

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)(1)(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.

(4) *Formulary*. Information about the plan's formulary, including—

(i) A list of drugs included on the plan's formulary;

(ii) The manner in which the formulary (including any tiered formulary structure and utilization management procedures used) functions;

(iii) The process for obtaining an exception to a plan's formulary or tiered cost-sharing structure; and

(iv) A description of how a Part D eligible individual may obtain additional information on the formulary, in accordance with paragraph (d) of this section.

(5) *Access*. The number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs and how the Part D sponsor meets the requirements of § 423.120(a)(1) for access to covered Part D drugs;

(6) *Out-of-network coverage*. Provisions for access to covered Part D drugs at out-of-network pharmacies, consistent with § 423.124(a).

(7) *Grievance, coverage determination, and appeal procedures*. All grievance, coverage determination, and appeal rights and procedures required under § 423.562 et. seq., including—

(i) Access to a uniform model form used to request a coverage determination under § 423.568 or § 423.570, and a uniform model form used to request a redetermination under § 423.582 or § 423.584, to the extent such uniform model forms have been approved for use by CMS;

(ii) Immediate access to the coverage determination and redetermination processes via an Internet Web site; and

(iii) A system that transmits codes to network pharmacies so that the network pharmacy is notified to populate and/or provide a printed notice at the point-of-sale to an enrollee explaining how the enrollee can request a coverage determination by contacting the plan sponsor's toll free customer service line or by accessing the plan sponsor's internet Web site.

(8) *Quality assurance policies and procedures*. A description of the quality assurance policies and procedures required under § 423.153(c), as well as the

medication therapy management program required under § 423.153(d).

(9) *Disenrollment rights and responsibilities*.

(10) *Potential for contract termination*. The fact that a Part D sponsor may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in a Part D plan;

(11) *Opioid information*. (i) Beginning January 1, 2022, and subject to paragraph (b)(11)(ii) of this section, a Part D sponsor must disclose to each enrollee at least once per year the following:

(A) The risks associated with prolonged opioid use.

(B) Coverage of non-pharmacological therapies, devices, and non-opioid medications—

(1) In the case of an MA-PD, under such plan; and

(2) In the case of a PDP, under such plan and Medicare Parts A and B.

(ii) The Part D sponsor may elect to, in lieu of disclosing the information described in paragraph (b)(11)(i) of this section to each enrollee under each plan offered by the Part D sponsor under this part, disclose such information to a subset of enrollees, such as enrollees who have been prescribed an opioid in the previous 2-year period.

(c) *Disclosure upon request of general coverage information, utilization, and grievance information*. Upon request of a Part D eligible individual, a Part D sponsor must provide the following information—

(1) *General coverage information*. General coverage information, including—

(i) *Enrollment procedures*. Information and instructions on how to exercise election options under this part;

(ii) *Rights*. A general description of procedural rights (including grievance, coverage determination, reconsideration, exceptions, and appeals procedures) under this part;

(iii) *Benefits*. (A) Covered services under the Part D plan;

(B) Any beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including cost-sharing for subsidy eligible individuals;

(C) Any maximum limitations on out-of-pocket expenses;

(D) The extent to which an enrollee may obtain benefits from out-of-network providers;

(E) The types of pharmacies that participate in the Part D plan's network and the extent to which an enrollee may select among those pharmacies; and

(F) The Part D plan's out-of-network pharmacy access policy.

(iv) Premiums;

(v) The Part D plan's formulary;

(vi) The Part D plan's service area; and

(vii) Quality and performance indicators for benefits under the Part D plan as determined by CMS.

(2) The procedures the Part D sponsor uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by CMS. These disputes are categorized as—

(i) Grievances according to § 423.564;

(ii) Appeals according to § 423.580 et. seq.; and

(iii) Exceptions according to § 423.578.

(4) Financial condition of the Part D sponsor, including the most recently audited information regarding, at a minimum, a description of the financial condition of the Part D sponsor offering the Part D plan.

(d) *Provision of specific information.* Each Part D sponsor offering qualified prescription drug coverage under a Part D plan must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include—

(1) A toll-free customer call center that—

(i) Is open during usual business hours.

(A) For coverage beginning on and after January 1, 2022, is open at least from 8:00 a.m. to 8:00 p.m. in all regions served by the Part D plan, with the following exceptions:

(1) From October 1 through March 31 of the following year, a customer call center may be closed on Thanksgiving Day and Christmas Day so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such

messages are returned within one (1) business day.

(2) From April 1 through September 30, a customer call center may be closed any Federal holiday, Saturday, or Sunday, so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(B) For coverage beginning on and after January 1, 2022, any call center serving pharmacists or pharmacies must be open so long as any network pharmacy in that region is open.

(ii) Provides customer telephone service, including to pharmacists, in accordance with standard business practices.

(A) For coverage beginning on and after January 1, 2022, limits average hold time to 2 minutes. The hold time is defined as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person.

(B) For coverage beginning on and after January 1, 2022, answers 80 percent of incoming calls within 30 seconds after the interactive voice response (IVR), touch-tone response system, or recorded greeting interaction.

(C) For coverage beginning on and after January 1, 2022, limits the disconnect rate of all incoming calls to 5 percent. The disconnect rate is defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center.

