

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**Subpart A—General Provisions**

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AUTHORITY: 42 U.S.C. 11101–11152; 42 U.S.C. 1396r–2; 42 U.S.C. 1320a–7e

SOURCE: 78 FR 20484, Apr. 5, 2013, unless otherwise noted.

Subpart A—General Provisions

§ 60.1 The National Practitioner Data Bank.

The Health Care Quality Improvement Act of 1986 (HCQIA), as amended, title IV of Public Law 99–660 (42 U.S.C. 11101 *et seq.*) (hereinafter referred to as “title IV”), 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 (hereinafter referred to as “section 1921”), as amended, (42 U.S.C. 1396r–2) expanded the requirements under the NPDB and requires each state to adopt a system of reporting to the Secretary adverse licensure or certification actions taken against health care practitioners,

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health care entities, providers, and suppliers, as well as certain final adverse actions taken by state law and fraud enforcement agencies against health care practitioners, providers, and suppliers. Section 1128E of the Social Security Act (hereinafter referred to as “section 1128E”), as amended, (42 U.S.C. 1320a–7e) authorizes the Secretary to implement a national healthcare fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions taken by Federal Government agencies and health plans against health care practitioners, providers, and suppliers. Information from section 1921 and section 1128E is to be reported and distributed through the NPDB. The regulations in this part set forth the reporting and disclosure requirements for the NPDB, as well as procedures to dispute the accuracy of information contained in the NPDB.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.2 Applicability.

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

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

Dept. of Health and Human Services**§ 60.3****§ 60.3 Definitions.**

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 HCQIA (42 U.S.C. 11112(c)), has designated an alternate entity to carry out the reporting activities of § 60.12 of this part due to a Board's failure to comply with § 60.8 of this part, the term Board of Medical Examiners or Board refers to this alternate entity.

Civil judgment means a court-ordered action rendered in a Federal or state court proceeding, other than a criminal proceeding. This reporting requirement does not include Consent Judgments that have been agreed upon and entered to provide security for civil settlements in which there was no finding or admission of liability.

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

Criminal conviction means a conviction as described in section 1128(i) of the Social Security Act.

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).

Exclusion means a temporary or permanent debarment of an individual or entity from participation in any Fed-

eral or state health-related program, in accordance with which items or services furnished by such person or entity will not be reimbursed under any Federal or state health-related program.

Federal Government agency includes, but is not limited to:

(1) The U.S. Department of Justice;

(2) The U.S. Department of Health and Human Services;

(3) Federal law enforcement agencies, including law enforcement investigators;

(4) Any other Federal agency that either administers or provides payment for the delivery of health care services, including, but not limited to the U.S. Department of Defense and the U.S. Department of Veterans Affairs; and

(5) Federal agencies responsible for the licensing and certification of health care practitioners, providers, and suppliers.

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, for purposes of this part:

(1) A hospital;

(2) An entity that provides health care services, and engages in professional review activity through a formal peer review process for the purpose of furthering quality health care, or a committee of that entity; or

(3) A professional society or a committee or agent thereof, including those at the national, state, or local level, of health care practitioners that engages in professional review activity through a formal peer review process, for the purpose of furthering quality health care.

(4) For purposes of paragraph (2) of this definition, an entity includes: a health maintenance organization which is licensed by a state or determined to be qualified as such by the Department of Health and Human Services; and any group or prepaid

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medical or dental practice which meets the criteria of paragraph (2).

Health care practitioner, licensed health care practitioner, licensed practitioner, or practitioner means an individual who is licensed or otherwise authorized by a state to provide health care services (or any individual who, without authority, holds himself or herself out to be so licensed or authorized).

Health care provider means, for purposes of this part, a provider of services as defined in section 1861(u) of the Social Security Act; any organization (including a health maintenance organization, preferred provider organization or group medical practice) that provides health care services and follows a formal peer review process for the purpose of furthering quality health care, and any other organization that, directly or through contracts, provides health care services.

