

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than \$2,500 during a contract period.

Service area (*Service area does not include facilities in which individuals are incarcerated.*) means for—

(1) A prescription drug plan, an area established in § 423.112(a) within which access standards under § 423.120(a) are met;

(2) An MA-PD plan, an area that meets the definition of MA service area as described in § 422.2 of this chapter, and within which access standards under § 423.120(a) are met;

(3) A fallback prescription drug plan, the service area described in § 423.859(b);

(4) A PACE plan offering qualified prescription drug coverage, the service area described in § 460.12(c) of this chapter; and

(5) A cost plan offering qualified prescription drug coverage, the service area defined in § 417.1 of this chapter.

Subsidy-eligible individual means a full subsidy eligible individual (as defined at § 423.772) or other subsidy eligible individual (as defined at § 423.772).

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier;

(1) Engaged in a pattern of improper billing;

(2) Submitted improper claims with suspected knowledge of their falsity;

(3) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(4) Is the subject of a fraud hotline tip verified by further evidence.

Tiered cost-sharing means a process of grouping Part D drugs into different cost sharing levels within a Part D sponsor's formulary.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68731, Dec. 5, 2007; 76 FR 21570, Apr. 15, 2011; 84 FR 25671, June 3, 2019; 86 FR 6114, Jan. 19, 2021; 88 FR 22337, Apr. 12, 2023]

§ 423.6 Cost-sharing in beneficiary education and enrollment-related costs.

The requirements of section 1857(e)(2) of the Act and § 422.6 of this chapter with regard to the payment of fees established by CMS for cost sharing of enrollment related costs apply to PDP sponsors under Part D.

Subpart B—Eligibility and Enrollment

§ 423.30 Eligibility and enrollment.

(a) *General rule.* (1) An individual is eligible for Part D if he or she does all of the following:

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B (but not including an individual enrolled solely for coverage of immunosuppressive drugs under § 407.1(a)(6)) of this subchapter.

(ii) Lives in the service area of a Part D plan, as defined under § 423.4.

(iii) Is a United States citizen or is lawfully present in the United States as determined in 8 CFR 1.3.

(2) Except as provided in paragraphs (b), (c), and (d) of this section, an individual is eligible to enroll in a PDP if:

(i) The individual is eligible for Part D in accordance with paragraph (a)(1) of this section;

(ii) The individual resides in the PDP's service area; and

(iii) The individual is not enrolled in another Part D plan.

(3) Retroactive Part A or Part B determinations. Individuals who become entitled to Medicare Part A or enrolled in Medicare Part B for a retroactive effective date are Part D eligible as of the month in which a notice of entitlement Part A or enrollment in Part B is provided.

(b) *Coordination with MA plans.* A Part D eligible individual enrolled in a MA-PD plan must obtain qualified prescription drug coverage through that plan. MA enrollees are not eligible to enroll in a PDP, except as follows:

(1) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage; and

(2) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MSA plan (as defined in section 1859(b)(3) of the Act).

(c) *Enrollment in a PACE plan.* A Part D eligible individual enrolled in a PACE plan that offers qualified prescription drug coverage under this Part must obtain such coverage through that plan.

(d) *Enrollment in a cost-based HMO or CMP.* A Part D eligible individual enrolled in a cost-based HMO or CMP (as defined under part 417 of this chapter) that elects to receive qualified prescription drug coverage under such plan is ineligible to enroll in another Part D plan. A Part D eligible individual enrolled in a cost-based HMO or CMP offering qualified prescription drug coverage is eligible to enroll in a PDP if the individual does not elect to receive qualified prescription drug coverage under the cost-based HMO or CMP and otherwise meets the requirements of paragraph (a)(2) of this section.

[70 FR 4525, Jan. 28, 2005, as amended at 80 FR 7962, Feb. 12, 2015; 87 FR 66510, Nov. 3, 2022]

§ 423.32 Enrollment process.

(a) *General rule.* A Part D eligible individual who wishes to enroll in a PDP may enroll during the enrollment periods specified in § 423.38, by filing the appropriate enrollment form with the PDP or through other mechanisms CMS determines are appropriate.

(b) *Enrollment form or CMS-approved enrollment mechanism.* The enrollment form or CMS-approved enrollment mechanism must comply with CMS instructions regarding content and format and must have been approved by CMS as described in § 423.2262.

(1) The enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the PDP sponsor. Individuals who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

(2) Part D eligible individuals enrolling or enrolled in a Part D plan must provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, and consent to the release of the information provided by the individual on other insurance, group health plan or other third-party payment arrangements, as well as any other information on reimbursement of Part D costs collected or obtained from other sources, in a form and manner approved by CMS.

(c) *Timely process an individual's enrollment request.* A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines and enroll Part D eligible individuals who are eligible to enroll in its plan under § 423.30(a) and who elect to enroll or are enrolled in the plan during the periods specified in § 423.38.

