dentist's name,

(2) The physician's or dentist's work address,

(3) The physician's or dentist's home address, if known,

(4) The physician's or dentist's Social Security number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note),

(5) The physician's or dentist's date of birth,

(6) Name of each professional school attended by the physician or dentist and year of graduation,

(7) For each professional license, the physician's or dentist's license number, the field of licensure and the name of the State or Territory in which the license is held,

(8) The physician's or dentist's Drug Enforcement Administration registration number, if known,

(9) A description of the acts or omissions or other reasons for the action taken,

(10) A description of the Board action, the date the action was taken, its effective date and duration,

(11) Classification of the action in accordance with a reporting code adopted by the Secretary, and

(12) Other information as required by the Secretary from time to time after publication in the **Federal Register** and after an opportunity for public comment.

(c) *Sanctions.* If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board has failed to submit a report as required by this section, the Secretary will designate another qualified entity for the reporting of information under § 60.11.

§ 60.9 Reporting licensure actions taken by States.

(a) *What actions must be reported.* Each State is required to adopt a system of reporting to the NPDB actions, as listed below, which are taken against a health care practitioner, physician, dentist, or entity (as defined in § 60.3). The actions taken must be as a result of formal proceedings (as defined in § 60.3). The actions which must be reported are:

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

(2) Any dismissal or closure of the formal proceeding by reason of the health care practitioner, physician, dentist, or entity surrendering the license, or the practitioner leaving the State or jurisdiction;

(3) Any other loss of the license of the health care practitioner, physician, dentist, or entity, whether by operation of law, voluntary surrender (excluding those due to non-payment of licensure renewal fees, retirement, or change to inactive status), or otherwise; and

(4) Any negative action or finding by such authority, organization, or entity regarding the health care practitioner, physician, dentist, or entity.

(b) *What information must be reported.* Each State must report the following information (not otherwise reported under § 60.8):

(1) If the subject is a *health care practitioner, physician, or dentist*, personal identifiers, including:

(i) Name;

(ii) Social Security Number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note);

(iii) Home address or address of record;

(iv) Sex; and

(v) Date of birth.

(2) If the subject is a *health care practitioner, physician, or dentist*, employment or professional identifiers, including:

(i) Organization name and type;

(ii) Occupation and specialty, if applicable;

(iii) National Provider Identifier (NPI), when issued by the Centers for Medicare & Medicaid Services (CMS);

(iv) Name of each professional school attended and year of graduation; and

(v) With respect to the professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the State or Territory in which the license is held.

(3) If the subject is a *health care entity*, identifiers, including:

(i) Name;

(ii) Business address;

(iii) Federal Employer Identification Number (FEIN), or Social Security Number when used by the subject as a Taxpayer Identification Number (TIN);

(iv) The NPI, when issued by CMS;

(v) Type of organization; and

(vi) With respect to the license (including certification and registration)

on which the reported action was taken, the license and the name of the State or Territory in which the license is held.

(4) For all *subjects*:

(i) A narrative description of the acts or omissions and injuries upon which the reported action was based;

(ii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary;

(iii) Classification of the action taken in accordance with a reporting code adopted by the Secretary, and the amount of any monetary penalty resulting from the reported action;

(iv) The date the action was taken, its effective date and duration;

(v) Name of the agency taking the action;

(vi) Name and address of the reporting entity; and

(vii) The name, title and telephone number of the responsible official submitting the report on behalf of the reporting entity.

(c) *What information may be reported, if known*: Entities described in paragraph (a) of this section may voluntarily report, if known, the following information:

(1) If the subject is a *health care practitioner, physician, or dentist*, personal identifiers, including:

(i) Other name(s) used;

(ii) Other address;

(iii) FEIN, when used by the individual as a TIN; and

(iv) If deceased, date of death.

(2) If the subject is a *health care practitioner, physician, or dentist*, employment or professional identifiers, including:

(i) Other State professional license number(s), field(s) of licensure, and the name(s) of the State or Territory in which the license is held;

(ii) Other numbers assigned by Federal or State agencies, including, but not limited to Drug Enforcement Administration (DEA) registration number(s), Unique Physician Identification Number(s) (UPIN), and Medicaid and Medicare provider number(s);

(iii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated; and

(iv) Nature of the subject's relationship to each associated or affiliated health care entity.

(3) If the subject is a *health care entity*, identifiers, including:

(i) Other name(s) used;

(ii) Other address(es) used;

(iii) Other FEIN(s) or Social Security Number(s) used;

(iv) Other NPI(s) used;

(v) Other State license number(s) and the name(s) of the State or Territory in which the license is held;

(vi) Other numbers assigned by Federal or State agencies, including, but not limited to Drug Enforcement Administration (DEA) registration number(s), Clinical Laboratory Improvement Act (CLIA) number(s), Food and Drug Administration (FDA) number(s), and Medicaid and Medicare provider number(s);

(vii) Names and titles of principal officers and owners;

(viii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated; and

(ix) Nature of the subject's relationship to each associated or affiliated health care entity.

