

**PART 57—VOLUNTEER SERVICES**

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AUTHORITY: Sec. 223, 58 Stat. 683, as amended by 81 Stat. 539; 42 U.S.C. 217b.

SOURCE: 34 FR 13868, Aug. 29, 1969, unless otherwise noted.

**§ 57.1 Applicability.**

The regulations in this part apply to the acceptance of volunteer and uncompensated services for use in the operation of any health care facility of the Department or in the provision of health care.

**§ 57.2 Definitions.**

As used in the regulations in this part:

*Secretary* means the Secretary of Health and Human Services.

*Department* means the Department of Health and Human Services.

*Volunteer services* are services performed by individuals (hereafter called volunteers) whose services have been offered to the Government and accepted under a formal agreement on a without compensation basis for use in the operation of a health care facility or in the provision of health care.

*Health care* means services to patients in Department facilities, beneficiaries of the Federal Government, or individuals or groups for whom health services are authorized under the programs of the Department.

*Health care facility* means a hospital, clinic, health center, or other facility established for the purpose of providing health care.

**§ 57.3 Volunteer service programs.**

Programs for the use of volunteer services may be established by the Secretary, or his designee, to broaden and strengthen the delivery of health services, contribute to the comfort and well being of patients in Department hospitals or clinics, or expand the services required in the operation of a health care facility. Volunteers may be

used to supplement, but not to take the place of, personnel whose services are obtained through the usual employment procedures.

**§ 57.4 Acceptance and use of volunteer services.**

The Secretary, or his designee, shall establish requirements for: Accepting volunteer services from individuals or groups of individuals, using volunteer services, giving appropriate recognition to volunteers, and maintaining records of volunteer services.

**§ 57.5 Services and benefits available to volunteers.**

(a) The following provisions of law may be applicable to volunteers whose services are offered and accepted under the regulations in this part:

(1) Subchapter I of Chapter 81 of Title 5 of the United States Code relating to medical services for work related injuries;

(2) Title 28 of the United States Code relating to tort claims;

(3) Section 7903 of Title 5 of the United States Code relating to protective clothing and equipment; and

(4) Section 5703 of Title 5 of the United States Code relating to travel and transportation expenses.

(b) Volunteers may also be provided such other benefits as are authorized by law or by administrative action of the Secretary or his designee.

**PART 60—NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS****Subpart A—General Provisions**

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

SOURCE: : 54 FR 42730, Oct. 17, 1989, unless otherwise noted.

### Subpart A—General Provisions

#### § 60.1 The National Practitioner Data Bank.

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

[75 FR 4676, Jan. 28, 2010]

#### § 60.2 Applicability of these regulations.

The regulations in this part establish reporting requirements applicable to hospitals; health care entities; Boards of Medical Examiners State licensing authorities; professional societies of physicians, dentists or other health care practitioners which take adverse licensure of professional review actions, State licensing or certification authorities, peer review organizations, and private accreditation entities that take negative actions or findings against health care practitioners, physicians, dentists, or entities; and entities (including insurance companies) making payments as a result of medical malpractice actions or claims. They also establish procedures to enable individuals or entities to obtain information from the NPDB or to dispute the accuracy of NPDB information.

[59 FR 61555, Dec. 1, 1994, as amended at 75 FR 4676, Jan. 28, 2010]

#### § 60.3 Definitions.

*Act* means the Health Care Quality Improvement Act of 1986, title IV of Pub. L. 99–660, as amended.

*Adversely affecting* means reducing, restricting, suspending, revoking, or denying clinical privileges or membership in a health care entity.

*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.

*Board of Medical Examiners*, or *Board*, means a body or subdivision of such body which is designated by a State for the purpose of licensing, monitoring and disciplining physicians or dentists. This term includes a Board of Osteopathic Examiners or its subdivision, a Board of Dentistry or its subdivision, or an equivalent body as determined by the State. Where the Secretary, pursuant to section 423(c)(2) of the Act, has designated an alternate entity to carry out the reporting activities of § 60.11

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due to a Board's failure to comply with § 60.8, the term *Board of Medical Examiners* or *Board* refers to this alternate entity.