(d) *Notice requirement.* The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

(e) *Maintenance of enrollment.* An individual who is enrolled in a PDP remains enrolled in that PDP until one of the following occurs:

(i) The individual successfully enrolls in another PDP or MA-PD plan;

(ii) The individual voluntarily disenrolls from the PDP;

(iii) The individual is involuntary disenrolled from the PDP in accordance with § 423.44(b)(2);

(iv) The PDP is discontinued within the area in which the individual resides; or

(iv) The individual is enrolled after the initial enrollment, in accordance with § 423.34(c).

(f) *Enrollees of cost-based HMOs or CMPs and PACE.* Individuals enrolled in a cost-based HMO or CMP plan (as defined in part 417 of this chapter) or PACE (as defined in § 460.6 of this chapter) that offers prescription drug coverage under this part as of December 31, 2005, remain enrolled in that plan as of January 1, 2006, and receive Part D benefits offered by that plan until one of the conditions in § 423.32(e) are met.

(g) *Passive enrollment by CMS.* In situations involving either immediate terminations as provided in § 423.509(a)(5) or § 422.510(a)(5) of this chapter, or other situations in which CMS determines that remaining enrolled in a plan poses potential harm to plan members, CMS may implement passive enrollment procedures.

(1) *Passive enrollment procedures.* Individuals will be considered to have enrolled in the plan selected by CMS unless individuals—

(i) Decline the plan selected by CMS, in a form and manner determined by CMS; or

(ii) Request enrollment in another plan.

(2) *Beneficiary notification.* The organization that receives the enrollment must provide notification that describes the costs and benefits of the new plan and the process for accessing care under the plan and the beneficiary's ability to decline the enrollment or choose another plan. Such notification must be provided to all potential enrollees prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical), in a form and manner determined by CMS.

(3) *Special election period.* All individuals will be provided with a special enrollment period, as described in § 423.38(c)(8)(ii).

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1543, Jan. 12, 2009; 83 FR 16736, Apr. 16, 2018]

§ 423.34 Enrollment of low-income subsidy eligible individuals.

(a) *General rule.* CMS must ensure the enrollment into Part D plans of low-income subsidy eligible individuals who fail to enroll in a Part D plan.

(b) *Definitions—Full-benefit dual-eligible individual.* For purposes of this section, a full-benefit dual eligible individual means an individual who is—

(1) Determined eligible by the State for—

(i) Medical assistance for full-benefits under Title XIX of the Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act; or

(ii) 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) for any month if the individual was eligible for medical assistance in any part of the month.

(2) Eligible for Part D in accordance with § 423.30(a) of this subpart.

Low-income subsidy-eligible individual. For purposes of this section, a low-income subsidy eligible individual means an individual who meets the definition of full subsidy eligible (including full benefit dual eligible individuals as set forth in this section) or other subsidy eligible in § 423.772 of this part.

(c) *Reassigning low income subsidy eligible individuals—(1) General rule.* Notwithstanding § 423.32(e) of this subpart, during the annual coordinated election period, CMS may reassign certain low income subsidy eligible individuals in another PDP if CMS determines that the further enrollment is warranted, except as specified in paragraph (c)(2) of this section.

(2) *Part D prescription drug plans that waive a de minimis premium amount.* If a Part D plan offering basic prescription drug coverage in the area where the beneficiary resides has a monthly beneficiary premium amount that exceeds the low-income subsidy amount by a de minimis amount, and the Part D plan volunteers to waive that de minimis amount in accordance with § 423.780, then CMS does not reassign low income subsidy individuals who would otherwise be enrolled under paragraph (d)(1) of this section on the basis that the monthly beneficiary premium exceeds the low-income subsidy by a de minimis amount. A Part D plan that volunteers to waive such a de minimis amount agrees to do so for each month during the contract year for which a beneficiary qualifies for 100 percent low-income premium subsidy as provided in § 423.780(f).

(d) *Automatic enrollment rules—(1) General rule.* Except for low income subsidy eligible individuals who are qualifying covered retirees with a group health plan sponsor, as specified in paragraph (d)(3) of this section, CMS

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enrolls those individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the beneficiary resides that has a monthly beneficiary premium amount that does not exceed the low income subsidy amount (as defined in § 423.780(b) of this part). In the event that there is more than one PDP in an area with a monthly beneficiary premium at or below the low income premium subsidy amount, individuals are enrolled in such PDPs on a random basis.

(2) *Individuals enrolled in an MSA plan or one of the following that does not offer a Part D benefit.* Low-income subsidy eligible individuals enrolled in an MA private fee-for-service plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage or an MSA plan and who fail to enroll in a Part D plan must be enrolled into a PDP plan as described in paragraph (d)(1) of this section.

(3) *Exception for individuals who are qualifying covered retirees.* (i) Full benefit dual eligible individuals who are qualifying covered retirees as defined in § 423.882 of this part, and for whom CMS has approved the group health plan sponsor to receive the retirement drug subsidy described in subpart R of this part, also are automatically enrolled in a Part D plan, consistent with this paragraph, unless they elect to decline that enrollment.