(4) For all *subjects*:

(i) Whether the subject will be automatically reinstated.

(ii) [Reserved]

(d) *Access to documents*. Each State must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in paragraphs (a)(1) through (4) of this section, as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921 of the Social Security Act.

§ 60.10 Reporting negative actions or findings taken by peer review organizations or private accreditation entities.

(a) *What actions must be reported*. Each State is required to adopt a system of reporting to the NPDB any negative actions or findings (as defined in § 60.3) which are taken against a health care practitioner, physician, dentist, or entity by a peer review organization or private accreditation entity. The health care practitioner, physician, dentist, or entity must be licensed or otherwise authorized by the State to provide health care services. The actions taken must be as a result of formal proceedings (as defined in § 60.3).

(b) *What information must be reported*. Each State must report the information as required in § 60.9(b).

(c) *What information should be reported, if known*: Each State should report, if known, the information as described in § 60.9(c).

(d) *Access to documents*. Each State must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in this section as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921 of the Social Security Act.

§ 60.11 Reporting adverse actions on clinical privileges.

(a) *Reporting to the Board of Medical Examiners*—(1) *Actions that must be reported and to whom the report must be made*. Each health care entity must report to the Board of Medical Examiners in the State in which the health care entity is located the following actions:

(i) Any professional review action that adversely affects the clinical privileges of a physician or dentist for a period longer than 30 days;

(ii) Acceptance of the surrender of clinical privileges or any restriction of such privileges by a physician or dentist—

(A) While the physician or dentist is under investigation by the health care entity relating to possible incompetence or improper professional conduct, or

(B) In return for not conducting such an investigation or proceeding; or

(iii) In the case of a health care entity which is a professional society, when it takes a professional review action concerning a physician or dentist.

(2) *Voluntary reporting on other health care practitioners*. A health care entity may report to the Board of Medical Examiners information as described in paragraph (a)(3) of this section concerning actions described in paragraph (a)(1) in this section with respect to other health care practitioners.

(3) *What information must be reported*. The health care entity must report the following information concerning actions described in paragraph (a)(1) of this section with respect to a physician or dentist:

(i) Name,

(ii) Work address,

(iii) Home address, if known,

(iv) Social Security Number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note),

(v) Date of birth,

(vi) Name of each professional school attended and year of graduation,

(vii) For each professional license: the license number, the field of licensure, and the name of the State or Territory in which the license is held,

(viii) Drug Enforcement Administration registration number, if known,

(ix) A description of the acts or omissions or other reasons for privilege loss, or, if known, for surrender,

(x) Action taken, date the action was taken, and effective date of the action, and

(xi) Other information as required by the Secretary from time to time after publication in the **Federal Register** and

after an opportunity for public comment.

(b) *Reporting by the Board of Medical Examiners to the National Practitioner Data Bank.* Each Board must report, in accordance with §§ 60.4 and 60.5, the information reported to it by a health care entity and any known instances of a health care entity's failure to report information as required under paragraph (a)(1) of this section. In addition, each Board must simultaneously report this information to the appropriate State licensing board in the State in which the health care entity is located, if the Board is not such licensing board.

(c) *Sanctions—(1) Health care entities.* If the Secretary has reason to believe that a health care entity has substantially failed to report information in accordance with this section, the Secretary will conduct an investigation. If the investigation shows that the health care entity has not complied with this section, the Secretary will provide the entity with a written notice describing the noncompliance, giving the health care entity an opportunity to correct the noncompliance, and stating that the entity may request, within 30 days after receipt of such notice, a hearing with respect to the noncompliance. The request for a hearing must contain a statement of the material factual issues in dispute to demonstrate that there is cause for a hearing. These issues must be both substantive and relevant. The hearing will be held in the Washington, DC, metropolitan area. The Secretary will deny a hearing if:

- (i) The request for a hearing is untimely,
- (ii) The health care entity does not provide a statement of material factual issues in dispute, or
- (iii) The statement of factual issues in dispute is frivolous or inconsequential.

In the event that the Secretary denies a hearing, the Secretary will send a written denial to the health care entity setting forth the reasons for denial. If a hearing is denied, or if as a result of the hearing the entity is found to be in noncompliance, the Secretary will publish the name of the health care entity in the **Federal Register**. In such case, the immunity protections provided under section 411(a) of the Act will not apply to the health care entity for professional review activities that occur during the 3-year period beginning 30 days after the date of publication of the entity's name in the **Federal Register**.