(iii)(A) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(B) For coverage beginning on and after January 1, 2022, interpreters must be available for 80 percent of incoming calls requiring an interpreter within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

(iv) Provides immediate access to the coverage determination and redetermination processes.

(v) At a minimum, for coverage beginning on and after January 1, 2022:

(A) Provides effective real-time communication with individuals using auxiliary aids and services, including

TTYs and all forms of Federal Communication Commission-approved telecommunications relay systems, when using automated-attendant systems. See 28 CFR 35.161 and 36.303(d).

(B) Connects 80 percent of incoming calls requiring TTY services to a TTY operator within 7 minutes.

(vi) For coverage beginning on and after January 1, 2022, provides the information described in paragraph (d)(4) of this section to enrollees who call the customer service call center.

(2) An Internet website that—

(i) Includes, at a minimum, the information required in paragraph (b) of this section.

(ii) Includes a current formulary for its Part D plan, updated at least monthly.

(iii) Provides current and prospective Part D enrollees with notice that is timely under § 423.120(b)(5) regarding any removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary.

(3) The provision of information in writing, upon request.

(4) Beginning on January 1, 2023, a Part D sponsor must implement, and make available directly to enrollees, in an easy to understand manner, the following complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit real-time information in their beneficiary-specific portal or computer application:

(i) Enrollee cost sharing amounts.

(ii) Formulary medication alternatives for a given condition.

(iii) Formulary status, including utilization management requirements applicable to each alternative medication, as appropriate for each enrollee and medication presented.

(5) The Part D sponsor may provide rewards and incentives to enrollees who use the beneficiary real time benefit tool (RTBT) described in paragraph (d)(4) of this section, provided the rewards and incentives comply with the requirements in paragraphs (d)(5)(i) through (vi) of this section, and the rewards and incentives information is made available to CMS upon request. Use is defined as logging into the RTBT, via portal or computer application, or calling the customer service call center to obtain the information

described in paragraph (d)(4) of this section. The rewards and incentives must meet the following:

(i) Be of reasonable value, both individually and in the aggregate.

(ii) Be designed so that all enrollees are eligible to earn rewards and incentives, and that there is no discrimination based on race, color, national origin, including limited English proficiency, sex, age, disability, chronic disease, health status, or other prohibited basis.

(iii) Not be offered in the form of cash or other cash equivalents.

(iv) Not be used to target potential enrollees.

(v) Be earned solely for logging onto the beneficiary RTBT and not for any other purpose.

(vi) Otherwise comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries.

(e) *Claims information.* A Part D sponsor must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage. The explanation of benefits must—

(1) List the item or service for which payment was made and the amount of the payment for each item or service.

(2) Include a notice of the individual's right to request an itemized statement.

(3) Include the cumulative, year-to-date total amount of benefits provided, in relation to—

(i) The deductible for the current year.

(ii) The initial coverage limit for the current year.

(iii) The annual out-of-pocket threshold for the current year.

(4) Include the cumulative, year-to-date total of incurred costs to the extent practicable.

(5) For each prescription drug claim, must include the cumulative percentage increase (if any) in the negotiated price since the first claim of the current benefit year and therapeutic alternatives with lower cost-sharing, when available as determined by the plan,

from the applicable approved plan formulary.

(6) Include any applicable formulary changes for which Part D plans are required to provide notice as described in § 423.120(b)(5).

(7) Be provided no later than the end of the month following any month when prescription drug benefits are provided under this part, including the covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii).

(f) *Disclosure requirements.* CMS may require a Part D plan sponsor to disclose to its enrollees or potential enrollees, the Part D plan sponsor's performance and contract compliance deficiencies in a manner specified by CMS.

(g) *Changes in rules.* If a Part D sponsor intends to change its rules for a Part D plan, it must do all of the following:

(1) Submit the changes for CMS review under the procedures of Subpart V of this part.

(2) For changes that take effect on January 1, notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period as defined in section 1860D–1(b)(1)(B) of the Act.

(3) Provide notice of all other changes in accordance with notice requirements as specified in this part.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54222, Sept. 18, 2008; 74 FR 1544, Jan. 12, 2009; 75 FR 19818, Apr. 15, 2010; 76 FR 21573, Apr. 15, 2011; 80 FR 7963, Feb. 12, 2015; 83 FR 16739, Apr. 16, 2018; 84 FR 23883, May 23, 2019; 86 FR 6115, Jan. 19, 2021]

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) *General requirements.* Except as provided under paragraph (c) of this section, a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeuti-

cally equivalent and bioequivalent version of that drug available at that pharmacy.

(b) *Timing of notice.* Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

(c) *Waiver of public disclosure requirement.* CMS waives the requirement under paragraph (a) of this section in any of the following cases:

(1) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(i) Offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies; and

(ii) Does not charge additional cost-sharing for access to covered Part D drugs dispensed at out-of-network pharmacies.

(2) An out-of-network pharmacy.

(3) An I/T/U network pharmacy.

(4) A network pharmacy that is located in any of the U.S. territories.

(5) A long-term care network pharmacy.

(6) Other circumstances where CMS deems compliance with the requirements of paragraph (a) of this section to be impossible or impracticable.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section under circumstances where CMS deems compliance with this requirement to be impossible or impracticable.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19818, Apr. 15, 2010]

§ 423.136 Privacy, confidentiality, and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, a PDP sponsor must establish procedures to do the following—

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The PDP sponsor must safeguard the