(ii) Before effectuating such an enrollment, CMS provides notice to such individuals of their choices and advises them to discuss the potential impact of Medicare Part D coverage on their group health plan coverage. The notice informs individuals that they will be deemed to have declined to enroll in Part D unless they affirmatively enroll in a Part D plan or contact CMS and confirm that they wish to be auto-enrolled in a PDP. Individuals who elect not to be auto-enrolled, may enroll in Medicare Part D at a later time if they choose to do so.

(iii) All other low income subsidy eligible beneficiaries who are qualified covered retirees are not enrolled by CMS into PDPs.

(4) *Enrollment in PDP plans that voluntarily waive a de minimis premium amount.* CMS may include in the proc-

ess specified in paragraph (d)(1) of this section that PDPs that voluntarily waive a de minimis amount as specified in § 423.780, if CMS determines that such inclusion is warranted.

(e) *Declining enrollment and disenrollment.* Nothing in this section prevents a low income subsidy eligible individual from—

(1) Affirmatively declining enrollment in Part D; or

(2) Disenrolling from the Part D plan in which the individual is enrolled and electing to enroll in another Part D plan during the special enrollment period provided under § 423.38.

(f) *Effective date of enrollment for full-benefit dual eligible individuals.* Enrollment of full-benefit dual eligible individuals under this section must be effective as follows:

(1) January 1, 2006 for individuals who are full-benefit dual-eligible individuals as of December 31, 2005.

(2) The first day of the month the individual is eligible for Part D under § 423.30(a)(1) for individuals who are Medicaid eligible and subsequently become newly eligible for Part D under § 423.30(a)(1) on or after January 1, 2006.

(3) For individuals who are eligible for Part D under § 423.30(a)(1) of this subpart and subsequently become newly eligible for Medicaid on or after January 1, 2006, enrollment is effective with the first day of the month when the individuals become eligible for both Medicaid and Part D.

(g) *Effective date of enrollment for non-full-benefit dual-eligible individuals who are low-income subsidy-eligible individuals.* The effective date for non-full-benefit dual-eligible individuals who are low-income subsidy-eligible individuals is no later than the first day of the second month after CMS determines that they meet the criteria for enrollment under this section.

[75 FR 19815, Apr. 15, 2010, as amended at 76 FR 21570, Apr. 15, 2011]

§ 423.36 Disenrollment process.

(a) *General rule.* An individual may disenroll from a PDP during the periods specified in § 423.38 by enrolling in a different PDP plan, submitting a disenrollment request to the PDP in the form and manner prescribed by CMS, or filing the appropriate

disenrollment request through other mechanisms as determined by CMS.

(b) *Responsibilities of the PDP sponsor.* The PDP sponsor must—

(1) Submit a disenrollment notice to CMS within timeframes CMS specifies;

(2) Provide the enrollee with a notice of disenrollment as CMS determines and approves; and

(3) File and retain disenrollment requests for the period specified in CMS instructions.

(c) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(1) There never was a legally valid enrollment; or

(2) A valid request for disenrollment was properly made but not processed or acted upon.

§ 423.38 Enrollment periods.

(a) *Initial enrollment period for Part D—Basic rule.* The initial enrollment period is the period during which an individual is first eligible to enroll in a Part D plan.

(1) *In 2005.* An individual who is first eligible to enroll in a Part D plan on or prior to January 31, 2006, has an initial enrollment period from November 15, 2005 through May 15, 2006.

(2) *February 2006.* An individual who is first eligible to enroll in a Part D plan in February 2006 has an initial enrollment period from November 15, 2005 through May 31, 2006.

(3) *March 2006 and subsequent months.* (i) Except as provided in paragraph (a)(3)(ii) and (a)(3)(iii) of this section, the initial enrollment period for an individual who is first eligible to enroll in a Part D plan on or after March 2006 is the same as the initial enrollment period for Medicare Part B under § 407.14 of this chapter.

(ii) Exception. For those individuals who are not eligible to enroll in a Part D plan at any time during their initial enrollment period for Medicare Part B, their initial enrollment period under this Part is the 3 months before becoming eligible for Part D, the month of eligibility, and the three months following eligibility to Part D.

(iii) An individual who becomes entitled to Medicare Part A or enrolled in Part B for a retroactive effective date has an initial enrollment period under

this Part beginning with the month in which notification of the Medicare determination is received and ending on the last day of the third month following the month in which the notification was received.

(b) *Annual coordinated election period—(1) For 2006.* This period begins on November 15, 2005 and ends on May 15, 2006.

(2) *For 2007 through 2010.* The annual coordinated election period for the following calendar year is November 15 through December 31.

(3) *For 2011 and subsequent years.* Beginning with 2011, the annual coordinated election period for the following calendar year is October 15 through December 7.

(c) *Special enrollment periods.* A Part D eligible individual may enroll in a PDP or disenroll from a PDP and enroll in another PDP or MA-PD plan (as provided at § 422.62(b) of this chapter), as applicable, under any of the following circumstances:

(1) The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable coverage as defined under § 423.56(a). Loss of creditable prescription drug coverage due to failure to pay any required premium is not considered involuntary loss of the coverage.

