

\$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]

§ 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:

- (1) Section 1115 of the Act.
- (2) Section 1915(c) or (d) of the Act.
- (3) State plan amendment under section 1915(i) of the Act.
- (4) Services are provided through enrollment in a Medicaid managed care organization with a contract under section 1903(m) of the Act or section 1932 of the Act.

Institutionalized individual means a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act.

Other subsidy eligible individuals means those individuals meeting the eligibility requirements under § 423.773(d).

Personal representative for purposes of this subpart means—

- (1) An individual who is authorized to act on behalf of the applicant;
- (2) If the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf, or
- (3) An individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

Resources means liquid resources of the applicant (and, if married, his or her spouse who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located. It exempts the value of any life insurance policy.

State means for purposes of this subpart each of the 50 States and the District of Columbia.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54253, Sept. 18, 2008; 74 FR 1548, Jan. 12, 2009; 76 FR 21576, Apr. 15, 2011]

§ 423.773 Requirements for eligibility.

(a) *Subsidy eligible individual.* A subsidy eligible individual is a Part D eligible individual residing in a State who is enrolled in, or seeking to enroll in a Part D plan and meets the following requirements:

- (1) Has income below 150 percent of the FPL applicable to the individual's family size.
- (2) Has resources at or below the resource thresholds set forth in § 423.773(b)(2) or (d)(2).

(b) *Full subsidy eligible individual.* A full subsidy eligible individual is a subsidy eligible individual who—

- (1) Has income below 135 percent of the FPL applicable to the individual's family size or, with respect to a plan year beginning on or after January 1, 2024, has income below 150 percent of the FPL applicable to the individual's family size; and
- (2) Has resources that do not exceed—
 - (i) For 2006, 3 times the amount of resources an individual may have and still be eligible for benefits under the Supplemental Security Income (SSI)

program under title XVI of the Act (including the assets or resources of the individual's spouse).

(ii) For years 2007 through 2023, the amount of resources allowable for the previous year under this paragraph (b)(2) increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of that previous year, rounded to the nearest multiple of \$10. The nearest multiple are rounded up if it is equal to or greater than \$5 and down if it is less than \$5.

(iii) For plan years beginning on or after January 1, 2024, the amount of resources specified at paragraph (d)(2) of this section.

(c)(1) *Individuals treated as full subsidy eligible.* An individual must be treated as meeting the eligibility requirements for full subsidy eligible individuals under paragraph (b) of this section if the individual is a—

(i) Full-benefit dual eligible individual;

(ii) Beneficiary of SSI benefits under title XVI of the Act; or

(iii) Eligible for Medicaid as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State's plan.

(2) CMS notifies an individual treated as a full-subsidy eligible under this paragraph (c) that he or she does not need to apply for the subsidies under this subpart, and, at a minimum, is deemed eligible for a full subsidy as follows:

(i) For an individual deemed eligible between January 1 and June 30 of a calendar year, the individual is deemed eligible for a full subsidy for the remainder of the calendar year.

(ii) For an individual deemed eligible between July 1 and December 31 of a calendar year, the individual is deemed eligible for the remainder of the calendar year and the following calendar year.

(d) *Other low-income subsidy individuals.* Other low-income subsidy individuals are subsidy eligible individuals who, for plan years beginning before January 1, 2024—

(1) Have income less than 150 percent of the FPL applicable to the individual's family size; and

(2) Have resources that do not exceed—

(i) For 2006, \$10,000 if single or \$20,000 if married (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the resource amount allowable for the previous year under this paragraph (d)(2), increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of the previous year, rounded to the nearest multiple of \$10. The nearest multiple will be rounded up if it is equal to or greater than \$5 and down if it is less than \$5.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19825, Apr. 15, 2010; 88 FR 22340, Apr. 12, 2023]

§ 423.774 Eligibility determinations, redeterminations, and applications.

(a) *Determinations of whether an individual is a subsidy eligible individual.* Determinations of eligibility for subsidies under this subpart are made by the State under its State plan under title XIX of the Act if the individual applies with the Medicaid agency, or if the individual applies with the Social Security Administration (SSA), the Commissioner of Social Security in accordance with the requirements of section 1860D-14(a)(3) of the Act.

(b) *Effective date of initial eligibility determinations.* Initial eligibility determinations are effective beginning with the first day of the month in which the individual applies, but no earlier than January 1, 2006 and remain in effect for a period not to exceed 1 year.

(c) *Redeterminations and appeals of low-income subsidy eligibility—(1) Redeterminations and appeals of low-income subsidy eligibility determinations—eligibility determinations made by States.* Redeterminations and appeals of low-income subsidy eligibility determinations by States must be made in the same manner and frequency as the redeterminations and appeals are made under the State's plan.

