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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:

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.

*Authorized generic drug* means a drug as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)).

*Biological product* means a product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

*Biosimilar biological product* means a biological product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that, in accordance with section 351(i)(2) of the Public Health Service Act (42 U.S.C. 262(i)(2)), is highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and

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has no clinically meaningful differences between the biological product and the reference product, in terms of the safety, purity, and potency of the product.

*Brand name biological product* means a product licensed under section 351(a) (42 U.S.C. 262(a)) or 351(k) (42 U.S.C. 262(k)) of the Public Health Service Act and marketed under a brand name.

*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 consider any number of factors including, but not limited, to the following:

(1) Documentation of a patient's medical condition.

(2) Identified instances of patient harm or death.

(3) Medical records, including claims (if available).

(4) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.

(5) Levels of morphine milligram equivalent (MME) dosages prescribed.

(6) Absent clinical indication or documentation in the care management

plan or in a manner that may indicate diversion.

(7) State-level prescription drug monitoring program (PDMP) data.

(8) Geography, time, and distance between a prescriber and the patient.

(9) Refill frequency and factors associated with increased risk of opioid overdose.

*Insurance risk* means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

*Interchangeable biological product* means a product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that FDA has determined meets the standards described in section 351(k)(4) of the Public Health Service Act (42 U.S.C. 262(k)(4)), which in accordance with section 351(i)(3) of the Public Health Service Act (42 U.S.C. 262(i)(3)), may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

*Limited Income Newly Eligible Transition (LI NET) sponsor* means a Part D sponsor selected by CMS to administer the LI NET program.

*MA* stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

*MA plan* has the meaning given the term in § 422.2 of this chapter.

*MA-PD plan* means an MA plan that provides qualified prescription drug coverage.

*Medicare prescription drug account* means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

*Monthly beneficiary premium* means the amount calculated under § 423.286 for Part D plans other than fallback prescription drug plans, and § 423.867(a) for fallback prescription drug plans.

*MTM program* means a medication therapy management program described at § 423.153(d).

*PACE Plan* means a plan offered by a PACE organization.

*PACE organization* is defined in § 460.6 of this chapter.

*Parent organization* means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

*Part D eligible individual* means an individual who meets the requirements at § 423.30(a).

*Part D plan (or Medicare Part D plan)* means a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

*Part D plan sponsor or Part D sponsor* refers to a PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

*PDP region* means a prescription drug plan region as determined by CMS under § 423.112.

*PDP sponsor* means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans. This includes fallback entities.

*Pharmacist* means any individual who holds a current valid license to practice pharmacy in a State or territory of the United States or the District of Columbia.

*Prescription drug plan or PDP* means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part. This includes fallback prescription drug plans.

*Reference product* means a product as defined in section 351(i)(4) of the Public Health Service Act (42 U.S.C. 262(i)(4)).