Health care supplier means, for purposes of this part, a provider of medical and other health care services as described in section 1861(s) of the Social Security Act; or any individual or entity, other than a provider, who furnishes, whether directly or indirectly, or provides access to, health care services, supplies, items, or ancillary services (including, but not limited to, durable medical equipment suppliers, manufacturers of health care items, pharmaceutical suppliers and manufacturers, health record services [such as medical, dental, and patient records], health data suppliers, and billing and transportation service suppliers). The term also includes any individual or entity under contract to provide such supplies, items, or ancillary services; health plans as defined in this section (including employers that are self-insured); and health insurance producers (including but not limited to agents, brokers, solicitors, consultants, and reinsurance intermediaries).

Health plan means, for purposes of this part, a plan, program or organization that provides health benefits, whether directly, through insurance reimbursement or otherwise, and includes but is not limited to:

- (1) A policy of health insurance;
- (2) A contract of a service benefit organization;

(3) A membership agreement with a health maintenance organization or other prepaid health plan;

(4) A plan, program, agreement, or other mechanism established, maintained, or made available by a self-insured employer or group of self-insured employers, a health care practitioner, provider, or supplier group, third-party administrator, integrated health care delivery system, employee welfare association, public service group or organization or professional association;

(5) An insurance company, insurance service, or insurance organization that is licensed to engage in the business of selling health care insurance in a state and which is subject to state law which regulates health insurance; and

(6) An organization that provides benefit plans whose coverage is limited to outpatient prescription drugs.

Hospital means, for purposes of this part, 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 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 Federal or State licensing or certification authority, peer review organization, or private accreditation entity means:

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

(2) Any recommendation by a peer review organization to sanction a health care practitioner; or

(3) Any negative action or finding that, under the state's law, is publicly available information and is rendered by a licensing or certification authority, including but not limited to, limitations on the scope of practice, liquidations, injunctions, and forfeitures. This definition also includes final adverse actions rendered by a Federal or state licensing or certification authority, such as exclusions, revocations, or

suspension of license or certification, that occur in conjunction with settlements in which no finding of liability has been made (although such a settlement itself is not reportable under the statute). This definition excludes administrative fines or citations and corrective action plans and other personnel actions, unless they are:

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

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.

Other adjudicated actions or decisions means formal or official final actions taken against a health care practitioner, provider, or supplier by a Federal governmental agency, a state law or fraud enforcement agency, or a health plan, which include the availability of a due process mechanism, and are based on acts or omissions that affect or could affect the payment, provision, or delivery of a health care item or service. For example, a formal or official final action taken by a Federal governmental agency, a state law or fraud enforcement agency, or a health plan may include, but is not limited to, a personnel-related action such as suspensions without pay, reductions in pay, reductions in grade for cause, terminations, or other comparable actions. A hallmark of any valid adjudicated action or decision is the availability of a due process mechanism. The fact that the subject elects not to use the due process mechanism provided by the authority bringing the action is immaterial, as long as such a process is available to the subject before the adjudicated action or decision is made final. In general, if an "adjudicated action or decision" follows an

agency's established administrative procedures (which ensure that due process is available to the subject of the final adverse action), it would qualify as a reportable action under this definition. This definition specifically excludes clinical privileging actions taken by Federal Government agencies or state law and fraud enforcement agencies and similar paneling decisions made by health plans. This definition does not include overpayment determinations made by Federal or state government programs, their contractors or health plans, and it does not include denial of claims determinations made by Federal Government agencies, state law or fraud enforcement agencies, or health plans. This definition also does not include business or administrative decisions taken by health plans that result in contract terminations unrelated to health care fraud or abuse or quality of care (e.g., when a practitioner's contract is terminated because the practitioner no longer practices at a facility in the health plan's network, or a health plan terminates all provider contracts in a certain geographic area because it ceases business operations in that area). For health plans that are not government entities, an action taken following adequate notice and the opportunity for a hearing that meets the standards of due process set out in section 412(b) of the HCQIA (42 U.S.C. 11112(b)) also would qualify as a reportable action under this definition.

Peer review organization means, for purposes of this part, an organization with the primary purpose of evaluating the quality of patient care practices or services ordered or performed by health care practitioners measured against objective criteria which define acceptable and adequate practice through an evaluation by a sufficient number of health care practitioners in such an area to ensure adequate peer review. The organization has due process mechanisms available to health care practitioners. This definition excludes utilization and quality control peer review organizations described in Part B of Title XI of the Social Security Act

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(referred to as QIOs) and other organizations funded by the Centers for Medicare & Medicaid Services (CMS) to support the QIO program.

