

(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 (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, as used in this subpart, means a Part D enrollee who is currently taking a covered Part D drug that is subject to a negative formulary change that 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 § 423.104(e). The term alternative prescription drug coverage must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under § 423.265(d)(2)); or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(f)(1)).

Applicable beneficiary means an individual who, on the date of dispensing a covered Part D drug—

(1) Is enrolled in a prescription drug plan or an MA-PD plan;

(2) Is not enrolled in a qualified retiree prescription drug plan;

(3) Is not entitled to an income-related subsidy under section 1860D–14(a) of the Act;

(4) Has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) of the Act during the year;

(5) Has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) of the Act; and

(6) Has a claim that—

(i) Is within the coverage gap;

(ii) Straddles the initial coverage period and the coverage gap;

(iii) Straddles the coverage gap and the annual out-of-pocket threshold; or

(iv) Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold.

Applicable drug means a Part D drug that is—

(1)(i) Approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA); or

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than, with respect to a plan year before 2019, a product licensed under subsection (k) of such section 351); and

(2)(i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;

(ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; or

(iii) Is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary.

At-risk beneficiary means a Part D eligible individual—

(1) Who is—

(i) Identified using clinical guidelines (as defined in this section);

(ii) Not an exempted beneficiary; and

(iii) Determined to be at-risk for misuse or abuse of such frequently abused drugs by a Part D plan sponsor under its drug management program in accordance with the requirements of § 423.153(f); or

(2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an at-risk beneficiary (as defined in the paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment.

Basic prescription drug coverage means coverage of Part D drugs that is either standard prescription drug coverage or basic alternative coverage.

Bioequivalent has the meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

Clinical guidelines, for the purposes of a drug management program under § 423.153(f), are criteria—

(1) To identify potential at-risk beneficiaries who may be determined to be at-risk beneficiaries under such programs; and

(2) That are developed in accordance with the standards in § 423.153(f)(16) and, beginning with contract year 2020, will be published in guidance annually.

Contracted pharmacy network means licensed pharmacies, including retail, mail-order, and institutional pharmacies under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.

Corresponding drug means, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product.

Coverage gap means the period in prescription drug coverage that occurs between the initial coverage limit and the out-of-pocket threshold. For purposes of applying the initial coverage limit, Part D sponsors must apply their plan specific initial coverage limit under basic alternative, enhanced alternative or actuarially equivalent Part D benefit designs.

Covered Part D drug means a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under §§ 423.566, 423.580, and 423.600, 423.610, 423.620, and 423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124.

Daily cost-sharing rate means, as applicable, the established—

(1) Monthly copayment under the enrollee's Part D plan, divided by the number of days in the approved

month's supply for the drug dispensed and rounded to the nearest cent; or

(2) Coinsurance percentage under the enrollee's Part D plan.

Dispensing fees means costs that—

(1) Are incurred at the point of sale and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed;

(2) Include only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with § 423.153(c)(2), measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and acquiring and maintaining technology and equipment necessary to operate the pharmacy. Dispensing fees should take into consideration the number of dispensing events in a billing cycle, the incremental costs associated with the type of dispensing methodology, and with respect to Part D drugs dispensed in LTC facilities, the techniques to minimize the dispensing of unused drugs. Dispensing fees may also take into account costs associated with data collection on unused Part D drugs and restocking fees associated with return for credit and reuse in long-term care pharmacies, when return for credit and reuse is permitted under the State in law and is allowed under the contract between the Part D sponsor and the pharmacy.

(3) Do not include administrative costs incurred by the Part D plan in the operation of the Part D benefit, including systems costs for interfacing with pharmacies.

Exempted beneficiary means with respect to a drug management program, an enrollee who—

(1) Has elected to receive hospice care or is receiving palliative or end-of-life care;

(2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy;

(3) Is being treated for cancer-related pain or

(4) Has sickle cell disease.

Frequently abused drug means a controlled substance under the Federal Controlled Substances Act that the Secretary determines is frequently abused or diverted, taking into account all of the following factors:

(1) The drug's schedule designation by the Drug Enforcement Administration.

(2) Government or professional guidelines that address that a drug is frequently abused or misused.

(3) An analysis of Medicare or other drug utilization or scientific data.