*Clinical privileges* means the authorization by a health care entity to a physician, dentist or other health care practitioner for the provision of health care services, including privileges and membership on the medical staff.

*Dentist* means a doctor of dental surgery, doctor of dental medicine, or the equivalent who is legally authorized to practice dentistry by a State (or who, without authority, holds himself or herself out to be so authorized).

*Formal peer review process* means the conduct of professional review activities through formally adopted written procedures which provide for adequate notice and an opportunity for a hearing.

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

*Health care entity* means:

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

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

*Health care practitioner* means an individual other than a physician or dentist, who is licensed or otherwise authorized by a State to provide health care services.

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*Hospital* means an entity described in paragraphs (1) and (7) of section 1861(e) of the Social Security Act.

*Medical malpractice action or claim* means a written complaint or claim demanding payment based on a physician's, dentists or other health care practitioner's provision of or failure to provide health care services, and includes the filing of a cause of action based on the law of tort, brought in any State or Federal Court or other adjudicative body.

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

- (a) A final determination of denial or termination of an accreditation status from a private accreditation entity that indicates a risk to the safety of a patient(s) or quality of health care services;
- (b) Any recommendation by a peer review organization to sanction a health care practitioner, physician, or dentist; or
- (c) Any negative action or finding that under the State's law is publicly available information and is rendered by a licensing or certification authority, including, but not limited to, limitations on the scope of practice, liquidations, injunctions and forfeitures. This definition excludes administrative fines or citations, and corrective action plans, unless they are:

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

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

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

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

*Peer review organization* means an organization with the primary purpose of evaluating the quality of patient care

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

*Physician* means a doctor of medicine or osteopathy legally authorized to practice medicine or surgery by a State (or who, without authority, holds himself or herself out to be so authorized).

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

- (a) Evaluates and seeks to improve the quality of health care provided by a health care entity;
- (b) Measures a health care entity's performance based on a set of standards and assigns a level of accreditation;
- (c) Conducts ongoing assessments and periodic reviews of the quality of health care provided by a health care entity; and
- (d) Has due process mechanisms available to health care entities.

*Professional review action* means an action or recommendation of a health care entity:

- (a) Taken in the course of professional review activity;
- (b) Based on the professional competence or professional conduct of an individual physician, dentist or other health care practitioner which affects or could affect adversely the health or welfare of a patient or patients; and
- (c) Which adversely affects or may adversely affect the clinical privileges or membership in a professional society of the physician, dentist or other health care practitioner.

(d) This term excludes actions which are primarily based on:

- (1) The physician's, dentist's or other health care practitioner's association,

or lack of association, with a professional society or association;

- (2) The physician's, dentist's or other health care practitioner's fees or the physician's, dentist's or other health care practitioner's advertising or engaging in other competitive acts intended to solicit or retain business;

(3) The physician's, dentist's or other health care practitioner's participation in prepaid group health plans, salaried employment, or any other manner of delivering health services whether on a fee-for-service or other basis;

(4) A physician's, dentist's or other health care practitioner's association with, supervision of, delegation of authority to, support for, training of, or participation in a private group practice with, a member or members of a particular class of health care practitioner or professional; or

(5) Any other matter that does not relate to the competence or professional conduct of a physician, dentist or other health care practitioner.

*Professional review activity* means an activity of a health care entity with respect to an individual physician, dentist or other health care practitioner:

- (a) To determine whether the physician, dentist or other health care practitioner may have clinical privileges with respect to, or membership in, the entity;
- (b) To determine the scope or conditions of such privileges or membership; or
- (c) To change or modify such privileges or membership.

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

- (a)(1) Is composed of a substantial number of the licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area and who are representative of the practicing physicians in the area, designated by the Secretary under section 1153, with respect to which the entity shall perform services under this part, or

(2) Has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the

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practice of medicine or surgery in such area to assure that adequate peer review of the services provided by the various medical specialties and subspecialties can be assured;

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

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

*Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

*State* means the fifty States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

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

[54 FR 42730, Oct. 17, 1989; 54 FR 43890, Oct. 27, 1989, as amended at 75 FR 4676, Jan. 28, 2010]

### Subpart B—Reporting of Information

SOURCE: : 75 FR 4677, Jan. 28, 2010, unless otherwise noted.

