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.

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

[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

Subpart A—General Provisions

Sec.

Subpart B—Reporting of Information

Subpart C—Disclosure of Information by the Healthcare Integrity and Protection Data Bank

AUTHORITY: 42 U.S.C. 1320a-7e.

SOURCE: 64 FR 57758, Oct. 26, 1999, unless otherwise noted.

Subpart A—General Provisions

§61.1 The Healthcare Integrity and Protection Data Bank.

(a) Section 1128E of the Social Security Act (the Act) authorizes the Secretary of Health and Human Services (the Secretary) to implement a national health care fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions taken against health care providers, suppliers, or practitioners. Section 1128E of the Act also directs the Secretary to maintain a database of final adverse actions taken against health care providers, suppliers or practitioners. This data bank will be known as the Healthcare Integrity and Protection Data Bank (HIPDB). Settlements in which no findings or admissions of liability have been made will be excluded from being reported. However, if another action is taken against the provider, supplier or practitioner of a health care item or service as a result of or in conjunction with the settlement, that action is reportable to the HIPDB.

(b) Section 1128E of the Act also requires the Secretary to implement the HIPDB in such a manner as to avoid duplication with the reporting requirements established for the National Practitioner Data Bank (NPDB) (See 45 CFR part 60). In accordance with the statute, the reporter responsible for reporting the final adverse actions to

both the HIPDB and the NPDB will be required to submit only one report, provided that reporting is made through the Department's consolidated reporting mechanism that will sort the appropriate actions into the HIPDB, NPDB, or both.

(c) The regulations in this part set forth the reporting and disclosure requirements for the HIPDB.

§ 61.2 Applicability of these regulations.

The regulations in this part establish reporting requirements applicable to Federal and State Government agencies and to health plans, as the terms are defined under § 61.3.

§ 61.3 Definitions.

The following definitions apply to this part:

Act means the Social Security Act.

Affiliated or associated means health care entities with which a subject of a final adverse action has a commercial relationship, including but not limited to, organizations, associations, corporations, or partnerships. It also includes a professional corporation or other business entity composed of a single individual.

Any other negative action or finding by a Federal or State licensing agency means any action or finding that under the State's law is publicly available information, and 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 citations, corrective action plans and personnel actions.

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.

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

Exclusion means a temporary or permanent debarment of an individual or entity from participation in any Federal 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.

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) 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;

(4) Federal and State law enforcement agencies, including States Attorneys General and law enforcement investigators;

(5) State Medicaid Fraud Control Units; and

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

Health care provider means a provider of services as defined in section 1861(u) of the Act; any health care entity (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 health care entity that, directly or through contracts, provides health care services.

Health care supplier means a provider of medical and other health care services as described in section 1861(s) of the 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 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 practitioner, provider or supplier group, third party administrator, integrated health care delivery system, employee welfare association, public service group or organization or professional association; and

(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.

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

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

Organization type means a brief 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 provider, supplier or practitioner by a Federal or State governmental 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 or State governmental 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 or State Government 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 Government agencies or health plans. 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.

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 any of the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and Guam.

Voluntary surrender 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 provider, supplier or practitioner 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 provider, supplier or practitioner voluntarily surrenders a license or certification (including program participation agreements or contracts) 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.

[64 FR 57758, Oct. 26, 1999, as amended at 65 FR 70507, Nov. 24, 2000]

Subpart B—Reporting of Information

§ 61.4 How information must be reported.

Information must be reported to the HIPDB as required under §§ 61.6, 61.7, 61.8, 61.9, 61.10, 61.11 and 61.15 in such form and manner as the Secretary may prescribe.

§ 61.5 When information must be reported.

(a) Information required under §§ 61.7, 61.8, 61.9, 61.10 and 61.11 must be submitted to the HIPDB—

(1) Within 30 calendar days from the date the final adverse action was taken or the date when the reporting entity became aware of the final adverse action; or

(2) By the close of the entity's next monthly reporting cycle, whichever is later.

(b) The date the final adverse action was taken, its effective date and duration of the action would be contained in the information reported to the HIPDB under §§ 61.7, 61.8, 61.9, 61.10 and 61.11.

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

(a) If errors or omissions are found after information has been reported, the reporter must send an addition or correction to the HIPDB. The HIPDB will not accept requests for readjudication of the case.

(b) A reporter that reports information on licensure, criminal convictions, civil or administrative judgments, exclusions, or adjudicated actions or decisions under §§ 61.7, 61.8, 61.9, 61.10 or 61.11 also must report any revision of the action originally reported. Revisions include, but are not limited to, reversal of a criminal conviction, reversal of a judgment or other adjudicated decisions or whether the action is on appeal, and reinstatement of a license.

(c) The subject will receive 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 HIPDB that will be permanently appended to the report, either directly or through a designated representative (The HIPDB will distribute the statement to queriers, where identifiable, and to the reporting entity and the subject of the report. The HIPDB will not edit the statement; only the subject can, upon request, make changes to the statement); or

(3) May follow the dispute process in accordance with § 61.15.