Government-funded health program means any program established, maintained, or funded, in whole or in part, by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, which uses public funds, in whole or in part, to provide to, or pay on behalf of, an individual the cost of Part D drugs, including any of the following:

(1) An approved State child health plan under title XXI of the Act providing benefits for child health assistance that meets the requirements of section 2103 of the Act;

(2) The Medicaid program under title XIX of the Act or a waiver under section 1115 of the Act;

(3) The veterans' health care program under Chapter 17 of title 38 of the United States Code;

(4) The Indian Health Service program under the Indian Health Care Improvement Act under Chapter 18 of title 25 of the United States Code; and

(5) Any other government-funded program whose principal activity is the direct provision of health care to persons.

Group health plan, for purposes of applying the definition of incurred costs in § 423.100, has the meaning given such

term in 29 U.S.C. 1167(1), but specifically excludes a personal health savings vehicle, as used in this subpart.

Immediate negative formulary change means an immediate substitution or market withdrawal that meets the requirements of § 423.120(e)(2)(i) or (ii) respectively.

Incurred costs means costs incurred by a Part D enrollee for—

(1)(i) Covered Part D drugs that are not paid for under the Part D plan as a result of application of any annual deductible or other cost-sharing rules for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(d)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.124(b); or

(ii) Nominal cost-sharing paid by or on behalf of an enrollee, which is associated with drugs that would otherwise be covered Part D drugs, as defined in § 423.100, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan processes and instructions for the submission of such information; and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(ii) Under State Pharmaceutical Assistance Program (as defined in § 423.464); by the Indian Health Service, an Indian tribe or tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service); or by a manufacturer as payment for an applicable discount (as defined in § 423.2305) or

under the Medicare Coverage Gap Discount Program (as defined in § 423.2305); or

(iii) Under § 423.782 of this part.

Insurance means a health plan that provides, or pays the cost of Part D drugs, including, but not limited to, any of the following:

(1) Health insurance coverage (as defined in 42 U.S.C. 300gg-91(b)(1));

(2) A Medicare Advantage plan (as described under section 1851(a)(2) of the Act); and

(3) A PACE organization (as defined under sections 1894(a)(3) and 1934(a)(13) of the Act) but specifically excluding a personal health savings vehicle.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Long-term care network pharmacy means a long-term care pharmacy that is a network pharmacy.

Maintenance change means one of the following negative formulary changes with respect to a covered Part D drug:

(1) Making any negative formulary changes to a drug within 90 days of adding a corresponding drug to the same or a lower cost-sharing tier and with the same or less restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements (other than immediate substitutions that meet the requirements of § 423.120(e)(2)(i)).

(2) Making any negative formulary changes to a reference product within 90 days of adding a biosimilar biological product other than an interchangeable biological product of that reference product to the same or a lower cost-sharing tier and with the same or

less restrictive PA, ST, or QL requirements.

(3) Removing a non-Part D drug.

(4) Adding or making more restrictive PA, ST, or QL requirements based upon a new FDA-mandated boxed warning.

(5) Removing a drug withdrawn from sale by the manufacturer or that FDA determines to be withdrawn for safety or effectiveness reasons if the Part D sponsor chooses not to treat it as an immediate negative formulary change.

(6) Removing a drug based on long term shortage and market availability.

(7) Making negative formulary changes based upon new clinical guidelines or information or to promote safe utilization.

(8) Adding PA to help determine Part B versus Part D coverage.

Negative formulary change means one of the following changes with respect to a covered Part D drug:

(1) Removing a drug from a formulary.

(2) Moving a drug to a higher cost-sharing tier.

(3) Adding or making more restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements. Negative formulary changes do not include safety-based claim edits which are not submitted to CMS as part of the formulary.

Negotiated price means the price for a covered Part D drug that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;

(2) Meets all of the following:

(i) Includes all price concessions (as defined in this section) from network pharmacies or other network providers;

(ii) Includes any dispensing fees; and

(iii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices; and

(3) Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale.

Network pharmacy means a licensed pharmacy that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.

Non-maintenance change means a negative formulary change that is not a maintenance change or an immediate negative formulary change.

Non-preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at a preferred pharmacy.

Or otherwise means through a government-funded health program.

Other specified entities means 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.

Out-of-network pharmacy means a licensed pharmacy that is not under contract with a Part D sponsor to provide negotiated prices to Part D plan enrollees.

Part D drug means—

(1) Unless excluded under paragraph (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1860D–2(e)(4) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act.

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act.

(iii) Insulin described in section 1927(k)(2)(C) of the Act.