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, that he or she never had creditable prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage.

(3) The individual's enrollment or non-enrollment in a Part D plan is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal government to act on its behalf.

(4)(i) Except as provided in paragraph (ii), the individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in § 423.772, who is making an allowable onetime-per-calendar-quarter election between January through September.

(ii) An individual described in paragraph (i) is not eligible for this special enrollment period if he or she has been notified that he or she has been identified as a “potential at-risk beneficiary” or “at-risk beneficiary” as defined in § 423.100 and such identification has not been terminated in accordance with § 423.153(f)).

(5) The individual elects to disenroll from a MA-PD plan and elects coverage under Medicare Part A and Part B in accordance with § 422.62(c) of this chapter.

(6) The PDP sponsor’s contract is terminated by the PDP sponsor or by CMS, as provided under § 423.507 through § 423.510, or the PDP plan is no longer offered in the area when the individual resides.

(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered.

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that the PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to any of the following:

(i) Failure to provide the individual on a timely basis benefits available under the plan.

(ii) Failure to provide benefits in accordance with applicable quality standards.

(iii) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan’s provisions in communications as outlined in subpart V of this part.

(9) The individual is making an election within 3 months after a gain, loss, or change to Medicaid or LIS eligibility, or notification of such a change, whichever is later.

(10) The individual is making an election within 3 months after notification of a CMS or State-initiated enrollment action or that enrollment action’s effective date, whichever is later.

(11) The individual is making an enrollment request into or out of an employer sponsored Part D plan, is disenrolling from a Part D plan to take employer sponsored coverage of any

kind, or is disenrolling from employer sponsored coverage (including Consolidated Omnibus Budget Reconciliation Act (COBRA) coverage) to elect a Part D plan.

(i) This special election period (SEP) is available to individuals who have (or are enrolling in) an employer or union sponsored Part D plan and ends 2 months after the month the employer or union coverage of any type ends.

(ii) The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to 3 months after the month in which the election is made.

(12) The individual is enrolled in a Part D plan offered by a Part D plan sponsor that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction.

(i) Consistent with the disclosure requirements at § 423.128(f), CMS may require the sponsor to notify current enrollees that if the enrollees believe they are affected by the matter(s) that gave rise to the sanction, the enrollees are eligible for a SEP to elect another PDP.

(ii) The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

(13) The individual is enrolled in a section 1876 cost contract that is non-renewing its contract for the area in which the enrollee resides.

(i) Individuals eligible for this SEP must meet Part D plan eligibility requirements.

(ii) This SEP begins December 8 of the then-current contract year and ends on the last day of February of the following year.

(14) The individual is disenrolling from a PDP to enroll in a Program of All-inclusive Care for the Elderly (PACE) organization or is enrolling in a PDP after disenrolling from a PACE organization.

(i) An individual who disenrolls from PACE has a SEP for 2 months after the effective date of PACE disenrollment to elect a PDP.

(ii) An individual who disenrolls from a PDP has a SEP for 2 months after the

effective date of PDP disenrollment to elect a PACE plan.

(15) The individual moves into, resides in, or moves out of an institution, as defined by CMS, and elects to enroll in, or disenroll from, a Part D plan.

(16) The individual who is not entitled to premium free Part A and enrolls in Part B during the General Enrollment Period for Part B that starts January 1, 2023, is eligible to request enrollment in a Part D plan. The special enrollment period begins when the individual submits their Part B application and continues for the first 2 months of Part B enrollment. The Part D plan enrollment is effective the first of the month following the month the Part D sponsor receives the enrollment request.

(17) The individual belongs to a qualified State Pharmaceutical Assistance Program (SPAP) and is requesting enrollment in a Part D plan.

(i) The individual is eligible to make one enrollment election per year.

(ii) This SEP is available while the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after either the month of the loss of eligibility or notification of the loss, whichever is later.

(18) The individual is enrolled in a Part D plan and elects to disenroll from that Part D plan to enroll in or maintain other creditable prescription drug coverage.

(19)(i) The individual is enrolled in a section 1876 cost contract and an optional supplemental Part D benefit under that contract and elects a Part D plan upon disenrolling from the cost contract.

(ii) The SEP begins the month the individual requests disenrollment from the cost contract and ends when the individual makes an enrollment election or on the last day of the second month following the month the cost contract enrollment ended, whichever is earlier.

(20) The individual is requesting enrollment in a Part D plan offered by a Part D plan sponsor with a Star Rating of 5 Stars. An individual may use this SEP only once for the contract year in which the Part D plan was assigned a 5-star overall performance rating, beginning the December 8 before that con-

tract year through November 30 of that contract year.

(21)(i) The individual is a non-U.S. citizen who becomes lawfully present in the United States.

(ii) This SEP begins the month the enrollee attains lawful presence status and ends the earlier of when the individual makes an enrollment election or 2 calendar months after the month the enrollee attains lawful presence status.

