

(4) The financial condition of the Part D sponsor.

(5) The history of prior offenses by the Part D sponsor or principals of the Part D sponsor.

(6) Such other matters as justice may require.

(b) *Amount of penalty.* CMS may impose civil money penalties in the following amounts:

(1) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D enrollees—up to \$25,000 as adjusted annually under 45 CFR part 102 for each determination.

(2) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D enrollees, CMS may calculate a CMP of up to \$25,000 as adjusted annually under 45 CFR part 102 for each Part D enrollee directly adversely affected (or with a substantial likelihood of being adversely affected) by a deficiency.

(3)(i) Definitions for calculating penalty amounts—

(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination penalty amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(ii) CMS sets minimum penalty amounts in accordance with paragraphs (b)(1) and (2) of this section.

(iii) CMS announces the standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties on an annual basis.

(iv) CMS has the discretion to issue penalties up to the maximum amount under paragraphs (b)(1) and (2) of this section when CMS determines that an organization's non-compliance war-

rants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

(4) For each week that a deficiency remains uncorrected after the week in which the Part D sponsor receives CMS' notice of the determination—up to \$10,000 as adjusted annually under 45 CFR part 102.

(5) If CMS makes a determination that a Part D sponsor has terminated its contract other than in a manner described under 423.510 and that the Part D sponsor has therefore failed to substantially carry out the terms of the contract, \$250 as adjusted annually under 45 CFR part 102 per Medicare enrollee from the terminated Part D sponsor or plans at the time the Part D sponsor terminated its contract, or \$100,000 as adjusted annually under 45 CFR part 102, whichever is greater.

(c) *Amount of penalty imposed by CMS or OIG.* CMS or the OIG may impose civil money penalties in the following amounts for a determination made under § 423.752(a):

(1) Civil money penalties of not more than \$25,000 as adjusted annually under 45 CFR part 102 for each determination made.

(2) With respect to a determination made under § 423.752(a)(4) or (a)(5)(i), not more than \$100,000 as adjusted annually under 45 CFR part 102 for each such determination except with respect to a determination made under § 423.752(a)(5), an assessment of not more than the amount claimed by such plan or PDP sponsor based upon the misrepresentation or falsified information involved.

(3) Plus with respect to a determination made under § 423.752(a)(2), double the excess amount charged in violation of such paragraph (and the excess amount charged must be deducted from the penalty and returned to the individual concerned).

(4) Plus with respect to a determination made under § 423.752(a)(4), \$15,000 as adjusted annually under 45 CFR part 102 for each individual not enrolled as a result of the practice involved.

[72 FR 68735, Dec. 5, 2007, as amended at 74 FR 1548, Jan. 12, 2009; 79 FR 29966, May 23, 2014; 81 FR 61562, Sept. 6, 2016; 86 FR 6121, Jan. 19, 2021; 89 FR 30841, Apr. 23, 2024]

§ 423.762 Settlement of penalties.

For civil money penalties imposed by CMS, CMS may settle civil money penalty cases at any time before a final decision is rendered.

[72 FR 68735, Dec. 5, 2007]

§ 423.764 Other applicable provisions.

The provisions of section 1128A of the Act (except paragraphs (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

[70 FR 4525, Jan. 28, 2005. Redesignated at 72 FR 68735, Dec. 5, 2007]

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§ 423.771 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–14 of the Act.

(b) *Scope.* This subpart sets forth the requirements and limitations for payments by and on behalf of low-income Medicare beneficiaries who enroll in a Part D plan.

§ 423.772 Definitions.

For purposes of this subpart, the following definitions apply:

Applicant means the Part D eligible individual applying for the subsidies available to subsidy eligible individuals under this subpart.

Best available evidence means evidence recognized by CMS as documentation or other information that is directly tied to State or Social Security Administration systems that confirm an individual's low-income subsidy eligibility status, and that must be accepted and used by the Part D sponsor to change low-income subsidy status.

Family size means the applicant, the spouse who is living in the same household, if any and the number of individuals who are related to the applicant or applicants, who are living in the same household and who are dependent on the applicant or the applicant's spouse for at least one-half of their financial support.

Federal poverty line (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 USC 9902(2)), including any revision required by that section.

Full-benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus program demonstrations or under a section 1115 demonstration that provides pharmacy-only benefits to these individuals.). It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month.

Full subsidy means the subsidies available to full subsidy eligible individuals under § 423.780(a) and § 423.782(a).

Full subsidy eligible individuals means individuals meeting the eligibility requirements under § 423.773(b).

Income means income as described under section 1905(p)(1) of the Act without use of any more liberal disregards under section 1902(r)(2) of the Act (that is defined by section 1612 of the Act) and exempts support and maintenance furnished in kind. This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant.

Individual receiving home and community-based services means a full-benefit dual-eligible individual who is receiving services under a home and community-based program authorized for a State in accordance with one of the following: