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services are offered and accepted under the regulations in this part:

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

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

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

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

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

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

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AUTHORITY: Secs. 401–432 of the Health Care Quality Improvement Act of 1986, Pub. L. 99–660, 100 Stat. 3784–3794, as amended by section

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402 of Pub. L. 100–177, 101 Stat. 1007–1008 (42 U.S.C. 11101–11152).

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 (the Act), title IV of Pub. L. 99–660, as amended, authorizes the Secretary to establish (either directly or by contract) a National Practitioner Data Bank to collect and release certain information relating to the professional competence and conduct of physicians, dentists and other health care practitioners. These regulations set forth the reporting and disclosure requirements for the National Practitioner Data Bank.

§ 60.2 Applicability of these regulations.

The regulations in this part establish reporting requirements applicable to hospitals; health care entities; Boards of Medical Examiners; professional societies of physicians, dentists or other health care practitioners which take adverse licensure of professional review actions; 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 National Practitioner Data Bank or to dispute the accuracy of National Practitioner Data Bank information.

[59 FR 61555, Dec. 1, 1994]

§ 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.

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 §60.9 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.

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.

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).

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

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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.

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.

[54 FR 42730, Oct. 17, 1989; 54 FR 43890, Oct. 27, 1989]

Subpart B—Reporting of Information

§ 60.4 How information must be reported.

Information must be reported to the Data Bank or to a Board of Medical Examiners as required under §§ 60.7, 60.8, and 60.9 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 60.9 must be submitted to the Data Bank within 30 days following the action to be reported, beginning with actions occurring on or after September 1, 1990, as follows:

(a) *Malpractice Payments (§ 60.7)*. Persons or entities must submit information to the Data Bank 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

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submitted simultaneously to the appropriate State licensing board.

(b) *Licensure Actions (§ 60.8)*. The Board must submit information within 30 days from the date the licensure action was taken.

(c) *Adverse Actions (§ 60.9)*. 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 § 60.9, this information must be submitted by the Board simultaneously to the appropriate State licensing board in the State in which the health care entity is located, if the Board is not such licensing Board.

[54 FR 42730, Oct. 17, 1989, as amended at 55 FR 50003, Dec. 4, 1990]

§ 60.6 Reporting errors, omissions, and revisions.

(a) Persons and entities are responsible for the accuracy of information which they report to the Data Bank. 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 Data Bank or, in the case of reports made under § 60.9, to the Board of Medical Examiners, as soon as possible.

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

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

[54 FR 42730, Oct. 17, 1989, as amended at 55 FR 50004, Dec. 4, 1990]

§ 60.7 Reporting medical malpractice payments.

(a) *Who must report*. Each entity, including an insurance company, which makes a payment under an insurance policy, self-insurance, or otherwise, for the benefit of a physician, dentist or

other health care practitioner in settlement of or in satisfaction in whole or in part of a claim or a judgment against such physician, dentist, or other health care practitioner for medical malpractice, must report information as set forth in paragraph (b) to the Data Bank 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) must report the following information:

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

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

(2) With respect to the reporting entity—

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

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

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

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

(iii) Date of judgment or settlement,

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

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

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

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

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

(c) *Sanctions.* Any entity that fails to report information on a payment required to be reported under this section is subject to a civil money penalty of up to \$10,000 for each such payment involved. This penalty will be imposed pursuant to procedures at 42 CFR part 1003.

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

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

[54 FR 42730, Oct. 17, 1989, as amended at 59 FR 61555, Dec. 1, 1994]

§ 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 Data Bank 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.

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

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

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

(4) The physician's or dentist's Social Security number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974,

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

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

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

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

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

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

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

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

(c) *Sanctions.* If, after notice of non-compliance and providing opportunity to correct noncompliance, the Secretary determines that a Board has failed to submit a report as required by this section, the Secretary will designate another qualified entity for the reporting of information under § 60.9.

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§ 60.9 Reporting adverse actions on clinical privileges.

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

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

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

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

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

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

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

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

(i) Name,

(ii) Work address,

(iii) Home address, if known,

(iv) Social Security number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974,

(v) Date of birth,

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

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

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

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

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

(xi) Other information as required by the Secretary from time to time after publication in the FEDERAL REGISTER

and after an opportunity for public comment.

