(2) Any cost-sharing obligations under Part D relating to Part D drugs.

(3) The effective date of paragraphs (b)(1) and (b)(2) of this section is January 1, 2006.

(c) *Noncovered drugs.* States may elect to provide coverage for outpatient drugs other than Part D drugs in the same manner as provided for non-full benefit dual eligible individuals or through an arrangement with a prescription drug plan or a MA-PD plan.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20509, Apr. 15, 2008]

§ 423.907 Treatment of territories.

(a) *General rules.* (1) Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under subpart P of this part.

(2) A territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs.

(3) Territories with plans approved by the Secretary will receive increased grants under section 1935(e)(3) of the Act as described in paragraph (c) of this section.

(b) *Plan requirements.* Plans submitted to the Secretary must include the following:

(1) A description of the medical assistance to be
provided.

(2) The low-income population (income less than 150
percent of the Federal poverty level) to receive medical assistance.

(3) An assurance that no more than 10 percent of the
amount of the increased grant will be used for administrative expenses.

(c) *Increased grant amounts.* The amount of the grant provided under section 1108 (f) of the Act as increased by section 1108 (g) of the Act for each territory with an approved plan for a year is the amount in paragraph (d) of this section multiplied by the ratio of—

(1) The number of individuals who are entitled to benefits under Part A or enrolled under Part B and who reside in the territory (as determined by the Secretary based on the most recent available data for the beginning of the year); and

(2) The sum of the number of individuals in all territories in paragraph (c)(1) of this section with approved plans.

(d) *Total grant amount.* The total grant amount is—

(1) For the last three quarters of fiscal year 2006, $28,125,000;

(2) For fiscal year 2007, $37,500,000; and

(3) For each subsequent year, the amount for the prior fiscal year increased by the annual percentage increase described in § 423.104(d)(5)(iv).

§ 423.908. Phased-down State contribution to drug benefit costs assumed by Medicare.

This subpart sets forth the requirements for State contributions for Part D drug benefits based on full-benefit dual eligible individual drug expenditures.

§ 423.910 Requirements.

(a) *General rule.* Each of the 50 States and the District of Columbia is required to provide for payment to CMS a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.

(b) *State contribution payment—*

(1) *Calculation of payment.* The State contribution payment is calculated by CMS on a monthly basis, as indicated in the following chart. For States that do not meet the monthly reporting requirement for the monthly enrollment reporting, the State contribution payment is calculated using a methodology determined by CMS.

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006

	Item	Illustrative Value	Source
(i)	Gross per capita Medicaid expenditures for prescription drugs for 2003 for full-benefit dual eligibles not receiving drug coverage through a comprehensive Medicaid managed care plan, excluding drugs not covered by Part D.	$2,000	CY MSIS data
(ii)	Aggregate State rebate receipts in calendar year 2003	$100,000,000	CMS–64
(iii)	Gross State Medicaid expenditures for prescription drugs in calendar year 2003.	$500,000,000	CMS–64
(iv) ...	Rebate adjustment factor	0.2000	(2) ÷ (3)
(v)	Adjusted 2003 gross per capita Medicaid expenditures for prescription drugs for full-benefit dual eligibles not in comprehensive managed care plans.	$1,600	(1) × [1 − (4)]
(vi) ...	Estimated actuarial value of prescription drug benefits under comprehensive capitated managed care plans for full-benefit dual eligibles for 2003.	$1,500	To be Determined
(vii) ...	Average number of full-benefit dual eligibles in 2003 who did not receive covered outpatient drugs through comprehensive Medicaid managed care plans.	90,000	CY MSIS data
(viii) ..	Average number of full-benefit dual eligibles in 2003 who received covered outpatient drugs through comprehensive Medicaid managed care plans.	10,000	CY MSIS data
(ix) ...	Base year State Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals (weighted average of (5) and (6)).	$1,590	[(7) × (5) + (8) × (6)] ÷ [(7) + (8)]
(x)	100 minus Federal Medical Assistance Percentage (FMAP) applicable to month of State contribution (as a proportion).	0.4000	FEDERAL REGISTER
(xi) ...	Applicable growth factor (cumulative increase from 2003 through 2006).	50.0%	NHE projections
(xii) ...	Number of full-benefit dual eligibles for the month	120,000	State submitted data
(xiii) ..	Phased-down State reduction factor for the month	0.9000	specified in statute
(xiv) ..	Phased-down State contribution for the month	$8,586,000	1 / 12 × (9) × (10) × [1 + (11)] × (12) × (13)

(2) *Method of payment.* Payments for the phased down State contribution begins in January 2006, and are made on a monthly basis for each subsequent month. State payment must be made in a manner specified by CMS that is similar to the manner in which State payments are made under the State Buy-in Program except that all payments must be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. The policy on collection of the Phased-down State contribution payment is the same as the policy that governs collection of Part A and Part B Medicare premiums for State Buy-in.

(c) *State Medicaid Statistical Information System (MSIS) Reporting.* Effective with calendar year (CY) 2003 and all subsequent MSIS data submittals, 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.* Effective June 2005, and each subsequent month, States must submit an electronic file, in a manner specified by CMS, 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.

(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 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]

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 § 423.2305) impacted by an initial determination or, if applicable, by a subsequent determination or decision issued under this part, and ''party'' means the affected party or CMS, as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

Part D sponsor has the meaning given the term in § 423.4.

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

§ 423.1004 Scope and applicability.

(a) *Scope.* This subpart sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the imposition of civil money penalties in accordance with part 423, subpart O.

§ 423.1006 Appeal rights.

(a) *Appeal rights of Part D sponsors.* (1) Any Part D sponsor dissatisfied with an initial determination as specified in § 423.1004, has a right to a hearing before an ALJ in accordance with this subpart and may request Departmental Appeals Board review of the ALJ decision.

(2) Part D sponsors may request judicial review of the Departmental Appeals Board's decision that imposes a CMP.