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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

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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

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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 en-

tered 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,