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

(c) *Sanctions—(1) Health care entities.* If the Secretary has reason to believe that a health care entity has substantially failed to report information in accordance with § 60.9, the Secretary will conduct an investigation. If the investigation shows that the health care entity has not complied with § 60.9, the Secretary will provide the entity with a written notice describing the non-compliance, giving the health care entity an opportunity to correct the non-compliance, and stating that the entity may request, within 30 days after receipt of such notice, a hearing with respect to the noncompliance. The request for a hearing must contain a statement of the material factual issues in dispute to demonstrate that there is cause for a hearing. These issues must be both substantive and relevant. The hearing will be held in the Washington, DC, metropolitan area. The Secretary will deny a hearing if:

(i) The request for a hearing is untimely,

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

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

In the event that the Secretary denies a hearing, the Secretary will send a written denial to the health care entity setting forth the reasons for denial. If a hearing is denied, or if as a result of the hearing the entity is found to be in noncompliance, the Secretary will publish the name of the health care entity in the FEDERAL REGISTER. In such case,

the immunity protections provided under section 411(a) of the Act will not apply to the health care entity for professional review activities that occur during the 3-year period beginning 30 days after the date of publication of the entity's name in the FEDERAL REGISTER.

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

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

[54 FR 42730, Oct. 17, 1989, as amended at 59 FR 61555, Dec. 1, 1994]

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

§ 60.10 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 Data Bank concerning a physician, dentist or other health care practitioner as follows:

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

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

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

(c) *Reliance on the obtained information.* Each hospital may rely upon the information provided by the Data Bank to the hospital. A hospital shall not be

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held liable for this reliance unless the hospital has knowledge that the information provided was false.

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§ 60.11 Requesting information from the National Practitioner Data Bank.

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

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

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

(3) Boards of Medical Examiners or other State licensing boards,

(4) Health care entities which have entered or may be entering employment or affiliation relationships with a physician, dentist or other health care practitioner, or to which the physician, dentist or other health care practitioner has applied for clinical privileges or appointment to the medical staff,

(5) An attorney, or individual representing himself or herself, who has filed a medical malpractice action or claim in a State or Federal court or other adjudicative body against a hospital, and who requests information regarding a specific physician, dentist, or other health care practitioner who is also named in the action or claim. Provided, that this information will be disclosed only upon the submission of evidence that the hospital failed to request information from the Data Bank as required by § 60.10(a), and may be used solely with respect to litigation resulting from the action or claim against the hospital,¹¹⁽⁶⁾ A health care entity with respect to professional review activity, and

(7) A person or entity who requests information in a form which does not permit the identification of any particular health care entity, physician,

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dentist, or other health care practitioner.

(b) *Procedures for obtaining National Practitioner Data Bank information.* Persons and entities may obtain information from the Data Bank by submitting a request in such form and manner as the Secretary may prescribe. These requests are subject to fees as described in § 60.12.

[54 FR 42730, Oct. 17, 1989; 54 FR 43890, Oct. 27, 1989]

§ 60.12 Fees applicable to requests for information.

(a) *Policy on Fees.* The fees described in this section apply to all requests for information from the Data Bank. These fees are authorized by section 427(b)(4) of the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11137). They reflect the costs of processing requests for disclosure and of providing such information. The actual fees will be announced by the Secretary in periodic notices in the FEDERAL REGISTER.

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

(1) Use of electronic data processing equipment to obtain information—the actual cost for the service, including computer search time, runs, printouts, and time of computer programmers and operators, or other employees,

(2) Photocopying or other forms of reproduction, such as magnetic tapes—actual cost of the operator's time, plus the cost of the machine time and the materials used,

(3) Postage—actual cost, and

(4) Sending information by special methods requested by the applicant, such as express mail or electronic transfer—the actual cost of the special service.

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

credit card; electronic fund transfer; check; and money order.

[54 FR 42730, Oct. 17, 1989, as amended at 60 FR 27899, May 26, 1995; 64 FR 9922, Mar. 1, 1999]

§ 60.13 Confidentiality of National Practitioner Data Bank information.

(a) *Limitations on disclosure.* Information reported to the Data Bank is considered confidential and shall not be disclosed outside the Department of Health and Human Services, except as specified in § 60.10, § 60.11 and § 60.14. Persons and entities which receive information from the Data Bank either directly or from another party must use it solely with respect to the purpose for which it was provided. Nothing in this paragraph shall prevent the disclosure of information by a party which is authorized under applicable State law to make such disclosure.

(b) *Penalty for violations.* Any person who violates paragraph (a) shall be subject to a civil money penalty of up to \$10,000 for each violation. This penalty will be imposed pursuant to procedures at 42 CFR part 1003.

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

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

(b) *Procedures for filing a dispute.* A physician, dentist or other health care practitioner has 60 days from the date on which the Secretary mails the report in question to him or her in which to dispute the accuracy of the report. The procedures for disputing a report are:

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

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

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

(c) *Procedures for revising disputed information.* (1) If the reporting entity revises the information originally submitted to the Data Bank, the Secretary will notify all entities to whom reports have been sent that the original information has been revised.

(2) If the reporting entity does not revise the reported information, the Secretary will, upon request, review the written information submitted by both parties (the physician, dentist or other health care practitioner), and the reporting entity. After review, the Secretary will either—

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

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

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[54 FR 42730, Oct. 17, 1989, as amended at 54 FR 43890, Oct. 27, 1989]

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

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