Physician means, for purposes of this part, 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:

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

(2) Measures a health care entity's, provider's, or supplier's performance based on a set of standards and assigns a level of accreditation;

(3) Conducts ongoing assessments and periodic reviews of the quality of health care provided by a health care entity, provider, or supplier; and

(4) Has due process mechanisms available to health care entities, providers, or suppliers.

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

(1) Taken in the course of professional review activity;

(2) Based on the professional competence or professional conduct of an individual health care practitioner which affects or could affect adversely the health or welfare of a patient or patients; and

(3) Which adversely affects or may adversely affect the clinical privileges or membership in a professional society of the health care practitioner.

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

(i) The health care practitioner's association, or lack of association, with a professional society or association;

(ii) The health care practitioner's fees or the health care practitioner's advertising or engaging in other competitive acts intended to solicit or retain business;

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

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

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

Professional review activity means an activity of a health care entity with respect to an individual health care practitioner:

(1) To determine whether the health care practitioner may have clinical privileges with respect to, or membership in, the entity;

(2) To determine the scope or conditions of such privileges or membership; or

(3) To change or modify such privileges or membership.

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:

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

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

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

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(3) 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.

State law or fraud enforcement agency includes, but is not limited to:

- (1) A state law enforcement agency;
- (2) A state Medicaid fraud control unit (as defined in section 1903(q) of the Social Security Act); and

(3) A state agency administering (including those providing payment for services) or supervising the administration of a state health care program (as defined in section 1128(h) of the Social Security Act).

State licensing or certification agency includes, but is not limited to, any authority of a state (or of a political subdivision thereof) responsible for the licensing or certification of health care practitioners (or any peer review organization or private accreditation entity reviewing the services provided by health care practitioners), health care entities, providers, or suppliers. Examples of such state agencies include Departments of Professional Regulation, Health, Social Services (including State Survey and Certification and Medicaid Single State agencies), Commerce, and Insurance.

Voluntary surrender of license or certification means a surrender made after a notification of investigation or a formal official request by a Federal or state licensing or certification authority for a health care practitioner, health care entity, provider, or supplier to surrender the license or certification (including certification agreements or contracts for participation in Federal or state health care programs). The definition also includes those instances where a health care practitioner, health care entity, provider, or supplier voluntarily surrenders a license or certification (including program participation agreements or con-

tracts) in exchange for a decision by the licensing or certification authority to cease an investigation or similar proceeding, or in return for not conducting an investigation or proceeding, or in lieu of a disciplinary action.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

Subpart B—Reporting of Information**§ 60.4 How information must be reported.**

Information must be reported to the NPDB as required under §§ 60.7, 60.8, 60.9, 60.10, 60.11, 60.12, 60.13, 60.14, 60.15 and 60.16 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 60.12 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; information required under § 60.11 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; and information required under §§ 60.9, 60.10, 60.13, 60.14, 60.15, and 60.16 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after August 21, 1996. Persons or entities responsible for submitting reports of malpractice payments (§ 60.7), negative actions or findings (§ 60.11), or adverse actions (§ 60.12) must additionally provide to their respective state authorities a copy of the report they submit to the NPDB. Following is the list of reportable actions:

- (a) Malpractice payments (§ 60.7);
- (b) Licensure and certification actions (§§ 60.8, 60.9, and 60.10);
- (c) Negative actions or findings (§ 60.11);
- (d) Adverse actions (§ 60.12);
- (e) Health Care-related Criminal Convictions (§ 60.13);
- (f) Health Care-related Civil Judgments (§ 60.14);
- (g) Exclusions from Federal or state health care programs (§ 60.15); and

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(h) Other adjudicated actions of decisions (§ 60.16).

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

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

(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 and, in the case of reports made under § 60.12 of this part, also to the Board of Medical Examiners, as soon as possible. The NPDB will not accept requests for readjudication of the case by the NPDB, and will not examine the underlying merits of a reportable action.

