60.9 Reporting licensure actions taken by States.
60.10 Reporting negative actions or findings taken by peer review organizations or private accreditation entities.
60.11 Reporting adverse actions on clinical privileges.

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

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

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

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.

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

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.

§ 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