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### § 60.4 How information must be reported.

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

### § 60.5 When information must be reported.

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

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

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

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

(d) *Adverse Actions (§ 60.11)*. A health care entity must report an adverse action to the Board within 15 days from the date the adverse action was taken. The Board must submit the information received from a health care entity within 15 days from the date on which it received this information. If required under § 60.11, this information must be submitted by the Board simultaneously to the appropriate State licensing

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board in the State in which the health care entity is located, if the Board is not such licensing Board.

### § 60.6 Reporting errors, omissions, and revisions.

(a) Persons and entities are responsible for the accuracy of information which they report to the NPDB. If errors or omissions are found after information has been reported, the person or entity which reported it must send an addition or correction to the NPDB or, in the case of reports made under § 60.11, to the Board of Medical Examiners, as soon as possible.

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

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

### § 60.7 Reporting medical malpractice payments.

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

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

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

- (i) Name,
- (ii) Work address,
- (iii) Home address, if known,
- (iv) Social Security Number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note),
- (v) Date of birth,
- (vi) Name of each professional school attended and year of graduation,
- (vii) For each professional license: the license number, the field of licensure, and the name of the State or Territory in which the license is held,
- (viii) Drug Enforcement Administration registration number, if known,
- (ix) Name of each hospital with which he or she is affiliated, if known;

(2) With respect to the reporting entity—

- (i) Name and address of the entity making the payment,
- (ii) Name, title, and telephone number of the responsible official submitting the report on behalf of the entity, and
- (iii) Relationship of the reporting entity to the physician, dentist, or other health care practitioner for whose benefit the payment is made;

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

- (i) Where an action or claim has been filed with an adjudicative body, identification of the adjudicative body and the case number,
- (ii) Date or dates on which the act(s) or omission(s) which gave rise to the action or claim occurred,
- (iii) Date of judgment or settlement,
- (iv) Amount paid, date of payment, and whether payment is for a judgment or a settlement,
- (v) Description and amount of judgment or settlement and any conditions attached thereto, including terms of payment,
- (vi) A description of the acts or omissions and injuries or illnesses upon which the action or claim was based,
- (vii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary, and
- (viii) Other information as required by the Secretary from time to time

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after publication in the FEDERAL REGISTER and after an opportunity for public comment.

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

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

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

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

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

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

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

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

(b) *Information that must be reported.* The Board must report the following information for each action:

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

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

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

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

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

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

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

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

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

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

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

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

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

### **§ 60.9 Reporting licensure actions taken by States.**

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

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

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

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

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

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

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

- (i) Name;
- (ii) Social Security Number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note);
- (iii) Home address or address of record;
- (iv) Sex; and
- (v) Date of birth.

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

- (i) Organization name and type;
- (ii) Occupation and specialty, if applicable;
- (iii) National Provider Identifier (NPI), when issued by the Centers for Medicare & Medicaid Services (CMS);
- (iv) Name of each professional school attended and year of graduation; and
- (v) With respect to the professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the State or Territory in which the license is held.

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

- (i) Name;
- (ii) Business address;
- (iii) Federal Employer Identification Number (FEIN), or Social Security Number when used by the subject as a Taxpayer Identification Number (TIN);
- (iv) The NPI, when issued by CMS;
- (v) Type of organization; and
- (vi) With respect to the license (including certification and registration) on which the reported action was taken, the license and the name of the State or Territory in which the license is held.

(4) For all *subjects*:

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

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

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

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

(v) Name of the agency taking the action;

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

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

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

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

- (i) Other name(s) used;
- (ii) Other address;
- (iii) FEIN, when used by the individual as a TIN; and
- (iv) If deceased, date of death.

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

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

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

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

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

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

- (i) Other name(s) used;
- (ii) Other address(es) used;
- (iii) Other FEIN(s) or Social Security Number(s) used;
- (iv) Other NPI(s) used;

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

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

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

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

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

(4) For all subjects:

(i) Whether the subject will be automatically reinstated.

(ii) [Reserved]

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

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

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

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

(c) *What information should be reported, if known:* Each State should re-

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port, if known, the information as described in § 60.9(c).