(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.

(v) A vaccine licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration.

(vi) Supplies that are directly associated with delivering insulin into the body, such as an inhalation chamber used to deliver the insulin through inhalation.

(vii) A combination product approved and regulated by the FDA as a drug, vaccine, or biologic described in paragraphs (1)(i), (ii), (iii), or (v) of this definition.

(2) Does not include any of the following:

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B).

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

(iii) Medical foods, defined as a food that is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation, and that are not regulated as drugs under section 505 of the Federal Food, Drug, and Cosmetic Act.

Person means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

Personal health savings vehicle means a vehicle through which individuals can set aside their own funds to pay for health care expenses, including covered Part D drugs, on a tax-free basis including any of the following—

(1) A Health Savings Account (as defined under section 220 of the Internal Revenue Code);

(2) A Flexible Spending Account (as defined in section 106(c)(2) of the Internal Revenue Code) offered in conjunction with a cafeteria plan under section 125 of the Internal Revenue Code; and

(3) An Archer Medical Savings Account (as defined under section 223 of the Internal Revenue Code); but spe-

cifically excluding a Health Reimbursement Arrangement (as described under Internal Revenue Ruling 2002-41 and Internal Revenue Notice 2002-45)

Plan allowance means the amount Part D plans that offer coverage other than defined standard coverage may use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at an out-of-network pharmacy or in a physician's office in accordance with the requirements of § 423.124(b).

Potential at-risk beneficiary means a Part D eligible individual who is not an exempted beneficiary (as defined in this section) and—

(1) Who is identified using clinical guidelines (as defined in this section); or

(2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as a potential at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment.

Preclusion list means a CMS compiled list of prescribers who—

(1) Meet all of the following requirements:

(i) The prescriber is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.

(ii) The prescriber is currently under a reenrollment bar under § 424.535(c) of this chapter.

(iii) CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph (1)(iii), CMS considers the following factors:

(A) The seriousness of the conduct underlying the prescriber's revocation;

(B) The degree to which the prescriber's conduct could affect the integrity of the Part D program; and

(C) Any other evidence that CMS deems relevant to its determination; or

(2) Meet both of the following requirements:

(i) The prescriber has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the individual to the extent applicable had he or she been enrolled in Medicare.

(ii) CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers all of the following factors:

(A) The seriousness of the conduct involved.

(B) The degree to which the prescriber's conduct could affect the integrity of the Part D program.

(C) Any other evidence that CMS deems relevant to its determination; or

(3) The prescriber, regardless of whether he or she is or was enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph are as follows:

(i) The severity of the offense.

(ii) When the offense occurred.

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

Preferred drug means a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

Preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy under its pharmacy network contract with a Part D plan.

Price concession means any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

Program size means the estimated population of potential at-risk beneficiaries in drug management programs (described in § 423.153(f)) operated by Part D plan sponsors that the Secretary determines can be effectively managed by such sponsors as part of the process to develop clinical guidelines.

Qualified prescription drug coverage means any standard prescription drug coverage or alternative prescription drug coverage

Required prescription drug coverage means coverage of Part D drugs under an MA-PD plan that consists of either—

(1) Basic prescription drug coverage; or

(2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium (as defined under section 1854(b)(2)(C) of the Act) applied under the plan due to the application of a credit against the premium of a rebate under § 422.266(b) of this chapter.

Retail pharmacy means any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.

Rural means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

Standard prescription drug coverage means coverage of Part D drugs that meets the requirements of § 423.104(d). The term standard prescription drug coverage must be either—

(1) *Defined standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(A) and (d)(5)(i)); or

(2) *Actuarially equivalent standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(B) or cost-sharing as described in § 423.104(d)(5)(ii), or both).

Suburban means a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental benefits means benefits offered by Part D plans, other than employer group health or waiver plans, that meet the requirements of § 423.104(f)(1)(ii).

Therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."

Third party payment arrangement means any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban means a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile.

Usual and customary (U&C) price means the price that an out-of-network pharmacy or a physician's office charges a customer who does not have any form of prescription drug coverage for a covered Part D drug.

Valid prescription means a prescription that complies with all applicable State law requirements constituting a valid prescription.

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§ 423.104 Requirements related to qualified prescription drug coverage.