(22) The individual was adversely affected by having requested, but not received, required notices or information in an accessible format, as outlined in section 504 of the Rehabilitation Act of 1973, within the same timeframe that the Part D plan sponsor or CMS provided the same information to individuals who did not request an accessible format.

(i) The SEP begins at the end of the election period during which the individual was seeking to make an election and the length is at least as long as the time it takes for the information to be provided to the individual in an accessible format.

(ii) Part D plan sponsors may determine eligibility for this SEP when the criterion is met, ensuring adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

(23) Individuals affected by an emergency or major disaster declared by a federal, state or local government entity are eligible for a SEP to make a Part D enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier, and ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later. The individual is eligible for this SEP provided the individual—

(i)(A) Resides, or resided at the start of the SEP eligibility period described in this paragraph (c)(23), in an area for

which a Federal, state or local government entity has declared an emergency or major disaster; or

(B) Does not reside in an affected area but relies on help making healthcare decisions from one or more individuals who reside in an affected area;

(ii) Was eligible for another election period at the time of SEP eligibility period described in this paragraph (c)(23); and

(iii) Did not make an election during that other election period due to the emergency or major disaster.

(24) The individual is using the SEP at § 422.62(b)(8) of this chapter to disenroll from a MA plan that includes Part D benefits.

(i) This SEP permits a one-time election to enroll in a Part D plan.

(ii) This SEP begins upon disenrollment from the MA plan and continues for 2 calendar months.

(25)(i) An individual using the MA Open Enrollment Period for Institutionalized Individuals (OEPI) to disenroll from a MA plan that includes Part D benefits plan is eligible for a SEP to request enrollment in a Part D plan.

(ii) The SEP begins with the month the individual requests disenrollment from the MA plan and ends on the last day of the second month following the month MA enrollment ended.

(26) An individual using the Medicare Advantage Open Enrollment Period (MA OEP) to elect original Medicare is eligible for a SEP to make a Part D enrollment election.

(27)(i) The individual is enrolled in a MA special needs plan (SNP) and is no longer eligible for the SNP because he or she no longer meets the specific special needs status.

(ii) The individual may request enrollment in a Part D plan that begins the month the individual's special needs status changes and ends the earlier of when he or she makes an election or 3 months after the effective date of involuntary disenrollment from the SNP.

(28) The individual is found, after enrollment into a Chronic Care SNP, not to have the required qualifying condition.

(i) This individual is eligible to enroll prospectively in a Part D plan.

(ii) This SEP begins when the MA organization notifies the individual of the lack of eligibility for the Chronic Care SNP and extends through the end of that month and the following 2 calendar months.

(iii) The SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

(29) The individual uses the SEP at § 422.62(b)(15) of this chapter to enroll in a MA Private Fee-for-Service plan without Part D benefits, or enrolls in a section 1876 cost plan, is eligible to request enrollment in a PDP or the cost plan's optional supplemental Part D benefit, if offered.

(i) This SEP begins the month the individual uses the SEP at § 422.62(b)(15) of this chapter and continues for 2 additional months.

(ii) [Reserved]

(30) An individual who uses the SEP at § 422.62(b)(23) of this chapter to disenroll from a MA plan is eligible to request enrollment in a PDP.

(i) This SEP begins the month the individual is notified of eligibility for the SEP at § 422.62(b)(23) of this chapter and continues for an additional 2 calendar months.

(ii) This SEP permits one enrollment into a PDP.

(iii) This SEP ends when the individual has enrolled in the PDP.

(iv) An individual may use this SEP to request enrollment in a PDP subsequent to having submitted a disenrollment to the MA plan or may simply request enrollment in the PDP, resulting in automatic disenrollment from the MA plan.

(31) The individual is enrolled in a plan offered by a Part D plan sponsor that has been placed into receivership by a state or territorial regulatory authority. The SEP begins the month the receivership is effective and continues until it is no longer in effect or until the enrollee makes an election, whichever occurs first. When instructed by CMS, the MA plan that has been placed

under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for this SEP and how to use the SEP.

(32) The individual is enrolled in a plan that has been identified with the low performing icon in accordance with § 423.186(h)(1)(ii). This SEP exists while the individual is enrolled in the low performing Part D plan.

(33) The individual was involuntarily disenrolled from an MA-PD plan due to loss of Part B but continues to be entitled to Part A. This SEP begins when the individual is advised of the loss of Part B and continues for 2 additional months.

(34) The individual enrolls in Medicare premium-Part A or Part B using an exceptional condition SEP, as described in 42 CFR parts 406.27 and 407.23. The SEP begins when the individual submits their premium-Part A or Part B application and continues for the first 2 months of enrollment in premium Part A or Part B. The Part D plan enrollment is effective the first of the month following the month the Part D plan receives the enrollment request.

(35) The individual meets other exceptional circumstances as CMS may provide.