(2) *Board of Medical Examiners.* If, after notice of noncompliance and providing opportunity to correct

noncompliance, the Secretary determines that a Board has failed to report information in accordance with paragraph (b) of this section, the Secretary will designate another qualified entity for the reporting of this information.

(Approved by the Office of Management and Budget under control number 0915-0126)

■ 6. Subpart C is revised as set forth below:

Subpart C—Disclosure of Information by the National Practitioner Data Bank

- 60.12 Information which hospitals must request from the National Practitioner Data Bank.
- 60.13 Requesting information from the National Practitioner Data Bank.
- 60.14 Fees applicable to requests for information.
- 60.15 Confidentiality of National Practitioner Data Bank information.
- 60.16 How to dispute the accuracy of National Practitioner Data Bank information.

Subpart C—Disclosure of Information by the National Practitioner Data Bank

§ 60.12 Information which hospitals must request from the National Practitioner Data Bank.

(a) *When information must be requested.* Each hospital, either directly or through an authorized agent, must request information from the NPDB concerning a physician, dentist or other health care practitioner as follows:

(1) At the time a physician, dentist or other health care practitioner applies for a position on its medical staff (courtesy or otherwise), or for clinical privileges at the hospital; and

(2) Every 2 years concerning any physician, dentist, or other health care practitioner who is on its medical staff (courtesy or otherwise), or has clinical privileges at the hospital.

(b) *Failure to request information.* Any hospital which does not request the information as required in paragraph (a) of this section is presumed to have knowledge of any information reported to the NPDB concerning this physician, dentist or other health care practitioner.

(c) *Reliance on the obtained information.* Each hospital may rely upon the information provided by the NPDB to the hospital. A hospital shall not be held liable for this reliance unless the hospital has knowledge that the information provided was false. (Approved by the Office of Management and Budget under control number 0915-0126)

§ 60.13 Requesting information from the National Practitioner Data Bank.

(a) *Who may request information and what information may be available.* Information in the NPDB will be available, upon request, to the persons or entities, or their authorized agents, as described below:

(1) Information reported under §§ 60.7, 60.8, and 60.11 is available to:

(i) A hospital that requests information concerning a physician, dentist or other health care practitioner who is on its medical staff (courtesy or otherwise) or has clinical privileges at the hospital;

(ii) A physician, dentist, or other health care practitioner who requests information concerning himself or herself;

(iii) A State Medical Board of Examiners or other State authority that licenses physicians, dentists, or other health care practitioners;

(iv) A health care entity which has entered or may be entering into an employment or affiliation relationship with a physician, dentist, or other health care practitioner, or to which the physician, dentist, or other health care practitioner has applied for clinical privileges or appointment to the medical staff;

(v) An attorney, or individual representing himself or herself, who has filed a medical malpractice action or claim in a State or Federal court or other adjudicative body against a hospital, and who requests information regarding a specific physician, dentist, or other health care practitioner who is also named in the action or claim. This information will be disclosed only upon the submission of evidence that the hospital failed to request information from the NPDB, as required by § 60.12(a), and may be used solely with respect to litigation resulting from the action or claim against the hospital;

(vi) A health care entity with respect to professional review activity; and

(vii) A person or entity requesting statistical information, in a form which does not permit the identification of any individual or entity.

(2) Information reported under §§ 60.9 and 60.10 is available to the agencies, authorities, and officials listed below that request information on licensure disciplinary actions and any other negative actions or findings concerning an individual health care practitioner, physician, dentist, or entity. These agencies, authorities, and officials may obtain data for the purposes of determining the fitness of individuals to provide health care services, protecting the health and safety of individuals receiving health care through programs

administered by the requesting agency, and protecting the fiscal integrity of these programs.

(i) Agencies administering Federal health care programs, including private entities administering such programs under contract;

(ii) Authorities of States (or political subdivisions thereof) which are responsible for licensing health care practitioners, physicians, dentists, and entities;

(iii) State agencies administering or supervising the administration of State health care programs (as defined in 42 U.S.C. 1128(h));

(iv) State Medicaid Fraud Control Units (as defined in 42 U.S.C. 1903(q));

(v) Law enforcement officials and agencies such as:

(A) United States Attorney General;

(B) United States Chief Postal

Inspector;

(C) United States Inspectors General;

(D) United States Attorneys;

(E) United States Comptroller General;

(F) United States Drug Enforcement

Administration;

(G) United States Nuclear Regulatory Commission;

(H) Federal Bureau of Investigation; and

(I) State law enforcement agencies, which include, but are not limited to, State Attorneys General.

