

§ 423.112

42 CFR Ch. IV (10–1–23 Edition)

a daily cost-sharing rate in accordance with § 423.153(b)(4).

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1544, Jan. 12, 2009; 75 FR 19816, Apr. 15, 2010; 76 FR 21571, Apr. 15, 2011; 77 FR 22169, Apr. 12, 2012; 80 FR 7963, Feb. 12, 2015; 86 FR 6115, Jan. 19, 2021]

§ 423.112 Establishment of prescription drug plan service areas.

(a) *Service area for prescription drug plan sponsors.* The service area for a prescription drug plan sponsor other than a fallback prescription drug plan sponsor consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

(b) *Establishment of PDP regions—(1) General.* CMS establishes PDP regions in a manner consistent with the requirements for the establishment of MA regions as described at § 422.455 of this chapter.

(2) *Relation to MA regions.* To the extent practicable, PDP regions are the same as MA regions. CMS may establish PDP regions that are not the same as MA regions if CMS determines that the establishment of these regions improves access to prescription drug plan benefits for Part D eligible individuals.

(c) *Authority for territories.* CMS establishes a PDP region or regions for States that are not within the 50 States and the District of Columbia.

(d) *Revision of PDP regions.* CMS may revise the PDP regions established under paragraphs (b) and (c) of this section.

(e) *Regional or national plan.* Nothing in this section prevents a prescription drug plan from being offered in two or more PDP regions in their entirety or in all PDP regions in their entirety.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19816, Apr. 15, 2010]

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access—(1) Standards for convenient access to network pharmacies.* Except as provided in paragraph (a)(7) of this section, a Part D sponsor (as defined in § 423.4 of this part) must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that, for beneficiaries residing in each State in a PDP sponsor's service area (as de-

fined in § 423.112(a) of this part), each State in a regional MA-organization's service area (as defined in § 422.2 of this part), the entire service area of a local MA organization (as defined in § 422.2 of this chapter) or the entire geographic area of a cost contract (as defined in § 417.401 of this chapter) all of the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D sponsor live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D sponsor live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D sponsor live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(2) *Applicability of some non-retail pharmacies to standards for convenient access.* Part D sponsors may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

(3) *Access to non-retail pharmacies.* A Part D sponsor's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met.

(4) *Access to home infusion pharmacies.* A Part D sponsor's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions. A Part D plan must ensure that such network pharmacies, at a minimum meet all the following requirements:

(i) Are capable of delivering home-infused drugs in a form that can be administered in a clinically appropriate fashion.

(ii) Are capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies.

(iii) Ensure that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing Part D home infusion drugs.

(iv) Provide delivery of home infusion drugs within 24 hours of discharge from an acute care setting, or later if so prescribed.

(5) *Access to long-term care pharmacies.* A Part D sponsor must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to all long-term care pharmacies in its service area. The sponsor must provide convenient access to long-term care pharmacies consistent with written policy guidelines and other CMS instructions.

(6) *Access to I/T/U pharmacies.* A Part D sponsor must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The sponsor must provide convenient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions.

(7) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of either of the following:

(i) An MA organization or cost contract (as described in section 1876(h) of the Act) that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization or cost contract, provided the organization's or plan's pharmacy network meets the access standard set forth—

(A) At § 422.112 of this chapter for an MA organization; or

(B) At § 417.416(e) of this chapter for a cost contract.

(ii) An MA organization offering a private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage; and

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in § 423.104(d)(2) and (d)(5).

(8) *Pharmacy network contracting requirements.* In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the Part D sponsor's standard terms and conditions;

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D sponsor's contracted pharmacy network; and

(iii) May not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D plan enrollee of the availability at that pharmacy of a prescribed medication at a cash price that is below the amount that the enrollee would be charged to obtain the same medication through the enrollee's Part D plan.

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mail-order and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D sponsor may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D

drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.

(b) *Formulary requirements.* A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet the following requirements—

(1) *Development and revision by a pharmacy and therapeutic committee.* A Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutic committee that—

(i) Includes a majority of members who are practicing physicians and/or practicing pharmacists.

(ii) Includes at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to—

(A) The Part D sponsor and Part D plan; and

(B) Pharmaceutical manufacturers.

(iii) Includes at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(iv) Clearly articulates and documents processes to determine that the requirements under paragraphs (b)(1)(i) through (iii) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

(v) Bases clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(vi) Considers whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.

(vii) Reviews policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.

(viii) Evaluates and analyzes treatment protocols and procedures related to the plan's formulary at least annu-

ally consistent with written policy guidelines and other CMS instructions.

(ix) Documents in writing its decisions regarding formulary development and revision and utilization management activities.

(x) Reviews and approves all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.

(xi) Meets other requirements consistent with written policy guidelines and other CMS instructions.

(2) *Provision of an Adequate Formulary.* A Part D plan's formulary must—

(i) Except as provided in paragraphs (b)(2)(ii) and (v) of this section, include within each therapeutic category and class of Part D drugs at least two Part D drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs, except that only one Part D drug must be included in a particular category or class of covered Part D drugs if the category or class includes only one Part D drug.

(ii) Include at least one Part D drug within a particular category or class of Part D drugs to the extent the Part D plan demonstrates, and CMS approves, the following—

(A) That only two drugs are available in that category or class of Part D drugs; and

(B) That one drug is clinically superior to the other drug in that category or class of Part D drugs.

(iii) Include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines.

(iv) Be approved by CMS consistent with § 423.272(b)(2).

(v) Until such time as there are established, through notice and comment rulemaking, criteria to identify, as appropriate, categories and classes of clinical concern, the categories and classes of clinical concern are as specified in section 1860D–4(b)(3)(G)(iv) of the Act.

(vi) Exceptions to paragraph (b)(2)(v) of this section are as follows:

(A) Drug or biological products that are rated as either of the following:

(1) Therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the Orange Book).

(2) Interchangeable (under the Food and Drug Administration's most recent publication of the Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations).

(B) Utilization management processes that limit the quantity of drugs due to safety.

(C) Subject to CMS review and approval, for enrollees that are not on existing therapy on the protected class Part D drug, and except for antiretroviral medications, prior authorization and step therapy requirements to confirm intended use is for a protected class indication, to ensure clinically appropriate use, to promote utilization of preferred formulary alternatives, or a combination thereof.

(D) Other drugs that CMS specifies through a process that is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents) and which permits public notice and comment.

(3) *Transition process.* A Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules). The transition process must:

(i)(A) Be applicable to all of the following:

(1) New enrollees into Part D plans following the annual coordinated election period.

(2) Newly eligible Medicare enrollees from other coverage.

(3) Individuals who switch from one plan to another after the start of the contract year.

(4) Current enrollees remaining in the plan affected by formulary changes.

(B) Not apply in cases in which a Part D sponsor substitutes a generic drug for a brand name drug as permitted under paragraph (b)(5)(iv) of this section.

(ii) Ensure access to a temporary supply of drugs within the first 90 days of coverage under a new plan. This 90 day timeframe applies to retail, home infusion, long-term care and mail-order pharmacies,

(iii) Ensure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (b)(3)(ii) of this section (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) by providing a one-time, temporary supply of at least an approved month's supply of medication, unless the prescription is written by a prescriber for less than an approved month's supply and requires the Part D sponsor to allow multiple fills to provide up to a total of an approved month's supply of medication.

(iv) Ensure written notice is provided to each affected enrollee within 3 business days after adjudication of the temporary fill. For long-term care residents dispensed multiple supplies of a Part D drug, in increments of 14-days-or-less, consistent with the requirements under § 423.154, the written notice must be provided within 3 business days after adjudication of the first temporary fill.

(v) Ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice under paragraph (b)(3)(iv) of this section.

(vi) A Part D sponsor must charge cost sharing for a temporary supply of drugs provided under its transition process such that the following conditions are met:

(A) For low-income subsidy (LIS) enrollees, a sponsor must not charge higher cost sharing for transition supplies than the statutory maximum co-payment amounts.

(B) For non-LIS enrollees, a sponsor must charge—

(1) The same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with § 423.578(b); and

(2) The same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met.

(4) *Limitation on changes in therapeutic classification.* Except as CMS may permit to account for new therapeutic uses and newly approved Part D drugs, a Part D sponsor may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year.

(5) *Provision of notice regarding formulary changes* (i) Prior to removing a covered Part D drug from its Part D plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must provide at least 30 days notice to CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists (for purposes of this paragraph (b)(5) these entities are referred to as "CMS and other specified entities") prior to the date such change becomes effective, and must either—

(A) Provide direct written notice to affected enrollees at least 30 days prior to the date the change becomes effective; or

(B) At the time an affected enrollee requests a refill of the Part D drug, provide such enrollee with an approved month's supply of the Part D drug under the same terms as previously allowed, and written notice of the formulary change.

(ii) The written notice must contain the following information—

(A) The name of the affected covered Part D drug;

(B) Whether the plan is removing the covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(C) The reason why the plan is removing such covered Part D drug from

the formulary, or changing its preferred or tiered cost-sharing status;

(D) Alternative drugs in the same therapeutic category or class or cost-sharing tier and expected cost-sharing for those drugs; and

(E) The means by which enrollees may obtain a coverage determination under § 423.566 or exception under § 423.578.

(iii) Part D sponsors may immediately remove from their Part D plan formularies covered Part D drugs deemed unsafe by the Food and Drug Administration or removed from the market by their manufacturer without meeting the requirements of paragraphs (b)(5)(i) of this section. Part D sponsors must provide retrospective notice of any such formulary changes to affected enrollees and CMS and other specified entities consistent with the requirements of paragraphs (b)(5)(ii)(A), (b)(5)(ii)(B), (b)(5)(ii)(C), and (b)(5)(ii)(D) of this section.

(iv) A Part D sponsor may immediately remove a brand name drug (as defined in § 423.4) from its Part D formulary or change the brand name drug's preferred or tiered cost-sharing without meeting the deadlines and refill requirements of paragraph (b)(5)(i) of this section provided that the Part D sponsor does all of the following:

(A) At the same time that it removes such brand name drug or changes its preferred or tiered cost-sharing, it adds a therapeutically equivalent (as defined in § 423.100) generic drug (as defined in § 423.4) to its formulary on the same or lower cost-sharing tier and with the same or less restrictive utilization management criteria.

(B) The Part D sponsor previously could not have included such therapeutically equivalent generic drug on its formulary when it submitted its initial formulary for CMS approval consistent with paragraph (b)(2) of this section because such generic drug was not yet available on the market.

(C) Before making any permitted generic substitutions, the Part D sponsor provides general notice to all current and prospective enrollees in its formulary and other applicable beneficiary communication materials advising them that—

(1) Such changes may be made at any time when a new generic is added in place of a brand name drug, and there may be no advance direct notice to the affected enrollees;

(2) If such a substitution should occur, affected enrollees will receive direct notice including information on the specific drugs involved and steps they may take to request coverage determinations and exceptions under §§ 423.566 and 423.578;

(D) Before making any permitted generic substitutions, the Part D sponsor provides advance general notice to CMS and other specified entities.

(E) The Part D sponsor provides notice of any such formulary changes to affected enrollees and CMS and other specified entities consistent with the requirements of paragraphs (b)(5)(i) (as applicable) and (ii) of this section. This would include direct notice to the affected enrollees.

(6) *Limitation on formulary changes prior to the beginning of a contract year.* Except as provided under paragraphs (b)(5)(iii) and (iv) of this section, a Part D sponsor may not remove a covered Part D drug from its Part D plan's formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug on its plan's formulary, between the beginning of the annual coordinated election period described in § 423.38(b) and 60 days after the beginning of the contract year associated with that annual coordinated election period.

(7) *Provider and patient education.* A Part D sponsor must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary.

(c) *Use of standardized technology.* (1) A Part D sponsor must issue and re-issue, as necessary, a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs as provided under § 423.104(g). The card or other technology must comply with standards CMS establishes.

(2) When processing Part D claims, a Part D sponsor or its intermediary must comply with the electronic transaction standards established by 45 CFR 162.1102. CMS will issue guidance on the

use of conditional fields within such standards.

