

Signed at Washington, DC, this 16th day of March, 2006.

**Victoria A. Lipnic,**

*Assistant Secretary for Employment Standards.*

**Charles E. James, Sr.,**

*Deputy Assistant Secretary for Federal Contract Compliance.*

[FR Doc. 06-2770 Filed 3-20-06; 8:45 am]

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## DEPARTMENT OF LABOR

### Office of Federal Contract Compliance Programs

#### 41 CFR Part 60-300

RIN 1215-AB46

#### **Affirmative Action and Nondiscrimination Obligations of Contractors and Subcontractors Regarding Disabled Veterans, Recently Separated Veterans, Other Protected Veterans, and Armed Forces Service Medal Veterans; Correction**

**AGENCY:** Office of Federal Contract Compliance Programs, Labor.

**ACTION:** Notice of proposed rulemaking; correction; and extension of comment period.

**SUMMARY:** On January 20, 2006, the Office of Federal Contract Compliance Programs (OFCCP) published in the **Federal Register** a notice of proposed rulemaking (NPRM). The NPRM (71 FR 3351) proposes new regulations to implement amendments to the affirmative action provisions of the Vietnam Era Veterans' Readjustment Assistance Act of 1974 ("VEVRAA NPRM"). This document corrects the e-mail address for submitting comments on the VEVRAA NPRM. Further, to ensure that all public comments are received, this document extends the comment period for the proposed rule for seven (7) days. Respondents who sent comments to the earlier e-mail address are encouraged to contact the person named below to find out if their comments were received and re-submit them to the e-mail address below if necessary.

**DATES:** The comment period for the VEVRAA NPRM published January 20, 2006 (71 FR 3351) is extended to March 28, 2006.

**FOR FURTHER INFORMATION CONTACT:** James C. Pierce, Acting Director, Division of Policy, Planning, and Program Development, Office of Federal Contract Compliance Programs, 200 Constitution Avenue, NW., Room N3422, Washington, DC 20210.

Telephone: (202) 693-0102 (voice) or (202) 693-1337 (TTY).

#### **SUPPLEMENTARY INFORMATION:**

##### **Correction**

Due to an upgrade in the computer system, the original e-mail address published in the proposed rules is not currently functioning and is not receiving e-mail comments. Accordingly, in FR Doc. 06-440 appearing on page 3351, in the **Federal Register** of Friday, January 20, 2006, the e-mail address shown, "*ofccp-mail@dol.esa.gov*," is corrected to read "*OFCCP-Public@dol.gov*."

Signed at Washington, DC, this 16th day of March, 2006.

**Victoria A. Lipnic,**

*Assistant Secretary for Employment Standards.*

**Charles E. James, Sr.,**

*Deputy Assistant Secretary for Federal Contract Compliance.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### 45 CFR Part 60

RIN 0906-AA43

#### **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, HHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This proposed rule would revise existing regulations under sections 401-432 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, and as amended by the Omnibus Budget Reconciliation Act of 1990.

The Medicare and Medicaid Patient and Program Protection Act of 1987, along with certain additional provisions in the Omnibus Budget Reconciliation Act of 1990, was designed to protect program beneficiaries from unfit health

care practitioners, and otherwise improve the anti-fraud provisions of the 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:** Comments on this proposed rule are invited. To be considered, comments must be received by May 22, 2006.

**ADDRESSES:** Written comments should be addressed to the Associate Administrator, Bureau of Health Professions (BHP), Health Resources and Services Administration, Room 8-05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Additionally, comments may be sent via e-mail to *policyanalysis@hrsa.gov*. All comments received will be available for public inspection and copying at the Practitioner Data Banks Branch, Office of Workforce Evaluation and Quality Assurance, BHP, Parklawn Building, 5600 Fishers Lane, Room 8-103, Rockville, MD 20857, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m. Comments also may be sent through the Federal eRulemaking Portal: *http://www.regulations.gov*. Follow instructions for submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Mr. Mark S. Pincus, Chief, Practitioner Data Banks Branch, Office of Workforce Evaluation and Quality Assurance, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, 5600 Fishers Lane, Room 8-103, Rockville, MD 20857; telephone number: (301) 443-2300.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

*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; and medical malpractice payments made for the benefit of any health care practitioner. Groups that have access to this data system 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, professional societies with formal peer review, and hospitals and other health care entities (such as health maintenance organizations).

