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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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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.

§61.7 Reporting licensure actions taken by Federal or State licensing and certification agencies.

(a) *What actions must be reported.* Federal and State licensing and certification agencies must report to the HIPDB the following final adverse actions that are taken against a health care provider, supplier, or practitioner (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 Federal or State health care programs (and the length of any such suspension), reprimand, censure or probation;

(2) Any other loss of the license or loss of the certification agreement or contract for participation in Federal or State health care programs, or the right to apply for, or renew, a license or certification agreement or contract of the provider, supplier, or practitioner, whether by operation of law, voluntary surrender, non-renewal (excluding nonrenewals due to nonpayment of fees, retirement, or change to inactive status), or otherwise; and

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

(b) 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;

(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;

(iii) National Provider Identifier (NPI), when issued by theCenters for Medicare & Medicaid Services (CMS);

(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 when used by the subject as a Taxpayer Identification Number (TIN);

(iv) The NPI, when issued by CMS;

(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:

(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) 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;

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

(iv) If deceased, date of death.

(2) If the subject is an individual, that individual's 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, to include, but not limited to Drug Enforcement Administration (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, to include, but not limited to Drug Enforcement Administration (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) *Sanctions for failure to report.* The Secretary will provide for a publication of a public report that identifies those Government agencies that have failed to report information on adverse actions as required to be reported under this section.

§ 61.8 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 providers, suppliers, and practitioners related to the delivery of a health care item or service (regardless of whether the conviction is the subject of a pending appeal).

(b) 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;

(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), when issued by theCenters for Medicare & Medicaid Services (CMS).

(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, when issued by CMS; 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 submitting the report on behalf of the reporting entity.

(c) 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; 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, to include, but not limited to Drug Enforcement Administration (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) 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, to include, but not limited to Drug Enforcement Administration (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) Prosecuting agency's case number;

(ii) Investigative agencies involved;

(iii) Investigative agencies case of file number(s); and

(iv) The date of appeal, if any.

(d) *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 criminal convictions as required to be reported under this section.

§61.9 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 providers, suppliers, or practitioners 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 multiclaimant 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) Entities described in paragraph (a) of this section must report the information as required in §61.8(b).

(c) Entities described in paragraph (a) of this section should report, if known the information as described in §61.8(c).

(d) *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 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.

§ 61.10 Reporting exclusions from participation in Federal or State health care programs.

(a) *Who must report.* Federal and State Government agencies must report health care providers, suppliers, or practitioners 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) 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;

(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), when issued by theCenters for Medicare & Medicaid Services (CMS).

(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, when issued by CMS; 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) 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;

(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, to include, but not limited to Drug Enforcement Administration (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) 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, to include, but not limited to Drug Enforcement Administration (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) *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.

§61.11 Reporting other adjudicated actions or decisions.

(a) *Who must report*. Federal and State governmental agencies and health plans must report other adjudicated actions or decisions as defined in §61.3 related to the delivery, payment or provision of a health care item or service against health care providers, suppliers, and practitioners (regardless of whether the other adjudicated action or decision is subject to a pending appeal).

(b) Entities described in paragraph (a) of this section must report the information as required in §61.10(b).

(c) Entities described in paragraph (a) of this section should report, if known the information as described in §61.10(c).

(d) *Sanctions for failure to report*. Any health plan that fails to report information on an other 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 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 Healthcare Integrity and Protection Data Bank

§61.12 Requesting information from the Healthcare Integrity and Protection Data Bank.

(a) *Who may request information and what information may be available*. Information in the HIPDB will be available, upon request, to the following persons or entities, or their authorized agents—

(1) Federal and State Government agencies;

(2) Health plans;

(3) A health care practitioner, provider, or supplier requesting information concerning himself, herself or itself; and

(4) A person or entity requesting statistical information, which does not permit identification of any individual or entity. (For example, researchers can use statistical information to identify the total number of practitioners excluded from the Medicare and Medicaid programs. Similarly, health plans can use statistical information to develop outcome measures in their efforts to monitor and improve quality care.)

(b) *Procedures for obtaining HIPDB information*. Eligible individuals and entities may obtain information from the HIPDB by submitting a request in such form and manner as the Secretary may prescribe. These requests are subject to fees set forth in §61.13. The HIPDB will comply with the Department's principles of fair information practice by providing each subject of a report with

a copy when the report is entered into the HIPDB.

(c) *Information provided in response to self-queries.* (1) At the time subjects request information as part of a ''self-query,'' the subject will receive—

(i) Any report(s) in the HIPDB specific to them; and

(ii) A disclosure history from the HIPDB of the name(s) of any entity (or entities) that have previously received the report(s).

(2) The disclosure history will be restricted in accordance with the Privacy Act regulations set forth in 45 CFR part 5b.

§ 61.13 Fees applicable to requests for information.

(a) *Policy on fees.* The fees described in this section apply to all requests for information from the HIPDB, except requests from Federal agencies. However, for purposes of verification and dispute resolution at the time the report is accepted, the HIPDB will provide a copy—at the time a report has been submitted automatically, without a request and free of charge—of every report to the health care provider, supplier or practitioner who is the subject of the report. For the same purpose, the Department will provide a copy of the report—at the time a report has been submitted automatically, without a request and free of charge—to the reporter that submitted it. The fees are authorized by section 1128E(d)(2) of the Act, and they reflect the full costs of operating the database. 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) Direct and indirect personnel costs;

(2) Physical overhead, consulting, and other indirect costs including 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 periodic notice in the FEDERAL REGISTER the method of payment of fees. In determining these methods, the Secretary will consider efficiency, effectiveness and convenience for users and for the Department. Methods may include credit card, electronic funds transfer and other methods of electronic payment.

§ 61.14 Confidentiality of Healthcare Integrity and Protection Data Bank information.

Information reported to the HIPDB is considered confidential and will not be disclosed outside the Department, except as specified in §§ 61.12 and 61.15. Persons and entities receiving information from the HIPDB, either directly or from another party, must use it solely with respect to the purpose for which it was provided. 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.

§ 61.15 How to dispute the accuracy of Healthcare Integrity and Protection Data Bank information.

(a) *Who may dispute the HIPDB information.* The HIPDB will routinely mail or transmit electronically to the subject a copy of the report filed in the HIPDB. In addition, as indicated in § 61.12(a)(3), 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.* If the subject disagrees with the reported information, the subject must request in writing that the HIPDB enter the report into ''disputed status.''

(2) The HIPDB 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 HIPDB, the HIPDB 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 HIPDB, either directly or through a designated representative, that will permanently append the report.

(c) *Procedures for requesting a Secretarial review.* The subject must request, in writing, that the Secretary of the Department review the report for accuracy. The subject must return this request to the HIPDB 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 HIPDB, the Secretary will inform the subject and the HIPDB 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 HIPDB 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 HIPDB or the reporting entity to revise the report. The Secretary will include a brief statement (Secretarial Statement) in the report describing the findings. The HIPDB 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 HIPDB 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 HIPDB 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 HIPDB, the Secretary will inform the subject and direct the HIPDB to void the report. The HIPDB will distribute a notice to previous queriers (where identifiable), the reporting entity and the subject of the report that the report has been voided.

[64 FR 57758, Oct. 26, 1999, as amended at 64 FR 71041, Dec. 20, 1999]

§ 61.16 Immunity.

Individuals, entities or their authorized agents and the HIPDB 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

Subpart A—General

Sec.

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