

§ 423.1

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AUTHORITY: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

SOURCE: 70 FR 4525, Jan. 28, 2005, unless otherwise noted.

Subpart A—General Provisions

§ 423.1 Basis and scope.

(a) *Basis.* (1) This part is based on the indicated provisions of the following sections of the Social Security Act:

42 CFR Ch. IV (10–1–23 Edition)

1106. Disclosure of Information in Possession of Agency.

1128J(d). Reporting and Returning of Overpayments.

1860D–1. Eligibility, enrollment, and information.

1860D–2. Prescription drug benefits.

1860D–3. Access to a choice of qualified prescription drug coverage.

1860D–4. Beneficiary protections for qualified prescription drug coverage.

1860D–11. PDP regions; submission of bids; plan approval.

1860D–12. Requirements for and contracts with prescription drug plan (PDP) sponsors.

1860D–13. Premiums; late enrollment penalty.

1860D–14. Premium and cost-sharing subsidies for low-income individuals.

1860D–14A. Medicare coverage gap discount program.

1860D–15. Subsidies for Part D eligible individuals for qualified prescription drug coverage.

1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

1860D–21. Application to Medicare Advantage program and related managed care programs.

1860D–22. Special rules for Employer-Sponsored Programs

1860D–23. State pharmaceutical assistance programs.

1860D–24. Coordination requirements for plans providing prescription drug coverage.

1860D–31. Medicare prescription drug discount card and transitional assistance program.

1860D–41. Definitions; treatment of references to provisions in Part C.

1860D–42. Miscellaneous provisions.

1860D–43. Condition for coverage of drugs under this part.

(2) The following specific sections of the Medicare Modernization Act also address the prescription drug benefit program:

Sec. 102 Medicare Advantage conforming amendments.

Sec. 103 Medicaid amendments.

Sec. 104 Medigap.

Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

(3) Section 1611 of Title 8 of the United States Code regarding individuals who are not lawfully present and ineligible for Federal public benefits.

(b) *Scope*. This part establishes standards for beneficiary eligibility, access, benefits, protections, and low-income subsidies in Part D, as well as establishes standards and sets forth requirements, limitations, procedures and payments for organizations participating in the Voluntary Medicare Prescription Drug Program.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 30683, May 28, 2008; 79 FR 29962, May 23, 2014; 80 FR 7962, Feb. 12, 2015]

§ 423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D-11(c) of the Act and with CMS actuarial guidelines.

Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).

Cost plan means a plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act.

Credible allegation of fraud means an allegation from any source, including but not limited to the following:

(1) Fraud hotline tips verified by further evidence.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D plan sponsor

(or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Eligible fallback entity or fallback entity is defined at § 423.855.

Fallback prescription drug plan is defined at § 423.855.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Fiscally sound operation means an operation which at least maintains a positive net worth (total assets exceed total liabilities).

Formulary means the entire list of Part D drugs covered by a Part D plan.

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

Full-benefit dual eligible individual has the meaning given the term at § 423.772, except where otherwise provided.

Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Group health plan is defined at § 423.882.

Immediate need individual means a beneficiary whose enrollment into LI NET is on the basis of presumed low income subsidy eligibility and immediate need of a Part D drug.

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by Medicare Advantage (MA) organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services are excluded, when determining inappropriate prescribing. Plan sponsors may