(b) An individual or entity which reports information on licensure or certification, negative actions or findings, clinical privileges, criminal convictions, civil or administrative judgments, exclusions, or adjudicated actions or decisions under § 60.8, § 60.9, § 60.10, § 60.11, § 60.12, § 60.13, § 60.14, § 60.15, or § 60.16 must also report any revision of the action originally reported. Revisions include, but are not limited to, reversal of a professional review action or reinstatement of a license. In the case of actions reported under § 60.9, § 60.10, § 60.13, § 60.14, § 60.15 or § 60.16, revisions also include whether an action is on appeal. Revisions are subject to the same time constraints and procedures of § 60.5, § 60.8, § 60.9, § 60.10, § 60.11, § 60.12, § 60.13, § 60.14, § 60.15, or § 60.16 as applicable to the original action which was reported.

(c) The subject will be sent a copy of all reports, including revisions and corrections to the report.

(d) Upon receipt of a report, the subject:

(1) Can accept the report as written;
(2) May provide a statement to the NPDB that will be permanently appended to the report, either directly or through a designated representative; (The NPDB will distribute the statement to queriers, where identifiable, and to the reporting entity and the subject of the report. Only the subject can, upon request, make changes to the

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statement. The NPDB will not edit the statement; however the NPDB reserves the right to redact personal identifying and offensive language that does not change the factual nature of the statement.); or

(3) May follow the dispute process in accordance with § 60.21.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 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 health care practitioner in settlement of or in satisfaction in whole or in part of a claim or a judgment against such 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 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, and

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

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(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 health care practitioner for whose benefit the payment is made;

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

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

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

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

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 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 or Individual Tax Identification Number (ITIN), if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note),
- (5) National Provider Identifier (NPI),
- (6) The physician's or dentist's date of birth,
- (7) Name of each professional school attended by the physician or dentist and year of graduation,
- (8) 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,
- (9) The physician's or dentist's Drug Enforcement Administration registration number, if known,
- (10) A description of the acts or omissions or other reasons for the action taken,
- (11) A description of the Board action, the date the action was taken, its effective date and duration,
- (12) Classification of the action in accordance with a reporting code adopted by the Secretary, and
- (13) 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

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this section, the Secretary will designate another qualified entity for the reporting of information under § 60.12 of this part.

§ 60.9 Reporting licensure and certification 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, health care entity, provider, or supplier (all as defined in § 60.3 of this part). 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 or certification authority of the state as a result of a formal proceeding, including revocation or suspension of a license, or certification agreement or contract for participation in a government health care program (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, health care entity, provider, or supplier surrendering the license or certification agreement or contract for participation in a government health care program, or leaving the state or jurisdiction;

(3) Any other loss of license or loss of the certification agreement or contract for participation in a government health care program, or the right to apply for, or renew, a license or certification agreement or contract of the health care practitioner, health care entity, provider or supplier, whether by operation of law, voluntary surrender, nonrenewal (excluding non-renewals due to nonpayment of fees, retirement, or change to inactive status), or otherwise;

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

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

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(1) If the subject is an individual, personal identifiers, including:

(i) Name,
(ii) Social Security Number or ITIN, 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 an individual, employment or professional identifiers, including:

(i) Organization name and type,
(ii) Occupation and specialty, if applicable,

(iii) National Provider Identifier (NPI),

(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 an organization, 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,
(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,

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- (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.* Reporting entities described in paragraph (a) of this section may voluntarily report, if known, the following information:
 - (1) If the subject is an individual, 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 an individual, 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 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 an organization, 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 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) The date of appeal, if any.

- (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.

- (e) *Sanctions for failure to report.* The Secretary will provide for a publication of a public report that identifies failures to report information on adverse actions as required to be reported under this section.

§ 60.10 Reporting Federal licensure and certification actions.

- (a) *What actions must be reported.* Federal licensing and certification agencies must report to the NPDB the following final adverse actions that are taken against a health care practitioner, physician, dentist, provider, or supplier (regardless of whether the final adverse action is the subject of a pending appeal):

- (1) Formal or official actions, such as revocation or suspension of a license or certification agreement or contract for participation in government health care programs (and the length of any such suspension), reprimand, censure or probation,

- (2) Any dismissal or closure of the proceedings by reason of the health care practitioner, provider, or supplier surrendering their license or certification agreement or contract for participation in government health care programs, or leaving the state or jurisdiction,

- (3) Any other loss of the license or loss of the certification agreement or contract for participation in government health care programs, or the right to apply for, or renew, a license

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or certification agreement or contract of the health care practitioner, provider, or supplier, whether by operation of law, voluntary surrender, non-renewal (excluding non-renewals due to nonpayment of fees, retirement, or change to inactive status), or otherwise, and

(4) Any other negative action or finding by such Federal agency that is publicly available information.