(a) *General.* Subject to the conditions and limitations set forth in this subpart, a Part D sponsor must provide enrollees with coverage of the benefits described in paragraph (c) of this section. The benefits may be provided directly by the Part D sponsor or through arrangements with other entities. CMS reviews and approves these benefits consistent with § 423.272, and using written policy guidelines and requirements in this part and other CMS instructions.

(b) *Availability of prescription drug plan.* A PDP sponsor offering a prescription drug plan must offer the plan—

(1) To all Part D eligible beneficiaries residing in the plan's service area; and

(2) At a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area.

(c) *Types of benefits.* The coverage provided by a Part D plan must be qualified prescription drug coverage.

(d) *Standard prescription drug coverage.* Standard prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements

(1) *Deductible.* An annual deductible equal to—

(i) For 2006, \$250; or

(ii) For years subsequent to 2006, The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of \$5.

(2) *Cost-sharing under the initial coverage limit.* (i) Subject to paragraph (d)(4) of this section, coinsurance for actual costs for covered Part D drugs covered under the Part D plan above the annual deductible specified in paragraph (d)(1) of this section, and up to the initial coverage limit under paragraph (d)(3) of this section, that is—

(A) Equal to 25 percent of actual cost; or

(B) Actuarially equivalent to an average expected coinsurance of no more than 25 percent of actual cost, as determined through processes and methods established under § 423.265(c) and (d).

(ii) *Tiered copayments.* A Part D plan providing actuarially equivalent standard coverage may apply tiered copayments, provided that any tiered copayments are consistent with paragraphs (d)(2)(i)(B) and (d)(4) of this section and are approved as described in § 423.272(b)(2).

(iii) *Tiered cost sharing under paragraph (d)(2)(ii) of this section* may not exceed levels annually determined by CMS to be discriminatory.

(iv) *Specialty tier* means a formulary cost sharing tier dedicated to high-cost Part D drugs with ingredient costs for a 30-day equivalent supply (as described in paragraph (d)(2)(iv)(A)(2) of this section) that are greater than the specialty tier cost threshold specified

in paragraph (d)(2)(iv)(A) of this section.

(A) *Specialty-tier cost threshold.* CMS sets the specialty-tier cost threshold for a plan year in accordance with this paragraph (d)(2)(iv)(A), using the following steps:

(1) *30-day equivalent ingredient cost.* Using the PDE data as specified in paragraph (d)(2)(iv)(C) of this section, CMS uses the ingredient cost reflected on the prescription drug event (PDE) to determine the ingredient cost in dollars for a 30-day equivalent supply of the Part D drug.

(2) *30-day equivalent supply.* CMS determines the 30-day equivalent supply as follows: If the days' supply reported on a PDE is less than or equal to 34, the number of 30-day equivalent supplies equals one. If the days' supply reported on a PDE is greater than 34, the number of 30-day equivalent supplies is equal to the number of days' supply reported on each PDE divided by 30.

(3) *Top 1 percent.* CMS determines the amount that equals the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs reflected in the PDE data.

(4) *Determination.* Except as provided in paragraph (d)(2)(iv)(B) of this section, the amount determined in paragraph (d)(2)(iii) of this section is the specialty-tier cost threshold for the plan year.

(5) *Claims history.* Except for newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, CMS approves placement of a Part D drug on a specialty tier when that Part D sponsor's claims data from the time period specified in paragraph (d)(2)(iv)(C) of this section demonstrates that greater than 50 percent of the Part D sponsor's PDEs for a given Part D drug, when adjusted for 30-day equivalent supplies, have ingredient costs for 30-day equivalent supplies, as described in paragraph (d)(2)(iv)(A)(2) of this section, that exceed the specialty-tier cost threshold.

(6) *No claims history.* For newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, CMS approves placement

of a Part D drug on a specialty tier when that Part D sponsor estimates that ingredient cost portion of their negotiated prices for a 30-day equivalent supply, as defined in subparagraph (d)(2)(iv)(A)(2), is anticipated to exceed the specialty-tier cost threshold more than 50 percent of the time, subject to the requirements at §§ 423.120(b), (e), and (f).

(B) *Limit on specialty-tier cost threshold adjustment.* (1) CMS increases the specialty-tier cost threshold for a plan year only if the amount determined in paragraph (d)(2)(iv)(A)(3) of this section for a plan year is at least 10 percent above the specialty tier cost threshold for the prior plan year.