(d) *Enrollment period to coordinate with MA annual 45-day disenrollment period.* Through 2018, an individual enrolled in an MA plan who elects Original Medicare from January 1 through February 14, as described in § 422.62(a)(5) of this chapter, may also elect a PDP during this time.

(e) *Enrollment period to coordinate with MA open enrollment period.* For 2019 and subsequent years, an individual who makes an election as described in § 422.62(a)(3) of this chapter, may make an election to enroll in or disenroll from Part D coverage. An individual who elects Original Medicare during the MA open enrollment period may elect to enroll in a PDP during this time.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19816, Apr. 15, 2010; 76 FR 21570, Apr. 15, 2011; 83 FR 16737, Apr. 16, 2018; 85 FR 33909, June 2, 2020; 88 FR 22337, Apr. 12, 2023]

§ 423.40 Effective dates.

(a) *Initial enrollment period.* (1) An enrollment made prior to the month of entitlement to Part A or enrollment in Part B is effective the first day of the month the individual is entitled to or enrolled in Part A or enrolled in Part B.

(2) Except as otherwise provided under § 423.34(f), an enrollment made during or after the month of entitlement to Part A or enrollment in Part B is effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(3) If the individual is not eligible to enroll in Part D on the first day of the calendar month following the month in which the election to enroll in Part D is made, the enrollment in Part D is effective the first day of the month the individual is eligible for Part D.

(4) In no case is an enrollment in Part D effective before January 1, 2006 or before entitlement to Part A or enrollment Part B.

(b) *Annual coordinated election periods*—(1) *General rule.* Except as provided under paragraph (b)(2) of this section, for an enrollment or change of enrollment in Part D made during an annual coordinated election period as described in § 423.38(b), the coverage or change in coverage is effective as of the first day of the following calendar year.

(2) *Exception for January 1, 2006 through May 15, 2006.* Enrollment elections made during the annual coordinated election period between January 1, 2006 and May 15, 2006 are effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.38(c), the coverage or change in coverage is effective the first day of the calendar month following the month in which the election is made, unless otherwise noted.

(d) *PDP enrollment period to coordinate with the MA annual disenrollment period.* Through 2018, an enrollment made from January 1 through February 14 by an individual who has disenrolled from an MA plan as described in § 422.62(a)(5) of

this chapter will be effective the first day of the month following the month in which the enrollment in the PDP is made.

(e) *PDP enrollment period to coordinate with the MA open enrollment period.* For 2019 and subsequent years, an enrollment made by an individual who elects Original Medicare during the MA open enrollment period as described in § 422.62(a)(3) of this chapter, will be effective the first day of the month following the month in which the election is made.

[70 FR 4525, Jan. 28, 2005, as amended at 76 FR 21570, Apr. 15, 2011; 83 FR 16737, Apr. 16, 2018; 85 FR 33911, June 2, 2020]

§ 423.44 Involuntary disenrollment from Part D coverage.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, a PDP sponsor may not—

(1) Involuntarily disenroll an individual from any PDP it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment—(1) Optional involuntary disenrollment.* A PDP sponsor may disenroll an individual from a PDP it offers in any of the following circumstances:

(i) Any monthly premium is not paid on a timely basis, as specified under paragraph (d)(1) of this section; or

(ii) The individual has engaged in disruptive behavior, as specified under paragraph (d)(2) of this section.

(2) *Required involuntary disenrollment.* A PDP sponsor must disenroll an individual from a PDP it offers in any of the following circumstances:

(i) The individual no longer resides in the PDP's service area.

(ii) The individual loses eligibility for Part D.

(iii) Death of the individual.

(iv) The PDP sponsor's contract is terminated by CMS or by a PDP or through mutual consent. The PDP sponsor must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at § 423.507 through § 423.510.

(v) The individual materially misrepresents information, as determined by CMS, to the PDP sponsor that the

individual has or expects to receive reimbursement for third-party coverage.

(vi) The individual is not lawfully present in the United States.

(c) *Notice requirement.* (1) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(2)(iv) of this section (that is, other than death or loss of Part D eligibility, the PDP sponsor must give the individual timely notice of the disenrollment with an explanation of why the PDP is planning to disenroll the individual.

(2) Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(iii) of this section must—

(i) Be provided to the individual before submission of the disenrollment notice to CMS; and

(ii) Include an explanation of the individual's right to file a grievance under the PDP's grievance procedures.

(d) *Process for disenrollment—(1)* Except as specified in paragraph (d)(1)(iv) of this section, a PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

(i) The PDP sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

(ii) The PDP sponsor gives the enrollee notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) The PDP sponsor provides the individual with a grace period, that is, an opportunity to pay past due premiums in full. The grace period must—

(A) Be at least 2 months; and

(B) Begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later.

(iv) *Reenrollment in the PDP.* If an individual is disenrolled from the PDP for failure to pay monthly PDP premiums, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs until the individual has paid any past premiums due to the PDP sponsor.

(v) A PDP sponsor may not disenroll an individual who had monthly premiums withheld per § 423.293(a) and (e)

of this part or who is in premium with-hold status, as defined by CMS.