The current regulations governing the NPDB which are not expanded or modified by section 1921 are not subject to review or comment under this Notice of Proposed Rulemaking, e.g., current reporting requirements for medical malpractice payers, current eligible entities which may query the NPDB.

#### *Section 1921 of the Social Security Act*

Section 1921 of the Social Security Act (herein referred to as section 1921), as amended by section 5(b) of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, and as amended by the Omnibus Budget Reconciliation Act of 1990, Public Law 101-508, 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 (except as noted below), or a private accreditation entity has concluded against a health care practitioner or health care 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 Quality Improvement Organizations (QIOs) as defined in Part B of title XI of the Social Security Act and appropriate entities with contracts under section 1154-3(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.

The Department has determined that the statutory language establishing reporting requirements at section 1921(a)(1) is unclear with respect to whether utilization and quality control peer review organizations (PROs) and their successor entities Quality Improvement Organizations (QIOs) are required to report to the NPDB.

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 \* \* \*". This indicates that the earlier reference to "any peer review organization" does not refer to "utilization and quality control peer review organizations described in Part B of title XI \* \* \*".

We are proposing therefore that the reporting requirements at section 1921(a) not apply to QIOs. We are requesting specific comment on this choice. We based this decision on several factors. First, the critical mission of the QIO program is its focus on maintaining collaborative relationships with providers and practitioners to improve the quality of health care services delivered to Medicare beneficiaries. The reporting of QIO sanction recommendations to the NPDB will significantly interfere with the progress that has been made towards this goal and will substantially reduce the ability of QIOs to carry out their statutory and contractual obligations.

Second, we believe that the established QIO process allows that these actions will ultimately be reported to the NPDB. A QIO is required in regulation to disclose information that displays practice or performance patterns of a practitioner or institution to Federal and State agencies that are responsible for the investigation of fraud and abuse of the Medicare or Medicaid programs or that are responsible for licensing and certification of practitioners and entities. In addition,

the QIO must disclose sanction reports directly to the Office of the Inspector General and, if requested, CMS, and provide notice to the State medical board or other appropriate licensing boards for other practitioners when it submits a report and recommendations to the OIG. Finally, the QIO must disclose, upon request, and may disclose without a request, sanction reports to State and Federal agencies responsible for the identification, investigation, or prosecution of fraud and abuse.

We are also concerned that QIO reporting may create misconceptions about the meaning of QIO sanction recommendations if reported to the NPDB. This is based on the fact that a sanction recommendation made by the QIO is only a recommendation, and may or may not trigger further action by the OIG or a State licensing board.

Furthermore, when the OIG does not impose the recommended sanction, the QIO continues to monitor the performance of the affected party. If a QIO sanction recommendation results in OIG imposition of an exclusion from Medicare/Medicaid, that information is reported to the NPDB. If a QIO sanction recommendation results in a licensure action by a State licensing board, that information is reported to the NPDB as well.

Section 1921 requires "any peer review organization" to report to the NPDB. As proposed, the QIOs and other organizations used by the CMS to support the QIO program are not required to report to the NPDB. However, as proposed, all other peer review organizations are still required to do so. We are also aware of other types of peer review organizations or peer review organization-like entities (public and private) which are not linked to the QIO program. It is unclear what negative actions these entities take, what negative findings they make, or to whom recommendations are presented. Thus, we request that reviewers, particularly peer review organizations which are not QIOs or supporting the QIO program, carefully review this portion of the proposed regulation. Specifically, reviewers are requested to provide comments regarding, but not limited to, the proposed definition of a peer review organization, potential reportable events, relationships with other entities, public or private status, and types of practitioners and entities reviewed.

Section 1921 requires that private accreditation organizations report actions to the NPDB. We request that the public carefully review this portion of the proposed rule and provide

comments on any limitation on reporting that may apply to these organizations.

#### *Section 1128E of the Social Security Act*

The Secretary recognizes that 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. This data bank is known as the Healthcare Integrity and Protection Data Bank (HIPDB). The HIPDB began collecting reports in November 1999.

#### *Distinctions Between the NPDB and the HIPDB*

Although section 422 of the HCQIA and sections 1921 and 1128E have overlapping components, we note that the statutes have unique characteristics, including differences in the types of reportable adverse actions and individuals or entities with access to adverse action information. For example, the HCQIA allows for the reporting of licensure actions based on professional conduct and competence only against physicians and dentists, whereas sections 1921 and 1128E allow for reporting of all licensure actions against all health care practitioners. Hospitals have access under the HCQIA and section 1921, but not under section 1128E. The chart below illustrates the differences among the HCQIA, section 1921, and section 1128E.

Section 1921 requires that reporting of licensure actions taken against physicians and dentists to the NPDB be expanded, which will match the reporting requirements of HIPDB. Currently, the HCQIA limits reporting by medical and dental boards only to those adverse actions related to professional competence or professional conduct. The change will make the reporting of adverse actions by all State licensure and certification authorities identical for both the NPDB and HIPDB. There will be no increased reporting burden for the medical and dental boards. No current NPDB reporting requirements will be changed for hospitals, other health care entities, professional societies, or medical malpractice payers.

HCQIA	Section 1128E
<p><b>Who Reports?</b></p> <ul style="list-style-type: none"> <li>• Medical malpractice payers</li> <li>• Boards of Medical/Dental Examiners</li> <li>• Hospitals</li> <li>• Other health care entities</li> <li>• Professional societies with formal peer review</li> </ul> <p><b>What Information Is Available?</b></p> <ul style="list-style-type: none"> <li>• Medical malpractice payments (all health care practitioners)</li> <li>• Adverse licensure actions (physicians/dentist)               <ul style="list-style-type: none"> <li>—Revocation, suspension, reprimand, probation, surrender, censure</li> </ul> </li> <li>• Adverse clinical privilege actions (primarily physicians/dentists)</li> <li>• Adverse professional society membership (primarily physicians/dentists)</li> </ul> <p><b>Who Can Query?</b></p> <ul style="list-style-type: none"> <li>• Hospitals</li> <li>• Other health care entities with formal peer review</li> <li>• Professional societies with formal peer review</li> <li>• Boards of Medical/Dental Examiners</li> <li>• Other health care practitioners State licensing boards</li> <li>• Plaintiff's attorney/<i>pro se</i> plaintiffs (plaintiffs representing themselves, limited circumstances)</li> <li>• Health care practitioners (self-query)</li> <li>• Researchers (statistical data only)</li> </ul>	<p>• Researchers (statistical data only)</p> <p style="text-align: center;"><b>Section 1128E</b></p> <p><b>Who Reports?</b></p> <ul style="list-style-type: none"> <li>• Federal and State Government Agencies</li> <li>• Health Plans</li> </ul> <p><b>What Information Is Available?</b></p> <ul style="list-style-type: none"> <li>• Licensing and certification actions (practitioners, providers, and suppliers) 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</li> <li>• Health care-related civil judgments (practitioners, providers, and suppliers)</li> <li>• Health care-related criminal convictions (practitioners, providers, and suppliers)</li> <li>• Exclusions from Federal or State health care programs (practitioners, providers, and suppliers)</li> <li>• Other adjudicated actions or decisions (practitioners, providers, and suppliers)</li> </ul> <p><b>Who Can Query?</b></p> <ul style="list-style-type: none"> <li>• Federal and State Government Agencies</li> <li>• Health Plans</li> <li>• Health care practitioners/providers/suppliers (self-query)</li> <li>• Researchers (statistical data only)</li> </ul>
Section 1921	HIPDB
<p><b>Who Reports?</b></p> <ul style="list-style-type: none"> <li>• State health care practitioner licensing boards</li> <li>• State health care entity licensing boards</li> <li>• Peer review organizations</li> <li>• Private accreditation organizations</li> </ul> <p><b>What Information Is Available?</b></p> <ul style="list-style-type: none"> <li>• Any adverse licensure actions (practitioners/entities)               <ul style="list-style-type: none"> <li>—Revocation, reprimand, censure, suspension (including length), probation</li> <li>—Any dismissal or closure of the proceedings by reason of the practitioner or entity surrendering the license or leaving the State or jurisdiction</li> <li>—Any other loss of the license</li> </ul> </li> <li>• 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</li> </ul> <p><b>Who Can Query?</b></p> <ul style="list-style-type: none"> <li>• Hospitals and other health care entities (Title IV)</li> <li>• Professional societies with formal peer review</li> <li>• State health care practitioner/entity licensing boards</li> <li>• Agencies administering Federal health care programs, or their contractors</li> <li>• State agencies administering State health care programs</li> <li>• Quality Improvement Organizations</li> <li>• State Medicaid Fraud Control Units</li> <li>• U.S. Comptroller General</li> <li>• U.S. Attorney General and other law enforcement</li> <li>• Health care practitioners/entities (self-query)</li> </ul>	<p><b>Who Reports?</b></p> <ul style="list-style-type: none"> <li>• Federal and State Government Agencies</li> <li>• Health Plans</li> </ul> <p><b>What Information Is Available?</b></p> <ul style="list-style-type: none"> <li>• 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</li> <li>• Health care-related civil judgments (practitioners, providers, and suppliers)</li> <li>• Health care-related criminal convictions (practitioners, providers and suppliers)</li> <li>• Exclusions from Federal or State health care programs (practitioners, providers, and suppliers)</li> <li>• Other adjudicated actions or decisions (practitioners, providers, and suppliers)</li> </ul> <p><b>Who Can Query?</b></p> <ul style="list-style-type: none"> <li>• Federal and State Government Agencies</li> <li>• Health Plans</li> <li>• Health care practitioners/providers/suppliers (self-query)</li> <li>• Researchers (statistical data only)</li> </ul> <p style="text-align: center;"><b>Expanded NPDB</b></p> <p><b>Who Reports?</b></p> <ul style="list-style-type: none"> <li>• Medical malpractice payers</li> <li>• State health care practitioner licensing and certification authorities (including medical and dental boards)</li> <li>• Hospitals</li> <li>• Other health care entities with formal peer review (HMO's, group practices, managed care organizations)</li> </ul>

- Professional societies with formal peer review
- State entity licensing and certification authorities
- Peer review organizations
- Private accreditation organizations

#### What Information Is Available?

- Medical malpractice payments (all health care practitioners)
- Any adverse licensure actions (all practitioners or entities)
  - 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 finding against a health care practitioner or entity
- Private accreditation organization negative actions or findings against a health care practitioner or entity

#### Who Can Query?

- 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 Units\*
- U.S. Comptroller General\*
- U.S. Attorney General and other law enforcement\*
- Health care practitioners (self query)
- Plaintiff's attorney/*pro se* plaintiffs (under limited circumstances)\*\*
- Quality Improvement Organizations\*
- Researchers (statistical data only)

\*Eligible to receive only those reports authorized by section 1921.

\*\*Eligible to receive only those reports authorized by HCQIA.

#### Maximum Coordination Between the NPDB and 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 also is proposing to implement this regulation in a manner to avoid the need for an entity which must report information to both the NPDB and the HIPDB to file two reports. We have made significant efforts to develop these proposed 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 consolidated reporting mechanism that will sort the appropriate actions into the HIPDB, NPDB or both. The required adjustments to the reporting mechanism are made easier because both data banks are operated through the same contractor and managed by HRSA.

#### II. Provisions of the Proposed Rule

We note that certain sections of the existing NPDB regulations satisfy section 1921 requirements for the NPDB and, therefore, are applicable to the section 1921 component of the NPDB. Specifically, the following provisions would apply: (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 proposed amendments are described below according to the sections of the regulations which they affect.

#### Section 60.3 Definitions

We propose to add the following new terms to this section:

*Affiliated or associated* refers to health care entities with which a subject of a report 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 formal or official proceeding held before a State licensing or certification authority, peer review organization, or private accreditation entity. We believe that by defining "formal proceeding" in this manner, State licensing authorities, peer review organizations, and private accreditation entities will have maximum flexibility in determining the process they will follow in conducting such proceedings.

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

(a) Receipt of less than full accreditation from a private accreditation entity that indicates a substantial risk to the safety of patient care or quality of health care services and includes, but is not limited to,

denial of accreditation or non-accreditation;

(b) Any recommendation by a peer review organization to sanction a practitioner; 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, and (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 the "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 measured against objective criteria which define acceptable and adequate practice through an evaluation by a sufficient number of health practitioners in such area to assure adequate peer review.