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

(1) If the subject is an individual, personal identifiers, including:

- (i) Name,
- (ii) Social Security Number or ITIN,
- (iii) Home address or address of record,
- (iv) Sex, and
- (v) Date of birth.

(2) If the subject is an individual, employment or professional identifiers, including:

- (i) Organization name and type,
- (ii) Occupation and specialty, if applicable,
- (iii) National Provider Identifier (NPI),

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

(v) With respect to the state 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 an organization, identifiers, including:

- (i) Name,
- (ii) Business address,
- (iii) Federal Employer Identification Number (FEIN), or Social Security Number (or ITIN) when used by the subject as a Taxpayer Identification Number (TIN),
- (iv) The NPI,
- (v) Type of organization, and
- (vi) With respect to the state 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:

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(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.* Reporting entities described in paragraph (a) of this section may voluntarily report, if known, the following information:

(1) If the subject is an individual, 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 an individual, 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 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 an organization, 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 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) The date of appeal, if any.

(d) Sanctions for failure to report. The Secretary will provide for a publication of a public report that identifies those agencies that have failed to report information on adverse actions as required to be reported under this section.

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

(a) *What actions must be reported.* Peer review organizations and private accreditation entities are required to report any negative actions or findings (as defined in § 60.3 of this part) which are taken against a health care practitioner, health care entity, provider, or supplier to the NPDB and provide a copy to the appropriate state licensing or certification agency. The health care practitioner, health care entity, provider, or supplier 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 peer review organization and private accreditation entity must report the information as required in § 60.9(b) of this part.

(c) *What information may be reported, if known.* Each peer review organization and private accreditation entity

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

(d) *Access to documents.* Each peer review organization and private accreditation entity 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.

§ 60.12 Reporting adverse actions taken against clinical privileges.

(a) *Reporting by health care entities to the NPDB—(1) Actions that must be reported and to whom the report must be made.* Each health care entity must report to the NPDB and provide a copy of the 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 NPDB 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,

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- (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) DEA 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 NPDB.* Each Board must report 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 of Medical Examiners 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 of Medical Examiners 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 HCQIA 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 of Medical Examiners 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.

§ 60.13 Reporting Federal or state criminal convictions related to the delivery of a health care item or service.

(a) *Who must report.* Federal and state prosecutors must report criminal convictions against health care practitioners, providers, and suppliers related to the delivery of a health care item or service (regardless of whether the conviction is the subject of a pending appeal).

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

- (1) If the subject is an individual, personal identifiers, including:

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- (i) Name,
- (ii) Social Security Number (or ITIN) (states must report this information, 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 an individual, that individual's employment or professional identifiers, including:
 - (i) Organization name and type,
 - (ii) Occupation and specialty, if applicable, and
 - (iii) National Provider Identifier (NPI).
- (3) If the subject is an organization, identifiers, including:
 - (i) Name,
 - (ii) Business address,
 - (iii) Federal Employer Number (FEIN), or Social Security Number (or ITIN) when used by the subject as a Taxpayer Identification Number (TIN),
 - (iv) The NPI, and
 - (v) Type of organization.
- (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) Name and location of court or judicial venue in which the action was taken,
 - (iv) Docket or court file number,
 - (v) Type of action taken,
 - (vi) Statutory offense(s) and count(s),
 - (vii) Name of primary prosecuting agency (or the plaintiff in civil actions),
 - (viii) Date of sentence or judgment,
 - (ix) Length of incarceration, detention, probation, community service, or suspended sentence,
 - (x) Amounts of any monetary judgment, penalty, fine, assessment, or restitution,
 - (xi) Other sentence, judgment, or orders,
 - (xii) If the action is on appeal,
 - (xiii) Name and address of the reporting entity, and
 - (xiv) The name, title, and telephone number of the responsible official sub-

mitting the report on behalf of the reporting entity.