(vi) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS (or a third party to which CMS has assigned this responsibility, such as a Part D sponsor) may reinstate enrollment in the PDP, without interruption of coverage, if the individual shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(vii) *No extension of grace period.* A beneficiary's enrollment in the PDP may not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

(2) *Disruptive behavior—(i) Definition.* A PDP enrollee is disruptive if his or her behavior substantially impairs the plans ability to arrange or provide for services to the individual or other plan members. An individual cannot be considered disruptive if the behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* A PDP may disenroll an individual whose behavior is disruptive as defined in § 423.44(d)(2)(i) only after the PDP sponsor meets the requirements described in this section and after CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The PDP sponsor must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness, Alzheimers disease, and developmental disabilities. In addition, the PDP sponsor must inform the individual of the right to use the PDP's grievance procedures. The individual has a right to submit any information

or explanation that he or she may wish to the PDP.

(iv) *Documentation.* The PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances. The PDP sponsor may request from CMS the ability to decline future enrollment by the individual. The PDP sponsor must submit this information and any documentation received by the individual to CMS.

(v) *CMS review of the proposed disenrollment.* CMS reviews the information submitted by the PDP sponsor and any information submitted by the individual (which the PDP sponsor has submitted to CMS) to determine if the PDP sponsor has fulfilled the requirements to request disenrollment for disruptive behavior. If the PDP sponsor has fulfilled the necessary requirements, CMS reviews the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS ensures that staff with appropriate clinical or medical expertise reviews the case before making a final decision. The PDP sponsor is required to provide a reasonable accommodation, as determined by CMS, for the individual in exceptional circumstances that CMS deems necessary. CMS notifies the PDP sponsor within 5 working days after making its decision.

(vi) *Exception for fallback prescription drug plans.* CMS reserves the right to deny a request from a fallback prescription drug plan as defined in § 423.855 to disenroll an individual for disruptive behavior.

(vii) *Effective date of disenrollment.* If CMS permits a PDP to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(3) *Loss of Part D eligibility.* If an individual is no longer eligible for Part D, CMS notifies the PDP that the disenrollment is effective the first day of the calendar month following the last month of Part D eligibility.

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(4) *Death of the individual.* If the individual dies, disenrollment is effective the first day of the calendar month following the month of death.

(5) *Individual no longer resides in the PDP service area—Basis for disenrollment.* (i) The PDP must disenroll an individual if the individual notifies the PDP that he or she has permanently moved out of the PDP service area.

(ii) *Special rule.* If the individual has not moved from the PDP service area, but has been absent from the service area for more than 12 consecutive months, the PDP sponsor must disenroll the individual from the plan effective on the first day of the 13th month after the individual left the service area.

(iii) *Incarceration.* The PDP must disenroll an individual if the PDP establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated and does not reside in the service area of the PDP as specified at § 423.4 or when notified of an incarceration by CMS as specified in paragraph (d)(5)(iv) of this section.

(iv) *Notification by CMS of incarceration.* When CMS notifies the PDP of the disenrollment due to the individual being incarcerated and not residing in the service area of the PDP as per § 423.4, disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

(6) *Plan termination.* (i) When a PDP contract terminates as provided in § 423.507 through § 423.510, the PDP sponsor must give each affected PDP enrollee notice of the effective date of the plan termination and a description of alternatives for obtaining prescription drug coverage under Part D, as specified by CMS.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified by CMS.

(7) *Misrepresentation of third-party reimbursement.* (i) If CMS determines an individual has materially misrepresented information to the PDP sponsor as described under § 423.44(b)(2)(v), the termination is effective the first day of the calendar month after the month in which the PDP sponsor gives the indi-

vidual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(ii) *Reenrollment in the PDP.* Once an individual is disenrolled from the PDP for misrepresentation of third party reimbursement, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

(8) *Individual is not lawfully present in the United States.* Disenrollment is effective the first day of the month following notice by CMS that the individual is ineligible in accordance with § 423.30(a)(1)(iii).

(e) *Involuntary disenrollment by CMS—*

(1) *General rule.* CMS will disenroll individuals who fail to pay the Part D income related monthly adjustment amount (Part D—IRMAA) specified in § 423.286(d)(4) and § 423.293(d) of this part.

(2) *Initial grace period.* For all Part D—IRMAA amounts directly billed to an enrollee in accordance with § 423.293(d)(2), the grace period ends with the last day of the third month after the billing month.

(3) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failing to pay the Part D—IRMAA within the initial grace period specified in paragraph (e)(2) of this section, CMS (or an entity acting on behalf of CMS) may reinstate enrollment, without interruption of coverage, if the individual shows good cause as specified in § 423.44(d)(1)(vi), pays all Part D—IRMAA arrearages, and any overdue premiums due the Part D plan sponsor within 3 calendar months after the disenrollment date.

(4) *Notice of termination.* Where CMS has disenrolled an individual in accordance with paragraph (e)(1) of this section, the Part D plan sponsor must provide notice of termination in a form and manner determined by CMS.