(2) *Redeterminations and appeals of low-income subsidy eligibility—eligibility determinations made by Commissioner of Social Security.* Redeterminations and appeals of eligibility determinations made by the Commissioner will be

made in the manner specified by the Commissioner of Social Security.

(d) *Application requirements.* (1) In order for applications for the subsidies under this subpart to be considered complete, applicants or personal representatives applying on the individual's behalf, must—

(i) Complete all required elements of the application; (ii) Provide any statements from financial institutions, as requested, to support information in the application; and

(iii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(2) *Multiple applications.* If the individual or his or her personal representative has previously filed an application with the State or SSA which seeks subsidy eligibility for any portion of the eligibility period covered by a subsequent application, the later application is void if the individual has received a positive subsidy determination on that earlier application from the State or SSA.

§ 423.780 Premium subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to a premium subsidy equal to 100 percent of the premium subsidy amount.

(b) *Premium subsidy amount.* (1) The premium subsidy amount is equal to the lesser of—

(i) Under the Part D plan selected by the beneficiary, the portion of the monthly beneficiary premium attributable to basic coverage (for enrollees in PDPs) or the portion of the MA monthly prescription drug beneficiary premium attributable to basic prescription drug coverage (for enrollees in MA-PD plans); or

(ii) The greater of the low-income benchmark premium amount (determined under paragraph (b)(2) of this section) for the PDP region in which the subsidy eligible individual resides or the lowest monthly beneficiary premium for a PDP that offers basic prescription drug coverage in the PDP region.

(2) *Calculation of the low-income benchmark premium amount.* (i) The low-

income benchmark premium amount for a PDP region is a weighted average of the premium amounts described in paragraph (b)(2)(ii) of this section, with the weight for each PDP and MA-PD plan equal to a percentage, the numerator being equal to the number of Part D low-income subsidy eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D low-income subsidy eligible individuals enrolled in all PDP and MA-PD plans (but not including PACE, private fee-for-service plans or 1876 cost plans) in a PDP region in the reference month.

(ii) *Premium amounts.* The premium amounts used to calculate the low-income benchmark premium amount are as follows:

(A) The monthly beneficiary premium for a PDP that is basic prescription drug coverage;

(B) The portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a PDP that is enhanced alternative coverage; or,

(C) The MA monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Act) for a MA-PD plan and determined before the application of the monthly rebate computed under section 1854(b)(1)(C)(i) of the Act for that plan and year involved.

(c) *Special rule for 2006 to weight the low-income benchmark premium.* For purposes of calculating the low-income benchmark premium amount for 2006, CMS assigns equal weighting to PDP sponsors (including fallback entities) and assigns MA-PD plans a weight based on prior enrollment. New MA-PD plans are assigned a zero weight. PACE, private fee-for-service plans and 1876 cost plans are not included.

(d) *Other low-income subsidy eligible individuals—sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium subsidy for plan years beginning before January 1, 2024, based on a linear sliding scale ranging from 100 percent of the premium subsidy amount described in paragraph (b) of this section as follows:

(1) For individuals with income at or below 135 percent of the FPL applicable to their family size, the full premium subsidy amount.

(2) For individuals with income greater than 135 percent but at or below 140 percent of the FPL applicable to the family size, a premium subsidy equal to 75 percent of the premium subsidy amount.

(3) For individual with income greater than 140 percent but at or below 145 percent of the FPL applicable to the family size a premium subsidy equal to 50 percent of the premium subsidy amount.

(4) For individuals with income greater than 145 percent but below 150 percent of FPL applicable to the family size a premium subsidy equal to 25 percent of the premium subsidy amount.

(e) *Waiver of late enrollment penalty for subsidy-eligible individuals.* Subsidy eligible individuals, as defined in § 423.773, are not subject to a late enrollment penalty, as defined in § 423.46.

(f) *Waiver of de minimis premium amounts.* CMS will permit a Part D plan to waive a de minimis amount that is above the monthly beneficiary premium defined in § 423.780(b)(2)(ii)(A) or (B) for full subsidy individuals as defined in § 423.780(a) or § 423.780(d)(1), provided waiving the de minimis amount results in a monthly beneficiary premium that is equal to the established low income benchmark as defined in § 423.780(b)(2).

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 18182, Apr. 3, 2008; 73 FR 20508, Apr. 15, 2008; 73 FR 54253, Sept. 18, 2008; 76 FR 21576, Apr. 15, 2011; 88 FR 22340, Apr. 12, 2023]

§ 423.782 Cost-sharing subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to the following:

(1) Elimination of the annual deductible under § 423.104(d)(1).