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

- (1) If the subject is an individual, personal identifiers, including:
 - (i) Other name(s) used,
 - (ii) Other address(es), and
 - (iii) FEIN, when used by the individual as a TIN.
- (2) If the subject is an individual, that individual's employment or professional identifiers, including:
 - (i) State professional license (including professional certification and registration) 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 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 an organization, identifiers, including:
 - (i) Other name(s) used,
 - (ii) Other address(es) used,
 - (iii) Other FEIN(s) or Social Security Number(s) (or ITINs) used,
 - (iv) Other NPI(s) used,
 - (v) State license (including certification and registration) 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 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

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

(4) For all subjects:

- (i) Prosecuting agency's case number,
- (ii) Investigative agencies involved,
- (iii) Investigative agencies case or file number(s), and

(iv) The date of appeal, if any.

(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.

(e) *Sanctions for failure to report.* The Secretary will provide for publication of a public report that identifies those agencies that have failed to report information on criminal convictions as required to be reported under this section.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

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

(a) *Who must report.* Federal and state attorneys and health plans must report civil judgments against health care practitioners, providers, or suppliers related to the delivery of a health care item or service (regardless of whether the civil judgment is the subject of a pending appeal). If a government agency is party to a multi-claimant civil judgment, it must assume the responsibility for reporting the entire action, including all amounts awarded to all the claimants, both public and private. If there is no government agency as a party, but there are multiple health plans as claimants, the health plan which receives the largest award must be responsible for reporting the total action for all parties.

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the information as required in § 60.13(b) of this part.

(c) *What information may be reported, if known.* Entities described in para-

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graph (a) of this section should report, if known the information as described in § 60.13(c) of this part.

(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.

(e) *Sanctions for failure to report.* Any health plan that fails to report information on a civil judgment required to be reported under this section will be subject to a civil money penalty (CMP) of not more than \$25,000 for each such adverse action not reported. Such penalty will be imposed and collected in the same manner as CMPs under subsection (a) of section 1128A of the Social Security Act. The Secretary will provide for publication of a public report that identifies those government agencies that have failed to report information on civil judgments as required to be reported under this section.

§ 60.15 Reporting exclusions from participation in Federal or state health care programs.

(a) *Who must report.* Federal Government agencies and state law and fraud enforcement agencies must report health care practitioners, providers, or suppliers excluded from participating in Federal or state health care programs, including exclusions that were made in a matter in which there was also a settlement that is not reported because no findings or admissions of liability have been made (regardless of whether the exclusion is the subject of a pending appeal).

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

(1) If the subject is an individual, personal identifiers, including:

(i) Name,

(ii) Social Security Number (or ITIN) (state law and fraud enforcement agencies must report this information if known, and if obtained in accordance

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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 an individual, that individual's employment or professional identifiers, including:

(i) Organization name and type,

(ii) Occupation and specialty, if applicable, and

(iii) National Provider Identifier (NPI).

(3) If the subject is an organization, identifiers, including:

(i) Name,

(ii) Business address,

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

(iv) The NPI, and

(v) Type of organization.

(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) If the action is on appeal,

(vi) Name of the agency taking the action,

(vii) Name and address of the reporting entity, and

(viii) 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 should report, if known, the following information:

(1) If the subject is an individual, personal identifiers, including:

(i) Other name(s) used,

(ii) Other address(es),

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

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

(v) If deceased, date of death.

(2) If the subject is an individual, that individual's employment or professional identifiers, including:

(i) State professional license (including professional registration and certification) 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 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 an organization, identifiers, including:

(i) Other name(s) used,

(ii) Other address(es) used,

(iii) Other FEIN(s) or Social Security Number(s) (or ITINs) used,

(iv) Other NPI(s) used,

(v) State license (including registration and certification) 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 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) If the subject will be automatically reinstated, and

(ii) The date of appeal, if any.

(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)

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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.

(e) *Sanctions for failure to report.* The Secretary will provide for publication of a public report that identifies those government agencies that have failed to report information on exclusions or debarments as required to be reported under this section.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.16 Reporting other adjudicated actions or decisions.

(a) *Who must report.* Federal Government agencies, state law or fraud enforcement agencies, and health plans must report other adjudicated actions or decisions as defined in § 60.3 of this part related to the delivery, payment or provision of a health care item or service against health care practitioners, providers, and suppliers (regardless of whether the other adjudicated action or decision is subject to a pending appeal).

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the information as required in § 60.15(b) of this part.

(c) *What information may be reported, if known.* Entities described in paragraph (a) of this section should report, if known, the information as described in § 60.15(c) of this part.

(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.

(e) *Sanctions for failure to report.* Any health plan that fails to report information on another adjudicated action or decision required to be reported under this section will be subject to a civil money penalty (CMP) of not more than \$25,000 for each such action not reported. Such penalty will be imposed

and collected in the same manner as CMPs under subsection (a) of section 1128A of the Social Security Act. The Secretary will provide for publication of a public report that identifies those government agencies that have failed to report information on other adjudicated actions as required to be reported under this section.

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

§ 60.17 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 health care practitioner, as follows:

(1) At the time a 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 for any 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 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.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.18 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:

Dept. of Health and Human Services**§ 60.18**

(1) Information reported under §§ 60.7, 60.8, and 60.12 of this part is available to:

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

(ii) A health care practitioner who requests information concerning himself or herself,

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

(iv) A health care entity which has entered or may be entering into an employment or affiliation relationship with a health care practitioner, or to which the 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 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 § 60.17(a) of this part, 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, 60.10, 60.11, 60.13, 60.14, 60.15, and 60.16 of this part is available to the agencies, authorities, and officials listed below that request information on licensure or certification actions, any other negative actions or findings, or final adverse actions concerning an individual practitioner, health care entity, provider, or supplier. 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 (including those providing payment for services) Federal health care programs, including private entities administering such programs under contract,

(ii) State licensing or certification agencies and Federal agencies responsible for the licensing and certification of health care practitioners, providers, or suppliers,

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

(iv) State law or fraud enforcement agencies,

(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, or

(H) Federal Bureau of Investigation,

(vi) Utilization and quality control peer review organizations described in part B of title XI and to appropriate entities with contracts under section 1154(a)(4)(C) of the Social Security Act with respect to eligible organizations reviewed under the contracts, but only with respect to information provided pursuant to §§ 60.9, 60.10, and 60.11 of this part, as well as information provided pursuant to §§ 60.13, 60.14, 60.15, and 60.16 of this part by Federal agencies and health plans,

(vii) Hospitals and other health care entities (as defined in section 431 of the Health Care Quality Improvement Act of 1986), with respect to 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, but only with respect to information provided pursuant to §§ 60.9, 60.10, and 60.11, as well as information provided pursuant to §§ 60.13, 60.14, 60.15, and

§ 60.19

60.16 by Federal agencies and health plans,

(viii) Health plans,

(ix) A health care practitioner, health care entity, provider, or supplier who requests information concerning himself, herself, or itself, and

(x) 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 NPDB 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 § 60.19 of this part.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.19 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, entity, provider, or supplier 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, insur-

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ance, 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.

§ 60.20 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 §§ 60.17, 60.18, and 60.21 of this part. Persons and entities receiving information from the NPDB, either directly or from another party, must use it solely with respect to the purpose for which it was provided. The Data Bank report may not be disclosed, but nothing in this section will prevent the disclosure of information by a party from its own files used to create such reports where disclosure is otherwise authorized under applicable state or Federal law.

(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.

Dept. of Health and Human Services**§ 60.22****§ 60.21 How to dispute the accuracy of National Practitioner Data Bank information.**

(a) *Who may dispute the NPDB information.* The NPDB will routinely mail or transmit electronically to the subject a copy of the report filed in the NPDB. In addition, as indicated in § 60.18, the subject may also request a copy of such report. The subject of the report or a designated representative may dispute the accuracy of a report concerning himself, herself, or itself as set forth in paragraph (b) of this section.

(b) *Procedures for disputing a report with the reporting entity.* (1) If the subject disagrees with the reported information, the subject must request in the format as determined by the Secretary that the NPDB enter the report into "disputed status."

(2) The NPDB will send the report, with a notation that the report has been placed in "disputed status," to queriers (where identifiable), the reporting entity and the subject of the report.

(3) The subject must attempt to enter into discussion with the reporting entity to resolve the dispute. If the reporting entity revises the information originally submitted to the NPDB, the NPDB will notify the subject and all entities to whom reports have been sent that the original information has been revised. If the reporting entity does not revise the reported information, or does not respond to the subject within 60 days, the subject may request that the Secretary review the report for accuracy. The Secretary will decide whether to correct the report within 30 days of the request. This time frame may be extended for good cause. The subject also may provide a statement to the NPDB, either directly or through a designated representative that will permanently append the report.