(3) A Part D sponsor must require its network pharmacies to submit claims to the Part D sponsor or its intermediary whenever the card described in paragraph (c)(1) of this section is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

(4) Beginning January 1, 2012, a part D sponsor must assign and exclusively use a unique—

(i) Part D BIN or RxBIN and Part D processor control number (RxPCN) combination in its Medicare line of business; and

(ii) Part D cardholder identification number (RxID) to each Medicare Part D enrollee to clearly identify Medicare Part D beneficiaries.

(5)(i) A Part D plan sponsor must reject, or must require its pharmacy benefit manager (PBM) to reject, a pharmacy claim for a Part D drug unless the claim contains the active and valid National Provider Identifier (NPI) of the prescriber who prescribed the drug.

(ii) The sponsor must communicate at point-of sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(ii).

(A) If the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to—

(1) Confirm that the NPI is active and valid; or

(2) Correct the NPI.

(B) If the pharmacy confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable.

(iii) A Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor—

(A) Has complied with paragraph (c)(5)(ii) of this section;

(B) Has verified that a submitted NPI was not in fact active and valid; and

(C) The agreement between the parties explicitly permits such recoupment.

(iv) With respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.

(6)(i) Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the preclusion list, defined in § 423.100.

(ii) Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary if the request pertains to a Part D drug that was prescribed by an individual who is identified by name in the request and who is included on the preclusion list, defined in § 423.100.

(iii) A Part D plan sponsor may not submit a prescription drug event (PDE) record to CMS unless it includes on the PDE record the active and valid individual NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in § 423.100, for the date of service.

(iv) With respect to Part D prescribers who have been added to an updated preclusion list but are not currently excluded by the OIG, the Part D plan sponsor must do all of the following:

(A) Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by an individual added to the preclusion list in this update and whom the plan sponsor has identified during the applicable 30-day period.

(B)(1) Subject to paragraph (c)(6)(iv)(B)(2) of this section, must ensure that reasonable efforts are made to notify the individual described in

paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section.

(2) Paragraph (c)(6)(iv)(B)(1) of this section applies only upon a prescriber writing a prescription in Medicare Part D when:

(i) The plan sponsor has enough information on file to either copy the prescriber on the notification previously sent to the beneficiary or send a new notice informing the prescriber that they may not see plan beneficiaries due to their preclusion status; and

(ii) The claim is received after the claim denial or reject date in the preclusion file.

(C) Must not reject a pharmacy claim or deny a beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section.

(v)(A) CMS sends written notice to the prescriber via letter of his or her inclusion on the preclusion list. The notice must contain the reason for the inclusion on the preclusion list and inform the prescriber of his or her appeal rights. A prescriber may appeal his or her inclusion on the preclusion list under this section in accordance with part 498 of this chapter.

(B) If the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(1) The notice described in paragraph (c)(6)(v)(A) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation.

(2) The appeals of the prescriber's inclusion on the preclusion list and the prescriber's revocation must be filed jointly by the prescriber and, as applicable, considered jointly under part 498 of this chapter.

(C)(1) Except as provided in paragraph (c)(6)(v)(C)(2) of this section, a prescriber will only be included on the preclusion list after the expiration of either of the following:

(i) If the prescriber does not file a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber may request a reconsideration.

(ii) If the prescriber files a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's reconsideration.

(2) An OIG excluded prescriber is added to the preclusion list effective on the date of the exclusion.

(vi) CMS has the discretion not to include a particular individual on (or if warranted, remove the individual from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to prescriptions. In making a determination as to whether such circumstances exist, CMS takes into account—

(A) The degree to which beneficiary access to Part D drugs would be impaired; and

(B) Any other evidence that CMS deems relevant to its determination.

(vii)(A) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the prescriber's reenrollment bar.

(B) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the prescriber had the prescriber been enrolled and then revoked.

(C) Except as provided in paragraph (c)(6)(vii)(D) of this section, an individual, regardless of whether the individual is or was enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are—

(1) The severity of the offense;

(2) When the offense occurred; and

(3) Any other information that CMS deems relevant to its determination.

(D) In cases where an individual is excluded by the OIG, the individual must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(viii) Payment denials under paragraph (c)(6) of this section that are based upon the prescriber's inclusion on the preclusion list are not appealable by beneficiaries.

(d) *Treatment of compounded drug products.* With respect to multi-ingredient compounds, a Part D sponsor must—

(1) Make a determination as to whether the compound is covered under Part D.

