

§§ 405.2426 through 405.2429 of this chapter. The agency must pay for ambulatory services other than dental services under paragraph (c) (1) or (2) of this section.

(d) For purposes of paragraph (c) (1) and (3) of this section, “visit” means a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan. Encounters with more than one health professional, and multiple encounters with the same health professional, that take place on the same day and at a single location constitute a single visit, except when the patient, after the first encounter, suffers illness or injury requiring additional diagnosis or treatment.

[43 FR 45253, Sept. 29, 1978, as amended at 51 FR 34833, Sept. 30, 1986]

### Subpart I—Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements

SOURCE: 68 FR 51917, Aug. 29, 2003, unless otherwise noted.

§§ 447.500–447.532 [Reserved]

#### § 447.534 Manufacturer reporting requirements.

(a)–(g) [Reserved]

(h) *Recordkeeping requirements.* (1)(i) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports that rebate period’s data to CMS. The records must include these data and any other materials from which the calculations of the average manufacturer price and best price are derived, including a record of any assumptions made in the calculations. The 10-year timeframe applies to a manufacturer’s quarterly submission of pricing data as well as any revised pricing data subsequently submitted to CMS.

(ii) A manufacturer must retain records beyond the 10-year period if both of the following circumstances exist:

(A) The records are the subject of an audit or of a government investigation related to pricing data that are used in average manufacturer price or best price of which the manufacturer is aware.

(B) The audit findings or investigation related to the average manufacturer price and best price have not been resolved.

(2) The provisions in paragraph (h)(1) of this section concerning record retention terminate on December 31, 2004.

(i) *Timeframe for reporting revised average manufacturer price or best price.* A manufacturer must report to CMS revisions to average manufacturer price or best price for a period not to exceed 12 quarters from the quarter in which the data were due.

(ii) [Reserved]

[68 FR 51917, Aug. 29, 2003, as amended at 69 FR 513, Jan. 6, 2004]

§§ 447.536–447.550 [Reserved]

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## § 455.1

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45262, Sept. 29, 1978, unless otherwise noted.

### § 455.1 Basis and scope.

This part sets forth requirements for a State fraud detection and investigation program, and for disclosure of information on ownership and control.

(a) Under the authority of sections 1902(a)(4), 1903(i)(2), and 1909 of the Social Security Act, Subpart A provides State plan requirements for the identification, investigation, and referral of suspected fraud and abuse cases. In addition, the subpart requires that the State—

(1) Report fraud and abuse information to the Department; and

(2) Have a method to verify whether services reimbursed by Medicaid were actually furnished to recipients.

(b) Subpart B implements sections 1124, 1126, 1902(a)(36), 1903(i)(2), and 1903(n) of the Act. It requires that providers and fiscal agents must agree to disclose ownership and control information to the Medicaid State agency.

[51 FR 34787, Sept. 30, 1986]

### § 455.2 Definitions.

As used in this part unless the context indicates otherwise—

*Abuse* means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

*Conviction* or *Convicted* means that a judgment of conviction has been entered by a Federal, State, or local court, regardless of whether an appeal from that judgment is pending.

*Exclusion* means that items or services furnished by a specific provider who has defrauded or abused the Medicaid program will not be reimbursed under Medicaid.

*Fraud* means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthor-

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ized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law.

*Furnished* refers to items and services provided directly by, or under the direct supervision of, or ordered by, a practitioner or other individual (either as an employee or in his or her own capacity), a provider, or other supplier of services. (For purposes of denial of reimbursement within this part, it does not refer to services ordered by one party but billed for and provided by or under the supervision of another.)

*Practitioner* means a physician or other individual licensed under State law to practice his or her profession.

*Suspension* means that items or services furnished by a specified provider who has been convicted of a program-related offense in a Federal, State, or local court will not be reimbursed under Medicaid.

[48 FR 3755, Jan. 27, 1983, as amended at 50 FR 37375, Sept. 13, 1985; 51 FR 34788, Sept. 30, 1986]

### § 455.3 Other applicable regulations.

Part 1002 of this title sets forth the following:

(a) State plan requirements for excluding providers for fraud and abuse, and suspending practitioners convicted of program-related crimes.

(b) The limitations on FFP for services furnished by excluded providers or suspended practitioners.

(c) The requirements and procedures for reinstatement after exclusion or suspension.

(d) Requirements for the establishment and operation of State Medicaid fraud control units and the rates of FFP for their fraud control activities.

[51 FR 34788, Sept. 30, 1986]

## Subpart A—Medicaid Agency Fraud Detection and Investigation Program

### § 455.12 State plan requirement.

A State plan must meet the requirements of §§ 455.13 through 455.23.

[52 FR 48817, Dec. 28, 1987]