*Private accreditation entity* means an entity or organization, including but not limited to the Joint Commission on Accreditation of Healthcare Organizations, National Committee for Quality Assurance, Utilization Review Accreditation Commission, Commission on Accreditation of Rehabilitation Facilities, and the Community Health Accreditation Program, that:

(a) Evaluates and seeks to improve the quality of health care providers 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; and

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

We believe that this definition of "private accreditation entity" is necessary in order to include voluntary reviews by all outside accrediting organizations.

*Quality Improvement Organization* means an entity 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.

A utilization and quality control Quality Improvement Organization (as defined in part B of title XI of the Social Security Act) means an entity which—

“(1)(A) 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 (B) has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area to assure that adequate peer review of the services provided by the various medical specialties and subspecialties can be assured; (2) is able, in the judgment of the Secretary, to perform review functions required under section 1154 in a manner consistent with the efficient and effective administration of this part and to perform reviews of the pattern of quality of care in an area of medical practice where actual performance is measured against objective criteria which define acceptable and adequate practice; and (3) has at least one individual who is a representative of consumers on its governing body.”

*Voluntary surrender* means a surrender made after a notification of investigation or a formal official request by a State licensing authority for a health care practitioner or entity to surrender a license. The definition also includes those instances where a health care practitioner 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.

Section 1921 specifically requires the reporting of a health care practitioner or entity who 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 are proposing that voluntary surrenders and licensure non-renewals due to nonpayment 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 actions.

#### *Section 60.5 When Information Must Be Reported*

We are proposing to amend this section 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 which are to be reported pursuant to section 1921.

#### *Section 60.7 Reporting Medical Malpractice Payments*

In accordance with 42 CFR 1003.103(c), the Department’s Office of Inspector General has raised the civil money penalty for each failure to report a medical malpractice payment from up to \$10,000 to up to \$11,000. Therefore, we propose to revise paragraph (c) to reflect this factual change.

#### *Section 60.8 Reporting Licensure Actions Taken by Boards of Medical Examiners*

We propose to revise paragraph (b)(10) of this section, to make it consistent with the reporting requirements for States in the newly proposed § 60.9, to require the reporting of the description of an action taken by a Board, to include the duration of a nonpermanent action.

#### *Section 60.9 (New) Reporting Licensure Actions Taken by States*

We propose to redesignate § 60.9 as § 60.11, and add a new § 60.9 to implement the reporting requirements of section 1921. Under this provision, each State, through the system adopted for reporting such information in section 1921(a)(1), would report directly to the NPDB.

The following actions resulting from formal proceedings would be reported:

1. Any adverse action taken by the licensing authority of the State resulting from 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 a formal proceeding due to the practitioner or entity surrendering the license or the practitioner leaving the State or jurisdiction;

3. Any other loss of the license of the practitioner or entity, whether by operation of law, voluntary surrender or non-renewal (excluding those due to nonpayment 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 practitioner or entity.

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

#### *Section 60.10 (New) Reporting Negative Actions or Findings Taken by Peer Review Organizations or Private Accreditation Entities*

We are proposing to redesignate § 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 which 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).

#### *Section 60.13 Requesting Information From the National Practitioner Data Bank [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 propose to redesignate § 60.11 as § 60.13 and revise redesignated § 60.13, paragraph (a), entitled “*Who may request information and what information may be available.*”, to clarify to whom information in the HCQIA and section 1921 components of the NPDB would be made available as outlined below:

(1) Information reported under §§ 60.7, 60.8, and 60.11 is available only 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, which does not permit the identification of any individual or entity. (For example, researchers can use statistical information to identify the total number of physicians with adverse licensure actions or medical malpractice payments in a specific State.)

(2) Information reported under §§ 60.9 and 60.10 is available only 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 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.