(c) *Procedures for requesting a review of a disputed report.* (1) The subject must request, in the format as determined by the Secretary, that the Secretary review the report for accuracy. The subject must return this request to the NPDB along with appropriate materials that support the subject's position. The Secretary will only review

the accuracy of the reported information, and will not consider the merits or appropriateness of the action or the due process that the subject received.

(2) After the review, if the Secretary:

(i) Concludes that the information is accurate and reportable to the NPDB, the Secretary will inform the subject and the NPDB of the determination. The Secretary will include a brief statement (Secretarial Statement) in the report that describes the basis for the decision. The report will be removed from "disputed status." The NPDB will distribute the corrected report and statement(s) to previous queriers (where identifiable), the reporting entity and the subject of the report.

(ii) Concludes that the information contained in the report is inaccurate, the Secretary will inform the subject of the determination and direct the NPDB or the reporting entity to revise the report. The Secretary will include a brief statement (Secretarial Statement) in the report describing the findings. The NPDB will distribute the corrected report and statement(s) to previous queriers (where identifiable), the reporting entity and the subject of the report.

(iii) Determines that the disputed issues are outside the scope of the Department's review, the Secretary will inform the subject and the NPDB of the determination. The Secretary will include a brief statement (Secretarial Statement) in the report describing the findings. The report will be removed from "disputed status." The NPDB will distribute the report and the statement(s) to previous queriers (where identifiable), the reporting entity and the subject of the report.

(iv) Determines that the adverse action was not reportable and therefore should be removed from the NPDB, the Secretary will inform the subject and direct the NPDB to void the report. The NPDB will distribute a notice to previous queriers (where identifiable), the reporting entity and the subject of the report that the report has been voided.

§ 60.22 Immunity.

Individuals, entities or their authorized agents, and the NPDB shall not be

held liable in any civil action filed by the subject of a report unless the individual, entity, or authorized agent submitting the report has actual knowledge of the falsity of the information contained in the report.

PART 63—GRANT PROGRAMS ADMINISTERED BY THE OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

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AUTHORITY: Sec. 602, Community Services Act (42 U.S.C. 2942); sec. 1110, Social Security Act (42 U.S.C. 1310).

SOURCE: 40 FR 23295, May 29, 1975, unless otherwise noted.

Subpart A—General

§ 63.1 Purpose and scope.

(a) *Applicability.* Except to the extent inconsistent with an applicable Federal

statute the regulations in this part apply to all grant awards of Federal assistance made by the Assistant Secretary for Planning and Evaluation or his designee, hereinafter referred to in this part as the Assistant Secretary. Such grants include those under section 232 of the Community Services Act (42 U.S.C. 2835), section 1110 of the Social Security Act (42 U.S.C. 1310), section 392A of the Communications Act of 1934, and such other authority as may be delegated to the Assistant Secretary for policy research activities.

(b) *Exceptions to applicability.* The award and administration of contracts and cooperative agreements by the Assistant Secretary shall not be covered by this subchapter. Contracts entered into by the Assistant Secretary shall be subject to the regulations in CFR Title 48, Chapter 3. Generally, the Assistant Secretary will select between grant and contract procedures and instruments, both with regard to the solicitation process and with respect to unsolicited proposals, on the basis of criteria set forth in the proposed revision of 45 CFR 75.201(a) published at 39 FR 27469 at any subsequent revision thereof.

(c) *Objectives—(1) Policy research.* The overall objective of policy research activities is to obtain information, as it relates to the mission of the Department of Health and Human Services, about the basic causes of and methods for preventing and eliminating poverty and dependency and about improved methods for delivering human resources services. Such information is obtained through the conduct of basic and applied research, statistical analyses, and demonstrations and evaluations which have demonstrated a high probability of impacting on the formulation or modification of major Departmental policies and programs.

(2) *Telecommunications demonstrations.* The overall objective of the Telecommunications Demonstration Program is to promote the development of nonbroadcast telecommunications facilities and services for the transmission, distribution, and delivery of