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 § 460.22 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).

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]

§ 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:

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B; and

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

(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.

§ 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 § 423.50.

(i) 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.

(ii) 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]

§ 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 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