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

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

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

(d) State Medicaid fraud control units (as defined in 42 U.S.C. 1903(q));

(e) Law enforcement officials and agencies such as:

(1) United States Attorney General;

(2) United States Chief Postal

Inspector;

(3) United States Inspectors General;

(4) United States Attorneys;

(5) United States Comptroller General;

(6) United States Drug Enforcement Administration;

(7) United States Nuclear Regulatory Commission;

(8) Federal Bureau of Investigation; and

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

(f) Utilization and quality control Quality Improvement Organizations (QIOs) 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;

(g) Hospitals and other health care entities (as defined in section 431 of HCQIA), with respect to physicians or other licensed health care practitioners that 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 health care entities;

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

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

*Section 60.14 Fees Applicable to Requests for Information [Redesignated]*

We propose to redesignate § 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 recover the full costs of operating the NPDB. Additionally, we are making 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.

*Section 60.15 Confidentiality of National Practitioner Data Bank Information [Redesignated]*

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

**III. Implementation Schedule**

The Omnibus Budget Reconciliation Act of 1990 required each State to have a system available, as of January 1, 1992, for the reporting of adverse action information on health care practitioners and health care entities. Therefore, we will announce through the issuance of notice(s) in the **Federal Register** a schedule when States are to begin reporting to, and when information will be available from, the NPDB. Reporters responsible for reporting final adverse actions to both the NPDB and the HIPDB will be asked to submit the report only once, provided reporting is made through the new consolidated reporting mechanism. The system is being configured to sort the appropriate actions into the NPDB, HIPDB, or both.

**IV. Regulatory Impact Statement**

*A. Regulatory Analysis*

The Office of Management and Budget (OMB) has reviewed this proposed 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 proposed 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. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues.

HRSA (for example) concludes that this proposed rule is a significant regulatory action under the Executive Order since it raises novel legal and policy issues under section 3(f)(4). HRSA concludes, however, that this proposed rule does not meet the significance threshold of \$100 million effect on the economy in any one year under section 3(f)(1). HRSA requests comments regarding this determination, and invites commenters to submit any relevant data that will assist the agency in estimating the impact of this rulemaking.

Consistent with section 1921, these proposed 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 proposed rulemaking 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 now know that States routinely collect and maintain much of this information. Many licensing boards also routinely collect and report much of this information to their 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. State Survey and Certification agencies also are required to report adverse information to CMS regarding certain health care entities. This information is already reported to the HIPDB under section 1128E. Actions that are already reported under section 1128E will only need to be reported once; the system will automatically route these reports to both Data Banks. Private accreditation entities also collect and maintain information on the Internet regarding health care entities that have been denied accreditation or are not accredited. We are unaware of any professional review organizations, which would be required to report, which maintain information regarding recommendations on the Internet. 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 intend not to impose new or added burdens on reporters and are proposing to give reporters the option of omitting certain discretionary data elements that they do not maintain or to which they do not have access. We invite you to comment on appropriateness of providing the option to omit reporting certain discretionary data elements and as classifying certain data elements "to be reported if known."

#### 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. In accordance with the Regulatory Flexibility Act, 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. For purposes of this rule, 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 the leading accrediting bodies (e.g., Joint

Commission on Accreditation of Healthcare Organizations, National Committee for Quality Assurance, Utilization Review Accreditation Commission and Commission on Accreditation of Rehabilitation Facilities), accreditation entities take approximately 100 negative findings or actions per year against health care practitioners or health care entities. We have little information on the potential volume of reporting by peer review organizations. We estimate that the number of reports will be small, but this is an issue that we believe can be better addressed after the review of public comments, however, we have provided an estimate of 100 reports per year. 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 which 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 rule 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 Boards are currently reporting to the NPDB and/or the HIPDB. Reports required under section 1921 will be the same as those currently being made and filing one report, in most cases, will meet the reporting obligation for 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 proposed 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 (which we believe will not be significant) would include the ability to transmit the information electronically (e.g., Internet service) and additional staff hours needed to transmit information. 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 proposed 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.

*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 and assigned control number 0915-0126.

This proposed rule also contains information collection requirements. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted a copy of this proposed 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 proposed rule would be used by authorized parties, specified in the proposed 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 and health care entities, peer review organizations, and private accreditation entities reviewing the services of a health care practitioner or entity.

