

Centers for Medicare & Medicaid Services, HHS**§ 423.560**

a determination concerning the following:

(i) The proposed new owner is in fact a successor in interest to the contract.

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program.

(iii) The successor organization meets the requirements to qualify as a PDP sponsor under subpart K of this part.

(b) *Provisions of a novation agreement.* A valid novation agreement requires the following:

(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* The previous owner must—

(i) Guarantee performance of the contract by the new owner during the contract period; or

(ii) Post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

§ 423.553 Effect of leasing of a PDP sponsor's facilities.

(a) *General effect of leasing.* If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D-12(b) of the Act.

(b) *Effect of lease of all facilities.* (1) If a PDP sponsor leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor, it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities.* If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compli-

ance with the applicable requirements and qualifying conditions specified in subpart K of this part.

Subpart M—Grievances, Coverage Determinations, Redeterminations, and Reconsiderations**§ 423.558 Scope.**

(a) This subpart sets forth the requirements relating to the following:

(1) Part D plan sponsors with respect to grievances, coverage determinations, and redeterminations.

(2) Part D IRE with respect to reconsiderations.

(3) Part D enrollees' rights with respect to grievances, coverage determinations, redeterminations, and reconsiderations.

(b) The requirements regarding reopenings, ALJ hearings, MAC review, and Judicial review are set forth in subpart U of this chapter.

[74 FR 65363, Dec. 9, 2009]

§ 423.560 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated

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in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter.

Drug Use means an enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment.

Enrollee means a Part D eligible individual who has elected or has been enrolled in a Part D plan.

Grievance means any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

Other prescriber means a health care professional other than a physician who is authorized under State law or other applicable law to write prescriptions.

Physician has the meaning given the term in section 1861(r) of the Act.

Projected value of a Part D drug or drugs includes any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.

Reconsideration means a review of an adverse coverage determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination by a Part D plan sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor obtains.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 74 FR 1546, Jan. 12, 2009]

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§ 423.562 General provisions.

(a) *Responsibilities of the Part D plan sponsor.* A Part D plan sponsor must meet all of the following requirements.

(1) A Part D plan sponsor, for each Part D plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 423.564 for addressing issues that do not involve coverage determinations;

(ii) Use a single, uniform exceptions and appeals process which includes, procedures for accepting oral and written requests for coverage determinations and redeterminations that are in accordance with § 423.128 (b)(7) and (d)(1)(iii).

(iii) A procedure for making timely coverage determinations, including determinations on requests for exceptions to a tiered cost-sharing structure or to a formulary; and

(iv) Appeal procedures that meet the requirements of this subpart for issues that involve coverage determinations.

(2) A Part D plan sponsor must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the Part D plan sponsor; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) A Part D plan sponsor must arrange with its network pharmacies to distribute notices instructing enrollees how to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist. These notices must comply with the standards established in § 423.128(b)(7)(iii).

(4) In accordance with subpart K of this part, if the Part D plan sponsor delegates any of its responsibilities under this subpart to another entity or individual through which the Part D plan sponsor provides covered benefits, the Part D plan sponsor is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(5) A Part D plan sponsor must employ a medical director who is responsible for ensuring the clinical accuracy

of all coverage determinations and redeterminations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

(b) *Rights of enrollees.* In accordance with the provisions of this subpart, enrollees have all of the following rights under Part D plans:

(1) The right to have grievances between the enrollee and the Part D plan sponsor heard and resolved by the plan sponsor, as described in § 423.564.

(2) The right to a timely coverage determination by the Part D plan sponsor, as specified in § 423.566 and § 423.568, including the right to request from the Part D plan sponsor an exception to its tiered cost-sharing structure or formulary, as specified in § 423.578.

(3) The right to request from the Part D plan sponsor an expedited coverage determination, as specified in § 423.570.

(4) If dissatisfied with any part of a coverage determination, all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination by the Part D plan sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of a redetermination, a Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, the right to a reconsideration or expedited reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.