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

## § 60.11 Reporting adverse actions on clinical privileges.

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

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

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

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

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

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

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

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

(i) Name,

(ii) Work address,

(iii) Home address, if known,

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

(v) Date of birth,

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

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

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

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

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

(xi) Other information as required by the Secretary from time to time after publication in the FEDERAL REGISTER and after an opportunity for public comment.

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

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

issues must be both substantive and relevant. The hearing will be held in the Washington, DC, metropolitan area. The Secretary will deny a hearing if:

(i) The request for a hearing is untimely,

(ii) The health care entity does not provide a statement of material factual issues in dispute, or

(iii) The statement of factual issues in dispute is frivolous or inconsequential.

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

(2) *Board of Medical Examiners.* If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board has failed to report information in accordance with paragraph (b) of this section, the Secretary will designate another qualified entity for the reporting of this information.

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

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

SOURCE: : 75 FR 4680, Jan. 28, 2010, unless otherwise noted.

**§ 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

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other health care practitioner as follows:

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

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

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

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

#### **§ 60.13 Requesting information from the National Practitioner Data Bank.**

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

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

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

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

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

(iv) A health care entity which has entered or may be entering into an employment or affiliation relationship with a physician, dentist, or other

health care practitioner, or to which the physician, dentist, or other health care practitioner has applied for clinical privileges or appointment to the medical staff;

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

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

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

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

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

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

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

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

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(v) Law enforcement officials and agencies such as:

- (A) United States Attorney General;
- (B) United States Chief Postal Inspector;
- (C) United States Inspectors General;
- (D) United States Attorneys;
- (E) United States Comptroller General;
- (F) United States Drug Enforcement Administration;
- (G) United States Nuclear Regulatory Commission;
- (H) Federal Bureau of Investigation; and
- (I) State law enforcement agencies, which include, but are not limited to, State Attorneys General.

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

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

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

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

(b) *Procedures for obtaining National Practitioner Data Bank information.* Persons and entities may obtain information from the NPDB by submitting a request in such form and manner as the Secretary may prescribe. These re-

quests are subject to fees as described in § 60.14.

### **§ 60.14 Fees applicable to requests for information.**

(a) *Policy on fees.* The fees described in this section apply to all requests for information from the NPDB. The amount of such fees will be sufficient to cover the full costs of operating the NPDB. The actual fees will be announced by the Secretary in periodic notices in the FEDERAL REGISTER. However, for purposes of verification and dispute resolution at the time the report is accepted, the NPDB will provide a copy—at the time a report has been submitted, automatically, without a request and free of charge—of the record to the health care practitioner or entity who is the subject of the report and to the reporter.

(b) *Criteria for determining the fee.* The amount of each fee will be determined based on the following criteria:

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

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

(3) Agency management and supervisory costs;

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

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

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

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

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### § 60.15 Confidentiality of National Practitioner Data Bank information.

(a) *Limitations on disclosure.* Information reported to the NPDB is considered confidential and shall not be disclosed outside the Department of Health and Human Services, except as specified in §§ 60.12, 60.13, and 60.16. Persons who, and entities which, receive information from the NPDB either directly or from another party must use it solely with respect to the purpose for which it was provided. Nothing in this paragraph shall prevent the disclosure of information by a party which is authorized under applicable State law to make such disclosure.

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

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

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

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

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

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

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

(c) *Procedures for revising disputed information.*

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(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.

## PART 61—HEALTHCARE INTEGRITY AND PROTECTION DATA BANK FOR FINAL ADVERSE INFORMATION ON HEALTH CARE PROVIDERS, SUPPLIERS AND PRACTITIONERS

### Subpart A—General Provisions

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61.1 The Healthcare Integrity and Protection Data Bank.

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### Subpart B—Reporting of Information

61.4 How information must be reported.

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61.6 Reporting errors, omissions, revisions, or whether an action is on appeal.

61.7 Reporting licensure actions taken by Federal or State licensing and certification agencies.

61.8 Reporting Federal or State criminal convictions related to the delivery of a health care item or service.

61.9 Reporting civil judgments related to the delivery of a health care item or service.

61.10 Reporting exclusions from participation in Federal or State health care programs.