(i) A compound that contains at least one ingredient covered under Part B as prescribed and dispensed or administered is considered a Part B compound, regardless of whether other ingredients in the compound are covered under Part B as prescribed and dispensed or administered.

(ii) Only compounds that contain at least one ingredient that independently meets the definition of a Part D drug, and that do not meet the criteria under paragraph (d)(1)(i) of this section, may be covered under Part D. For purposes of this paragraph (d) these compounds are referred to as Part D compounds.

(iii) For a Part D compound to be considered on-formulary, all ingredients that independently meet the definition of a Part D drug must be considered on-formulary (even if the particular Part D drug would be considered off-formulary if it were provided separately—that is, not as part of the Part D compound).

(iv) For a Part D compound that is considered off-formulary—

(A) Transition rules apply such that all ingredients in the Part D compound that independently meet the definition of a Part D drug must become payable in the event of a transition fill under § 423.120(b)(3); and

(B) All ingredients that independently meet the definition of a Part D drug must be covered if an exception

under § 423.578(b) is approved for coverage of the compound.

(2) Establish consistent rules for beneficiary payment liabilities for both ingredients of the Part D compound that independently meet the definition of a Part D drug and non-Part D ingredients.

(i) For low income subsidy beneficiaries the copayment amount is based on whether the most expensive ingredient that independently meets the definition of a Part D drug in the Part D compound is a generic or brand name drug (as described under § 423.782).

(ii) For any non-Part D ingredient of the Part D compound (including drugs described under § 423.104(f)(1)(ii)(A)), the Part D sponsor's contract with the pharmacy must prohibit balance billing the beneficiary for the cost of any such ingredients.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008; 74 FR 2888, Jan. 16, 2009; 75 FR 19816, Apr. 15, 2010; 75 FR 32860, June 10, 2010; 76 FR 21572, Apr. 15, 2011; 77 FR 22169, Apr. 12, 2012; 79 FR 29962, May 23, 2014; 80 FR 7963, Feb. 12, 2015; 80 FR 25966, May 6, 2015; 83 FR 16738, Apr. 16, 2018; 84 FR 15840, Apr. 16, 2019; 84 FR 23883, May 23, 2019; 84 FR 26579, June 7, 2019]

§ 423.124 Special rules for out-of-network access to covered Part D drugs at out-of-network pharmacies.

(a) *Out-of-network access to covered part D drugs*—(1) *Out-of-network pharmacy access.* A Part D sponsor must ensure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when the enrollees—

(i) Cannot reasonably be expected to obtain such drugs at a network pharmacy; and

(ii) Do not access covered Part D drugs at an out-of-network pharmacy on a routine basis.

(2) *Physician's office access.* A Part D sponsor must ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office.

(b) *Financial responsibility for out-of-network access to covered Part D drugs.* A Part D sponsor that provides its Part D

enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs as provided in paragraph (a) of this section to assume financial responsibility for any differential between the out-of-network pharmacy's (or provider's) usual and customary price and the Part D sponsor's plan allowance, consistent with the requirements of §§ 423.104(d)(2)(i)(B) and 423.104(e).

(c) *Limits on out-of-network access to covered Part D.* A Part D sponsor must establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs.

§ 423.128 Dissemination of Part D plan information.

(a) *Detailed description.* A Part D sponsor must disclose the information specified in paragraph (b) of this section in the manner specified by CMS—

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this part, except as provided in paragraph (b)(11)(ii) of this section;

(2) In a clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter, by the first day of the annual coordinated election period.

(b) *Content of Part D plan description.* The Part D plan description must include the following information about the qualified prescription drug coverage offered under the Part D plan—

(1) *Service area.* The plan's service area.

(2) *Benefits.* The benefits offered under the plan, including—

(i) Applicable conditions and limitations.

(ii) Premiums.

(iii) Cost-sharing (such as copayments, deductibles, and coinsurance), and cost-sharing for subsidy eligible individuals.

(iv) Any other conditions associated with receipt or use of benefits.

(3) *Cost-sharing.* A description of how a Part D eligible individual may obtain more information on cost-sharing requirements, including tiered or other copayment levels applicable to each drug (or class of drugs), in accordance with paragraph (d) of this section.