(iv) If the IRE affirms the plan's adverse coverage determination, in whole or in part, the right to an ALJ hearing if the amount in controversy meets the requirements in § 423.1970.

(v) If the ALJ affirms the IRE's adverse coverage determination, in whole or in part, the right to request MAC review of the ALJ hearing decision, as specified in § 423.1974.

(vi) If the MAC affirms the ALJ's adverse coverage determination, in whole or in part, the right to judicial review of the hearing decision if the amount

in controversy meets the requirements in § 423.1976.

(c) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 422, subpart M of this chapter (concerning the administrative review and hearing processes under titles II and XVIII, and representation of parties under title XVIII of the Act) and any interpretive rules or CMS rulings issued under these regulations, apply under this subpart to the extent they are appropriate.

(d) *Relation to ERISA Requirements.* Consistent with section 1860D-22(b) of the Act, provisions of this subpart may, to the extent applicable under the regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009; 76 FR 21575, Apr. 15, 2011]

§ 423.564 Grievance procedures.

(a) *General rule.* Each Part D plan sponsor must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the Part D plan sponsor or any other entity or individual through whom the Part D plan sponsor provides covered benefits under any Part D plan it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b). Upon receiving a complaint, a Part D plan sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization complaint process.* Under section 1154(a)(14) of the Act, the quality improvement organization (QIO) must review enrollees' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the Part D plan sponsor. For quality of care issues, an enrollee may file a grievance with the Part D plan sponsor, file a written complaint with

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the QIO, or both. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance.* (1) An enrollee may file a grievance with the Part D plan sponsor either orally or in writing.

(2) An enrollee must file a grievance no later than 60 calendar days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification.* (1) The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 calendar days after the date the Part D plan sponsor receives the oral or written grievance.

(2) The Part D plan sponsor may extend the 30 calendar day timeframe by up to 14 calendar days if the enrollee requests the extension or if the Part D plan sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Part D plan sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.

(3) The Part D plan sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(f) *Expedited grievances.* A Part D plan sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves a refusal by the Part D plan sponsor to grant an enrollee's request for an expedited coverage determination under § 423.570 or an expedited redetermination under § 423.584, and the

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enrollee has not yet purchased or received the drug that is in dispute.

(g) *Record keeping.* The Part D plan sponsor must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the enrollee was notified of the disposition.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009]

§423.566 Coverage determinations.

(a) *Responsibilities of the Part D plan sponsor.* Each Part D plan sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug benefits an enrollee is entitled to receive under the plan, including basic prescription drug coverage as specified in § 423.100 and supplemental benefits as specified in § 423.104(f)(1)(ii), and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. The Part D plan sponsor must have a standard procedure for making determinations, in accordance with § 423.568, and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with § 423.570.

(b) *Actions that are coverage determinations.* The following actions by a Part D plan sponsor are coverage determinations:

(1) A decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan;

(2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;

(3) A decision concerning an exceptions request under § 423.578(a);

(4) A decision concerning an exceptions request under § 423.578(b); or

(5) A decision on the amount of cost sharing for a drug.

(c) Who can request a coverage determination. Individuals who can request a standard or expedited coverage determination are—

(1) The enrollee;

(2) The enrollee's appointed representative, on behalf of the enrollee; or

(3) The prescribing physician or other prescriber, on behalf of the enrollee.

(d) *Who must review coverage determinations.* If the Part D plan sponsor expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the coverage determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the Part D plan sponsor issues the coverage determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1546, Jan. 12, 2009; 76 FR 21576, Apr. 15, 2011]

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Method and place for filing a request.* An enrollee must ask for a standard coverage determination by making a request with the Part D plan sponsor in accordance with the following:

(1) Except as specified in paragraph (a)(2) of this section, the request may be made orally or in writing.

(2) Requests for payment must be made in writing (unless the Part D plan sponsor has implemented a voluntary policy of accepting oral payment requests).

(3) The Part D plan sponsor must establish and maintain a method of docu-

menting all oral requests and retain the documentation in the case file.

(b) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's or other prescriber's supporting statement.