(5) *Effective date of disenrollment.* After a grace period and notice of termination has been provided in accordance with paragraphs (e)(2) and (4) of this section, the effective date of

disenrollment is the first day following the last day of the initial grace period.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1543, Jan. 12, 2009; 75 FR 19816, Apr. 15, 2010; 76 FR 21570, Apr. 15, 2011; 79 FR 29962, May 23, 2014; 80 FR 7962, Feb. 12, 2015]

§ 423.46 Late enrollment penalty.

(a) *General.* A Part D eligible individual must pay the late penalty described under § 423.286(d)(3), except as described at § 423.780(e), if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:

(1) The individual was eligible to enroll in a Part D plan;

(2) The individual was not covered under any creditable prescription drug coverage; and

(3) The individual was not enrolled in a Part D plan.

(b) *Role of Part D plan in determination of the penalty.* Part D sponsors must obtain information on prior creditable coverage from all enrolled or enrolling beneficiaries and report this information to CMS in a form and manner determined by CMS.

(c) *Reconsideration.* Individuals determined to be subject to a late enrollment penalty may request reconsideration of this determination, consistent with § 423.56(g) of this part. Such review will be conducted by CMS, or an independent review entity contracted by CMS, in accordance with guidance issued by CMS. Decisions made through this review are not subject to appeal, but may be reviewed and revised at the discretion of CMS.

(d) *Record retention.* Part D plan sponsors must retain all information collected concerning a creditable coverage period determination in accordance with the enrollment records retention requirements described in § 423.505(e)(1)(iii).

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54251, Sept. 18, 2008; 74 FR 1543, Jan. 12, 2009]

§ 423.48 Information about Part D.

Each Part D plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information

necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition.* Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount or coverage provided during the coverage gap, and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.

(b) *Types of coverage.* The following coverage is considered creditable if it meets the definition provided in paragraph (a) of this section:

(1) Prescription drug coverage under a PDP or MA-PD plan.

(2) Medicaid coverage under title XIX of the Act or under a waiver under section 1115 of the Act.

(3) Coverage under a group health plan, including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D-22(a)(2) of the Act.

(4) Coverage under State Pharmaceutical

Assistance Programs (SPAP) as defined at § 423.454.

(5) Coverage of prescription drugs for veterans, survivors and dependents under chapter 17 of title 38, U.S.C.

(6) Coverage under a Medicare supplemental policy (Medigap policy) as defined at § 403.205 of this chapter.

(7) Military coverage under chapter 55 of title 10,

U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for outpatient prescription drugs and that does not meet the definition of an excepted benefit

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(as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(10) Coverage provided by a PACE organization.

(11) Coverage provided by a cost-based HMO or CMP under part 417 of this chapter.

(12) Coverage provided through a State High-Risk Pool as defined under 42 CFR 146.113(a)(1)(vii).

(13) Other coverage as the Secretary may determine appropriate.

(c) *General disclosure requirements.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, each entity that offers prescription drug coverage under any of the types described in § 423.56(b), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in the coverage whether the coverage is creditable prescription drug coverage.

(d) *Disclosure of non-creditable coverage.* In the case that the coverage of the type described in § 423.56(b) is not creditable prescription drug, the disclosure described in paragraph (c) of this section to Part D eligible individuals must also include:

(1) The fact that the coverage is not creditable prescription drug coverage, as provided by CMS;

(2) That there are limitations on the periods in a year in which the individual may enroll in Part D plans; and

(3) That the individual may be subject to a late enrollment penalty, as described under § 423.46.

(e) *Disclosure to CMS.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, all other entities listed under paragraph (b) of this section must disclose whether the coverage they provide is creditable prescription drug coverage to CMS in a form and manner described by CMS.

(f) *Notification content and timing requirements.* The disclosure notification to Part-D eligible individuals required

in § 423.56(c) and (d) must be provided in a form and manner prescribed by CMS. Notices must be provided, at minimum, at the following times:

(1) Prior to an individual's initial enrollment period for Part D, as described under § 423.38(a);

(2) Prior to the effective date of enrollment in the prescription drug coverage and upon any change that affects whether the coverage is creditable prescription drug coverage;

(3) Prior to the commencement of the Annual Coordinated Election Period as defined in § 423.38(b); and

(4) Upon request by the individual.

(g) *When an individual is not adequately informed of coverage.* If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage, the individual may apply to CMS to have the coverage treated as creditable prescription drug coverage for purposes of applying the late penalty described in § 423.46.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20505, Apr. 15, 2008; 77 FR 22168, Apr. 12, 2012]

Subpart C—Benefits and Beneficiary Protections

§ 423.100 Definitions.

As used in this part, unless otherwise specified—

Actual cost means the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a).

Affected enrollee means a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing and such drug removal or cost-sharing change affects the Part D enrollee's access to the drug during the current plan year.

Alternative prescription drug coverage means coverage of Part D drugs, other than standard prescription drug coverage that meets the requirements of