(2) If an increase is made in accordance with this paragraph (d)(2)(iv)(B), CMS rounds the amount determined in paragraph (d)(2)(iv)(A)(3) of this section to the nearest \$10, and the resulting dollar amount is the specialty-tier cost threshold for the plan year.

(C) *Data used to determine the specialty-tier cost threshold.* CMS uses PDEs from the plan year that ended 12 months prior to the applicable plan year.

(D) *Maximum number of specialty tiers and maximum allowable cost sharing.* A Part D plan may maintain up to two specialty tiers. CMS sets the maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost sharing specialty tier as follows:

(1) For Part D plans with the full deductible provided under the Defined Standard benefit, as specified in paragraph (d)(1) of this section, 25 percent coinsurance.

(2) For Part D plans with no deductible, 33 percent coinsurance.

(3) For Part D plans with a deductible that is greater than \$0 and less than the deductible provided under the Defined Standard benefit, a coinsurance percentage that is determined by subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL) under section 1860D–2(b)(3) of the Act, dividing this difference by the difference between the ICL and the plan's deductible, and rounding to the nearest 1 percent.

(3) *Initial coverage limit.* Except as provided in paragraphs (d)(4) and (d)(5)

of this section, the initial coverage limit is equal to—

(i) *For 2006.* \$2,250.

(ii) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of \$10.

(4) *Cost-sharing in the coverage gap for applicable beneficiaries.* (i) Coinsurance in the coverage gap (as defined in § 423.100) for costs for covered Part D drugs that are not applicable drugs (as defined in § 423.100) under the Medicare coverage gap discount program that is—

(A) Equal to the generic gap coinsurance percentage described in paragraph (d)(4)(iii) of this section; or

(B) Actuarially equivalent to an average expected coinsurance for covered Part D drugs that are not applicable drugs under the Medicare coverage gap discount program, as determined through processes and methods established under § 423.265 (c) and (d).

(ii) Coinsurance in the coverage gap for the actual cost minus the dispensing fee and any vaccine administration fee for covered Part D drugs that are applicable drugs under the Medicare coverage gap discount program that is—

(A) Equal to the difference between the applicable gap coinsurance percentage described in paragraph (d)(4)(iv) of this section and the discount percentage determined under the Medicare coverage gap discount program; or

(B) Actuarially equivalent to an average expected coinsurance for covered Part D drugs that are applicable drugs under the Medicare coverage gap discount program, as determined through processes and methods established under § 423.265 (c) and (d).

(iii) *Generic gap coinsurance percentage.* The generic gap coinsurance percentage is equal to—

(A) For 2011, 93 percent.

(B) For years 2012 through 2019, the amount specified in this paragraph for the previous year, decreased by 7 percentage points.

(C) For 2020 and each subsequent year, 25 percent.

(iv) *Applicable gap coinsurance percentage.* The applicable gap coinsurance percentage is equal to—

(A) For 2013 and 2014, 97.5 percent.

(B) For 2015 and 2016, 95 percent.

(C) For 2017, 90 percent.

(D) For 2018, 85 percent.

(E) For 2019, 80 percent.

(F) For 2020 and subsequent years, 75 percent.

(5) *Protection against high out-of-pocket expenditures.* (i) After an enrollee's incurred costs exceed the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section, cost-sharing equal to the greater of—

(A) *Copayments.* (1) In 2006, \$2 for a generic drug or preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act) and \$5 for any other drug; and

(2) For subsequent years, the copayment amounts specified in this paragraph for the previous year increased by the annual percentage increase described in paragraph (d)(5)(iv) of this section and rounded to the nearest multiple of 5 cents; or

(B) *Coinsurance.* Coinsurance of five percent of actual cost.

(ii) As determined through processes and methods established under § 423.265(c) and (d), a Part D plan may substitute for cost-sharing under paragraph (d)(5)(i) of this section an amount that is actuarially equivalent to expected cost-sharing under paragraph (d)(5)(i) of this section.

(iii) *Annual out-of-pocket threshold.* For purposes of this part, the annual out-of-pocket threshold equals—

(A) *For 2006.* \$3,600.

(B) *For each year 2007 through 2013.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of \$50.

(C) *For years 2014 and 2015.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, minus 0.25 percentage point.

(D) *For each year 2016 through 2019.* The amount specified in this paragraph for the previous year, increased by the lesser of—

(1) The annual percentage increase specified in (d)(5)(v) of this section plus 2 percentage points; or

(2) The annual percentage increase specified in (d)(5)(iv) of this section.

(E) *For 2020.* The amount specified in this paragraph for 2013 increased by the annual percentage increases specified in paragraph (d)(5)(iv) of this section for 2014 through 2020, and rounded to the nearest \$50.

(F) *For 2021 and subsequent years.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest \$50.

(iv) *Annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals and is based on data for the 12-month period ending in July of the previous year.

(v) *Additional annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending in July of the previous year.

(e) *Alternative prescription drug coverage.* Alternative prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements—

(1) Has an annual deductible that does not exceed the annual deductible specified in paragraph (d)(1) of this section;

(2) Imposes cost-sharing no greater than that specified in paragraphs (d)(5)(i) or (ii) of this section once the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section is met;

(3) Has a total or gross value that is at least equal to the total or gross value of defined standard coverage.

(4) Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the

amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under § 423.782 for the coverage; and

(5) Provides coverage that is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, for costs incurred for covered Part D drugs, that are equal to the initial coverage limit under paragraph (d)(3) of this section, of an amount equal to at least the product of—

(i) The amount by which the initial coverage limit described in paragraph (d)(3) of this section for the year exceeds the deductible described in paragraph (d)(1) of this section; and

(ii) 100 percent minus the coinsurance percentage specified in paragraph (d)(2)(i) of this section.

(f) *Enhanced alternative coverage.* (1) Enhanced alternative coverage must meet the requirements under paragraph (e) of this section and includes—

(i) Basic prescription drug coverage, as defined in § 423.100; and

(ii) Supplemental benefits, which include—

(A) Coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100; or

(B) Any of the following changes or combination of changes that increase the actuarial value of benefits under the Part D plan above the actuarial value of defined standard prescription drug coverage, as determined through processes and methods established under § 423.265—

(1) A reduction in the annual deductible described in paragraph (d)(1) of this section;

(2) A reduction in the cost-sharing described in paragraphs (d)(2) or (d)(5) of this section, or

(3) An increase in the initial coverage limit described in paragraph (d)(3) of this section.

(C) Both the coverage described in paragraph (f)(1)(ii)(A) of this section and the changes or combination of changes described in paragraph (f)(1)(ii)(B) of this section.

(2) *Restrictions on the offering of enhanced alternative coverage by PDP sponsors.* A PDP sponsor may not offer enhanced alternative coverage in a service area unless the PDP sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

(3) *Restrictions on the offering of enhanced alternative coverage by MA organizations.* Effective January 1, 2006, an MA organization—

(i) May not offer an MA coordinated care plan, as defined in § 422.4 of this chapter, in an area unless either that plan (or another MA plan offered by the MA organization in that same service area) includes required prescription drug coverage; and

(ii) May not offer prescription drug coverage (other than that required under Parts A and B of title XVIII of the Act) to an enrollee—

(A) Under an MSA plan, as defined in § 422.2 of this chapter; or

(B) Under another MA plan (including a private fee-for-service plan, as defined in § 422.4 of this chapter) unless the drug coverage under the other plan provides qualified prescription drug coverage and unless the requirements of paragraph (f)(3)(i) of this section are met.

(4) *Restrictions on the offering of enhanced alternative coverage by cost plans.*

(i) A cost plan that elects to offer qualified prescription drug coverage may offer enhanced alternative coverage as an optional supplemental benefit under § 417.440(b)(2)(ii) of this chapter only if the cost plan also offers basic prescription drug coverage. An enrollee in the cost plan may, at the individual's option, elect whether to receive qualified prescription drug coverage under the cost plan and, if so, whether to receive basic prescription drug coverage or, if offered by the cost plan, enhanced alternative coverage.

(ii) A cost plan that offers qualified prescription drug coverage as an optional supplemental benefit under § 417.440(b)(2)(ii) of this chapter may not offer prescription drug coverage that is not qualified prescription drug coverage. A cost plan that does not offer qualified prescription drug coverage under § 417.440(b)(2)(ii) of this chapter may offer prescription drug

coverage that is not qualified prescription drug coverage under § 417.440(b)(2)(i) of this chapter.

(g) *Negotiated prices*—(1) *Access to negotiated prices.* A Part D sponsor is required to provide its Part D enrollees with access to negotiated prices for covered Part D drugs included in its Part D plan's formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for covered Part D drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit. Negotiated prices must be provided when the negotiated price for a covered Part D drug under a Part D sponsor's benefit package is less than the applicable cost-sharing before the application of any deductible, before any initial coverage limit, before the annual out-of-pocket threshold, and after the annual out-of-pocket threshold.