(c) *Timeframe for requests for payment.* When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination and make payment (when applicable) no later than 14 calendar days after receipt of the request.

(d) *Written notice for favorable decisions by a Part D plan sponsor.* If a Part D plan sponsor makes a completely favorable decision under paragraph (b) of this section, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification.

(e) *Form and content of the approval notice.* The notice of any approval under paragraph (d) of this section must explain the conditions of the approval in a readable and understandable form.

(f) *Written notice for denials by a Part D plan sponsor.* If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is mailed to the enrollee within 3 calendar days of the oral notification.

(g) *Form and content of the denial notice.* The notice of any denial under paragraph (f) of this section must meet the following requirements:

(1) Use approved notice language in a readable and understandable form.

(2) State the specific reasons for the denial.

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions

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for, obtaining an expedited redetermination and the rest of the appeals process.

(ii) For payment denials, describe the standard redetermination process and the rest of the appeals process.

(3) Inform the enrollee of his or her right to a redetermination.

(4) Comply with any other notice requirements specified by CMS.

(h) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (b) or (c) of this section, the failure constitutes an adverse coverage determination, and the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

[75 FR 19823, Apr. 15, 2010, as amended at 76 FR 21576, Apr. 15, 2011]

§423.570 Expediting certain coverage determinations.

(a) *Request for expedited determination.* An enrollee or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a coverage determination involving issues described in §423.566(b) of this part. This does not include requests for payment of Part D drugs already furnished.

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or an enrollee's prescribing physician or other prescriber on behalf of the enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the determination, as directed by the Part D plan sponsor.

(2) A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for an expedited determination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited determinations:

(1) An efficient and convenient means for accepting oral or written requests submitted by enrollees, prescribing physicians, or other prescribers.

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(2) A method for documenting all oral requests and maintaining the documentation in the case file; and

(3) A means for issuing prompt decisions on expediting a determination, based on the following requirements:

(i) For a request made by an enrollee, provide an expedited determination if it determines that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by an enrollee's prescribing physician or other prescriber, provide an expedited determination if the physician or other prescriber indicates that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If a Part D plan sponsor denies a request for expedited determination, it must take the following actions:

(1) Make the determination within the 72-hour timeframe established in §423.568(b) for a standard determination. The 72-hour period begins on the day the Part D plan sponsor receives the request for expedited determination, or, for an exceptions request, the physician's or other prescriber's supporting statement.

(2) Give the enrollee and prescribing physician or other prescriber prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor must process the request using the 72 hour timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's or other prescriber's support and

(iv) Provides instructions about the plan's grievance process and its timeframes.

(3) Subsequently deliver to the enrollee, within 3 calendar days, equivalent written notice.

(e) *Actions on accepted requests for expedited determination.* If a Part D plan sponsor grants a request for expedited determination, it must make the determination and give notice in accordance with § 423.572.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 74 FR 1546, Jan. 12, 2009; 75 FR 19823, Apr. 15, 2010]

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeline for determination and notification.* Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's or other prescriber's supporting statement.

(b) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(c) *Content of the notice of expedited determination.* (1) If the determination is completely favorable to the enrollee, the notice must explain the conditions of the approval in a readable and understandable form.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Use approved language in a readable and understandable form;

(ii) State the specific reasons for the denial;

(iii) Inform the enrollee of his or her right to a redetermination;

(iv) Describe—

(A) Both the standard and expedited redetermination processes, including the enrollee's right to request an expedited redetermination;

(B) Conditions for obtaining an expedited redetermination; and

(C) Other aspects of the appeal process.

(d) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the timeframe specified in paragraph (a) of this section, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1564, Jan. 12, 2009; 75 FR 19823, Apr. 15, 2010]

§ 423.576 Effect of a coverage determination.

The coverage determination is binding on the Part D plan sponsor and the enrollee unless it is reviewed and revised under § 423.580 through § 423.604 and § 423.1970 through § 423.1976 or is reopened and revised under § 423.1978.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009]

§ 423.578 Exceptions process.

(a) *Requests for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (a)(4) of this section.