(vi) Utilization and quality control peer review organizations described in part B of title XI and appropriate entities with contracts under section 1154(a)(4)(C) of the Social Security Act with respect to eligible organizations reviewed under the contracts;

(vii) Hospitals and other health care entities (as defined in section 431 of the HCQIA), with respect to physicians or other licensed health care practitioners who have entered (or may be entering) into employment or affiliation relationships with, or have applied for clinical privileges or appointments to the medical staff of, such hospitals or other health care entities;

(viii) A physician, dentist, or other health care practitioner who, and an entity which, requests information concerning himself, herself, or itself; and

(ix) A person or entity requesting statistical information, in a form which does not permit the identification of any individual or entity. (For example, researchers may use statistical information to identify the total number of nurses with adverse licensure actions in a specific State. Similarly, researchers may use statistical information to identify the total number of health care entities denied accreditation.)

(b) *Procedures for obtaining National Practitioner Data Bank information.*

Persons and entities may obtain information from the NPDB by submitting a request in such form and manner as the Secretary may prescribe. These requests are subject to fees as described in § 60.14.

§ 60.14 Fees applicable to requests for information.

(a) *Policy on fees.* The fees described in this section apply to all requests for information from the NPDB. The amount of such fees will be sufficient to cover the full costs of operating the NPDB. The actual fees will be announced by the Secretary in periodic notices in the **Federal Register**.

However, for purposes of verification and dispute resolution at the time the report is accepted, the NPDB will provide a copy—at the time a report has been submitted, automatically, without a request and free of charge—of the record to the health care practitioner or entity who is the subject of the report and to the reporter.

(b) *Criteria for determining the fee.*

The amount of each fee will be determined based on the following criteria:

(1) Direct and indirect personnel costs, including salaries and fringe benefits such as medical insurance and retirement;

(2) Physical overhead, consulting, and other indirect costs including materials and supplies, utilities, insurance, travel and rent and depreciation on land, buildings and equipment;

(3) Agency management and supervisory costs;

(4) Costs of enforcement, research, and establishment of regulations and guidance;

(5) Use of electronic data processing equipment to collect and maintain information—the actual cost of the service, including computer search time, runs and printouts; and

(6) Any other direct or indirect costs related to the provision of services.

(c) *Assessing and collecting fees.* The Secretary will announce through notice in the **Federal Register** from time to time the methods of payment of NPDB fees. In determining these methods, the Secretary will consider efficiency, effectiveness, and convenience for the NPDB users and the Department. Methods may include: Credit card, electronic fund transfer, and other methods of electronic payment.

§ 60.15 Confidentiality of National Practitioner Data Bank information.

(a) *Limitations on disclosure.* Information reported to the NPDB is considered confidential and shall not be disclosed outside the Department of

Health and Human Services, except as specified in §§ 60.12, 60.13, and 60.16. Persons who, and entities which, receive information from the NPDB either directly or from another party must use it solely with respect to the purpose for which it was provided.

Nothing in this paragraph shall prevent the disclosure of information by a party which is authorized under applicable State law to make such disclosure.

(b) *Penalty for violations.* Any person who violates paragraph (a) shall be subject to a civil money penalty of up to \$11,000 for each violation. This penalty will be imposed pursuant to procedures at 42 CFR part 1003.

§ 60.16 How to dispute the accuracy of National Practitioner Data Bank information.

(a) *Who may dispute National Practitioner Data Bank information.*

Any physician, dentist, or other health care practitioner or health care entity may dispute the accuracy of information in the NPDB concerning himself, herself or itself. The Secretary will routinely mail a copy of any report filed in the NPDB to the subject individual or entity.

(b) *Procedures for filing a dispute.*

The subject of the report may dispute the accuracy of the report within 60 days from the date on which the Secretary mails the report to the subject individual or entity. The procedures for disputing a report are:

(1) Informing the Secretary and the reporting entity, in writing, of the disagreement, and the basis for it,

(2) Requesting simultaneously that the disputed information be entered into a “disputed” status and be reported to inquirers as being in a “disputed” status, and

(3) Attempting to enter into discussion with the reporting entity to resolve the dispute.

(c) *Procedures for revising disputed information.*

(1) If the reporting entity revises the information originally submitted to the NPDB, the Secretary will notify all entities to whom reports have been sent that the original information has been revised.

(2) If the reporting entity does not revise the reported information, the Secretary will, upon request, review the written information submitted by both parties (the subject individual or entity and the reporting entity). After review, the Secretary will either—

(i) If the Secretary concludes that the information is accurate, include a brief statement by the physician, dentist or other health care practitioner or health care entity describing the disagreement concerning the information, and an

explanation of the basis for the decision that it is accurate, or

(ii) If the Secretary concludes that the information is incorrect, send corrected information to previous inquirers.

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