(2) *Interaction with Medicaid best price.* Prices negotiated with a pharmaceutical manufacturer, including discounts, subsidies, rebates, and other price concessions, for covered Part D drugs by the following entities are not taken into account in establishing Medicaid's best price under section 1927(c)(1)(C) of the Act—

(i) A Part D plan, as defined in § 423.4; or

(iii) A qualified retiree prescription drug plan (as defined in § 423.882) for Part D eligible individuals.

(3) *Disclosure.* (i) A Part D sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, as well as data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers that are passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals described in § 423.782, or in the form of lower monthly beneficiary premiums or lower covered Part D drug prices at the point of sale.

(ii) Information on negotiated prices disclosed to CMS under paragraph (g)(3) of this section is protected under

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the confidentiality provisions applicable under section 1927(b)(3)(D) of the Act.

(4) *Audits.* CMS and the Office of the Inspector General may conduct periodic audits of the financial statements and all records of Part D sponsors pertaining to any qualified prescription drug coverage they may offer under a Part D plan.

(h) *Valid prescription.* A Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription.

(i) *Daily cost-sharing rate.* Beginning January 1, 2014, a Part D sponsor is required to provide its enrollees access to 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; 89 FR 30833, Apr. 23, 2024]

§ 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

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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 defined 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 annually 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 authoriza-

tion 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 of immediate changes as permitted under paragraph (e)(2) 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) Notice of formulary changes. Part D sponsors must provide notice of changes to CMS-approved formularies as specified in § 423.120(f).

(6) Changes to CMS-approved formularies. Changes to CMS-approved formularies may be made only in accordance with paragraph (e) of this section.

(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.

(e) *Approval of changes to CMS-approved formularies.* A Part D sponsor may not make any negative formulary changes to its CMS-approved formulary except as specified in this section.

(1) *Negative change request.* Except as provided in paragraph (e)(2) of this section, prior to implementing a negative formulary change, Part D sponsors must submit to CMS, at a time and in a form and manner specified by CMS, a negative formulary change request.

(2) *Exception for immediate negative formulary changes.* A negative change request is not required in the following circumstances:

(i) *Immediate substitutions.* A Part D sponsor may make negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug to its formulary on the same or lower cost sharing tier and with the same or less restrictive formulary prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements, so long as the Part D sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval consistent with paragraph (b)(2) of this section because such drug was not yet available on the market, and the Part D sponsor has provided advance general

notice as specified in paragraph (f)(2) of this section.

(ii) *Market withdrawals.* A Part D sponsor may immediately remove from its formulary any Part D drugs withdrawn from sale by their manufacturer or that the Food and Drug Administration (FDA) determines to be withdrawn for safety or effectiveness reasons.

(3) *Approval process for negative formulary changes—(i) Maintenance changes.* Negative change requests for maintenance changes are deemed approved 30 days after submission unless CMS notifies the Part D sponsor otherwise.

(ii) *Non-maintenance changes.* Part D sponsors must not implement non-maintenance changes until they receive notice of approval from CMS. Affected enrollees are exempt from non-maintenance changes for the remainder of the contract year.

(4) *Limitation on formulary changes prior to the beginning of a contract year.* Except as provided in paragraph (e)(2) of this section, a Part D sponsor may not make a negative formulary change that takes effect 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.

(f) *Provision of notice regarding changes to CMS-approved formularies—*

(1) *Notice of negative formulary changes.* Except as specified in paragraphs (f)(2) and (3) of this section, prior to making any negative formulary change, a Part D sponsor must provide notice to CMS and other specified entities at least 30 days prior to the date such change becomes effective, and must either: provide written notice to affected enrollees at least 30 days prior to the date the change becomes effective, or when 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. The requirement to provide notice to CMS is satisfied upon a Part D sponsor's submission of a negative change request described in paragraph (e) of this section. The requirement to provide notice to other

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specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2).