(1) The exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.

(2) The exceptions criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a determination made by the enrollee's prescribing physician or other prescriber under paragraph (a)(4) of this section.

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(ii) Consideration of whether the requested Part D drug that is the subject of the exceptions request is the therapeutic equivalent, as defined in § 423.100, of any other drug on the plan's formulary.

(iii) Consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested prescription drug that is the subject of the exceptions request.

(3) An enrollee or the enrollee's prescribing physician or other prescriber may file a request for an exception.

(4) A prescribing physician or other prescriber must provide an oral or written supporting statement that the preferred drug for the treatment of the enrollee's conditions—

(i) Would not be as effective for the enrollee as the requested drug;

(ii) Would have adverse effects for the enrollee; or

(iii) Both paragraphs (a)(4)(i) and (a)(4)(ii) of this section apply.

(5) If the physician or other prescriber provides an oral supporting statement, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement to demonstrate the medical necessity of the drug. The Part D plan sponsor may require the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up.

(6) In no case is a Part D plan sponsor required to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains a separate tier dedicated to generic drugs.

(7) If a Part D plan sponsor maintains a formulary tier in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception.

(b) *Request for exceptions involving a non-formulary Part D drug.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and maintain exceptions procedures subject to CMS' approval for receipt of an off-formulary drug. The Part D plan spon-

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sor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (b)(5) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug. Formulary use includes the application of cost utilization tools, such as a dose restriction, including the dosage form, that causes a particular Part D drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular Part D drug not to be covered until the requirements of the plan's coverage policy are met, or a therapeutic substitution requirement.

(1) The plan's formulary exceptions process must address each of the following circumstances:

(i) Situations where a formulary changes during the year, and situations where an enrollee is already using a given drug.

(ii) Continued coverage of a particular Part D prescription drug that the Part D plan sponsor is discontinuing coverage on the formulary for reasons other than safety or because the Part D prescription drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer.

(iii) An exception to a plan's coverage policy that causes a Part D prescription drug not to be covered because of cost utilization tools, such as a requirement for step therapy, dosage limitations, or therapeutic substitution.

(2) The exception criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a prescribing physician's or other prescriber's determination made under paragraph (b)(5) of this section;

(ii) A process for gathering and comparing applicable medical and scientific evidence on the safety and effectiveness of the requested non-formulary drug with the formulary drug for the enrollee, including safety information generated by an authoritative government body; and

(iii) A description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

(3) If the Part D plan sponsor covers a non-formulary drug, the cost(s) incurred by the enrollee for that drug are treated as being included for purposes of calculating and meeting the annual out-of-pocket threshold.

(4) An enrollee, the enrollee's appointed representative, or the prescribing physician or other prescriber (on behalf of the enrollee) may file a request for an exception.

(5) A prescribing physician or other prescriber must provide an oral or written supporting statement that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition because—

(i) All of the covered Part D drugs on any tier of a plan's formulary for treatment for the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects for the enrollee, or both;

(ii) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements—

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(B) Has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee; or

(iii) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or ad-

versely affect the drug's effectiveness or patient compliance.

(6) If the physician or other prescriber provides an oral supporting statement, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up.

(c) *Requirements for exceptions*—(1) *General rule.* A decision by a Part D plan sponsor concerning an exceptions request under this section constitutes a coverage determination as specified at § 423.566.

(2) When a Part D plan sponsor does not make a timely decision. If the Part D plan sponsor fails to make a decision on an exceptions request and provide notice of the decision within the time-frame required under § 423.568(a) or § 423.572(a), as applicable, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(3) *When a tiering exceptions request is approved.* Whenever an exceptions request made under § 423.578(a) is approved, the Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies for preferred drugs, and may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(i) The enrollee's prescribing physician or other prescriber continues to prescribe the drug.

(ii) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(iii) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(4) *When a non-formulary exceptions request is approved.* Whenever an exceptions request made under § 423.578(b) is approved—

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(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician or other prescriber continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(ii) The Part D plan sponsor must not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(iii) An enrollee may not request a tiering exception for a non-formulary prescription drug approved under § 423.578(b).

(d) *Notice regarding formulary changes.* Whenever a Part D plan sponsor removes a covered part D drug from its formulary or makes any changes in the preferred or tiered cost-sharing status of such a drug, the Part D plan sponsor must provide notice in accordance with § 423.120(b)(5).

(e) *Limitation of the exceptions procedures to Part D drugs.* Nothing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug.

(f) *Implication of the physician's or other prescriber's supporting statement.* Nothing in this section should be construed to mean that the physician's or other prescriber's supporting statement required for an exceptions request will result in an automatic favorable decision.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1546, Jan. 12, 2009]

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.1978) may request that

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it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request a standard redetermination under the procedures described in § 423.582. An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of an enrollee) may request an expedited redetermination as specified in § 423.584.

[74 FR 1547, Jan. 12, 2009, as amended at 74 FR 65363, Dec. 9, 2009]

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination. The Part D plan sponsor may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for a redetermination must be filed within 60 calendar days from the date of the notice of the coverage determination.

(c) *Extending the time for filing a request—(1) General rule.* If an enrollee or prescribing physician or other prescriber acting on behalf of an enrollee shows good cause, the Part D plan sponsor may extend the timeframe for filing a request for redetermination.

(2) *How to request an extension of timeframe.* If the 60 calendar day period in which to file a request for a redetermination has expired, an enrollee or a prescribing physician or other prescriber acting on behalf of an enrollee may file a request for redetermination and extension of time frame with the Part D plan sponsor. The request for redetermination and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for redetermination was not filed on time.

(d) *Withdrawing a request.* The person who files a request for redetermination

may withdraw it by filing a written request with the Part D sponsor.

[74 FR 1547, Jan. 12, 2009, as amended at 74 FR 65363, Dec. 9, 2009]

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in § 423.566(b). (This does not include requests for payment of drugs already furnished.)

(b) *How to make a request.* (1) To ask for an expedited redetermination, an enrollee or a prescribing physician or other prescriber acting on behalf of an enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the redetermination, as directed by the Part D plan sponsor.

(2) A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for an expedited redetermination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited redetermination:

(1) *Handling of requests.* The Part D plan sponsor must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision making.* The Part D plan sponsor must promptly decide whether to expedite the redetermination or follow the timeframe for standard redetermination based on the following requirements:

(i) For a request made by an enrollee, the Part D plan sponsor must provide an expedited redetermination if it determines that applying the standard timeframe for making a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a prescribing physician or other pre-

scriber, the Part D plan sponsor must provide an expedited redetermination if the physician or other prescriber indicates that applying the standard timeframe for conducting a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial of a request.* If a Part D plan sponsor denies a request for expedited redetermination, it must take the following actions:

(1) Make the determination within the 7 calendar day timeframe established in § 423.590(a). The 7 calendar day period begins the day the Part D plan sponsor receives the request for expedited redetermination.

(2) Give the enrollee prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor processes the enrollee's request using the 7 calendar day timeframe for standard redetermination;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's or other prescriber's support; and

(iv) Provides instructions about the expedited grievance process and its timeframes.

(3) Subsequently deliver, within three calendar days, equivalent written notice.

(e) *Action following acceptance of a request.* If a Part D plan sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice in accordance with § 423.590(d).

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 74 FR 1547, Jan. 12, 2009; 74 FR 65363, Dec. 9, 2009]

§ 423.586 Opportunity to submit evidence.

The Part D plan sponsor must provide the enrollee or the prescribing physician or other prescriber, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In

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the case of an expedited redetermination, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the Part D plan sponsor must inform the enrollee or the prescribing physician or other prescriber of the conditions for submitting the evidence.

[74 FR 1548, Jan. 12, 2009]

§ 423.590 Timeframes and responsibility for making redeterminations.

(a) *Standard redetermination—request for covered drug benefits.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must notify the enrollee in writing of its redetermination (and effectuate it in accordance with § 423.636(a)(1)) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(2) If the Part D plan sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(b) *Standard redetermination—request for payment.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination (and effectuate it in accordance with § 423.636(a)(2)) no later than 7 calendar days from the date it receives the request for redetermination.

(2) If the Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 7 calendar days from the date it receives the request for redetermination.

(c) *Effect of failure to meet timeframe for standard redeterminations.* If the Part D plan sponsor fails to provide the enrollee with a redetermination within the timeframes specified in paragraphs (a) or (b) of this section, the failure constitutes an adverse redetermination

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decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(d) *Expedited redetermination—(1) Timeframe.* A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician or other prescriber involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited redetermination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(3) How the Part D plan sponsor must request additional information. If the Part D plan sponsor must receive medical information, the Part D plan sponsor must request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the Part D plan sponsor requests additional information, the Part D plan sponsor is responsible for meeting the timeframe and notice requirements.

(e) *Failure to meet timeframe for expedited redetermination.* If the Part D plan sponsor fails to provide the enrollee or the prescribing physician or other prescriber, as appropriate, with the results of its expedited redetermination within the timeframe described in paragraph (d) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(f) *Who must conduct the review of an adverse coverage determination.* (1) A person or persons who were not involved in making the coverage determination must conduct the redetermination.

(2) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the redetermination must be made by a physician with expertise in the field of medicine that

is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician or other prescriber.

(g) *Form and content of an adverse redetermination notice.* The notice of any adverse determination under paragraphs (a)(2), (b)(2), (d)(1) or (d)(2) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(i) For adverse drug coverage redeterminations, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process;

(ii) For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and

(4) Comply with any other notice requirements specified by CMS.

(h) *Form and content of a completely favorable redetermination notice.* The notice of any completely favorable determination under paragraphs (a)(1), (d)(1) or (d)(2) of this section must explain the conditions of the approval in a readable and understandable form.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 75 FR 19823, Apr. 15, 2010]

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. An enrollee must file a written request for reconsideration with the IRE within 60 calendar days of the date of the redetermination by the Part D plan sponsor.

(b) When an enrollee files an appeal, the IRE is required to solicit the views of the prescribing physician or other prescriber. The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing. A

written account of the prescribing physician's or other prescriber's views (prepared by either the prescribing physician, other prescriber, or IRE, as appropriate) must be contained in the IRE's record.

(c) In order for an enrollee to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician or other prescriber must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

(d) The independent review entity must conduct the reconsideration as expeditiously as the enrollee's health condition requires but must not exceed the deadlines applicable in § 423.590, including those deadlines that are applicable when a request for an expedited reconsideration is received and granted.

(e) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsideration need not, in all cases, be of the same specialty or subspecialty as the prescribing physician or other prescriber.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 74 FR 65363, Dec. 9, 2009]

§ 423.602 Notice of reconsideration determination by the independent review entity.

(a) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and the Part D plan sponsor, and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the IRE's decision in understandable language;

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- (2) If the reconsideration determination is adverse (that is, does not completely reverse the adverse coverage determination by the Part D plan sponsor), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.1970;
- (3) Describe the procedures that must be followed to obtain an ALJ hearing; and
- (4) Comply with any other requirements specified by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009]

§ 423.604 Effect of a reconsideration determination.

A reconsideration determination is final and binding on the enrollee and the Part D plan sponsor, unless the enrollee files a request for a hearing under the provisions of § 423.1972.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009]

§ 423.610—§ 423.634 [Reserved]

§ 423.636 How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.

(a) *Reversals by the Part D plan sponsor*—(1) *Requests for benefits*. If, on redetermination of a request for benefit, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(2) *Requests for payment*. If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 7 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor*—(1) *Requests for benefits*. If, on appeal of a request for benefit, the determination by the Part D plan sponsor is reversed in whole or in part by

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the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Requests for payment*. If, on appeal of a request for payment, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize payment for the benefit within 72 hours, but make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

§ 423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

(a) *Reversals by the Part D plan sponsor*. If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor*. If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.