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA-PD plan below the out-of-pocket limit (under § 423.104), including Part D drugs covered under the PDP or MA-PD plan obtained after the initial coverage limit (under § 423.104(d)(4)), as follows:

(i) Except as provided under paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, copayment amounts not to exceed the copayment amounts specified in § 423.104(d)(5)(A). This applies to both:

(A) Those full-benefit dual eligible individuals who are not institutionalized and who have income above 100 percent of the Federal poverty line applicable to the individual's family size and

(B) Those individuals who have income under 135 percent of the Federal poverty line applicable to the individual's family size who meet the resources test described at § 423.773(b)(2).

(ii) Full-benefit dual-eligible individuals who are institutionalized or who are receiving home and community-based services have no cost-sharing for Part D drugs covered under their PDP or MA-PD plans.

(iii) Full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered Part D drugs equal to the lesser of:

(A) A copayment amount of not more than \$1 for a generic drug, biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved, or preferred drugs that are multiple source (as defined under section 1927(k)(7)(A)(i) of the Act) or \$3 for any other drug in 2006, or for years after 2006 the amounts specified in this paragraph (a)(2)(iii)(A) for the percentage increase in the Consumer Price Index, rounded to the nearest multiple of 5 cents or 10 cents, respectively; or

(B) The copayment amount charged to other individuals under this paragraph (a)(2)(i) of this section.

(3) Elimination of all cost-sharing for covered Part D drugs covered under the PDP or MA-PD plan above the out-of-pocket limit (under § 423.104(d)(5)).

(b) *Other low-income subsidy eligible individuals.* Other low-income subsidy eligible individuals are entitled to the following:

(1) In 2006, reduction in the annual deductible to \$50. This amount is increased each year beginning in 2007 by

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the annual percentage increase in average per capita aggregate expenditures for Part D drugs, rounded to the nearest multiple of \$1.

(2) Fifteen percent coinsurance for all covered Part D drugs obtained after the annual deductible under the plan up to the out-of-pocket limit (under § 423.104(d)(5)(iii)).

(3) For covered Part D drugs above the out-of-pocket limit (under § 423.104(d)(5)(iii)) in 2006, copayments not to exceed \$2 for a generic drug, biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved, or preferred drugs that are multiple source drugs (as defined under section 1927(k)(7)(A)(i) of the Act) and \$5 for any other drug. For years beginning in 2007, the amounts specified in this paragraph (b)(3) for the previous years increased by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

(c) When the out-of-pocket cost for a covered Part D drug under a Part D sponsor's plan benefit package is less than the maximum allowable copayment, coinsurance or deductible amounts under paragraphs (a) and (b) of this section, the Part D sponsor may only charge the lower benefit package amount.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 76 FR 21576, Apr. 15, 2011; 83 FR 16753, Apr. 16, 2018]

§ 423.800 Administration of subsidy program.

(a) *Notification of eligibility for low-income subsidy.* CMS notifies the Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy under this section and the amount of the subsidy.

(b) *Reduction of premium or cost-sharing by PDP sponsor or organization.* Based on information provided by CMS under paragraph (a) of this section, or obtained under paragraph (d) of this section, the Part D sponsor offering the Part D plan in which a subsidy eligible individual is enrolled must reduce the individual's premiums and cost-sharing as applicable, and provide information

to CMS on the amount of those reductions, in a manner determined by CMS. The Part D sponsor must track the application of the subsidies under this subpart to be applied to the out-of-pocket threshold.

(c) *Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy.* The Part D sponsor offering the Part D plan must reimburse subsidy eligible individuals, and organizations paying cost-sharing on behalf of such individuals, any excess premiums and cost-sharing paid by such individual or organization after the effective date of the individual's eligibility for a subsidy under this subpart.

(d) *Use of the best available evidence process to establish cost-sharing.* Part D sponsors must—

(1) Accept best available evidence as defined in § 423.772 of this part received from beneficiaries or other individuals acting directly on their behalf; and

(2) Update the subsidy eligible individual's LIS status, and respond to requests for assistance in securing acceptable evidence of subsidy eligibility from beneficiaries or other individuals acting directly on their behalf in accordance with the process(es) established by CMS, and within the reasonable timeframe(s) as determined by CMS.

(e) *Timeframe for refunds and recoveries due to retroactive adjustments to cost sharing.* Sponsors must process retroactive adjustments to cost-sharing for low-income subsidy eligible individuals and any resulting refunds and recoveries in accordance with the timeframe specified in § 423.466(a) of this part.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1549, Jan. 12, 2009; 75 FR 19825, Apr. 15, 2010]

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback Prescription Drug Plans)

§ 423.851 Scope.

This subpart sets forth—the rights of beneficiaries to a choice of at least two sources of qualified prescription drug coverage; requirements and limitations on the bid submission, review and approval of fallback prescription drug