*Estimated Annual Reporting:* We estimate that the public reporting burden for the proposed rule is 11,444 hours. Each State is required to adopt a system of reporting to the Secretary certain adverse licensure actions taken against health care practitioners 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 <sup>8</sup>
Errors and Omissions 60.6 (a) <sup>1</sup>	23	1	23	15 min	6	\$25	\$150
Revisions 60.6 (b) <sup>1</sup> .....	7	1	7	30 min	4	25	100
Licensure Actions 60.9 <sup>2</sup> .....	0	0	0	0	0	0	0
Negative Actions: Private Accreditation Entities 60.10 <sup>3</sup> .....	4	25	100	45 min	75	25	1,875
Negative Actions: Peer review organizations 60.10 <sup>3</sup> .....	25	4	100	45 min	75	25	1,875
Queries: Agencies administering Federal health care programs 60.13(a)(2)(i) <sup>4</sup> .....	10	25.5	255	5 min	21	25	525
Queries: State Agencies 60.13(a)(2)(iii) <sup>4</sup> .....	51	20	1020	5 min	85	25	2,125
Queries: State Medicaid 60.13(a)(2)(iv) <sup>4</sup> .....	51	20	1020	5 min	85	25	2,125
Queries: Law Enforcement 60.13(a)(2)(v) <sup>4</sup> .....	262	.71	185	5 min	15	25	225
Queries: QIOs 60.13(a)(2)(vi) <sup>4</sup> ..	51	5	255	5 min	21	25	525
Queries: Hospitals and other health care entities 60.13(a)(2)(vii) <sup>4</sup> .....	10,930	10.5	114,765	5 min	9,564	25	239,000
Self-Query 60.13(1)(b) <sup>5</sup> .....	0	0	0	0	0	0	0
Initial Request for Dispute of Report 60.16(b) <sup>7</sup> .....	18	1	18	15 min	5	45	225
Practitioner Requests for Secretarial Review 60.16(b) <sup>7</sup> .....	3	1	3	8 hours	24	200	4,800
Subject Statements 60.16(b) <sup>7</sup> ...	40	1	40	60 min	40	100	4,000
Entity Registration 60.3 <sup>6</sup> .....	1,500	1	1,500	60 min	1,500	25	37,000
Entity Update 60.3 <sup>6</sup> .....	225	1	225	5 min	19	25	475



Section No.	Number of respondents	Frequency of response	Number of responses	Hours per response	Burden hours	Hourly cost	Total cost <sup>8</sup>
Total .....	13,200	.....	119,516	.....	11,518	.....	295,025

<sup>1</sup> Although OMB has previously approved the burden under 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 and health care entities are also 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 also 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 also responsible for reporting revisions. 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.

<sup>2</sup> 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 also 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 associated with the HIPDB.

<sup>3</sup> Section 1921 requires each State to adopt a system of reporting to the NPDB any negative action or finding concluded against health care practitioners 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 also required to be reported to the HIPDB and were included in the HIPDB regulations. Therefore, this regulation includes the burden estimates only for those negative actions or findings taken by peer review organizations and private accreditation entities. We speculate that there may be 25 professional review organizations that may meet the definition proposed in this NPRM. We estimate that each of these organizations may report a finding 4 times a year to the NPDB. The section of the NPRM that deals with professional review organizations and the associated public burden estimates may require substantial revision based on the public comments received. We estimate that, under § 60.10 there will be an average of 4 private accreditation entities reporting approximately 25 times each during the year to the NPDB for a total of 100 reports. 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.

<sup>4</sup> 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, utilization and quality control 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 and health care entities. Based on current NPDB querying patterns, we estimate an approximate total of 117,500 new (section 1921-only) queries per year on health care practitioners and health care entities. The costs associated with preparing these queries are estimated at \$25 per hour.

<sup>5</sup> 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 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.

<sup>6</sup> To access the NPDB, entities are required to certify that they meet section 1921 reporting and/or querying requirements. An eligible entity also must complete and submit an *Entity Registration Form* to the NPDB. The information 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. All other eligible entities must complete and submit the *Entity Registration Form*. We estimate that an additional 1,500 entities will register with the NPDB each year for the next three years for a total of 4,500 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, 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 4,500 new registrants, we estimate that approximately 225 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.

<sup>7</sup> 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 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 \$50 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 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 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.

<sup>8</sup> 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.

*Request for Comment:* In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Written comments and recommendations concerning the proposed information collection requirements should be sent to: John Kraemer, Human Resources and

Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments must be

received within 60 days of publication of this proposed regulation.

**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: June 7, 2005.

**Elizabeth M. Duke,**

*Administrator, Health Resources and Services Administration.*

Approved: November 7, 2005.

**Michael O. Leavitt,**

*Secretary of Health and Human Services.*

Accordingly, 45 CFR part 60 is proposed to be amended 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. These regulations 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 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 revising the reference to “§ 60.9” in the third sentence of the definition of “Board of Medical Examiners” to read “§ 60.11”; and by adding the following terms and their 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”, inserted in the appropriate 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 formal or official proceeding held before a State licensing or certification authority, peer review organization, or private accreditation entity.

\* \* \* \* \*

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

(1) Receipt of less than full accreditation from a private accreditation entity that indicates a substantial risk to the safety of a patient or patients or quality of health care services and includes, but is not limited to, denial of accreditation or non-accreditation; or

(2) Any recommendation by a peer review organization to sanction a practitioner.

(3) Any negative action or finding that under the State’s law is publicly available information and is rendered by a licensing or certification authority, including, but not limited to, limitations on the scope of practice, liquidations, injunctions and forfeitures. This definition excludes administrative fines,

or citations and corrective action plans, unless they are:

(i) Connected to the delivery of health care services; and

(ii) 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 measured against objective criteria which define acceptable and adequate practice through an evaluation by a sufficient number of health practitioners in such area to assure adequate peer review. This definition excludes Quality Improvement Organizations (QIOs) funded by the Centers for Medicare & Medicaid Services (CMS) and other organizations used by CMS to support the QIO program.

\* \* \* \* \*

*Private accreditation entity* means an entity or organization that:

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

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

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

\* \* \* \* \*

*Quality Improvement Organization* means a utilization and quality control Quality Improvement Organization (as defined in part B of title XI of the Social Security Act) means an entity which—

“(1)(A) 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 (B) has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area to assure that adequate

peer review of the services provided by the various medical specialties and subspecialties can be assured; (2) is able, in the judgment of the Secretary, to perform review functions required under section 1154 in a manner consistent with the efficient and effective administration of this part and to perform reviews of the pattern of quality of care in an area of medical practice where actual performance is measured against objective criteria which define acceptable and adequate practice; and (3) has at least one individual who is a representative of consumers on its governing body.”

\* \* \* \* \*

*Voluntary surrender* means a surrender made after a notification of investigation or a formal official request by a State licensing authority for a health care practitioner or entity to surrender a license. The definition also includes those instances where a health care practitioner 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 after August 31, 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 after December 31, 1991, 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,
- (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 of up to \$11,000 for each such payment involved. This penalty will be imposed pursuant to procedures at 42 CFR part 1003.

(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) 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, and 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.

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

#### **§ 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 or entity (both 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 practitioner or entity surrendering the license, or the practitioner leaving the State or jurisdiction;

(3) Any other loss of the license of the practitioner or entity, whether by operation of law, voluntary surrender (excluding those due to nonpayment 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 practitioner 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*, 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;

(iii) Home address or address of record;

(iv) Sex; and

(v) Date of birth.

(2) If the subject is a *health care practitioner*, 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;

(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*, 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*, 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; and

(ii) The amount of any monetary penalty resulting from the reported action.

(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 or health care entity by a peer review organization or private accreditation entity. The health care practitioner or health care entity must be licensed or otherwise authorized by the State to provide health care services.

(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 the 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,
- (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

(2) *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

(3) *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

(4) *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. If a hearing is held, it will be 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.

(2) 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**.

(3) *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 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 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

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

(vi) Utilization and quality control Quality Improvement 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 recover 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 may 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) of this section 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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## DEPARTMENT OF DEFENSE

### Defense Acquisition Regulations System

#### 48 CFR Parts 232 and 252

RIN 0750–AF28

#### Defense Federal Acquisition Regulation Supplement; Electronic Submission and Processing of Payment Requests (DFARS Case 2005–D009)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Proposed rule with request for comments.

**SUMMARY:** DoD is proposing to amend the Defense Federal Acquisition