(2) *Advance general notice of immediate negative formulary changes.* In the case of immediate negative formulary changes described in paragraph (e)(2) of this section, a Part D sponsor must provide advance general notice to all current and prospective enrollees and other specified entities in its formulary and other applicable beneficiary communication materials advising that the Part D sponsor may make immediate negative formulary changes consistent with the requirements of paragraph (e)(2) at any time. Such advance general notice must include information about how to access the plan's online formulary; about how to contact the plan; and that written notice of any change made will describe the specific drugs involved. Advance general notice of immediate substitutions must also specify that the written notice will contain information on the steps that enrollees may take to request coverage determinations and exceptions. Advance general notice of immediate substitutions is provided to CMS during bid submission. Advance general notice of market withdrawals is provided to CMS in the advance notice of immediate negative formulary changes that Part D sponsors provide to enrollees and other specified entities required earlier in this paragraph (f)(2).

(3) *Retrospective notice and update.* In the case of a negative formulary change described in paragraph (e)(2) of this section, the Part D sponsor must provide notice to other specified entities and written notice to affected enrollees as soon as possible, but no later than by the end of the month following any month in which the change takes effect. The requirement to provide notice to other specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2). Part D sponsors also must submit such changes to CMS, in a form and manner specified by CMS, in their next required or scheduled formulary update.

(4) *Content of written notice:* Any written notice required under this paragraph (other than advance general no-

tice) must contain all of the following information:

(i) The name of the affected covered Part D drug.

(ii) Whether the plan is removing the covered Part D drug from the formulary, moving it to a higher cost-sharing tier, or adding or making more restrictive PA, ST, or QL requirements.

(iii) The reason for the negative formulary change.

(iv) Appropriate alternative drugs on the formulary in the same or a lower cost-sharing tier and the expected cost sharing for those drugs.

(v) For formulary changes other than those described in paragraph (e)(2)(ii) of this section, the means by which enrollees may obtain a coverage determination under § 423.566, including an exception to a coverage rule under § 423.578.

(5) *Notice of other formulary changes.* Part D sponsors provide appropriate notice of all formulary changes other than negative formulary changes by providing—

(i) Advance general notice to all current and prospective enrollees, CMS, and other specified entities in formulary and other applicable beneficiary communication materials advising them that the Part D sponsor may make formulary changes other than negative formulary changes at any time and providing information about how to access the plan's online formulary and how to contact the plan; and

(ii) Notice of specific formulary changes to other specified entities by complying with § 423.128(d)(2) and to CMS by submitting such changes to CMS in their next required or scheduled formulary update.

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§ 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.

(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 informa-

tion 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 re-

sponse (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) Establishes contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.

(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(f) regarding any negative formulary changes 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 negative formulary changes applicable to an enrollee for which Part D plans are required to provide notice as described in § 423.120(f).

(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.

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§ 423.129 Resolution of complaints in complaints tracking module.

(a) *Definitions.* For the purposes of this regulation, the following terms have the following meanings:

Assignment date is the date CMS assigns a complaint to a particular Part D sponsor in the Complaints Tracking Module.

Complaints Tracking Module is an electronic system maintained by CMS to record and track complaints submitted to CMS about Medicare health and drug plans from beneficiaries and others.

Immediate need complaint is a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 2 or fewer days.

Urgent complaint is a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they do not have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 3 to 14 days.

(b) *Timelines for complaint resolution—*

(1) *Immediate need complaints.* The Part D sponsor must resolve immediate need complaints within 2 calendar days of the assignment date.

(2) *Urgent complaints.* The Part D sponsor must resolve urgent complaints within 7 calendar days of the assignment date.

(3) *All other complaints.* The Part D sponsor must resolve all other complaints within 30 calendar days of the assignment date.

(4) *Extensions.* Except for immediate need complaints, urgent complaints, and any complaint that requires expedited treatment under § 423.564(f), if a complaint is also a grievance within the scope of § 423.564 and the requirements for an extension of the time to provide a response in § 423.564(e)(2) are met, the Part D sponsor may extend the timeline to provide a response.

(5) *Coordination with timeframes for grievances, PACE service determination requests, and PACE appeals.* When a complaint under this section is also a grievance within the scope of §§ 423.564 or 460.120, a PACE service determination request within the scope of § 460.121, or a PACE appeal within the definition of § 460.122, the Part D sponsor must comply with the shortest applicable timeframe for resolution of the complaint.

(c) *Timeline for contacting individual filing a complaint.* Regardless of the type of complaint received, the Part D sponsor must attempt to contact the individual who filed a complaint within 7 calendar days of the assignment date.

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§ 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 therapeutically 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: