

§ 423.1000

States are required to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles. Calendar year 2003 submittals must be complete and must be accepted, based on CMS' data quality review, by December 31, 2004.

(d) *State monthly enrollment reporting.*—

(1) States must submit an electronic file as specified in paragraph (d)(2) of this section, identifying each full-benefit dual eligible individual enrolled in the State for each month. This file must include specified information including identifying information, a dual eligible type code, available income data and institutional status. The file includes data on enrollment for the current month, plus retroactive changes in enrollment characteristics for prior months. This file will be used by CMS to establish the monthly enrollment for those individuals with Part D drug coverage who are also determined by the State to be eligible for full Medicaid benefits subject to the phased down State contribution payment. This file is due to CMS no later than the last day of the reporting month. For States that do not submit an acceptable file by the end of the month, the phased down State contribution for that month is based on data deemed appropriate by CMS.

(2)(i) For the period prior to April 1, 2022, States must submit the file at least monthly and may submit updates to that file on a more frequent basis.

(ii) For the period beginning April 1, 2022, States must submit the file at least monthly and must submit updates to that file on a daily basis.

(e) *Data match.* CMS performs those periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals needed to establish the State contribution payment.

(f) *Rebate adjustment factor.* CMS establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during calendar year 2003 as reported on CMS 64 Medicaid expenditure reports for the four quarters of calendar year 2003 that were received by CMS on or before March 31, 2004. Rebates include rebates received under the national rebate

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agreement and under a State supplemental rebate program, as reported on CMS–64 expenditure reports for the four quarters of calendar year 2003.

(g) *Annual per capita drug expenditures.* CMS notifies each State no later than October 15 before each calendar year, beginning October 15, 2005, of their annual per capita drug payment expenditure amount for the next year.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20509, Apr. 15, 2008; 85 FR 25634, May 1, 2020]

Subpart T—Appeal Procedures for Civil Money Penalties

SOURCE: 72 FR 68736, Dec. 5, 2007, unless otherwise noted.

§ 423.1000 Basis and scope.

(a) *Statutory basis.* (1) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected party has had notice and opportunity for a hearing.

(2) Section 1857 (g) of the Act provides that, for Part D sponsors found to be out of compliance with the requirements in part 423, specified remedies may be imposed instead of, or in addition to, termination of the Part D sponsor's contract. Section 1857(g)(4) of the Act makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on Part D sponsors.

(3) Section 1860D–14A(e)(2) of the Act specifies that the Secretary must impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with its Discount Program Agreement. Section 1860D–14A(e)(2)(B) of the Act makes certain provisions of section 1128A of the Act applicable to such civil money penalties imposed on manufacturers.

(b) [Reserved]

[72 FR 68736, Dec. 5, 2007, as amended 77 FR 22171, Apr. 12, 2012]

§ 423.1002 Definitions.

As used in this subpart—

Affected party means any Part D sponsor or manufacturer (as defined in