

Prescription Drug Benefit Manual

Chapter 18 - Part D Enrollee Grievances, Coverage Determinations, and Appeals

Last Updated - Rev. ~~98~~, 1/1/~~1110~~

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10 - Part D Enrollee Grievances, Coverage Determinations, and Appeals (Rev. 1, 11/30/05)

This chapter deals with coverage determinations and appeals for Part D plan enrollees, and with other complaints enrollees may have with a Part D plan sponsor or any of its contractors.

Additional information related to Part D grievances, coverage determinations, and appeals may be found on the Part D Enrollment and Appeals Guidance page:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/06_RxContracting_EnrollmentAppeals.asp

Please note that this chapter does not address or provide guidance for Medicare Advantage (MA) issues that do not relate to the Medicare Part D prescription drug benefit. MA organizations or Medicare cost plans and health care prepayment plans should consult Chapter 13 of the Managed Care Manual for issues related to grievances, organization determinations, or appeals concerning benefits under Part C or Section 1876, as appropriate.

10.1 - Definition of Terms (Rev. 8, 1/1/10)

Unless otherwise stated in this Chapter, the following definitions apply:

Appeal: 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 a 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 (IRE), Administrative Law Judge (ALJ) hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Complaint: A complaint may involve a grievance, coverage determination, or both. A complaint also may involve a low-income subsidy (LIS) or late enrollment penalty (LEP) determination. Every complaint must be handled under the appropriate process.

Coverage Determination: Any decision made by or on behalf of a Part D plan sponsor regarding payment or benefits to which an enrollee believes he or she is entitled.

Effectuation: Compliance with a complete or partial reversal of a Part D plan sponsor's original adverse coverage determination. Compliance may entail payment of a claim, or authorization for or provision of a benefit.

Enrollee: A Part D eligible individual who has elected a Part D plan offered by a Part D plan sponsor.

Grievance: Any complaint or dispute, other than one that involves a coverage determination or an LIS or LEP 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. A grievance may also include a complaint that a Part D plan sponsor refused to expedite a coverage determination or redetermination. Grievances may include complaints regarding the timeliness, appropriateness, access to, and/or setting of a provided item.

Independent Review Entity (IRE): An independent entity contracted by CMS to review Part D plan sponsor denials of coverage determinations.

Inquiry: Any oral or written request to a Part D plan sponsor or one of its contractors that does not involve a request for a coverage determination/exception request.

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

Quality Improvement Organization (QIO): Organizations comprised of practicing doctors and other health care experts under contract to the Federal government to monitor and improve the care given to Medicare enrollees. They review complaints raised by enrollees about the quality of care provided by physicians, inpatient hospitals, hospital outpatient departments, hospital emergency rooms, skilled nursing facilities, home health agencies, Medicare managed care plans, Medicare Part D prescription drug plans, and ambulatory surgical centers. The QIOs also review continued stay denials in acute inpatient hospital facilities as well as coverage terminations in skilled nursing facilities (SNFs), home health agencies (HHAs) and comprehensive outpatient rehabilitation facilities (CORFs).

Quality of Care Issue: A quality of care issue may be filed through the Part D plan sponsor's grievance process and/or a QIO. A QIO must determine whether the quality of services (including both inpatient and outpatient services) provided by a Part D plan sponsor meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings.

Redetermination: The first level of the appeal process, which involves a Part D plan sponsor reevaluating an adverse coverage determination, the findings upon which it was based, and any other evidence submitted or obtained.

Representative: 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, requesting a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in part 423, subpart M of the Medicare Part D regulations, the representative has all of the rights and responsibilities of an enrollee in 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 the Medicare Part C regulations.

10.2 - Responsibilities of the Part D Plan Sponsor (Rev. 8, 1/1/10)

Each Part D plan sponsor and each Part D plan that it offers must establish and maintain procedures for:

1. Standard and expedited coverage determinations;
2. Standard and expedited appeals; and
3. Standard and expedited grievances.

Part D plan sponsors also must provide written information to enrollees about the grievance and appeal procedures that are available to them through the Part D plan sponsor, at the following times:

1. Grievance procedure - at initial enrollment, upon involuntary disenrollment initiated by the Part D plan sponsor, upon denial of an enrollee's request for expedited review, upon an enrollee's request, and annually thereafter;
2. Appeal procedure, including the right to expedited review - at initial enrollment, upon notification of an adverse coverage determination or denial, and annually thereafter. If a plan changes its formulary or the cost-sharing status of a drug that has been prescribed for an enrollee, the plan must provide written information about the grievance and appeal procedures to enrollees who are affected by the change; and
3. Quality of care complaint process available under the Quality Improvement Organization (QIO) process as described in [§1154\(a\)\(14\)](#) of the Social Security Act (the Act) - at initial enrollment, and annually thereafter.

Each plan sponsor must conduct meaningful and thorough coverage determinations and redeterminations by:

1. Attempting to contact prescribing physicians or other prescribers to obtain supporting statements and additional medical documentation necessary to evaluate a request, as appropriate;

2. Attempting to obtain representation documentation from a non-enrollee appellant who presents as a representative;
3. Ascertaining state law and validating the representative status of a non-enrollee appellant who presents as a representative on behalf of an incompetent or incapacitated enrollee; and
4. Issuing determinations in a timely manner and in accordance with exceptions policies and criteria.

Plan sponsors must promote timely, efficient, and meaningful reconsideration appeals at the IRE level by:

1. Promptly identifying all requests for case files from the IRE, including requests that are made by fax;
2. Pursuant to an expedited case file request, delivering (by **overnight delivery** or **fax**) the complete case file to the IRE no later than 24 hours after receiving the request from the IRE;
3. Pursuant to a standard case file request, delivering (by **overnight delivery** or **fax**) the complete case file to the IRE as promptly as possible, but no later than 48 hours after receiving the request from the IRE; and
4. Complying with other applicable procedures for appeals processing set forth in the IRE Reconsideration Process Manual.

As with all contractual responsibilities in the Part D program, the plan may delegate any of its grievance, coverage determination, and/or appeals responsibilities to another entity or individual that provides or arranges Part D benefits. In cases of delegation, the Part D plan sponsor remains responsible and must therefore ensure that requirements are met completely by its delegated entity and/or individual.

10.3 – Rights of Part D Enrollees (Rev. 1, 11/30/05)

Relative to grievances, coverage determinations, and appeals, the rights of Part D enrollees include, but are not limited to, the following:

10.3.1 - Grievances (Rev. 1, 11/30/05)

1. The right to have grievances heard and resolved in accordance with the guidelines that are described in this chapter of the manual;
2. The right to request quality of care grievance data from Part D plan sponsors; and

3. The right to make a quality of care complaint under the QIO process.

10.3.2 - Coverage Determinations (Rev. 1, 11/30/05)

1. The right to a timely coverage determination;
2. The right to request an expedited coverage determination as described in this chapter;
3. The right to receive information from a network pharmacist regarding the enrollee's ability to obtain a detailed written notice from the Part D plan sponsor regarding the enrollee's Part D benefits;
4. The right to a detailed written notice of a Part D plan sponsor's decision to deny a benefit in whole or in part, which includes the enrollee's appeal rights; and
5. The right to receive notice when a coverage determination is forwarded to the IRE.

10.3.3 - Appeals (Rev. 1, 11/30/05)

1. The right to a timely redetermination;
2. The right to request an expedited redetermination as provided in this chapter;
3. The right to request and receive appeal data from Part D plan sponsors;
4. The right to receive notice when an appeal is forwarded to the IRE;
5. The right to a reconsideration by the IRE, upon request, if the plan sponsor upholds the original adverse determination in whole or in part;
6. The right to request an expedited reconsideration as provided in this chapter.
7. The right to an ALJ hearing if the IRE upholds the original adverse determination in whole or in part and the remaining amount in controversy meets the appropriate threshold requirement;
8. The right to request MAC review if the ALJ hearing decision is unfavorable to the enrollee in whole or in part;
9. The right to judicial review of the hearing decision if the ALJ hearing and/or MAC review is unfavorable to the enrollee, in whole or in part, and the amount remaining in controversy meets the appropriate threshold requirement;

10. The right to request and be given timely access to the enrollee's case file and a copy of that case file subject to federal and state law regarding confidentiality of patient information. The Part D plan sponsor shall have the right to charge the enrollee a reasonable amount for providing a copy of the case file (e.g., the costs of mailing and/or an amount comparable to the charges established by a QIO for duplicating the case file material. At the time the request for case file material is made, the Part D plan sponsor should inform the enrollee of the per page duplicating cost. Based on the extent of the case file material requested, the Part D plan sponsor should provide an estimate of the total duplicating cost for which the enrollee will be responsible. The Part D plan sponsor may also charge the enrollee the cost of mailing the material to the address specified. If enrollee case files are stored offsite, then the Part D plan sponsor may not charge the enrollee an additional cost for courier delivery to a plan location that would be over and above the cost of mailing the material to the enrollee.

10.4 - Representatives

10.4.1 - Representative Filing on Behalf of the Enrollee

(Rev. **98**, 1/1/**11+0**)

An enrollee may have a representative who is either appointed by the enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, requesting a coverage determination, or in dealing with any of the levels of the appeals process. An enrollee may appoint any individual (such as a relative, friend, advocate, attorney, physician or other prescriber, or an employee of a pharmacy, charity, state pharmaceutical assistance program, or other secondary payor) to act as his or her representative. Alternatively, an enrollee's representative (surrogate) may be appointed by a court or authorized under State or other applicable law to act on the enrollee's behalf. A surrogate could include, but is not limited to, a court appointed guardian, an individual who has Durable Power of Attorney or a health care proxy, or a person designated under a health care consent statute.

Note: Part D plan sponsors with benefit areas comprising more than one state should develop internal policies to ensure that they are aware of the different State representation requirements in their benefit areas. With the exception of incapacitated or legally incompetent enrollees where appropriate legal papers, or other legal authority, support this representation, or where a state's authorized representative rules require otherwise, both the enrollee making the appointment and the representative accepting the appointment must sign, date, and complete an appointment of representative form or similar written statement.

If an enrollee wishes to appoint a representative to act on his or her behalf, the enrollee must submit a written representative statement to the Part D plan sponsor. An enrollee may use Form CMS-1696 (see [Appendix 2](#)) or an equivalent written notice to make the appointment. A notice is an "equivalent written notice" if it:

1. Includes the name, address, and telephone number of enrollee;
2. Includes the enrollee's HICN;
3. Includes the name, address, and telephone number of the individual being appointed;
4. Contains a statement that the enrollee is authorizing the representative to act on his or her behalf for the claim(s) at issue, and a statement authorizing disclosure of individually identifying information to the representative;
5. Is signed and dated by the enrollee making the appointment; and
6. Is signed and dated by the individual being appointed as representative, and is accompanied by a statement that the individual accepts the appointment.

See [Chapter 29](#), §270.1.3, of the Medicare Claims Processing Manual for more information about whether a notice is an "equivalent written notice."

If an appointment is made using Form CMS-1696 or an equivalent written notice, the plan sponsor must accept it. Plan sponsors are prohibited from requiring the use of a specific form (other than Form CMS-1696 or an equivalent written notice) for appointments.

A surrogate asserting that he or she is acting in accordance with a state's authorized representative requirements must include a statement verifying his or her status under State law in the same manner that an appointed representative must submit a valid Form CMS-1696 or other equivalent notice. The Part D plan sponsor is responsible for determining whether a person or entity who asserts surrogate status is an appropriate surrogate under state law. If a surrogate submits the statement described above and the plan sponsor determines that the surrogate is acting in accordance with a state's authorized representative requirements, the plan sponsor or other appeal entity cannot also require the authorized representative to submit an additional Form CMS-1696 or other equivalent notice. The plan sponsor must submit an attestation to the IRE certifying the validity of the representation under state law if the IRE requests an enrollee's case file.

A signed Form CMS-1696 or other equivalent notice must be included with each oral or written request for a grievance, coverage determination, or appeal. However, once a signed form or statement has been submitted, the enrollee is not required to obtain a new signed form or statement for the life of an appeal, so long as a copy of the original signed form or statement is included in the enrollee's case file or is submitted with each appeal request. In addition, an enrollee is not required to obtain a new signed form or statement for any new appeal filed by the representative within one calendar year from the date that a valid representative form is executed. However, the representative must file a copy of

the original form or other conforming written instrument with each new request for a grievance or coverage determination.

Except in the case of incapacitated or incompetent enrollees, a grievance or a request for a coverage determination or redetermination from a representative is not valid until supported with an executed appointment of representative form or statement. It is the Part D plan sponsor's obligation to inform the enrollee and purported representative, in writing, that the grievance or request will not be considered until the appropriate documentation is provided.

When a grievance or a request for a coverage determination or redetermination is filed by a person claiming to be a representative, but the party does not provide appropriate documentation upon the Part D plan sponsor's request, the Part D plan sponsor must make and document its reasonable efforts to secure the necessary appointment forms. What is reasonable depends on the circumstances. For example, if a request is expedited, contacting the enrollee and/or representative by mail to obtain the necessary appointment forms or notice may not be reasonable. However, if the enrollee and/or the party who submitted the request does not have a telephone, the plan sponsor may determine that contacting the enrollee and/or the party by overnight delivery is reasonable. The Part D plan sponsor is not required to undertake a review until or unless such forms are obtained, but it may choose to begin the review while continuing efforts to obtain a valid appointment of representation form. However, the time frame for acting on a grievance or a request for a coverage determination or redetermination does not commence until the properly executed appointment form is received. If the Part D plan sponsor does not receive the form or statement within a reasonable time, the Part D plan sponsor should dismiss the request on the grounds that a valid request was not received. What is reasonable depends on the circumstances. If the plan sponsor determines that a dismissal is appropriate, it must send a written dismissal letter to the enrollee and the person asserting representative status. The plan sponsor should explain in the dismissal letter that it will process the request if the enrollee or representative resubmits the request with a properly executed Form CMS-1696 or other equivalent notice. If the person asserting representative status is requesting a redetermination, the plan sponsor should also explain that any submission of a properly executed form or equivalent notice after the 60-day filing deadline for requesting the appeal has expired must be accompanied by a good cause statement explaining why the form/notice was not filed timely (see [§70.3](#) for more information about good cause extensions).

If an appeal is initiated by a representative and submitted to the IRE, the IRE will examine the form or equivalent written notice for compliance with the appointment of representative requirements or other legal authority, such as a Power of Attorney or Durable Power of Attorney executed pursuant to state law. In addition, the IRE may review a plan sponsor's attestation certifying the validity of a surrogate acting on behalf of an enrollee under state law. If the IRE discovers a defect in the form or other notice submitted with the request (e.g., the form or notice is not valid and/or was not properly executed), the IRE may require the representative to submit a valid Form CMS-1696 or other equivalent written notice. In addition, the IRE may dismiss cases in which a

required appointment of representative form is absent. The IRE must make its determination regarding the validity of the form or notice and notify the representative of its decision within a timely manner. If a copy of a valid Form CMS-1696 or other equivalent notice (i.e., a photocopy of the original form or notice) has been submitted with the request for IRE review, or the IRE is satisfied with a plan sponsor's attestation certifying the validity of a surrogate acting on behalf of an enrollee under state law, the IRE cannot require the representative to submit a new form (either Form CMS-1696 or any other form, including a form developed by the IRE) or notice to obtain a review by the IRE.

Note: If an enrollee's prescribing physician or other prescriber requests a standard coverage determination, expedited coverage determination, or a standard or expedited redetermination on an enrollee's behalf, and the plan sponsor misses the decision-making time frame and automatically forwards the request to the IRE for review for failure to meet the adjudication time frame under §§[40.4](#), [50.6](#), and [70.8.2](#), the prescribing physician or other prescriber is not required to submit a signed Form CMS-1696 or other equivalent notice to the IRE because a prescribing physician or other prescriber may request a standard coverage determination, expedited coverage determination, or a standard or expedited redetermination on an enrollee's behalf without being a representative.

10.4.2 - Authority of a Representative (Rev. 2, 6/22/06)

Unless otherwise stated in the rules described in subpart M of part 423, the representative has all of the rights and responsibilities of an enrollee in filing a grievance, requesting a coverage determination, or in dealing with any of the levels of the Part D appeals process. For instance, a representative may, on behalf of an enrollee:

1. Obtain information about the enrollee's claim to the extent consistent with current Federal and state law;
2. Submit evidence;
3. Make statements about facts and law; and
4. Make any request or give any notice about the proceedings.

If an enrollee has identified a representative, any notice or other correspondence that should be sent to the enrollee under subpart M of part 423 should be sent to the enrollee's representative instead of to the enrollee.

Note: A valid appointment of representation form or other conforming written instrument submitted with a request that involves an MA benefit is not valid for requests that involve Part D prescription drug benefits, unless there is a specific annotation on the form or statement indicating that the appointment is valid for such requests. Enrollees

must properly execute a separate Form CMS-1696 if he or she wishes the MA representative to also serve as his or her Part D representative (or vice versa). If a representative (who is representing an enrollee in regards to an MA claim) files a Part D grievance or requests a coverage determination or appeal that involves a Part D benefit without a newly executed appointment of representation form or other conforming written instrument, the plan should explain to the representative that a new representative form must be executed, and provide the representative with a reasonable opportunity to submit the new form or other conforming written instrument before dismissing the request.

10.5 - Authority of an Enrollee's Prescribing Physician or Other Prescriber

(Rev. **98**, 1/1/1110)

A prescribing physician or other prescriber may act on behalf of an enrollee in requesting a standard or expedited coverage determination, or a standard or expedited redetermination without being the enrollee's representative. In these situations, the physician does not have all of the rights and responsibilities of an enrollee as described in §10.4.2. However, an enrollee's prescribing physician or other prescriber is entitled to receive the notifications described in §§[40.2](#), [40.3.2](#), [40.3.4](#), [40.3.5](#), [50.3](#), [50.4](#), [50.5](#)and, [70.8.1](#), and [70.9](#).

Note: The regulations do not prohibit an enrollee's prescribing physician or other prescriber from becoming an enrollee's representative.

20 - Complaints

20.1 - Complaints That Apply to Both Grievances and Coverage Determinations

(Rev. **1**, 11/30/05)

Complaints may include both grievances and coverage determinations (i.e., a single complaint may contain a grievable issue and an appealable issue). If an enrollee addresses two or more issues in one complaint, each issue should be processed separately and simultaneously (to the extent possible) under the proper procedure.

20.2 - Distinguishing Between Grievances and Coverage Determinations

(Rev. **8**, 1/1/10)

Grievance procedures are separate and distinct from the procedures that apply to coverage determinations. Plan sponsors must determine whether the issues in an enrollee's complaint meet the definition of a grievance, coverage determination, or both, and resolve an enrollee's complaints or disputes through the appropriate procedure.

Complaints that may fall into the grievance category include, but are not limited to, complaints about:

- Difficulty getting through to the plan sponsor on the telephone;
- The quality of care or benefits provided;
- Interpersonal aspects of care, such as rudeness by a pharmacist or staff member;
- A plan's benefit design;
- A plan sponsor's failure to issue a decision in a timely manner (this type of grievance is not a substitute for automatically forwarding an enrollee's request to the IRE if the plan fails to act timely, but is an additional right that may be exercised by an enrollee);
- A plan sponsor's denial of an enrollee's request for an expedited coverage determination or expedited redetermination;
- The appeals process; or
- A plan's written communications, including its written notices.

The facts surrounding a complaint will determine whether the grievance or coverage determination process should be initiated. If the facts don't clearly indicate that a complaint is a grievance, the plan sponsor should process the complaint as a request for a coverage determination. The following are offered as examples of when each process should begin:

Example 1

An enrollee who currently takes a particular brand-name drug is dismayed to find out that the plan has made a formulary change and will no longer cover the drug used by the enrollee. The enrollee calls the plan and complains. The enrollee states that he/she has tried the generic equivalent before and it was not effective, and therefore wants the plan to continue coverage of the brand-name drug. This complaint should be treated as a request for a coverage determination, subject to the appeals process, for continuation of coverage for the brand-name drug.

Example 2

An enrollee who currently does not take any prescription medications reads in his annual notice of change that the plan will no longer be covering a particular brand-name drug. The enrollee calls the plan to complain about this reduction in benefits, even though it does not directly affect the enrollee at the current time. Because the enrollee does not take the prescription drug affected by the change, the complaint should not be interpreted as a request for a coverage determination. The complaint should therefore be handled as a grievance.

Example 3

A Part D enrollee's plan benefits cover six 500 mg tablets of Zithromax over a 30 day period. The enrollee presents the prescription to the pharmacist, and the prescription is covered by the plan. The enrollee returns to the pharmacist, asserting that the pharmacist gave the enrollee six 250 mg tablets of Zithromax, and asks the pharmacist to correct the mistake by providing six 500 mg tablets of Zithromax (i.e., the enrollee does not have a new prescription for Zithromax). Where an enrollee complains that contractually covered and previously rendered benefits were not properly delivered, this type of complaint (i.e., the request for the pharmacist to correct the mistake) should be classified as a grievance (quality of care complaint) as opposed to an appeal.

Note that not all complaints about dosages should be treated as grievances. As discussed in §[30.2.2](#), some complaints involving dosing issues must be processed as coverage determinations/formulary exceptions.

In some cases, Part D plan sponsors will need to process complaints using the Part D plan sponsor's grievance procedures and its coverage determination procedures. For example, an enrollee might complain that because he/she had to wait so long to fill a prescription, he/she obtained the medication out of network and wants to be reimbursed for out-of-pocket expenses. The enrollee's complaint contains both a request for payment (i.e., a request for a coverage determination) and a grievance about the timeliness of benefits. Therefore, complaints must be reviewed on a case-by-case basis.

Note: Under [42 CFR 423.568](#), we do not specify how an enrollee must make his or her request for a standard coverage determination. Given the short time frames involved, plan sponsors are encouraged, but not required, to accept requests for standard coverage determinations orally in addition to accepting such requests in writing. In the event that a plan does not accept oral requests for standard coverage determinations, and it determines that an enrollee's oral complaint should be classified as a standard request for a coverage determination, the plan must provide the enrollee with an explanation of the procedures the enrollee must follow to file a request for a standard coverage determination. For example, the plan may explain the procedures orally and direct the enrollee to the appropriate section of the Evidence of Coverage for additional information. If an enrollee files an oral request for an expedited coverage determination or redetermination, which must be accepted orally and in writing, and the plan sponsor does not grant the request to expedite, the plan sponsor cannot require the enrollee to re-file the request in writing. Instead, the plan sponsor must transfer the request to the standard process as described in §§[50.3](#) and [70.8.1](#).

20.2.1 - Quality of Care Complaints (Rev. 2, 6/22/06)

Complaints concerning the quality of care received under Medicare may be acted upon by the Part D plan sponsor, but also may be addressed through the QIO complaint process

under §1154(a)(14) of the Act. (See also the QIO Manual chapter regarding the Beneficiary Complaint Process.) This process is separate and distinct from the Part D plan sponsor's grievance process. All grievances regarding quality of care that are submitted to the Part D plan sponsor, regardless of whether they are filed orally or in writing, must be responded to in writing by the Part D plan sponsor. When the Part D plan responds to an enrollee's grievance in writing, it must include a description of the enrollee's right to file the grievance with the QIO. For any complaint filed with the QIO, the Part D plan must cooperate with the QIO in resolving the complaint.

In situations where an enrollee files a grievance with the QIO and the Part D plan sponsor, the plan sponsor must comply with the requirements at 42 CFR Part 476 regarding timely submission of requested information/documentation to the QIO.

20.2.2 - Co-Payment Complaints **(Rev. 8, 1/1/10)**

Part D plan sponsors must determine how to categorize complaints about co-payments on a case-by-case basis. The plan sponsor is responsible for determining if an enrollee has a general inquiry or complaint about the co-payment amount, or if there are facts and circumstances specific to that enrollee that warrant treating the complaint as a request for a coverage determination.

Example 1

Part D plan sponsors must subject complaints about co-payments to the coverage determination process when an enrollee believes that a Part D plan sponsor has asked him or her to pay a different cost-sharing amount than the enrollee believes he or she is required to pay for a prescription drug. [See the related note below pertaining to co-payment disagreements that involve the calculation of true out-of-pocket costs.]

Example 2

When a Part D enrollee receives a retroactive determination of Low-Income Subsidy (LIS) eligibility, the Part D plan sponsor is required to automatically reimburse the enrollee for any excess cost-sharing that occurred due to the retroactive LIS determination. Under this process, an enrollee may be eligible to receive reimbursement for excess premiums and co-payments for Part D drugs paid during the retroactive period of LIS eligibility. This type of reimbursement activity does not fall under the Part D coverage determination or appeals processes, and is not subject to the rules contained in part 423, subpart M of the Medicare Part D regulations or the guidance contained in this chapter. Instead, Part D plan sponsors must make LIS reimbursement adjustments in accordance with the guidance contained in Chapter 13, §70.3.1 of the Prescription Drug Benefit Manual.

Example 3

When an enrollee requests a plan sponsor to cover a particular non-preferred drug at the preferred cost-sharing level for reasons of medical necessity and indicates that he

or she has a prescription for the drug, the plan must process the request as a tiering exception.

Example 4

If an enrollee expresses general dissatisfaction about a co-payment amount, the Part D plan sponsor should process the enrollee's complaint as a grievance.

Disagreements about the calculation of True Out-of-Pocket (TrOOP) Costs

In general, complaints about the calculation of TrOOP costs should be processed as grievances. However, the regulations at 42 CFR 423.566(b)(5) state that a dispute about a plan sponsor's decision on the amount of cost-sharing for a drug is considered a coverage determination and is subject to appeal. Therefore, when an enrollee disputes the amount he or she is asked to pay for a drug and the basis for the dispute is the plan sponsor's TrOOP calculation, the complaint must be resolved as a coverage determination (whether or not the co-payment complaint involving the TrOOP calculation was previously raised by the enrollee and processed as a grievance). In such circumstances, the enrollee must:

- Allege that a plan sponsor made an error in calculating his or her TrOOP costs, and the error caused the plan sponsor to charge him or her full-price for a drug because the enrollee was placed between the initial coverage limit and annual out-of-pocket threshold as a result of the calculation, and
- Produce some evidence (e.g., receipts, records, an Explanation of Benefits) in support of the allegation.

Note: A disagreement about TrOOP calculation that results from a dispute over low-income subsidy eligibility cannot be resolved under the Medicare Part D coverage determination and appeals processes. Instead, such a dispute must be resolved with the agency responsible for making the determination. The decision letter from the agency making the eligibility determination will provide specific instructions about appealing the decision. See §70 in the Guidance to States on the Low-Income Subsidy for more information: <http://www.cms.hhs.gov/States/Downloads/StateLISGuidance4-4.pdf>. Also see the Social Security Agency (SSA) website for more information about appealing Part D subsidy determinations made by SSA: <https://secure.ssa.gov/apps10/poms.nsf/lnx/0603040000!opendocument>

20.2.3 - Benefit Design Complaints
(Rev. 2, 6/22/06)

Although complaints about a plan sponsor's benefit design should generally be processed as grievances, plan sponsors must take great care in processing such complaints because some complaints that involve a plan's benefit design should be processed as requests for coverage determinations.

Example 1

An enrollee receives a prescription for Drug X and is told at the pharmacy counter that she must pay a \$25 co-pay for the drug (the co-pay amount that applies to drugs in the plan's high-cost or unique drug tier). The enrollee requests a tiering exception for Drug X. Under the plan's formulary, Drug X is contained in the high-cost or unique drug tier, and the plan has exempted drugs in that tier from the exceptions process (which is permissible under 42 CFR 423.578(a)(7)). The enrollee is aware, and is not disputing, that Drug X is contained in the plan's high-cost or unique drug tier, but she would like the drug to be covered at the cost-sharing amount applicable to drugs in the preferred tier. This is a benefit design issue that must be handled through the **grievance** process.

Example 2

An enrollee receives a prescription for Drug X and is told at the pharmacy counter that she must pay a \$25 co-pay for the drug (the co-pay amount that applies to drugs in the plan's high-cost or unique drug tier). The enrollee requests a coverage determination for Drug X and argues that she should only be required to pay a \$10 co-pay because Drug X is in the plan's preferred brand tier (the co-pay amount that applies to drugs in the plan's preferred brand tier is \$10) and the plan incorrectly charged the co-pay amount that applies to drugs in the plan's high-cost or unique drug tier. This type of complaint involves a dispute about the amount an enrollee believes he/she is required to pay for a drug and must be handled through the **coverage determination** process, even if Drug X is in the plan's high-cost or unique drug tier. See 42 CFR 423.566(b)(5).

20.2.4 - Non-Part D and Excluded Drug Complaints **(Rev. 8, 1/1/10)**

A transaction with an enrollee or a physician or other prescriber that involves a request for coverage of a drug that is either not a covered Part D drug (as defined in section 1860D-2(e)(1) of the Act) or is statutorily excluded from coverage under Part D may be handled as an inquiry, grievance, or coverage determination, depending on the nature of the transaction.

Under 42 CFR 423.566(b)(1), a coverage determination is a decision by a plan sponsor not to provide or pay for a **Part D drug** that the enrollee believes may be covered by the plan. Drugs that do not meet the definition of a "covered Part D drug" under section 1860D-2(e)(1) of the Act and drugs excluded from coverage under section 1860D-2(e)(2) of the Act are not Part D drugs. Thus, strictly interpreted, a decision by a plan sponsor not to cover a drug that does not meet the definition of a covered Part D drug under section 1860D-2(e)(1) of the Act or is excluded from coverage under section 1860D-2(e)(2) of the Act is not a coverage determination (note that drugs that could be excluded if section 1862(a) of the Act were applied to Medicare Part D are subject to the coverage determination process). **However, in some cases, an enrollee may use the coverage determination process to argue that:**

- **A drug is a covered Part D drug under section 1860D-2(e)(1) of the Act or is covered under section 1860D-2(e)(1) for a specific indication;**
- **A drug is not excluded under section 1860D-2(e)(2) of the Act or is not excluded under section 1860D-2(e)(2) for a specific indication;**
- **A drug is not excluded under section 1860D-43 of the Act; or**
- **A drug is covered by the plan as a supplemental benefit.**

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These cases must be treated as requests for coverage determinations to ensure that the issue is properly resolved. Conversely, if an enrollee is not disputing that a drug is not a covered Part D drug or is excluded from coverage, but has a question or general complaint about the drug not being covered, the transaction should be processed as an inquiry or a grievance.

If a drug is not a covered Part D drug or is excluded from coverage, it is never covered by Medicare, regardless of medical necessity. However, an appeal entity may overturn a plan's decision not to cover a drug if the appeal entity determines that the drug is:

- A covered Part D drug under section 1860D-2(e)(1) of the Act or covered under section 1860D-2(e)(1) for the indication it is being prescribed for;
- Not excluded from coverage under section 1860D-2(e)(2) of the Act or being used for an indication that isn't excluded under section 1860D-2(e)(2)-;
- Not Excluded from coverage under section 1860D-43 of the Act; or
- Included on the plan sponsor's formulary as a supplemental benefit.

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The following examples illustrate when a transaction should be processed as an inquiry, grievance, or coverage determination.

20.2.4.1 – Inquiry **(Rev. 9, 1/1/11)**

Not all transactions that involve non-covered Part D or excluded drugs should be classified as grievances or coverage determinations. In general, an initial transaction involving a non-covered Part D or excluded drug should be treated as an inquiry unless the enrollee or the enrollee's physician or other prescriber files a grievance or requests a coverage determination by:

- Complaining about the policy that causes the drug not to be a covered Part D drug (i.e., files a grievance);

- Complaining about the policy that causes the drug to be an excluded drug (i.e., files a grievance);
- Arguing that the drug is a covered Part D drug under 1860D-2(e)(1) of the Act or is covered under 1860D-2(e)(1) for the indication it was prescribed for (i.e., makes a request for a coverage determination);
- Arguing that the drug is not excluded under 1860D-2(e)(2) of the Act or is not excluded under 1860D-2(e)(1) for the indication it was prescribed for (i.e., makes a request for a coverage determination);
- Arguing that the drug is not excluded under 1860D-43 of the Act; or
- Arguing that the drug is covered by the plan as a supplemental benefit (i.e., makes a request for a coverage determination).

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Inquiries are routine questions about a benefit (i.e., inquires are not complaints), and do not automatically invoke a plan sponsor's grievance or coverage determination process.

When a plan sponsor receives an inquiry about drug that is not a covered Part D drug or is an excluded drug, it must provide the person making the request with the following information:

1. The plan sponsor must explain that certain drugs are not covered Part D drugs under 1860D-2(e)(1) of the Act, or are excluded from coverage under section 1860D-2(e)(2) of the Act;
2. The plan sponsor must explain that the requested drug is not a covered Part D drug under 1860D-2(e)(1) of the Act or is statutorily excluded under section 1860D-2(e)(2) of the Act and the plan does not offer the drug as a supplemental benefit;
3. The plan sponsor must explain that the requested drug is not a covered Part D drug under 1860D-43 of the Act;
4. The plan sponsor must emphasize that, because the drug is not a covered Part D drug under 1860D-2(e)(1) of the Act or is excluded from coverage under 1860D-2(e)(2) or 1860D-43 and is not offered as a supplemental benefit, the enrollee may not obtain it through the coverage determination, exceptions, or appeals processes.
5. The plan sponsor must explain that the enrollee should work with his or her physician or other prescriber to determine if a drug on the plan sponsor's formulary is medically appropriate for treating the enrollee's condition; and

5. The plan sponsor must explain that the enrollee, physician, or other prescriber has the right to contact the plan sponsor and request a coverage determination if he or she believes that the drug is:

- A covered Part D drug under section 1860D-2(e)(1) of the Act or covered under 1860D-2(e)(1) for the indication it is being prescribed for;
- [Not excluded under section 1860D-2\(e\)\(2\) of the Act or not excluded under 1860D-2\(e\)\(2\) for the purpose for which it was prescribed;](#)
- [Not excluded under section 1860D-43 of the Act;](#) or
- Covered by the plan as a supplemental benefit.

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The plan sponsor must also explain how the enrollee, physician, or other prescriber can make the request for a coverage determination.

A plan sponsor must provide this information either **orally or in writing**. If a plan sponsor chooses to provide this information in writing, it may use the model notice contained in [Appendix 12](#). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures. If a plan sponsor chooses to provide this information orally, the information provided must include all information that is required to be included in a written notice.

Example of an inquiry involving an excluded drug:

1. An enrollee calls his or her plan sponsor to determine if Valium is covered for him or her (it doesn't matter if the enrollee has a prescription for the drug or not).
2. The plan sponsor tells the enrollee that certain drugs are excluded from coverage under Part D, and Valium is one of those drugs.
3. The enrollee does not complain about the exclusion of the requested drug from coverage. Nor does the enrollee argue that the plan sponsor incorrectly classified/identified the requested drug as excluded from coverage, the drug is not excluded for the purpose for which it was prescribed, or the drug is covered by the plan as a supplemental benefit.
4. The transaction should be treated as an **inquiry**.

Example of an inquiry involving a drug that is not a covered Part D drug:

1. An enrollee attempts to fill a prescription for Actiq. The pharmacist receives an electronic notice indicating that the drug is subject to a prior authorization (PA) requirement. The PA requires the enrollee's physician or other prescriber to contact the plan sponsor and indicate the condition that the drug is being prescribed for.

2. The enrollee's physician or other prescriber calls the plan sponsor and explains that Actiq was prescribed to treat the enrollee's back pain. The plan sponsor explains to the physician or other prescriber that certain drugs are not covered Part D drugs under 1860D-2(e)(1) of the Act when not prescribed for a medically accepted indication (as defined in section 1927(k)(6) of the Act). Because the only medically accepted indication for Actiq is breakthrough cancer pain, Actiq is not a covered Part D drug when prescribed for the management of other types of pain.

3. The transaction should be treated as an **inquiry**, unless the physician or other prescriber:

- Complains about the policy that causes the drug not to be a covered Part D drug (process the complaint as a **grievance**); or
- Argues that Actiq is being used to treat a medically accepted indication (as defined in section 1927(k)(6) of the Act) (process the complaint as a **coverage determination**).

20.2.4.2 – Grievance **(Rev. 9, 1/1/11)**

If an enrollee is not disputing that a drug is not a covered Part D drug (as defined in 1860D-2(e)(1) of the Act) or is excluded under 1860D-2(e)(2) [or 1860D-43](#) of the Act, but he/she is complaining about the policy that causes the drug to be excluded or not a covered Part D drug, the complaint should be processed as a grievance because it's a complaint about the plan sponsor's benefit design structure. This complaint may occur after an inquiry is made, or it may be the initial transaction with the enrollee, physician, or other prescriber. Decisions made under a plan sponsor's grievance process are not subject to appeal.

Example of a grievance involving an excluded drug:

1. An enrollee attempts to fill a Valium prescription. The pharmacist receives an electronic notice indicating that the drug is not covered and provides the enrollee with the Pharmacy Notice.
2. The enrollee calls the plan sponsor to ask why the prescription was not covered. The plan sponsor explains to the enrollee that certain drugs are excluded from coverage under Part D, and Valium is one of those drugs.
3. The enrollee has a general complaint about the drug being excluded, but does not argue that the plan sponsor incorrectly classified/identified the requested drug as excluded from coverage, the drug is not excluded for the purpose for which it was prescribed, or the drug is covered by the plan as a supplemental benefit after the plan explains that it is an excluded drug.
4. This request should be treated as a **grievance**.

20.2.4.3 - Coverage Determination **(Rev. 9, 1/1/11)**

A plan sponsor must process a complaint as a coverage determination (which is subject to appeal) if an enrollee, physician, or other prescriber argues that a drug is a covered Part D drug under section 1860D-2(e)(1) of the Act, a covered Part D drug under 1860D-2(e)(1) of the Act for the purpose it is being prescribed, not an excluded drug under 1860D-2(e)(2) of the Act, not excluded under 1860D-2(e)(2) of the Act for the purpose for which it was prescribed, [not excluded under 1860D-43 of the Act](#), or covered by the plan as a supplemental benefit. This complaint may occur after an inquiry is made, or it may be the initial transaction with the enrollee, physician, or other prescriber. If such a complaint is not processed as a coverage determination (and, for example, a plan sponsor mistakenly classified a covered Part D drug as an excluded drug), the enrollee would not have appeal rights and the issue could not be properly resolved.

If, after receiving the complaint, the plan sponsor verifies that the drug is not a covered Part D drug under 1860D-2(e)(1) of the Act or is excluded from coverage under 1860D-2(e)(2) [or 1860D-43](#) of the Act, it must issue an adverse coverage determination explaining that certain drugs are not covered Part D drugs or are excluded from coverage under Part D and the requested drug is one of those drugs. As with any adverse coverage determination, the enrollee can appeal the decision (it would not be handled as a grievance). On appeal, the plan sponsor or any subsequent appeal entity will determine if the drug is a covered Part D drug under section 1860D-2(e)(1) of the Act or is excluded from coverage under section 1860D-2(e)(2) [or 1860D-43](#) of the Act. If it is not a covered Part D drug or is excluded, the appeal entity will uphold the plan sponsor's coverage determination (i.e., the scope of review on appeal is limited to whether the requested drug is a covered Part D or excluded drug, is a covered Part D or excluded drug for the purpose for which it was prescribed, or is covered by the plan as a supplemental benefit).

Example of a coverage determination involving an excluded drug:

1. An enrollee attempts to fill a prescription for Orlistat. The pharmacist receives an electronic notice indicating that the drug is not covered and provides the enrollee with the Pharmacy Notice.
2. The enrollee calls the plan sponsor to ask why the prescription is not covered. The plan sponsor explains to the enrollee that certain drugs are excluded from Part D coverage under section 1927(d)(2) of the Act, and Orlistat is one of those drugs because its FDA labeled indications relate to the treatment for and maintenance of weight loss.
3. The enrollee argues that Orlistat is being used to treat her diabetes, which is a medically accepted off-label use that is not excluded under section 1927(d)(2) of the Act, and requests the plan sponsor to cover the drug.
4. This request must be treated as a **coverage determination**.

5. If the plan sponsor determines that the drug is excluded from Part D coverage because it is being prescribed for a use that is excluded under section 1927(d)(2) of the Act, it must issue an adverse coverage determination explaining that the requested drug is excluded from Part D coverage. See the Orlistat example in §40.3.3 of this chapter for sample language that should be included in this type of decision.

6. The enrollee has the right to appeal this decision and argue that the drug isn't excluded from coverage because it is being used to treat a medically accepted off-label use that is not excluded under section 1927(d)(2) of the Act. If the IRE determines that the requested drug is being prescribed for a use that is excluded under section 1927(d)(2) of the Act, it will issue an adverse decision explaining that the drug is excluded from coverage under Part D.

20.2.5 - Enrollment or Disenrollment Complaints (Rev. 8, 1/1/10)

Complaints that involve CMS determinations related to enrollment in, or disenrollment from a Part D plan must be processed according to the procedures set forth in Chapter 3 of this manual:

http://www.cms.hhs.gov/MedicarePresDrugEligEnrol/01_Overview.asp

20.3 - Procedures for Handling a Grievance (Rev. 1, 11/30/05)

An enrollee may file a grievance with the Part D plan sponsor either orally or in writing no later than 60 days after the event or incident that precipitates the grievance.

Although the regulations at [42 CFR 423.564\(d\)\(2\)](#) do not require a Part D plan sponsor to consider a grievance that is filed after the 60-day deadline, nothing in the regulations prevents a plan sponsor from doing so on a case-by-case basis. If a plan intends to accept grievances that are not filed timely, it is responsible for developing the criteria it will use to evaluate such requests. However, an enrollee who files a quality of care grievance with a QIO is not required to file the grievance within a specific time period. Therefore, quality of care grievances filed with a QIO may be filed and investigated beyond the 60-day time frame stated in [42 CFR 423.564\(d\)\(2\)](#).

Each Part D plan sponsor must provide meaningful procedures for timely hearing and resolving standard and expedited grievances between enrollees and the Part D plan sponsor or any other entity or individual through which the Part D plan sponsor provides benefits.

The Part D plan sponsor must include the following requirements in its grievance procedures:

1. Ability to accept any information or evidence concerning the grievance;

2. Ability to respond within 24 hours to an enrollee's expedited grievance that a Part D plan sponsor refused to grant a request for an expedited coverage determination under [42 CFR 423.570](#) or an expedited redetermination under [42 CFR 423.584](#), and the enrollee has not received the drug in dispute;
3. Timely transmission of grievances to appropriate decision-making levels when appropriate;
4. Prompt, appropriate action, including a full investigation of the complaint if necessary;
5. Notification of investigation results to all concerned parties, as expeditiously as the enrollee's case requires, based on the enrollee's health status, but not later than 30 days after the plan receives the oral or written grievance, consistent with applicable Federal law. The Part D plan sponsor may extend the 30-day time frame by up to 14 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. CMS has developed a model notice that Part D plan sponsors can use to notify enrollees whenever a Part D plan sponsor extends the deadline, (see [Appendix 7](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures;
6. The Part D plan sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures:
 - a. All grievances submitted in writing must be responded to in writing.
 - b. Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.
 - c. 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; and
7. Procedures for tracking and maintaining records about the receipt and disposition of grievances. Consistent with [§140](#) of this chapter, Part D plan sponsors must disclose grievance data to Medicare enrollees upon request. Part D plan sponsors must be able to log or capture enrollees' grievances in a centralized location that may be readily accessed.

CMS has developed a model notice that a Part D plan sponsor can use to notify an enrollee of its decision regarding a grievance (see [Appendix 8](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

20.3.1 - Procedures for Handling Grievances Misclassified as Appeals (Rev. 1, 11/30/05)

If a Part D plan sponsor misclassifies a grievance as an appeal and issues a denial notice, and the IRE determines that the complaint was misclassified as an appeal, the IRE must dismiss the appeal and return the complaint to the Part D plan sponsor for proper processing. The Part D plan sponsor must notify the enrollee in writing that the complaint was misclassified and will be handled through the Part D plan sponsor's grievance process. Part D plan sponsors are expected to audit their own appeals and grievance systems for the presence of errors, and institute appropriate quality improvement projects as needed.

20.4 - Written Explanation of Grievance Procedures (Rev. 1, 11/30/05)

The Part D plan sponsor must provide all enrollees with written grievance procedures upon initial enrollment, involuntary disenrollment (i.e., initiated by the Part D plan sponsor under [42 CFR 423.44](#)), annually, and upon request. Additionally, the Part D plan sponsor must notify enrollees about any changes to its grievance procedures 30 days in advance of the effective date of the change. A plan sponsor must provide an enrollee with written notice about his or her right to file an expedited grievance when a plan sponsor denies the enrollee's request for an expedited coverage determination or expedited redetermination. CMS has developed a model notice that plan sponsors may use to notify enrollees whenever these actions occur (see [Appendix 3](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

Any time a written grievance notification is required, Part D plan sponsors must include at least the following information:

1. How and where to file a grievance; and
2. The differences between appeals and grievances.

30 - Coverage Determinations (Rev. 2, 6/22/06)

A coverage determination is any determination (i.e., an approval or denial) made by the Part D plan sponsor, or its delegated entity, with respect to the following:

1. A decision about whether 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 excluded 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 a tiering exceptions request under [42 CFR 423.578\(a\)](#);
4. A decision concerning a formulary exceptions request under [42 CFR 423.578\(b\)](#);
5. A decision on the amount of cost sharing for a drug; or
6. A decision whether an enrollee has, or has not, satisfied a prior authorization or other utilization management requirement. See [§30.1](#).

Each Part D plan sponsor must establish procedures for making timely coverage determinations regarding the benefits an enrollee is entitled to receive under a Part D plan.

Once a coverage determination has been made, the appeals process may be triggered if the Part D plan sponsor's decision is unfavorable. If a Part D enrollee disputes a coverage determination, the case must be handled using the federally mandated appeals process. If an enrollee complains about any other aspect of the Part D plan sponsor's operations (e.g. the manner in which a benefit was provided), the Part D plan sponsor must address the issue through the grievance process.

When the Part D plan sponsor decides not to provide or pay for a requested benefit, in whole or in part, the decision is an adverse coverage determination. If a Part D plan sponsor makes an adverse coverage determination, it must provide the enrollee with a written denial notice that includes his or her appeal rights. See [§40.3.2](#) and [§40.3.3](#).

A plan sponsor is not required to treat the presentation of a prescription at the pharmacy counter as a request for a coverage determination. Accordingly, the plan sponsor is not required to provide the enrollee with a written denial notice at the pharmacy as a result of the transaction. However, as required under [42 CFR 423.562\(a\)\(3\)](#), plans must arrange with their network pharmacies to post or distribute the standardized notice developed by CMS to notify enrollees of their right to request and receive detailed written notices from plan sponsors regarding their prescription drug coverage, including information about the exceptions process. See [§40.3.1](#).

30.1 - Prior Authorization or Other Utilization Management Requirements

(Rev. 98, 1/1/1110)

When a plan sponsor processes a coverage determination request that involves a prior authorization (PA) or other utilization management (UM) requirement, the plan sponsor's determination on whether to grant approval of a drug for an individual enrollee constitutes a coverage determination and is subject to appeal. In addition, if a plan sponsor denies a drug because the enrollee failed to seek PA, the denial also constitutes a coverage determination and is subject to appeal (Note: this denial would occur after an enrollee has formally requested a coverage determination with a plan sponsor because, as indicated in §30 above, the presentation of a prescription at the pharmacy counter is not considered a request for a coverage determination unless a plan sponsor chooses to treat it as such). Thus, the adjudication time frame, notice, and other requirements applicable to coverage determinations under part 423, subpart M of the Medicare Part D regulations apply to requests that involve a PA or other UM requirement in the same manner that they apply to all coverage determination requests. However, the decision to place a medication on a PA list or subject it to a UM requirement is not a coverage determination and is not subject to appeal.

Part D plan sponsors must determine how to categorize requests that involve PAs or other UM requirements on a case-by-case basis because some of these requests are subject to the exceptions process while others are not.

Attempting to Satisfy a PA or other UM requirement

A case where an enrollee/physician/other prescriber is attempting to satisfy a PA requirement (i.e., the enrollee/physician/other prescriber is aware that a PA requirement exists and, for example, submits a PA form to the plan sponsor in an attempt to satisfy the PA requirement) should be processed as a coverage determination. The plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 24 hours after receiving the request for expedited cases, or no later than 72 hours after receiving the request for standard cases. Where an enrollee/physician/other prescriber is attempting to satisfy a PA requirement and the plan has a PA form available for seeking prior authorization for the requested drug, the plan should promptly provide the physician or other prescriber with the necessary PA form. A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form for physicians (a/k/a model Part D Exception & Prior Authorization Request Form) to request an override to a PA or other UM requirement: http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf.

Asking a Plan Sponsor to Waive a PA or other UM Requirement

Where an enrollee or an enrollee's prescribing physician or other prescriber is asking a plan sponsor to waive seeking an exception to a PA or other UM requirement (e.g., a physician or other prescriber indicates that an enrollee would suffer adverse effects if he or she were required to satisfy the PA requirement), he or she is asking for an exception

and the prescribing physician or other prescriber must submit a statement to support the request consistent with the requirements set forth in [42 CFR 423.578\(b\)\(5\)](#). A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form for physicians to request an exception and/or submit a supporting statement. **Plan sponsors are required to accept any request or supporting statement that is made in writing, and are prohibited from requiring a physician or other prescriber to make a written request or submit a supporting statement on a specific form.** If the exception request involves benefits not yet received~~As with other exception requests~~, the plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 24 hours after receiving the physician's or other prescriber's supporting statement for expedited cases, or no later than 72 hours after receiving the physician's or other prescriber's supporting statement for standard cases. If the exception request involves reimbursement for benefits already received, the plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision (and make payment when appropriate) no later than 14 calendar days after receiving the request.

~~Finally, if an enrollee/physician/other prescriber asks for coverage for a non-formulary drug, the plan should contact the enrollee/physician/other prescriber and explain the need for a supporting statement in order to process the request. A physician or other prescriber may use the Medicare Part D Coverage Determination Request Form for physicians to request an exception and/or submit a supporting statement. The request should be processed as a formulary exception request and not as a PA request since PA requirements do not apply to non-formulary drugs.~~

Examples

The following examples illustrate when a transaction involving a PA or other UM requirement is, or is not, a coverage determination:

Example 1

1. An enrollee provides his or her pharmacist with a prescription.
2. The pharmacist enters the prescription into the system and receives an electronic notice indicating that the claim has been rejected due to a requirement for PA review and approval. Without the approval, the enrollee must pay the full price for the prescription.
3. A transaction that occurs at a pharmacy, including a rejection from a plan sponsor or pharmacy benefit manager (PBM), is not a coverage determination, unless the plan sponsor chooses to treat the presentation of the prescription at the pharmacy as a claim for benefits.
4. If the enrollee, physician, or other prescriber subsequently submits a request for the prescription with supporting information to the plan sponsor (i.e., the information is submitted in an attempt to satisfy the PA or UM requirement

and/or support the medical necessity of the prescription), the plan sponsor's decision to approve or deny coverage of the prescription is a coverage determination.

Note: If a plan determines that the PA or UM requirement has been satisfied and approves coverage, it must take whatever steps are necessary to ensure that the edit will be overridden at the pharmacy and the prescription can be filled immediately.

Example 2

1. An enrollee calls his or her plan sponsor to determine if Prilosec is covered for him or her (it doesn't matter if the enrollee has a prescription for the drug).
2. Under the plan's formulary, Prilosec is subject to a PA requirement.
3. The plan sponsor tells the enrollee that there is a PA requirement and explains how the PA requirement can be satisfied.
4. The transaction is not a coverage determination because the plan sponsor is explaining the plan's benefit design structure, and the enrollee/physician/other prescriber is not attempting to satisfy the UM requirement or argue that the UM requirement should not apply for reasons of medical necessity.

Example 3

1. An enrollee presents a prescription to his or her pharmacist.
2. The pharmacist receives an electronic notice indicating that the drug is subject to a PA requirement and tells the enrollee that there is a PA requirement.
3. The enrollee/physician/other prescriber calls the plan sponsor to ask about the UM requirement and the plan sponsor explains the procedures that the enrollee/physician/other prescriber must follow for the PA requirement to be satisfied.
4. The transaction is not a coverage determination because the plan sponsor is explaining the plan's benefit design structure (and the enrollee/physician/other prescriber has not attempted to satisfy the UM requirement).

Example 4

1. An enrollee presents a prescription to his or her pharmacist.
2. The pharmacist receives an electronic notice indicating that the drug is subject to a PA or other UM requirement and tells the enrollee that there is a UM requirement.

3. The enrollee/physician/other prescriber calls the plan sponsor and the plan sponsor explains the procedures that the enrollee/physician/other prescriber must follow for the PA requirement to be satisfied.
4. The enrollee/physician/other prescriber attempts to satisfy the PA requirement.
5. The plan sponsor's decision to approve or deny coverage is a coverage determination because the enrollee/physician/other prescriber has attempted to satisfy the UM requirement.

30.2 - Exceptions **(Rev. 8, 1/1/10)**

Coverage determinations include a plan sponsor's decision on an enrollee's exceptions request. Enrollees may request an exception to a plan's tiered cost-sharing structure, or formulary.

Once an exception is granted, the plan sponsor is prohibited from requiring the enrollee to request approval for a refill or new prescription to continue using the Part D prescription drug approved under the exceptions process for the remainder of the plan year, so long as the enrollee remains enrolled in the plan, the physician or other prescriber continues to prescribe the drug and it continues to be safe for treating the enrollee's condition. A plan sponsor may choose not to require an enrollee to resubmit an exceptions request at the beginning of a new plan year. For example, if a plan sponsor grants an exception request near the end of a plan year, it may choose not to require the enrollee to request a new exception when the new plan year begins.

If a plan sponsor decides **not** to continue coverage under an approved exception into the subsequent plan year for a renewing enrollee, the plan **must** send a written notice to the enrollee at least 60 days prior to the end of the plan year, **unless**:

- The plan sponsor sent an approval letter to the enrollee when it granted the exception at the coverage determination or redetermination level, and clearly identified the date that coverage will end in the approval letter; or
- The plan sponsor sent an approval letter to the enrollee when it effectuated a reversal of its adverse coverage determination or redetermination decision by the IRE or other appeal entity, and clearly identified the date that coverage will end in the approval letter. The approval letter is not the decision letter, but is a letter explaining the terms of the approval as ordered by the IRE or other appeal adjudicator.

Alternatively, if a plan sponsor decides to allow coverage under an approved exception to continue into the subsequent plan year for a renewing enrollee, the plan

sponsor **must** send a written notice to the enrollee at least 60 days prior to the date coverage ends, **unless**:

- The plan sponsor sent an approval letter to the enrollee when it granted the exception at the coverage determination or redetermination level, and clearly identified the date that coverage will end in the approval letter; or
- The plan sponsor sent an approval letter to the enrollee when it effectuated a reversal of its adverse coverage determination or redetermination decision by the IRE or other appeal entity, and clearly identified the date that coverage will end in the approval letter.

If a plan sponsor is required to send a written notice to the enrollee at least 60 days prior to the end of the plan year or the date coverage ends, the notice must:

- Explain that the exception will not be extended,
- Provide the date that coverage will end (e.g., on December 31, 2010),
- Explain the right to request a new exception once the current exception expires, and
- Provide instructions for making a new exceptions request.

Plans are prohibited from assigning drugs approved under the exceptions process to a special tier, co-payment, or other cost-sharing requirement.

If a plan sponsor changes its formulary or the cost-sharing status of a drug during the plan year, it must: (1) give direct written notice to affected enrollees at least 60 days in advance of such change becoming effective, or (2) if the 60-day notice is not given, provide enrollees with a 60-day supply of the drug affected by the change and the notice when the enrollee requests a refill. The written notice must contain the following information:

1. The name of the affected covered Part D drug;
2. Whether the plan is removing the covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;
3. The reason why the plan is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;
4. Alternative drugs in the same therapeutic category, class, or cost-sharing tier, and expected cost-sharing for those drugs; and

5. The means by which enrollees may obtain a coverage determination under [42 CFR 423.566](#) or an exception under [42 CFR 423.578](#).

CMS has developed a model notice that a Part D plan sponsor can use to notify enrollees whenever it changes its formulary or the cost-sharing status of a drug during the plan year (see [Appendix 10](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures. A plan may also use the EOB to notify enrollees of mid-year formulary or cost-sharing status changes.

Note: Except as provided under [42 CFR 423.120 \(b\)\(5\)\(iii\)](#), a Part D sponsor may not remove a covered Part D drug from its formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug on its formulary, between the beginning of the annual coordinated election period described in [42 CFR 423.38\(b\)](#) and 60 days after the beginning of the contract year associated with that annual coordinated election period. See [42 CFR 423.120\(b\)\(6\)](#).

30.2.1 - Tiering Exception

(Rev. ~~98~~, 1/1/~~1110~~)

If a plan utilizes a tiered cost-sharing structure to manage its Part D drug benefits, it must establish and maintain reasonable and complete exceptions procedures that permit enrollees to obtain a non-preferred drug at the more favorable cost-sharing terms applicable to drugs in the preferred tier. ~~A plan is not required to begin processing an enrollee's request for a tiering exception until the enrollee's prescribing physician or other prescriber provides a supporting statement. A supporting statement provided by a physician or other prescriber is entitled to great weight when reviewing the exception or other coverage determination request. The physician or other prescriber may provide either a written or an oral supporting statement.~~

If an enrollee wishes to obtain a tiering exception, his or her prescribing physician or other prescriber must provide the plan sponsor with a written statement indicating factor(s) (1) and/or (2) discussed in section 30.2.1.1. Plan sponsors have the option of accepting an oral statement indicating factor(s) (1) and/or (2) from an enrollee's prescribing physician or other prescriber. A supporting statement provided by a physician or other prescriber is entitled to great weight when reviewing the exception or other coverage determination request.

A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form for physicians (a/k/a model Part D Exception & Prior Authorization Request Form) to request an exception and/or submit a supporting statement:

http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf.

Plan sponsors are prohibited from requiring a physician or other prescriber to submit a supporting statement on a specific form.

Note: Under 42 CFR §423.578(c)(4)(iii), an enrollee is prohibited from requesting a tiering exception for a non-formulary drug approved under the formulary exception process. However, a drug that is subject to a UM requirement is a formulary drug (i.e., a UM requirement placed on a formulary drug does not make that drug a non-formulary drug). Therefore, an enrollee who requests a UM exception and receives an approval, may also request a tiering exception for the same formulary drug.

30.2.1.1 – Supporting Statement Criteria **(Rev. 9, 1/1/11)**

The physician's or other prescriber's supporting statement must indicate that the preferred drug for the treatment of the enrollee's condition:

- (1) Would not be as effective as the requested non-preferred drug; and/or
- (2) Would have adverse effects.

30.2.1.2 - Processing Timeframes **(Rev. 9, 1/1/11)**

Requests for Benefits

If an enrollee or an enrollee's prescriber is requesting an exception for a benefit not yet received, the 24 hour (expedited request) or 72-hour (standard request) timeframe for resolving the request does not begin until the enrollee's prescribing physician or other prescriber provides a supporting statement indicating factor(s) (1) and/or (2) discussed in § 30.2.1.1. See §§40.2 and 50.4. Also see §30.2.1.3.

Requests for Reimbursement

If an enrollee or an enrollee's prescriber is requesting reimbursement for a prescription drug that must be resolved under the exceptions process, the 14-day timeframe for resolving the request begins when the request is received (i.e., the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber's supporting statement when a reimbursement request involves an exception) See §§30.3 and 40.2. Also see §30.2.1.3.

30.2.1.3 - Requests for Additional Information **(Rev. 9, 1/1/11)**

Written Supporting Statements

If the physician or other prescriber provides a written statement, ~~the adjudication time frame begins when the written statement indicating factors (1) and/or (2) discussed below is received by the plan sponsor. If the supporting statement indicates~~ indicating factors (1) and/or (2) discussed in §30.2.1.1 but the plan sponsor believes it needs additional information to support one of those factors, the plan sponsor must obtain the additional information, make its decision, and notify the enrollee and/or physician or other

prescriber, as appropriate, within 24 hours (expedited requests for benefits), ~~or~~ 72 hours (standard requests for benefits), or 14 calendar days (reimbursement requests) after receiving the initial written statement ~~indicating factors (1) and/or (2) discussed below~~ (i.e., the time frame is not tolled if the plan asks for additional information after it has received a written supporting statement indicating factors (1) and/or (2) ~~discussed below~~).

CMS has developed a model notice that Part D plan sponsors can use to request a supporting statement and/or additional information (see [Appendix 11](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

~~A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form for physicians (a/k/a model Part D Exception & Prior Authorization Request Form) to request an exception and/or submit a supporting statement:~~

~~http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf.~~

~~**Plan sponsors are prohibited from requiring a physician or other prescriber to submit a supporting statement on a specific form.**~~

Oral Supporting Statements

If the physician or other prescriber provides an oral statement and the plan sponsor determines that the oral statement does not sufficiently demonstrate the medical necessity of the requested drug, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement indicating factors (1) and (2) discussed in §30.2.1.1 below. If the plan sponsor requires a written statement, it must ~~request it~~ immediately contact the enrollee's prescribing physician or other prescriber (or the enrollee and the enrollee's prescribing physician or other prescriber) and request the supporting statement. The plan sponsor's request must explicitly state that the physician or other prescriber is required to indicate factors (1) and/or (2) ~~discussed below~~ in the written supporting statement. The plan sponsor may also request the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up. If the plan sponsor requires the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up, the plan sponsor must clearly identify the type of information that should be submitted.

- Requests for Reimbursement

When a reimbursement request must be resolved under the exceptions process and the plan sponsor requires the prescribing physician or other prescriber to submit a written follow-up supporting statement following an oral statement, the written statement must be obtained within the 14 calendar-day timeframe discussed in §§30.2.1.2, 30.3, and 40.2 if the enrollee or prescriber wants the information to be considered (i.e., the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber's supporting statement when a reimbursement request involves an exception).

- Requests for Benefits

If ~~the exception request involves benefits not yet received and~~ the plan sponsor requires the prescribing physician or other prescriber to submit a written follow-up supporting statement following the oral statement, the adjudication time frame begins when the plan sponsor receives the physician's or other prescriber's written follow-up supporting statement indicating factors (1) and/or (2) discussed ~~in §30.2.1.1 below~~. ~~If the written follow-up supporting statement indicates factors (1) and/or (2) but the plan sponsor believes it needs additional information to support one of those factors, the plan sponsor must obtain the additional information, make its decision, and notify the enrollee and/or physician or other prescriber, as appropriate, within 24 hours (expedited requests) or 72 hours (standard requests) after receiving the written follow-up statement indicating factors (1) and/or (2) discussed below (i.e., the time frame is not tolled if the plan asks for additional information after it has received a written follow-up supporting statement indicating factors (1) and/or (2) discussed below).~~ If the plan sponsor does not request a written follow-up supporting statement, the adjudication time frame begins when the oral supporting statement indicating factors (1) and/or (2) discussed below is received.

~~CMS has developed a model notice that Part D plan sponsors can use to request a supporting statement and/or additional information (see Appendix 11). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.~~

~~The physician's or other prescriber's supporting statement must indicate that the preferred drug for the treatment of the enrollee's condition:~~

- ~~(1) Would not be as effective as the requested non-preferred drug; and/or~~
- ~~(2) Would have adverse effects.~~

~~A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form for physicians (a/k/a model Part D Exception & Prior Authorization Request Form) to request an exception and/or submit a supporting statement:
http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf.~~

~~Plan sponsors are prohibited from requiring a physician or other prescriber to make a written request or submit a supporting statement on a specific form.~~

~~Although As previously noted,~~ the adjudication time frame does not begin until the plan receives ~~the written follow-up supporting statement~~the prescribing physician's or other prescriber's supporting statement indicating factors (1) and/or

~~(2) discussed above. However, a plan sponsor must not keep the request open indefinitely. If an exception request is submitted without the physician's or other prescriber's supporting statement, or the physician's or other prescriber's supporting statement does not indicate factors (1) and/or (2), the plan must contact the enrollee's prescribing physician or other prescriber, or the enrollee and the enrollee's prescribing physician or other prescriber, and request the supporting statement. The plan sponsor's request must explicitly state that the physician or other prescriber is required to indicate one of the two factors in the written supporting statement. A plan must provide the prescribing physician or other prescriber with a reasonable opportunity to provide the supporting statement before making its determination.~~ If the plan does not receive the physician's or other prescriber's supporting statement indicating factors (1) and/or (2) within a reasonable period of time, the plan should make its determination based on whatever evidence exists, if any. Therefore, in cases involving an exceptions request where the plan sponsor is waiting for submission of the supporting statement, the plan sponsor must wait at least 24 hours after the expiration of the time frame that would otherwise apply to a coverage determination request. In other words, a plan must wait a minimum of 96 hours after receiving a standard request or a minimum of 48 hours after receiving an expedited request before issuing its determination.

Example:

1/1/06: Plan sponsor receives a standard request for a coverage determination at 12 PM. The enrollee is requesting approval for a Part D drug that is not on the plan's formulary (i.e., a formulary exceptions request). Neither the enrollee nor the enrollee's prescribing physician or other prescriber submitted the prescribing physician's or other prescriber's supporting statement with the request. The adjudication time frame does not begin until the prescribing physician's or other prescriber's supporting statement indicating factors (1) and/or (2) is received.

1/2/06: The plan sponsor contacts the enrollee and the enrollee's prescribing physician or other prescriber in an attempt to obtain the prescribing physician's or other prescriber's supporting statement.

1/3/06: The plan sponsor again contacts the enrollee and the enrollee's prescribing physician or other prescriber in an attempt to obtain the prescribing physician's or other prescriber's supporting statement.

1/4/06: If the standard coverage determination request in this example did not involve an exception request, the plan sponsor would have been required to notify the enrollee of its decision by 12 PM (i.e., 72 hours after receipt of the request). However, because the request in this example involves an exception, the plan sponsor must wait at least 24 more hours for the prescribing physician's or other prescriber's supporting statement before making a decision.

1/5/06: If the plan sponsor has not received the physician's or other prescriber's supporting statement by 12 PM, the plan sponsor may make a decision based on any evidence it has received, if any.

In the absence of the prescribing physician's or other prescriber's supporting statement, the plan may choose to wait longer than these minimum time frames to issue a coverage determination, but the plan should not leave the request open indefinitely (as noted above, a plan sponsor has an obligation to contact the enrollee and/or physician or other prescriber and clearly identify the information needed to process the request). If no evidence exists to support the exception request, the plan sponsor should deny the request for lack of medical necessity. The denial notice to the enrollee must clearly explain that the request was denied due to a lack of medical necessity and the prescribing physician or other prescriber did not produce the necessary supporting statement. The enrollee then has the right to appeal the denial.

30.2.1.4 – Approval of a Request **(Rev. 9, 1/1/11)**

A plan must grant a tiering exception when it determines that ~~factor(s) (1) and/or (2) discussed in §30.2.1.1 have been met~~ the preferred drug for treatment of the enrollee's condition would not be as effective for the enrollee as the requested non-preferred drug and/or would have adverse effects. The regulations at [42 CFR 423.578\(f\)](#) affirmatively state that nothing in the regulations should be construed to mean that the physician's or other prescriber's supporting statement will result in an automatic favorable determination.

When a tiering exception is approved, the plan sponsor must provide coverage for the non-preferred drug at the cost-sharing level that applies for the preferred drug tier. Tiering exceptions are limited however. An enrollee may not use the tiering exceptions process to request a brand drug at the price of a generic drug. In addition, if a plan maintains a formulary tier in which it places very high cost and unique items, it may design its exception process so that drugs placed in that tier are not eligible for a tiering exception. The following examples illustrate possible cost-sharing tiers and permissible tiering exceptions between the tiers:

Example 1

- Tier 1 (least expensive tier): Generic (all generics)
- Tier 2: Brand
- Tier 3 (most expensive tier): Specialty

The tiering exception process does not apply to this type of cost-sharing structure, unless the plan allows tiering exceptions for drugs on the specialty tier.

Example 2

- Tier 1 (least expensive tier): Generic (all generics)
- Tier 2: Brand

- Tier 3: Brand
- Tier 4 (most expensive tier): Specialty

An enrollee may request a tiering exception to cover a Tier 3 brand drug at the Tier 2 cost-sharing level if there is a brand drug in Tier 2 approved for treating the same condition that the requested Tier 3 brand drug is being used to treat.

Example 3

- Tier 1 (least expensive tier): Generic
- Tier 2: Generic
- Tier 3: Brand
- Tier 4: Brand
- Tier 5 (most expensive tier): Specialty

An enrollee may request a tiering exception to cover a Tier 4 brand drug at the Tier 3 cost-sharing level (so long as there is a brand drug in Tier 3 approved for treating the same condition that the requested Tier 4 brand drug is being used to treat), or a tiering exception to cover a Tier 2 generic drug at the Tier 1 cost-sharing level (so long as there is a generic drug in Tier 1 for treating the same condition that the requested Tier 2 generic drug is being used to treat).

Example 4

- Tier 1 (least expensive tier): Generic (all generics) with 2 sub-levels of cost-sharing within the generic tier
- Tier 2: Brand (all brands) with 2 sub-levels of cost-sharing within the brand tier
- Tier 3 (most expensive tier): Specialty

An enrollee may request a tiering exception to cover a non-preferred generic drug within the generic tier at the cost of a preferred generic drug in the generic tier (so long as there is a generic drug in the preferred generic sub-level for treating the same condition that the requested generic drug in the preferred generic sub-level is being used to treat), or a tiering exception to cover a non-preferred brand drug within the brand tier at the cost of a preferred brand drug in the brand tier (so long as there is a brand drug in the cheaper brand sub-level for treating the same condition that the requested brand drug in the more expensive brand sub-level is being used to treat).

Example 5

- Tier 1 (least expensive tier): Generic
- Tier 2: Mix of generic and brand
- Tier 3: Brand
- Tier 4 (most expensive tier): Specialty

An enrollee may request a tiering exception to cover a Tier 2 generic drug at the Tier 1 cost-sharing level (so long as there is a generic drug in Tier 1 for treating the same condition that the requested Tier 2 generic drug is being used to treat), or a tiering exception to cover a Tier 3 brand drug at the Tier 2 brand cost-sharing level (so long as there is a brand drug in Tier 2 for treating the same condition that the requested brand Tier 3 drug is being used to treat). An enrollee is prohibited from requesting a tiering exception to cover a Tier 2 brand drug at the Tier 1 generic cost-sharing level.

Note: Under 42 CFR §423.578(c)(4)(iii), an enrollee is prohibited from requesting a tiering exception for a *non-formulary drug* approved under the formulary exception process. However, a drug that is subject to a UM requirement is a formulary drug (i.e., a UM requirement placed on a formulary drug does not make that drug a non-formulary drug). Therefore, an enrollee who requests a UM exception and receives an approval, may also request a tiering exception for the same formulary drug.

30.2.2 - Formulary Exception

(Rev. 89, 1/1/4011)

If a plan utilizes a formulary to manage its Part D drug benefits, it must have procedures in place that ensure enrollees have access to Part D drugs that are not included on its formulary.

Formulary use includes the application of cost utilization tools, such as:

- (1) A dose restriction, including the number and/or dosage form, that causes a particular Part D drug not to be covered for the number of doses and/or dosage form prescribed,
- (2) 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
- (3) A therapeutic substitution requirement.

Note: Not all complaints about a plan sponsor's application of costs utilization tools should be handled through the formulary exceptions process. If an enrollee is merely complaining about the existence of a utilization management requirement, the complaint must be handled through the grievance process. If an enrollee is attempting to satisfy a utilization management requirement, the plan must handle the complaint through the coverage determination process. However, if an enrollee argues that a utilization management requirement should not apply in his or her situation because one of the three factors discussed below exist, the plan sponsor must process the complaint as a request for a formulary exception.

If an enrollee wishes to obtain a formulary exception, his or her prescribing physician or other prescriber must provide the plan sponsor with a written statement indicating factor(s) (1), (2), and/or (3) discussed in §30.2.2.1. Plan sponsors have the option of accepting an oral statement indicating factor(s) (1), (2), and/or (3) from an enrollee's prescribing physician or other prescriber. A supporting statement provided by a physician or other prescriber is entitled to great weight when reviewing the exception or other coverage determination request.

A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form for physicians (a/k/a model Part D Exception & Prior Authorization Request Form) to request an exception and/or submit a supporting

statement:

http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf.

Plan sponsors are prohibited from requiring a physician or other prescriber to submit a supporting statement on a specific form.

30.2.2.1 – Supporting Statement Criteria

(Rev. 9, 1/1/11)

The physician's or other prescriber's supporting statement must indicate that the requested prescription drug should be approved because:

- (1) All covered Part D drugs on any tier of a plan's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects;
- (2) The number of doses available under a dose restriction for the prescription drug:
 - (a) Has been ineffective in the treatment of the enrollee's disease or medical condition or,
 - (b) Based on both sound clinical evidence and medical and scientific evidence, 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
- (3) 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, 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.

30.2.2.2 - Processing Timeframes

(Rev. 9, 1/1/11)

Requests for Benefits

If an enrollee or an enrollee's prescriber is requesting an exception for a benefit not yet received, the 24-hour (expedited request) or 72-hour (standard request) timeframe for resolving the request does not begin until the enrollee's prescribing physician or other prescriber provides a supporting statement indicating factor(s) (1), (2), and/or (3) discussed in §30.2.2.1. See §§40.2 and 50.4. Also see §30.2.2.3.

Requests for Reimbursement

If an enrollee or an enrollee's prescriber is requesting reimbursement for a prescription drug that must be resolved under the exceptions process, the 14-day timeframe for resolving the request begins when the request is received (i.e., the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber's supporting statement when a reimbursement request involves an exception) See §§30.3 and 40.2. Also see §30.2.2.3.

~~A plan is not required to process an enrollee's request for a formulary exception until the enrollee's prescribing physician or other prescriber provides a supporting statement indicating one of the three factors discussed below. A supporting statement provided by a physician or other prescriber is entitled to great weight when reviewing the exception or other coverage determination request. The physician or other prescriber may provide either a written or an oral supporting statement.~~

30.2.2.3 - Requests for Additional Information **(Rev. 9, 1/1/11)**

Written Supporting Statements

~~If the physician or other prescriber provides a written statement indicating factor(s) (1), (2), and/or (3) discussed in §30.2.2.1, the adjudication time frame begins when the written statement indicating one of the three factors discussed below is received by the plan sponsor. ~~If the supporting statement indicates one of the three factors~~ but the plan sponsor believes it needs additional information to support one of those factors, the plan sponsor must obtain the additional information, make its decision, and notify the enrollee and/or physician or other prescriber, as appropriate, within 24 hours (expedited requests for benefits), ~~or 72 hours (standard requests~~ for benefits), or 14 calendar days (reimbursement requests) after receiving the initial written statement ~~indicating one of the three factors discussed below~~ (i.e., the time frame is not tolled if the plan asks for additional information after it has received a written supporting statement indicating one of the three factors ~~discussed below~~).~~

CMS has developed a model notice that Part D plan sponsors can use to request a supporting statement and/or additional information (see [Appendix 11](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

~~A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form for physicians (a/k/a model Part D Exception & Prior Authorization Request Form) to request an exception and/or submit a supporting statement:
http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf.~~

~~Plan sponsors are prohibited from requiring a physician or other prescriber to submit a supporting statement on a specific form.~~

Oral Supporting Statements

If the physician or other prescriber provides an oral supporting statement and the plan sponsor determines that the oral statement does not sufficiently demonstrate the medical necessity of the requested drug, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement indicating factor(s) (1), (2), and/or (3) discussed in section 30.2.2.1 one of the three factors discussed below if the plan sponsor determines that the oral statement does not sufficiently demonstrate the medical necessity of the requested drug. If the plan sponsor requires a written statement, it must request it immediately contact the enrollee's prescribing physician or other prescriber (or the enrollee and the enrollee's prescribing physician or other prescriber) and request the supporting statement. The plan sponsor's request must explicitly state that the physician or other prescriber is required indicate one of factor(s) (1), (2), and/or (3) the three factors discussed below in the written supporting statement. The plan sponsor may also request the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up. If the plan sponsor requires the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up, it must clearly identify the type of information that must be submitted.

- Requests for Reimbursement

When a reimbursement request must be resolved under the exceptions process and the plan sponsor requires the prescribing physician or other prescriber to submit a written follow-up supporting statement following an oral statement, the written statement indicating factor(s) (1), (2), and/or (3) discussed in §30.2.2.1 must be obtained within the 14 calendar-day timeframe discussed in §§30.3 and 40.2 if the enrollee or prescriber wants the information to be considered (i.e., the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber's supporting statement when a reimbursement request must be resolved under the exceptions process).

- Requests for Benefits

If the exception request involves benefits not yet received and the plan sponsor requires the prescribing physician or other prescriber to submit a written supporting statement after the prescribing physician or other prescriber submits an oral supporting statement, the adjudication time frame begins when the plan receives the physician's or other prescriber's written follow-up supporting statement indicating factor(s) (1), (2), and/or (3) discussed in §30.2.2.1 one of the three factors discussed below. If the written follow up supporting statement indicates one of the three factors but the plan sponsor believes it needs additional information to support one of those factors, the plan sponsor must obtain the additional information, make its decision, and notify the enrollee and/or physician or other prescriber, as appropriate, within 24 hours (expedited requests) or 72 hours (standard requests) after receiving the written follow up statement indicating one of the three factors discussed below (i.e., the time frame is not tolled if the plan asks for additional information after it has received a written follow up supporting statement indicating one of the three factors discussed

below). If the plan sponsor does not request a written follow-up supporting statement, the time frame begins when the oral supporting statement indicating one of the three factors discussed below is received.

CMS has developed a model notice that Part D plan sponsors can use to request a supporting statement and/or additional information (see [Appendix 11](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

The physician's or other prescriber's supporting statement must indicate that the requested drug is medically required and other formulary drugs and dosage limits will not be as effective because:

- (1) All covered Part D drugs on any tier of a plan's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects;
- (2) The number of doses available under a dose restriction for the prescription drug:
 - (a) Has been ineffective in the treatment of the enrollee's disease or medical condition or;
 - (b) Based on both sound clinical evidence and medical and scientific evidence, 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
- (3) 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, 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.

A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form for physicians (a/k/a model Part D Exception & Prior Authorization Request Form) to request an exception and/or submit a supporting statement:
http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf.

Plan sponsors are prohibited from requiring a physician or other prescriber to make a written request or submit a supporting statement on a specific form.

~~Although As previously noted,~~ the adjudication time frame does not begin until the plan receives the written follow-up supporting statement~~prescribing physician's or other prescriber's supporting statement indicating one of the three factors discussed above.~~ However, a plan sponsor must not keep the request open indefinitely. ~~If an exception request is submitted without the physician's or other prescriber's supporting statement, or the physician's or other prescriber's supporting statement does not indicate one of the three factors, the plan must contact the enrollee's prescribing physician or other prescriber, or the enrollee and the enrollee's prescribing physician or other prescriber, and request the supporting statement. The plan sponsor's request must explicitly state that the physician or other prescriber is required to indicate one of the three factors in the written supporting statement.~~ A plan must provide the prescribing physician or other prescriber with a reasonable opportunity to provide the supporting statement before making its determination. If the plan does not receive the physician's or other prescriber's supporting statement indicating one of the three factors within a reasonable period of time, the plan should make its determination based on whatever evidence exists, if any. Therefore, in cases involving an exceptions request for benefits where the plan sponsor is waiting for submission of the supporting statement, the plan sponsor must wait at least 24 hours after the expiration of the time frame that would otherwise apply to a coverage determination request. In other words, a plan sponsor must wait a minimum of 96 hours after receiving a standard request or a minimum of 48 hours after receiving an expedited request before issuing its determination.

Example:

1/1/06: Plan sponsor receives a standard request for a coverage determination at 12 PM. The enrollee is requesting approval for a Part D drug that is not on the plan's formulary (i.e., a formulary exceptions request) and the enrollee has not purchased the drug in dispute. Neither the enrollee nor the enrollee's prescribing physician or other prescriber submitted the prescribing physician's or other prescriber's supporting statement with the request. The adjudication time frame does not begin until the prescribing physician's or other prescriber's supporting statement indicating one of the three factors discussed above is received.

1/2/06: The plan sponsor contacts the enrollee and the enrollee's prescribing physician or other prescriber in an attempt to obtain the prescribing physician's or other prescriber's supporting statement.

1/3/06: The plan sponsor contacts the enrollee and the enrollee's prescribing physician or other prescriber in an attempt to obtain the prescribing physician's or other prescriber's supporting statement.

1/4/06: If the standard coverage determination request in this example involved an exceptions request, the plan sponsor would have been required to notify the enrollee of its decision by 12 PM (i.e., 72 hours after receipt of the request). However, because the request in this example involves an exception, the plan sponsor must wait at least 24 more hours for the prescribing physician's or other prescriber's supporting statement before making a decision.

1/5/06: If the plan sponsor has not received the physician's or other prescriber's supporting statement by 12 PM, the plan sponsor may make a decision based on any evidence it has received, if any.

In the absence of the prescribing physician's or other prescriber's supporting statement, the plan may choose to wait longer than these minimum time frames to issue a coverage determination, but the plan should not leave the request open indefinitely (as noted above, a plan sponsor has an obligation to contact the enrollee and/or physician or other prescriber and clearly identify the information needed to process the request). If no evidence exists to support the exception request, the plan should deny the request for lack of medical necessity. The denial notice to the enrollee must clearly explain that the request was denied due to a lack of medical necessity because the prescribing physician or other prescriber did not produce the necessary supporting statement. The enrollee then has the right to appeal the denial.

30.2.2.4 – Approval of a Request **(Rev. 9, 1/1/11)**

A plan must grant a formulary exception when it determines that ~~factor(s) (1), (2), and/or (3) discussed in §30.2.2.1 have been met one of the three factors discussed above has been demonstrated, and the drug would be covered but for the fact that it is an off-formulary drug.~~ This language ensures that drugs that otherwise would not be covered (for example, because they are obtained out of network or excluded under §1862(a) of the Act), are not covered through the exceptions process. The regulations at 42 CFR 423.578(f) affirmatively state that nothing in the regulations should be construed to mean that the physician's or other prescriber's supporting statement will result in an automatic favorable determination.

Unlike under the tiering exceptions process, the regulations do not specify what level of cost sharing applies when an exception is approved under the formulary exceptions process. Instead, a plan sponsor has the flexibility to determine what level of cost sharing will apply for non-formulary drugs approved under the exceptions process. However, a plan sponsor is limited to choosing a single cost-sharing level that applies to one of its existing formulary tiers. For example, a plan sponsor may apply the non-preferred level of cost sharing for all non-formulary drugs approved under the exception process. Part D sponsors may also elect to apply a second less expensive level of cost sharing for approved formulary exceptions for generic drugs, so long as the second level of cost

sharing is associated with an existing formulary tier and is uniformly applied to all approved formulary exceptions for generic drugs.

Note: Under 42 CFR §423.578(c)(4)(iii), an enrollee is prohibited from requesting a tiering exception for a *non-formulary drug* approved under the formulary exception process. However, a drug that is subject to a UM requirement is a formulary drug (i.e., a UM requirement placed on a formulary drug does not make that drug a non-formulary drug). Therefore, an enrollee who requests a UM exception and receives an approval, may also request a tiering exception for the same formulary drug.

30.3 - Requests for Reimbursement

(Rev. 98, ~~1/1/11+4/10~~)

The regulations at [42 CFR 423.566\(b\)\(1\)](#) state that any decision by a plan sponsor to reimburse an enrollee for a Part D drug, including a decision about reimbursing an enrollee for a drug obtained at an out-of-network (e.g., non-preferred) pharmacy and a decision to reimburse an enrollee for all or part of a cost share amount that the enrollee believes he or she was incorrectly charged, is a coverage determination. Therefore, plan sponsors must process all requests for reimbursement submitted by enrollees as coverage determinations pursuant to the rules provided in [§423.568](#) of the regulations and §§[40](#) and [130.1](#) of this chapter.

~~**Note:** The reimbursement processing timeframes contained in this section of Chapter 18 reflect the current requirements contained in [§423.568](#) of the regulations. However, plan sponsors should ensure enrollees' requests for reimbursement are processed in accordance with the processing timeframes contained in the Compliance/Monitoring section of the 2010 Parts C and D Combined Call Letter, which is located on the Prescription Drug Coverage Contracting webpage: (<http://www.cms.hhs.gov/PrescriptionDrugCovContra>). Pursuant to the guidance contained in the Call Letter, beginning January 1, 2009, plan sponsors that make a determination, and either send payment or the standard denial notice to the enrollee within 14 calendar days after receipt of the request will not have any enforcement actions taken against them for non-compliance with the 72-hour deadline in 42 CFR §568(b). However, if a plan sponsor notifies the enrollee of its favorable determination within 72 hours, the sponsor will still have 30 calendar days to mail the payment.~~

30.3.1 - Form and Content of Reimbursement Requests (Rev. ~~98, 1/1/11+1/10~~)

Consistent with §40.1 of this chapter, **plan sponsors are required to accept all reimbursement requests that are made in writing** (when submitted by an enrollee, an enrollee's prescribing physician or other prescriber, or an enrollee's representative) **and are prohibited from requiring use of a specific form.** A plan sponsor may develop a form for requesting reimbursement and encourage its members to use the form, but the plan sponsor cannot require its members to use the form. Similarly, a plan sponsor may encourage its members to include copies of their prescriptions with their reimbursement requests, but the plan sponsor cannot require it.

Note: When a reimbursement request must be resolved under the exceptions process described in §30.2, the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber's supporting statement. The enrollee or prescriber must submit the prescriber's supporting statement with the reimbursement request (or within the 14 calendar-day adjudication time frame) if she or he wants the plan sponsor to consider the information. If an enrollee or prescriber does not submit the prescriber's supporting statement with the reimbursement request, the plan sponsor should make reasonable and diligent efforts to obtain the missing information within the 14 calendar-day timeframe. See §§30.2.1.3, 30.2.2.3, and 30.3.2 for more information.

30.3.2 - Processing Reimbursement Requests (Rev. 98, 1/1/11/4/40)

~~*Note: The reimbursement processing timeframes contained in this section of Chapter 18 reflect the current requirements contained in §423.568 of the regulations. However, plan sponsors should ensure enrollees' requests for reimbursement are processed in accordance with the processing timeframes contained in the Compliance/Monitoring section of the 2010 Parts C and D Combined Call Letter, which is located on the Prescription Drug Coverage Contracting webpage: (<http://www.cms.hhs.gov/PrescriptionDrugCovContra>). Pursuant to the guidance contained in the Call Letter, beginning January 1, 2009, plan sponsors that make a determination, and either send payment or the standard denial notice to the enrollee within 14 calendar days after receipt of the request will not have any enforcement actions taken against them for non-compliance with the 72-hour deadline in 42 CFR §568(b). However, if a plan sponsor notifies the enrollee of its favorable determination within 72 hours, the sponsor will still have 30 calendar days to mail the payment.~~

As noted in §30.3, plan sponsors must process all requests for reimbursement submitted by enrollees (or their representatives, prescribing physicians, or other prescribers) as standard coverage determinations (see §40 of this chapter for more information about standard coverage determinations). ~~However, the timeframe for processing standard requests for reimbursement is different from the timeframe for processing standard requests for benefits. Thus, a plan sponsor must make a reimbursement decision and provide notice of its decision no later than 72 hours* after receiving the reimbursement request, or no later than 72 hours* after receiving the physician's or other prescriber's supporting statement if the reimbursement request involves an exception (see §30.2 of this chapter for more information about exception requests).~~

~~If a plan sponsor does not have all of the information it needs to make a decision, the plan sponsor should make reasonable and diligent efforts to obtain the missing information within the standard timeframe for making a decision and notifying the enrollee of the decision (i.e., within 72 hours* after receiving the request or physician's or other prescriber's supporting statement). When a plan sponsor could acquire missing information, such as a National Drug Code (NDC) number, by contacting the enrollee's pharmacist, physician, or other prescriber, it should do so instead of relying on the enrollee to provide the information.~~

- ~~• If a plan sponsor is issuing an unfavorable reimbursement decision, it must make the decision and provide notice the decision no later than 14 calendar days after receiving the reimbursement request.~~
- ~~• If a plan sponsor is issuing a favorable reimbursement decision, it must make the decision, provide notice notify the enrollee of the decision, and make payment no later than 14 calendar days after receiving the reimbursement request, within the 72-hour* timeframe, and send payment to the enrollee within 30 days* after receiving the request pursuant to §130.1 of this chapter.~~

If a plan sponsor is not able to obtain all of the information it needs to reach a favorable decision on the merits of the case within the 14 calendar-day 72-hour* timeframe, it should issue an unfavorable decision ~~within the 72-hour* timeframe.~~

- If a plan sponsor does not have all of the information it needs to make a decision, the plan sponsor should make reasonable and diligent efforts to obtain the missing information within the 14 calendar-day timeframe. When a plan sponsor could acquire missing information, such as a National Drug Code (NDC) number, by contacting the enrollee's pharmacist, physician, or other prescriber, it should do so instead of relying on the enrollee to provide the information.
- If a plan is issuing an unfavorable decision because it was not able to obtain all of the information it needed to make a favorable decision, the plan sponsor must, pursuant to §423.568(c) of the regulations and §40.3.3 of this chapter, clearly explain in the decision letter the reason for the denial using language the enrollee can understand. Merely providing the technical reason for the denial without additional information generally will not satisfy the notice requirements. For example, if a plan sponsor denies a request because the enrollee did not provide the NDC number (and the plan sponsor could not obtain it from the enrollee's pharmacist, physician, or other prescriber within the allowable timeframe), the plan sponsor should not simply state that the claim was denied because the member did not provide the NDC number. The plan should also briefly explain what an NDC number is (e.g., a ten-digit, three-segment number used to identify a drug), where he or she can get it (e.g., from the pharmacist who filled the prescription or the physician or other prescriber who wrote the prescription), and how the enrollee can submit the information with his or her appeal request.

~~Occasionally, a plan sponsor will have enough information to determine that a reimbursement request is payable, but not enough to determine the exact amount. When this situation occurs, the plan sponsor could issue a favorable decision within the 72-hour* timeframe (the plan sponsor is not required to say how much the payment will be in its notice to the enrollee), and utilize the remainder of the 30-day* payment period described in §§40.2 and 130.1 of this chapter to determine how much the enrollee should be reimbursed and make payment. If a plan sponsor chooses to send the payment within the 30-day* timeframe after notifying the enrollee of the favorable decision within the 72-hour* timeframe, the initial notice to the enrollee must include the following information:~~

- ~~• The plan sponsor is approving the request;~~
- ~~• Payment will be sent within 30 days* after the request was received;~~
- ~~• If the enrollee does not agree with the amount received, he or she can request an appeal with the plan sponsor; and~~

- ~~• Briefly explain that the member may not receive the entire amount he or she paid out of pocket because certain items (e.g., co-payment amounts) are not reimbursable, and include a brief summary of items that are generally subtracted.~~

30.4 - Procedures for Handling Misclassified Coverage Determinations (Rev. 8, 1/1/10)

All adverse coverage determinations are subject to the appeals procedures. Sometimes complaints do not appear to involve coverage determinations and are misclassified as grievances exclusively. This may occur because the plan did not issue the written notice of an adverse coverage determination (i.e., a denial notice). Upon discovery of such an error, the Part D plan sponsor must notify the enrollee in writing that the complaint was misclassified and will be handled through the appeals process. The time frame for processing the complaint begins on the date the complaint is received by the Part D plan sponsor, as opposed to the date the Part D plan sponsor discovers its error. Part D plan sponsors are expected to audit their own appeals and grievance systems for the presence of errors and institute appropriate quality improvement projects as needed.

30.4.1 - Quality of Care (Rev. 8, 1/1/10)

A complaint received by a Part D plan sponsor concerning the quality of a benefit received by an enrollee is generally treated as a grievance. However, quality of care complaints occasionally involve complaints about the denial of benefits. For example, if an enrollee complains of poor care because his/her pharmacist would not provide a prescribed medication, the complaint may involve a denial of benefits that should be simultaneously processed through the grievance and coverage determination processes (i.e., the complaint about the pharmacist is a grievance, and the complaint about not receiving the prescribed medication is a denial of benefits).

30.4.2 - Service Accessibility (Rev. 8, 1/1/10)

A complaint concerning the timely receipt of a Part D drug that has already been provided may be treated as a grievance. However, when enrollees complain that they have been unable to obtain Part D drugs that they believe they are entitled to receive (and a delay would adversely affect the health of the enrollees), the complaints should be addressed as coverage determinations, which may be appealed.

When an enrollee complains that he/she had to wait so long for a Part D drug that he/she obtained the drug out-of-network, the complaint should be treated as a coverage determination (i.e., a request to be reimbursed for the out-of-network benefits) as well as a grievance (i.e., a complaint about the timeliness of the benefit).

30.4.3 - Employer-Sponsored Benefits (Rev. 8, 1/1/10)

Part D appeal procedures apply to all Part D benefits offered under an Employer/Union-Only Group Waiver Plan (EGWP). These plans are offered by Medicare Advantage Organizations, PDP Sponsors, or Cost Plan Sponsors. For employers and unions that directly contract with CMS to offer these plans ("Direct EGWPs"), Part D appeal procedures apply to all Part D benefits unless the applicable contract governing this arrangement provides otherwise. Non-Medicare supplemental benefits offered by an EGWP or Direct EGWP are not considered Part D benefits and are not subject to the Part D guidelines contained in this chapter. Please see Chapter 12 of this Manual for additional information on prescription drug benefits for EGWPs and Direct EGWPs.

40 - Standard Coverage Determinations

40.1 - How to Request a Standard Coverage Determination (Rev. 98, 1/1/11+1/1/10)

An enrollee, an enrollee's representative, or an enrollee's prescribing physician or other prescriber may request a standard coverage determination.

If a request involves Part D drug benefits that an enrollee has not received yet, the request may be filed with the plan sponsor by phone or in writing.

If a request involves reimbursement for a Part D drug that an enrollee has already received, the request must be filed with the plan sponsor in writing (unless the plan sponsor allows enrollees to submit oral requests for reimbursement).

~~by filing a signed written request with the Part D plan sponsor.~~ A written request may be made on CMS's Model Coverage Determination Request Form (http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp) (<http://www.cms.gov/MedPrescriptDrugApplGriev/Downloads/ModelCoverageDeterminationRequestForm.pdf>), the model Medicare Part D Coverage Determination Request Form for physicians (http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf), a request form developed by a plan sponsor or any other entity, or any other written document. **Plan sponsors are required to accept any request that is made in writing** (when made by an enrollee, an enrollee's prescribing physician or other prescriber, or an enrollee's representative) **and are prohibited from requiring an enrollee or physician or other prescriber to make a written request on a specific form.**

~~A Part D plan sponsor may, but is not required to, accept oral requests for standard coverage determinations. If a Part D plan sponsor chooses to accept an oral request, the~~ Plan sponsors must **establish and maintain a process for documenting the oral requests in writing and retaining the documentation in the case file, in the enrollee's own words, repeat the request back to the enrollee to confirm the accuracy, and place the request into**

~~a tracking system. If a department other than one that responds to coverage determinations receives the request, it should transfer the call to the appropriate department.~~

~~If an enrollee attempts to request reimbursement by phone but the plan sponsor does not accept oral requests for reimbursement standard coverage determinations, and it determines that an enrollee's oral complaint should be classified as a standard request for a coverage determination, the plan sponsor must explain the procedures the enrollee must follow to file a written request for reimbursement a standard coverage determination. For example, the plan may explain the procedures orally and direct the enrollee to the appropriate section of the Evidence of Coverage for additional information. If an enrollee or prescribing physician or other prescriber files an oral request for an expedited coverage determination (which must be accepted orally and in writing), and the plan sponsor does not grant the request to expedite, the plan sponsor cannot require the enrollee to re-file the request in writing. Instead, the plan sponsor must accept the oral request and process it according to the procedures described in §50.3.~~

40.2 - Standard Time Frames for Coverage Determinations (Rev. ~~98, 1/1/11~~ 4/10)

Requests for Benefits

When a party has made a request for coverage ~~or payment~~ of a Part D drug benefit ~~that has not been received yet~~, 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 the date and time the plan receives the request for a standard coverage determination, ~~or no later than 72 hours after receiving the physician's or other prescriber's supporting statement if the request involves an exception (see §30.2 of this chapter for more information about exception requests). If the Part D plan sponsor's decision is favorable, it must effectuate the decision in accordance with §130.1.~~

Requests for Reimbursement

~~When a party requests reimbursement for a Part D drug that an enrollee has already received, the plan sponsor must make the decision and provide notice of the decision as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after receiving the reimbursement request.~~

~~If a plan sponsor is issuing a favorable reimbursement decision, it must make the decision, provide notice of the decision, and make payment as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after receiving the reimbursement request (see §130.1 for more information about effectuating favorable decisions).~~

~~When a reimbursement request must be resolved under the exceptions process described in §30.2, the 14 calendar-day timeframe for processing a reimbursement request is not~~

tolled pending receipt of a prescriber's supporting statement. See §§30.2.1.3, 30.2.2.3, and 30.3.2 for more information.

All Standard Requests (Benefits or Reimbursement)

Note: Plan sponsors must have processes in place to accept coverage determination requests and physicians' or other prescribers' supporting statements 24 hours a day, 7 days a week (including holidays). Although it is not necessary to begin processing requests as soon as they are received, plan sponsors must make determinations within the appropriate time frame. Because some requests will be received after normal business hours, it will be necessary for plan sponsors to have a process for handling such requests appropriately. For example, if an enrollee submits an oral expedited coverage determination request at midnight on a Saturday, the plan sponsor must have procedures in place to make a decision and notify the enrollee of its decision by midnight on Sunday.

Each plan sponsor generally has the flexibility to develop the procedures it uses to ensure that timely coverage determinations and redeterminations are made. For example, a plan sponsor may employ an answering service for after-hours requests. An enrollee can make his or her request with the answering service and the call-center representative can page a pharmacist or other on-call reviewer to handle the request within the applicable time frame.

Requests or supporting statements are deemed "received" on:

- The date and time the plan sponsor initially stamps a document sent by regular mail (e.g., via US Postal Service);
- The date and time a delivery service that has the ability to track when a shipment is delivered (e.g., US Postal Service, UPS, Federal Express, or DHL) delivers the document;
- The date and time a faxed document is successfully transmitted to the plan sponsor, as indicated on the fax confirmation sheet;
- The date and time an oral request is made by telephone with a customer service representative; or
- The date and time a message is left on the plan sponsor's voicemail system if the plan sponsor utilizes a voicemail system to accept requests or supporting statements after normal business hours.

~~If the Part D plan sponsor's decision is favorable, it must effectuate the decision in accordance with §130.1.~~

A plan sponsor may not extend the applicable adjudication time frame by dispensing a temporary supply of the requested medication. For example, if a plan sponsor receives a

request outside of its normal business hours, it cannot approve a 72-hour supply of the requested medication and defer issuing a decision for 72 hours; the plan sponsor must make its determination within the appropriate time frame.

~~If the enrollee's request involves an exception, 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 the date and time the plan receives the physician's or other prescriber's supporting statement. If the Part D plan sponsor's decision is favorable, it must effectuate the decision in accordance with §130.1.~~

~~**Note:** A standard exceptions request may involve a prospective request for benefits or a retrospective request for payment. Although the adjudication time frame does not begin until the plan receives the prescribing physician's or other prescriber's supporting statement, the plan is not required to wait an indefinite period of time before issuing its decision. See §§30.2.1 and 30.2.2 for more information.~~

~~If the enrollee is requesting payment for drugs he or she already received, the plan sponsor must notify the enrollee of its decision within the 72 hour time frame described above, unless the request for payment involves an exceptions request (see preceding note). If the plan sponsor's decision is favorable, it must authorize payment and notify the enrollee within the 72 hour time frame, and make payment (i.e., mail the payment) within 30 calendar days of the request. See §130.1.~~

The decision-making and notification time frames that are measured in hours must be met within the number of hours indicated (plans must indicate the date and time that each request is received).

Example:

3/1/05, 1:00 PM: The plan receives a request for a standard coverage determination. The 72-hour decision-making and notification time frame begins.

3/4/05: The plan must make its coverage determination and notify the enrollee of its decision by 1:00 PM. If it does not, it must forward the enrollee's request and case file containing any oral and/or written evidence obtained to the IRE for review within 24 hours of the expiration of the time frame. See §40.4.

40.3 - Notice Requirements for Standard Coverage Determinations

40.3.1 - Notification by Network Pharmacists (Rev. 1, 11/30/05)

The Part D plan sponsor must educate network pharmacies about their responsibilities to Part D enrollees. When a pharmacist explains to an enrollee that a drug is not on a plan's formulary, or is subject to prior authorization, step therapy, or other limitation, the

transaction does not constitute a coverage determination, unless the plan treats the presentation of the prescription as a request for a coverage determination.

Plans must arrange with network or preferred pharmacies to provide enrollees with standard notices (the Part D plan sponsor must use the approved notice in [Appendix 5](#)) when enrollees disagree with the information relayed to them by their pharmacists. The notices explain an enrollee's right to receive, upon request, a detailed written decision from the Part D plan sponsor regarding his or her Part D prescription drug benefits, including information about the exceptions process. Plan sponsors must arrange with their network pharmacies to either post the notice in the pharmacy, or distribute the notice to enrollees.

Note: Pharmacies Serving Long-Term-Care Facilities

Given the uniqueness of the long-term-care (LTC) setting, enrollees will generally not present the prescription to a pharmacist. In most instances, the treating physician, other prescriber, or a staff-person sends the prescription to the pharmacy. If there is an issue with a requested prescription, the pharmacist contacts the treating physician, other prescriber, or staff-person and the physician or other prescriber determines what course of action is appropriate (e.g., the physician or other prescriber may either prescribe a different medication or request an exception). If the network or preferred pharmacy is off-site, it must send (fax or deliver) the notice described above to the location in the LTC facility designated to accept such notices. If the network or preferred pharmacy is on-site, it must deliver the notice described above to the location in the LTC facility designated to accept such notices. The LTC facility staff is responsible for providing the enrollee (or the enrollee's representative) and the enrollee's treating physician or other prescriber with the notice. A copy of the notice should be placed in the enrollee's file at the LTC facility.

40.3.2 - Oral Notification by Part D Plan Sponsors

(Rev. ~~98~~, ~~1/1/11/4/10~~)

~~A plan sponsor must provide written notice of any favorable or adverse decision it issues. However, a~~ plan sponsor may make its initial notification orally so long as it also mails a written. ~~However, if a plan sponsor issues an adverse standard coverage determination, in whole or part, it must provide written notice of the determination. Therefore, if a plan sponsor first makes its adverse notification orally, a follow-up written decision must be mailed within 3 calendar days of the oral notification. A plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with written notice of an adverse determination after providing oral notice to the physician or other prescriber.~~ If a plan sponsor's decision is adverse, the oral (if provided) and written notices must satisfy the requirements in ~~§40.3.440.3-3~~. If a plan sponsor's decision is favorable, the oral (if provided) and written notices must satisfy the requirements in §40.3.5.

- If an enrollee files the request, notice must be provided to the enrollee.

- As noted in §10.4.2, if an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee.
- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. However, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber. If an enrollee has a representative, the plan sponsor must notify the enrollee's representative instead of the enrollee. Additionally, if an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify the enrollee and the enrollee's prescribing physician or other prescriber.

40.3.3 – Good Faith Effort to Provide Oral Notice (Rev. 8, 1/1/10)

In certain situations, the regulations permit a plan sponsor to satisfy a notification requirement by first providing oral notice of a coverage determination or expedited redetermination decision to an enrollee. If a plan sponsor intends to provide oral notice, it is responsible for obtaining a telephone number from the enrollee (if a plan sponsor doesn't have an enrollee's telephone number on file when a request is made, it should obtain the telephone number when the request is being made). If the plan sponsor does not have an enrollee's telephone number on file when a request is made, it cannot expect to notify the enrollee of a decision orally and must ensure that the notification requirement is satisfied in writing. When a plan sponsor has an enrollee's telephone number on file, relies on it to provide oral notice, but is unable to reach the enrollee at the number provided because, for example, it is either incorrect, out-of-service, or no person (or voice-mail system) answers, the plan sponsor's good-faith effort to provide oral notice satisfies the notification requirement if:

1. The good-faith effort is documented in writing and included in the case file,
2. Written notice of the decision is immediately sent to the enrollee, and
3. The plan sponsor is not at fault for its inability to reach the enrollee by phone (e.g., the plan sponsor did not make a transcribing error when writing the telephone number).

40.3.4 - Written Notification of Adverse Decisions by Part D Plan Sponsors (Rev. 98, 1/1/11/4/10)

If the Part D plan sponsor denies, in whole or in part, a request for a Part D benefit or payment for a prescription drug purchased by an enrollee, it must provide written notice of its determination (Part D plan sponsors that do not provide notice of a decision within the required timeframe should not use the notice described in this section to notify the

enrollee that his or her decision was not made timely and is being forwarded to the IRE, but should provide notice as described in [§40.4](#) instead).

- [If an enrollee files the request, notice must be provided to the enrollee.](#)
- [As noted in §10.4.2, if an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee.](#)
- [If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, as described in §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber and the plan sponsor does not notify the prescribing physician or other prescriber of an adverse determination orally as described in §40.3.2, the plan sponsor must provide written notice to the enrollee and the enrollee's prescribing physician or other prescriber.](#)

The Part D plan sponsor must use the approved notice in [Appendix 1](#). The standardized denial notice form has been written in a manner that is understandable to the enrollee and provides:

1. The specific reason for the denial that takes into account the enrollee's presenting medical condition, disabilities, and special language requirements, if any;
2. Information regarding the right to appoint a representative to file an appeal on the enrollee's behalf;
3. For coverage denials, a description of both the standard and expedited redetermination processes and time frames, including conditions for obtaining an expedited reconsideration, and the rest of the appeals process; and
4. For payment denials, a description of the standard redetermination process and time frames, and the rest of the appeals process.

The denial rationale must be specific to each individual case and written in a manner calculated for an enrollee to understand. Examples of language that satisfies point 1 above (because it is specific to the individual's case):

Example 1 (fully unfavorable)

The drug that you have requested, Protium, is not on our formulary. Instead, the drug Nexium is on our formulary and is indicated for treating your condition. Neither you nor your prescribing physician or other prescriber has submitted any documentation or medical records supporting the medical necessity for receiving

Protium instead of Nexium. Therefore, we are denying your request to receive Protium. However, you may obtain a prescription for Nexium.

Example 2 (fully unfavorable)

This decision is in response to your request for the drug Valium. Section 1927(d)(2) of the Social Security Act (the Act) permits the exclusion of certain drugs or classes of drugs from coverage under Part D. Valium is a benzodiazepine, which is one of the excluded classes of drugs under section 1927(d)(2) of the Act. Because Valium is excluded from coverage and we do not offer it as a supplemental benefit, we are denying your request. [Note: This language is an example of the language that should be included in a plan sponsor's adverse coverage determination decision when an enrollee argues that a requested drug is not an excluded drug. See [§20.2.4](#)]

Example 3 (fully unfavorable)

This decision is in response to your request for the drug Orlistat. Sections 1860D-2(e)(2) and 1927(d)(2) of the Social Security Act (the Act) permit the exclusion of certain drugs or classes of drugs from coverage under Medicare Part D when the drugs are being prescribed to treat uses excluded under the Act. Drugs used for the treatment and maintenance of weight loss are excluded from Medicare Part D coverage under section 1927(d)(2) of the Act. Your physician or other prescriber prescribed Orlistat for the treatment and maintenance of weight loss. Because Orlistat is excluded from coverage under Medicare Part D for the treatment and maintenance of weight loss and we do not offer it as a supplemental benefit, we are denying your request. [Note: This language is an example of the language that should be included in a plan sponsor's adverse coverage determination decision when an enrollee argues that a requested drug is not an excluded drug because it is being used for an indication that isn't excluded under sections 1860D-2(e)(2) and 1927(d)(2) of the Act. See [§20.2.4](#)]

Example 4 (partially favorable)

The drug that you have requested, Nexium, is subject to step therapy and has a quantity limit of 30 tablets per 30 days. You have satisfied the step therapy criteria. However, we cannot approve your request for 300 tablets for 30 days because of the quantity limit. Therefore, we've approved 30 tablets of Nexium for 30 days.

Note: In Example 4, only part of the decision is favorable, so the plan sponsor must use the notice in [Appendix 1](#) and explain the enrollee's right to appeal the unfavorable portion of the decision. Also, the plan sponsor should explain what other information is necessary to make a decision regarding the denied portion of the request.

40.3.5 - Written Notification of Favorable Decisions **(Rev. 9, 1/1/11)**

If a Part D plan sponsor completely approves a request for a Part D benefit or payment for a prescription drug purchased by an enrollee, it must provide written notice of its determination. A plan sponsor may make its initial notification orally, so long as it also mails a written follow-up decision within 3 calendar days of the oral notification.

- If an enrollee files the request, notice must be provided to the enrollee.
- If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).
- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.

The note in §40.3.2 regarding a good-faith effort to provide oral notice also applies to this section.

Any written notice must be written in a manner that is understandable to the enrollee. In addition, the oral (if provided) and written approval notice must explain the conditions of the approval. The conditions of approval may include (but are not limited to):

- The duration of an approval;
- Limitations associated with an approval; and/or
- Any coverage rules applicable to subsequent refills.

The plan sponsor may develop its own notice that meets the regulatory requirements in 42 CFR 423.568(e).

Part D plan sponsors that do not provide notice of a decision within the required timeframe should not use the notice described in this section to notify the enrollee that his or her decision was not made timely and is being forwarded to the IRE, but should provide notice as described in §40.4 instead.

40.4 - Effect of Failure to Provide Timely Notice

(Rev. ~~98, 1/1/11+4/40~~)

If a Part D plan sponsor does not provide notice of its standard coverage determination within the required time frame, it must forward the complete case file to the IRE contracted by CMS within 24 hours of the expiration of the adjudication time frame.

Note: Because the adjudication time frame for an exceptions request involving a request for benefits does not begin until the plan sponsor receives the physician's or other prescriber's supporting statement as indicated in §§~~30.2.1.230.2.1~~ and ~~30.2.2.230.2.2~~, plan sponsors must not automatically forward case files to the IRE if a physician or other prescriber has not submitted an oral or written supporting statement. Instead, plan sponsors should issue decisions in accordance with the guidance provided in §§[30.2.1](#) and [30.2.2](#).

Note: If a plan sponsor makes a completely favorable decision soon after the adjudication timeframes expires (i.e., within 24 hours) and notifies the enrollee of the decision, the plan sponsor should not forward the case file to the IRE and provide the notice described in this section. Plan sponsors should use this exception sparingly. If a plan sponsor does not regularly meet the adjudication timeframe and CMS finds that the plan sponsor uses this exception frequently, CMS may consider the plan sponsor in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with [subpart O of 42 CFR Part 423](#).

The case file must contain the enrollee's request and any oral and/or written evidence obtained by the plan sponsor. Part D plan sponsors should also refer to §§70.30 and 70.40 to determine how to prepare the case file for the IRE and what documents/items to send with the case file. The Part D plan sponsor must deliver a hard copy of the case file to the IRE by overnight delivery at its designated address, or by fax at its designated fax number. The Part D plan sponsor should refer to the IRE's Reconsideration Process Manual for additional instructions.

Although the Part D plan sponsor's failure to provide notice of a decision within the required timeframe constitutes an adverse decision, the plan sponsor must not send a standard denial notice to the enrollee. Instead, the Part D plan sponsor must notify the enrollee that it has forwarded his or her request to the IRE for review. The plan sponsor must send the notification within 24 hours of the expiration of the adjudication time frame. The notice must advise the enrollee of his/her right to submit additional evidence that may be pertinent to the enrollee's case, if the enrollee chooses, and direct the enrollee to submit such evidence to the IRE, and include information on how to contact the IRE. CMS has developed a model notice that Part D plan sponsors can use to notify enrollees whenever cases are forwarded to the IRE (see [Appendix 6](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

If CMS determines that the Part D plan sponsor has a pattern of not concluding standard coverage determinations within the required time frame or not forwarding the enrollee's request to the IRE for review within the required time frame, the Part D plan sponsor may be considered to be in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with [subpart O of 42 CFR Part 423](#).

Transition Period Note:

~~The memoranda "Next Steps on Formulary Transition Policies" dated March 17, 2006 and "Reminder of Part D Transition Policy and Expectations for the Upcoming Contract Year" dated November 1, 2006 explain the steps a p~~Plan sponsors ~~must take to~~ ensure ~~new enrollees receive a meaningful transition process when they have a meaningful transition process for a new enrollee who has~~ been, prior to enrollment, stabilized on a medication that is either not on the plan formulary or is subject to utilization management requirements. Two of the steps involve plan sponsors providing a temporary supply of the requested medication and sending the enrollee a written notice explaining when the supply will end and the procedures for requesting an exception. A transition process is not meaningful if an enrollee who is in the transition period files an exception request and the plan sponsor does not make a decision timely or does not forward the enrollee's request/case file to the IRE within the appropriate time frame. Therefore, ~~as explained in the memorandum "Critical Steps As Transition Period Ends" dated March 30, 2006,~~ **when an enrollee who is in the transition period files an exception request and the plan does not make its decision timely and/or fails to forward a request/case file to the IRE as required, the plan sponsor should provide the enrollee with a temporary supply of the requested prescription drug (when not medically contraindicated) until the case is resolved by the plan sponsor or the IRE issues a reconsideration decision.** ~~The memoranda referenced above can be viewed on the HPMS-Guidance History webpage:~~
~~<http://www.cms.hhs.gov/PrescriptionDrugCovContra/HPMSGH/list.asp>~~

For more information about the transition policy, see Chapter 6 (Part D Drugs and Formulary Requirements), §30.4 of the Prescription Drug Benefit Manual:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp.

**50 - Expedited Coverage Determinations
(Rev. 8, 1/1/10)**

An enrollee, his or her representative, or the enrollee's prescribing physician or other prescriber, may request that a Part D plan sponsor expedite a coverage determination when the enrollee or his/her physician or other prescriber believes that waiting for a decision under the standard time frame may place the enrollee's life, health, or ability to regain maximum function in serious jeopardy.

A claim for payment for prescription drugs that the enrollee has already received will not be expedited. However, if a case includes both a payment denial and a pre-benefit denial, the enrollee has a right to request an expedited coverage determination for the pre-benefit denial.

50.1 - Making a Request for an Expedited Coverage Determination (Rev. 98, 1/1/11/1/10)

An enrollee, an enrollee's representative, or an enrollee's prescribing physician or other prescriber may request an expedited coverage determination.

~~The request may be filed with the plan sponsor by phone or in writing. When asking for an expedited coverage determination, the enrollee or prescribing physician or other prescriber must submit either an oral or written request directly to the plan. The Part D plan sponsor must accept both oral and written requests.~~ A written request may be made on CMS's Model Coverage Determination Request Form (<http://www.cms.gov/MedPrescriptDrugApplGriev/Downloads/ModelCoverageDeterminationRequestForm.pdf>) (~~http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp~~), the model Medicare Part D Coverage Determination Request Form for physicians (http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf), a request form developed by a plan sponsor or any other entity, or any other written document. **Plan sponsors are required to accept any request that is made in writing** (when made by an enrollee, an enrollee's prescribing physician or other prescriber, or an enrollee's representative) **and are prohibited from requiring an enrollee or physician or other prescriber to make a written request on a specific form.**

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

The Part D plan sponsor must automatically expedite the coverage determination when a request is made or supported by a prescribing physician or other prescriber, and the physician or other prescriber indicates, either orally or in writing, that applying the standard time for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. The prescribing physician or other prescriber need not be the enrollee's representative to make the request.

For a request made by an enrollee, the Part D plan sponsor must expedite the determination if the plan sponsor finds that the enrollee's health, life, or ability to regain maximum function may be seriously jeopardized by waiting for a standard coverage determination.

If the Part D plan sponsor decides to expedite the coverage determination, it must render a decision in accordance with the provisions specified in [§50.4](#).

If the Part D plan sponsor denies the request to expedite, the plan follows the requirements specified in [§50.3](#).

50.2 - How the Part D Plan Sponsor Processes Requests for Expedited Coverage Determinations (Rev. 8, 1/1/10)

The Part D plan sponsor must establish and maintain procedures that:

1. Establish efficient and convenient means for enrollees and/or their prescribing physicians or other prescribers to submit oral/written requests;
2. Document all oral requests in writing and maintain the documentation in the case file;
3. Promptly decide whether to expedite a determination based on whether applying the standard time frame for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function; and
4. Develop a meaningful process for receiving requests for expedited reviews. These procedures must include designating an office and/or department to receive both oral and written requests, including a telephone number for oral requests, and may include a facsimile number to facilitate receipt of requests for expedited coverage determinations. The procedures must be clearly explained in member materials. In addition, Part D plan sponsors will be accountable for educating staff to ensure that requests for expedited review are referred immediately to the Part D plan sponsor's designated office or department for processing such requests. The 24-hour period begins when the enrollee's request is received by the Part D plan sponsor. If the enrollee's request involves an exception, 24-hour period begins when the plan receives the prescribing physician's or other prescriber's supporting statement. See the note in [§40.2](#) regarding when a request or supporting statement is deemed received by a plan sponsor.

50.2.1 - Defining the Medical Exigency Standard (Rev. 1, 11/30/05)

The medical exigency standard requires a Part D plan sponsor and the IRE to make decisions as “expeditiously as an enrollee’s health condition requires.” This standard is set forth in regulations at 42 CFR [423.568\(a\)](#) (standard coverage determinations), [423.572\(a\)](#) (expedited coverage determinations), [423.590\(a\)](#) (standard redeterminations), [423.590\(d\)\(1\)](#) (expedited redeterminations), [423.600\(d\)](#) (reconsiderations by the IRE), [423.636\(a\)\(1\)](#) (plan sponsor effectuating standard redeterminations), [423.638\(a\)](#) (plan sponsor effectuating expedited redeterminations), and [423.638\(b\)](#) (plan sponsor effectuating expedited reversals by the IRE or higher level of appeal). This standard requires the plan sponsor or IRE to apply, at a minimum, established, accepted standards of medical practice in assessing an individual’s medical condition. Evidence of an individual’s condition can be demonstrated by indications from the treating provider or

from the individual's medical record (e.g., an individual's diagnosis, symptoms, or test results).

The medical exigency standard was established by regulation to ensure that plan sponsors develop a system for determining the urgency of both standard and expedited requests for Part D prescription drug benefits, evaluate incoming requests against pre-established criteria, and give each request priority according to that system (i.e., plan sponsors must treat every case in a manner that is appropriate to its medical particulars or urgency). Plan sponsors should not systematically take the maximum time permitted for making decisions.

50.3 - Action Following Denial for Expediting Review

(Rev. **98, 1/1/11+4/40**)

If a Part D plan sponsor denies a request to expedite a coverage determination, it must automatically transfer the request to the standard coverage determination process (as described in §40.2 above), provide prompt oral notice of the denial, and subsequently deliver (i.e., mail) written notice within 3 calendar days after providing oral notice.

- As noted in §10.4.2, if an enrollee has identified a representative, the plan sponsor must provide notice to the enrollee's representative instead of the enrollee.
- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.

The oral notice and written follow-up notice must: give the enrollee and his or her prescribing physician or other prescriber, if involved, prompt oral notice of the denial, which includes the enrollee's rights described below, and subsequently deliver (i.e., mail) to the enrollee, within 3 calendar days, a written letter of the enrollee's rights that:

1. Explains that the plan will automatically transfer and process the request using the 72 hour time frame for standard determinations;
2. Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the plan's decision not to expedite the determination;
3. Informs the enrollee of the right to resubmit a request for an expedited determination and that, if the enrollee gets his or her prescribing physician's or other prescriber's support indicating that applying the standard time frame for making determinations could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function, the request will be expedited automatically; and

4. Provides instructions about the expedited grievance process and its time frames.

CMS has developed a model notice that Part D plan sponsors can use ~~to notify enrollees~~ whenever a request to expedite is denied, (see [Appendix 3](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

50.4 - Action on Accepted Requests for Expedited Determinations (Rev. ~~98, 1/1/11~~**4/10**)

If a plan sponsor grants a request to expedite a coverage determination, a determination must be made in accordance with the following requirements:

1. A Part D plan sponsor that approves a request to expedite a coverage determination must make the determination, whether favorable or adverse, and ~~provide notice to the enrollee and the physician or other prescriber involved, as appropriate,~~ of its decision as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. See the note in [§40.2](#) regarding when a request or supporting statement is deemed received by a plan sponsor. If the Part D plan sponsor's decision is favorable, it must effectuate the decision in accordance with [§130.1](#).
2. If the ~~enrollee's~~ request involves an exception, the Part D plan sponsor must ~~provide notice to the enrollee and the physician or other prescriber involved, as appropriate,~~ of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after the date the plan receives the physician's or other prescriber's supporting statement. See the note in [§40.2](#) regarding when a request or supporting statement is deemed received by a plan sponsor. If the Part D plan sponsor's decision is favorable, it must effectuate the decision in accordance with [§130.1](#).

Note: A plan sponsor may not extend the applicable adjudication time frame by dispensing a temporary supply of the requested medication. For example, if a plan sponsor receives a request outside of its normal business hours, it cannot approve a 72-hour supply of the requested medication and defer issuing a decision for 72 hours; the plan sponsor must make its determination within the appropriate time frame.

Note: A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the written notice described in this section to notify the enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide the enrollee with the notice described in §50.6 instead.

50.5 - Notification of the Result of an ~~Adverse~~ Expedited Coverage Determination
(Rev. ~~98, 1/1/11/1/10~~)

50.5.1 - Written Notification of Adverse Decisions
(Rev. ~~9, 1/1/11~~)

~~If the Part D plan sponsor denies, in whole or in part, a Part D benefit, it must provide written notice of its determination.~~

~~If an enrollee has a representative, the plan sponsor must notify the enrollee's representative instead of the enrollee. If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify the enrollee and the enrollee's prescribing physician or other prescriber.~~

~~A plan sponsor may make its initial notification orally, so long as it also mails a written follow-up decision within 3 calendar days of the oral notification. However, if a plan sponsor issues an adverse expedited coverage determination, in whole or in part, it must provide written notice of the determination.~~

- ~~• If an enrollee files the request, notice must be provided to the enrollee.~~
- ~~• If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).~~
- ~~• If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.~~

~~(a Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the written notice described in this section to notify the enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide the enrollee with the notice described in §50.6 instead). Therefore, if a plan sponsor first makes its adverse notification orally, a follow-up written decision must be mailed within 3 calendar days of the oral notification. A plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with written notice of an adverse determination after providing oral notice to the physician or other prescriber. If a plan sponsor's decision is adverse, the oral (if provided) and written notices must satisfy the requirements stated below. The note in §40.3.2 regarding a good-faith effort to provide oral notice also applies to this section.~~

~~If a plan sponsor's decision is adverse, the oral (if provided) and written notices must satisfy the requirements stated below. The Part D plan sponsor must use approved notice~~

language in [Appendix 1](#). The standardized denial notice form has been written in a manner that is understandable to the enrollee and provides:

1. The specific reason for the denial that takes into account the enrollee's presenting medical condition, disabilities, and special language requirements, if any;
2. Information regarding the right to appoint a representative to file an appeal on the enrollee's behalf; and
3. A description of both the standard and expedited redetermination processes and time frames, including conditions for obtaining an expedited redetermination, and the rest of the appeals process.

The denial rationale must be specific to each individual case and written in a manner calculated for an enrollee to understand.

See [§40.3.3](#) for examples of language that satisfies point 1 above (because it is specific to the individual's case).

50.5.2 - Written Notification of Favorable Decisions **(Rev. 9, 1/1/11)**

If a Part D plan sponsor completely approves a request for a Part D benefit, it must provide written notice of its determination. A plan sponsor may make its initial notification orally, so long as it also mails a written follow-up decision within 3 calendar days of the oral notification.

- If an enrollee files the request, notice must be provided to the enrollee.
- If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).
- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.

The note in §40.3.2 regarding a good-faith effort to provide oral notice also applies to this section.

Any written notice must be written in a manner that is understandable to the enrollee. In addition, the oral (if provided) and written approval notice must explain the conditions of the approval. The conditions of approval may include (but are not limited to):

- The duration of an approval;
- Limitations associated with an approval; and/or
- Any coverage rules applicable to subsequent refills.

The plan sponsor may develop its own notice that meets the regulatory requirements in 42 CFR 423.568(e).

Part D plan sponsors that do not provide notice of a decision within the required timeframe should not use the notice described in this section to notify the enrollee that his or her decision was not made timely and is being forwarded to the IRE, but should provide notice as described in §50.6 instead.

50.6 - Effect of Failure to Provide Timely Notice (Rev. **98, 1/1/11/1/10**)

If a Part D plan sponsor does not provide notice of its expedited coverage determination within the required time frame, it must forward the complete case file to the IRE contracted by CMS within 24 hours of the expiration of the adjudication time frame.

Note: Because the adjudication time frame for an exceptions request involving a request for benefits does not begin until the plan sponsor receives the physician's or other prescriber's supporting statement as indicated in §§30.2.1.230.2.1 and 30.2.2.230.2.2, plan sponsors must not automatically forward case files to the IRE if a physician or other prescriber has not submitted an oral or written supporting statement. Instead, plan sponsors should issue decisions in accordance with the guidance provided in §§30.2.1 and 30.2.2.

Note: If a plan sponsor makes a completely favorable decision soon after the adjudication timeframes expires (i.e., within 24 hours) and notifies the enrollee of the decision, the plan sponsor should not forward the case file to the IRE and provide the notice described in this section. Plan sponsors should use this exception sparingly. If a plan sponsor does not regularly meet the adjudication timeframe and CMS finds that the plan sponsor uses this exception frequently, CMS may consider the plan sponsor in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with subpart O of 42 CFR Part 423.

The case file must contain the enrollee's request and any oral and/or written evidence obtained by the plan sponsor. Part D plan sponsors should also refer to §§70.30 and 70.40 to determine how to prepare the case file for the IRE and what documents/items to send with the case file. The Part D plan sponsor must deliver a hard copy of the case file

to the IRE by overnight delivery at its designated address, or by fax at its designated fax number. The Part D plan sponsor should refer to the IRE's Reconsideration Process Manual for additional instructions.

Although the Part D plan sponsor's failure to provide notice of a decision within the required timeframe constitutes an adverse decision, the plan sponsor must not send the ~~adverse~~ decision notice described in §~~50.5.150.5~~ to the enrollee. Instead, the Part D plan sponsor must notify the enrollee that it has forwarded his or her request to the independent entity for review. The plan sponsor must send the notification within 24 hours of the expiration of the adjudication time frame. The notice must advise the enrollee of his/her right to submit additional evidence that may be pertinent to the enrollee's case, if the enrollee chooses. The notice must direct the enrollee to submit such evidence to the IRE, and must include information on how to contact the IRE. CMS has developed a model notice that Part D plan sponsors can use to notify enrollees whenever cases are forwarded to the IRE, (see [Appendix 6](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

If CMS determines that the Part D plan sponsor has a pattern of not concluding expedited coverage determinations within the required time frame or not forwarding the enrollee's request to the IRE for review within the required time frame, the Part D plan sponsor may be considered to be in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with [subpart O of 42 CFR Part 423](#).

Transition Period Note:

The "Transition Period Note" in §[40.4](#) also applies to this section.

60 - Appeals

60.1 - Parties to the Coverage Determination for Purposes of an Appeal (Rev. ~~98, 1/1/111/1/10~~)

The parties to a coverage determination include the enrollee and the enrollee's representative, if applicable. In some cases, as described in §[10.5](#), the enrollee's prescribing physician or other prescriber is also a party. However, an enrollee's prescribing physician or other prescriber does not have all of the rights and responsibilities of the enrollee with respect to party status, unless the physician or other prescriber is the enrollee's representative.

Only the enrollee or the enrollee's representative may request an appeal, with the exception that the enrollee's prescribing physician or other prescriber may request a standard or expedited redetermination. ~~(Note: An expedited redetermination can not involve a request for payment of prescription drug benefits that the enrollee has paid for out of pocket).~~

70 - Redetermination

(Rev. 1, 11/30/05)

The Part D plan sponsor's adverse coverage determination must inform the enrollee of his/her right to a redetermination and the right to be represented by an attorney or other representative in the appeals process. Instructions on how and where to file a request for redetermination must also be included. In addition, the member handbook or other materials must include information about free legal services available for qualified individuals. The redetermination consists of a review of an adverse coverage determination, the evidence and findings upon which it was based, and any other evidence that the parties submit or that is obtained by the Part D plan sponsor.

70.1 - Who May Request a Redetermination

(Rev. ~~98, 1/1/11~~ 1/1/14)

An enrollee, ~~or an enrollee's representative, or an~~ may request any appeal. ~~In addition, the enrollee's prescribing physician or other prescriber may request a standard or an expedited redetermination without being the enrollee's representative. However, these are the only appeals that an enrollee's prescribing physician or other prescriber may request on an enrollee's behalf unless he or she is the enrollee's representative.~~

Note: Under [42 CFR 423.580](#), a non-representative physician or other prescriber may request a *standard* redetermination on an enrollee's behalf only after he or she has provided notice to the enrollee that he or she is making the appeal request ([physicians or other prescribers are not required to provide such notice to enrollees when requesting expedited redeterminations](#)).

- (MA-PD plans only) If the redetermination request comes from an enrollee's primary care physician in the MA-PD plan's network, enrollee notice verification (i.e., proof that the physician notified the enrollee of the redetermination request) is not required.
- (PDP and MA-PD plans) If the enrollee's records indicate that he or she previously visited the requesting physician or other prescriber, the plan sponsor may assume the physician or other prescriber has informed the enrollee about the request and further verification is not needed.
- (PDP and MA-PD plans) If the enrollee's records indicate that he or she has not previously visited the requesting physician or other prescriber, the plan sponsor should undertake reasonable efforts to confirm that the physician or other prescriber has given the enrollee appropriate notice of the appeal. For example:
 - If the physician/prescriber makes the request by phone, the plan sponsor may verbally confirm with the physician/prescriber that the enrollee

knows the physician/prescriber is making the request on the enrollee's behalf.

- If the plan sponsor has developed its own redetermination request form, it may amend the form to include boilerplate language and a checkbox indicating the physician/prescriber is making the request on the enrollee's behalf with the enrollee's knowledge and approval.
- If the physician/prescriber makes the request by fax, letter, or email, the enrollee is copied on the correspondence, and/or the request includes a statement affirming the enrollee knows the physician/prescriber is making the request on the enrollee's behalf with the enrollee's knowledge and approval.
- A customer service representative may call the enrollee and ask if the physician/prescriber is making the request on his or her behalf with his or her knowledge and approval.

70.2 - How to Request a Standard Redetermination

(Rev. ~~98, 1/1/11~~~~1/1/10~~)

A party ([see §70.1](#)) may request a standard redetermination by filing a signed written request with the Part D plan sponsor. Except when the filing time frame is extended, the request must be filed within 60 calendar days from the date ~~printed or written on the written coverage determination notice of the notice of the coverage determination (i.e., the date printed or written on the notice) (i.e., the 60-day timeframe does not begin on the date verbal notice is received).~~

A Part D plan sponsor may accept oral requests for redetermination. If a Part D plan sponsor chooses to accept an oral appeal request, the Part D plan sponsor must document the oral request in writing in the enrollee's own words, repeat the request back to the enrollee to confirm the accuracy, and place the request into a tracking system. If a department other than one that responds to redeterminations receives the request, it should transfer the call to the appropriate department.

In the event that a plan does not accept oral requests for standard redeterminations, and it determines that an enrollee's oral complaint should be classified as a standard request for a redetermination, the plan must explain the procedures the enrollee must follow to file a written request for a standard redetermination. If an enrollee, prescribing physician, or other prescriber files an oral request for an expedited redetermination (which must be accepted orally and in writing) and the plan sponsor does not grant the request to expedite, the plan sponsor cannot require the enrollee to re-file the request in writing. Instead, the plan sponsor must transfer the request to the standard process as described in [§70.7](#).

70.3 - Good Cause Extension (Rev. 8, 1/1/10)

If a party shows good cause, the Part D plan sponsor may extend the time frame for filing a request for redetermination. The Part D plan sponsor should consider the circumstance that kept the party from making the request on time and whether any actions by the plan may have misled the party. Examples of circumstances where good cause may exist include (but are not limited to) the following situations:

1. The party was prevented by serious illness from contacting the plan in person, in writing, or through a friend, relative, or other person;
2. The party had a death or serious illness in his or her immediate family;
3. Important records were destroyed or damaged by fire or other accidental cause;
4. The plan or its designated entity gave the enrollee, the enrollee's representative, or the enrollee's prescribing physician or other prescriber incorrect or incomplete information about when and how to request a redetermination;
5. The enrollee, representative, or prescribing physician or other prescriber did not receive notice of the determination or decision; or
6. The enrollee, representative, or prescribing physician or other prescriber sent the request to another Government agency in good faith within the time limit and the request did not reach the correct plan until after the time period had expired.

The party requesting the good-cause extension must file a written request with the Part D plan sponsor, and include the reason why the request was not filed timely. If the Part D plan sponsor denies a party's request for a good cause extension, the party may file a grievance with the Part D plan sponsor, but the party does not have the right to appeal the plan sponsor's denial of the good-cause extension.

70.4 - Withdrawal of Request for Redetermination (Rev. ~~91, 1/1/1111/30/05~~)

The party ([see §70.1](#)) who files a request for redetermination may submit a written request to the Part D plan asking to withdraw the request at any time before a decision is mailed. A plan sponsor may also accept such requests orally, provided that the Part D plan sponsor sends (i.e., mails) a written confirmation of the withdrawal to the party within 3 calendar days from the date of the oral request.

If a withdrawal request is received by a Part D plan sponsor before the plan has made its redetermination decision, the plan may dismiss the appeal. However, if the withdrawal request is received after the Part D plan sponsor has forwarded a case file to the IRE

because the plan sponsor did not provide notice of its decision within the appropriate time frame, the plan must forward the withdrawal request to the IRE for processing.

70.5 - Opportunity to Submit Evidence (Rev. 8, 1/1/10)

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 issues in dispute, in person as well as in writing. A plan sponsor satisfies the in-person requirement if it accepts evidence by telephone or fax, or accepts evidence that is hand-delivered by enrollees to a plan's physical location.

Note: The in-person requirement is not intended to require plan sponsors to provide in-person hearings for enrollees.

In the case of an expedited redetermination, the opportunity to present evidence is limited by the short time frame for making a decision. Therefore the Part D plan sponsor may develop reasonable conditions for submitting evidence and must inform the parties of such conditions. For example, a plan may set a deadline for submitting evidence or require oral evidence to be submitted by telephone.

The Part D plan sponsor must take all of the evidence submitted orally and/or in writing into account when making a decision. In addition, the Part D plan sponsor must, upon an enrollee's request, provide the enrollee with a copy of the contents of the case file, including, but not limited to, a copy of supporting medical records and other pertinent information used to support the decision. The Part D plan sponsor must abide by all Federal and state laws regarding confidentiality and disclosure for mental health records, medical records, or other health information. See [45 CFR 164.500](#) et seq. (regarding the privacy of individually identifiable health information).

The Part D plan sponsor must make every reasonable effort to accommodate an enrollee's request for case file material including, but not limited to, allowing the enrollee or representative to obtain the material at a plan location or mailing the material to any address specified by the enrollee or representative. The Part D plan sponsor shall have the right to charge the enrollee a reasonable amount (e.g., comparable to charges established by a QIO) for duplicating the case file material. At the time that the request for case file material is made, the Part D plan sponsor must inform the enrollee of the per page duplicating cost, and based on the extent of the case file material requested, provide an estimate of the total duplicating cost for which the enrollee will be responsible. The Part D plan sponsor may also charge the enrollee the cost of mailing the material to the address specified. The Part D plan sponsor may not charge the enrollee an additional cost for courier delivery of the material to a plan location that would be over and above the cost of mailing the material to the enrollee.

70.6 - Who Must Conduct a Redetermination (Rev. 1, 11/30/05)

The Part D plan sponsor must designate someone other than the person involved in making the initial coverage determination to make a redetermination. If the original denial was based on a lack of medical necessity (i.e., the non-preferred or non-formulary drug was not medically necessary for treating the enrollee's condition when compared with the preferred or formulary drug, or the drug was denied because it was not reasonable and necessary under section [1862\(a\)\(1\)](#) of the Act), the redetermination must be performed by a physician with expertise in the field of medicine that is appropriate for the drug benefits at issue.

70.6.1 - Meaning of Physician With Expertise in the Field of Medicine (Rev. 8, 1/1/10)

The physician need not, in all cases, be of the same specialty or subspecialty as the enrollee's prescribing physician or other prescriber. The physician must, however, possess the appropriate level of training and expertise to evaluate the necessity of the requested drug. This does not require the physician to always possess identical specialty training. For example, where there are few practitioners in a highly specialized field of medicine, a plan sponsor may not be able to hire a physician of the same specialty or subspecialty to review the adverse coverage determination.

70.7 - Time Frames and Responsibilities for Conducting Standard Redeterminations (Rev. ~~92~~, [1/1/11/6/22/06](#))

The Part D plan sponsor must ~~provide written notice~~[notify the enrollee in writing](#) of its redetermination, whether favorable or adverse, as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date the Part D plan sponsor receives the request for a standard redetermination ([See the note in §40.2 regarding when a request is deemed received by a plan sponsor](#)).

~~(Part D plan sponsors that do not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in [§70.7.1](#) instead). [See the note in §40.2 regarding when a request is deemed received by a plan sponsor](#).~~

If the decision is adverse, ~~the plan sponsors~~ must process the decision in accordance with [§70.9.1](#). [If the decision is completely favorable, the plan sponsor must process the decision in accordance with §70.9.2](#). In addition, if the Part D plan sponsor overturns its adverse coverage determination, it must effectuate it in accordance with [§130.2](#).

~~**Note:**~~ A plan sponsor may not extend the applicable adjudication time frame by dispensing a temporary supply of the requested medication. For example, if a plan

sponsor receives a request outside of its normal business hours, it cannot approve a 72-hour supply of the requested medication and defer issuing a decision for 72 hours; the plan sponsor must make its determination within the appropriate time frame.

Occasionally, the Part D plan sponsor may not have all of the information it needs to make a redetermination. The plan must make reasonable and diligent efforts to obtain all necessary medical records and other pertinent information within the required time limits and document its attempts. If the Part D plan sponsor cannot obtain all relevant documentation, it must make the decision based on the evidence available. If a plan does not make a decision in the applicable time frame, the plan must forward the request and case file containing any oral and/or written evidence obtained to the IRE for review as described in [§70.7.1](#).

70.7.1 - Effect of Failure to Meet the Time Frame for Standard Redetermination (Rev. 3, 2/1/07)

Although the Part D plan sponsor's failure to provide notice of a decision within the required timeframe constitutes an adverse decision, the plan sponsor must not send the adverse decision notice described in [§70.7](#) to the enrollee. Instead, if the Part D plan sponsor fails to provide the enrollee with a redetermination within the time frames specified in [§70.7](#), it must forward the complete file to the IRE and provide notice, according to the procedures set forth in [§70.10](#). If CMS determines that the Part D plan sponsor has a pattern of not concluding its standard redeterminations within the required time frames or not making reasonable and diligent effort to gather and forward information to the IRE, then the Part D plan sponsor may be considered to be in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with [subpart O of 42 CFR Part 423](#).

Transition Period Note:

The "Transition Period Note" in [§40.4](#) also applies to this section.

70.7.2 - Processing a Standard Pre-Benefit Redetermination as a Request for Payment (Rev. 8, 1/1/10)

If an enrollee has requested a standard pre-benefit redetermination and the Part D plan sponsor becomes aware that the enrollee has obtained the prescription drug before it completes its redetermination, the Part D plan sponsor must stop processing the claim as a pre-benefit redetermination, and process the claim as a request for payment instead (i.e., process the claim as a redetermination request for payment).

If, after the enrollee submitted the pre-benefit appeal, the Part D plan sponsor is not aware that the enrollee has already received the requested drug and the plan continues to deny the pre-benefit redetermination and sends the case to the IRE on appeal, the IRE must stop processing the claim as a pre-benefit reconsideration, and process the claim as

a request for payment if it receives information indicating that the drug has been obtained.

70.8 - Expediting Certain Redeterminations

(Rev. ~~98, 1/1/11~~1/1/10)

~~A party (see §70.1) may request an expedited redetermination by an enrollee, the enrollee's representative, or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a redetermination~~ in situations where applying the standard time frame could seriously jeopardize the enrollee's life, health, or ability to regain maximum function. ~~The Part D plan sponsor must accept both oral and written requests.~~ A request for payment of a benefit already provided to an enrollee is not eligible to be reviewed as an expedited redetermination.

To ask for an expedited redetermination, the party must submit an oral or written request directly to the plan or entity responsible for making the redetermination within 60 calendar days from the date of the notice of the coverage determination (Part D plan sponsor must accept both oral and written requests). The Part D plan sponsor may extend the time frame for filing an expedited request as noted in §70.3. A request may be withdrawn. An enrollee may withdraw his or her request as described in §70.4.

The enrollee's prescribing physician or other prescriber may provide oral or written support for a request made by an enrollee. The Part D plan sponsor must expedite a redetermination if it determines, or an enrollee's prescribing physician or other prescriber indicates, that applying the standard time frame could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

If an enrollee requests an appeal of a plan sponsor's adverse expedited coverage determination, the plan may choose to expedite the redetermination without requiring the enrollee's prescribing physician or other prescriber to submit a new statement indicating that applying the standard time frame could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. However, if a plan sponsor chooses to do so, it should, at a minimum, ensure that the enrollee has not obtained the drug in dispute (i.e. paid for the drug out-of-pocket).

70.8.1 - How the Part D Plan Sponsor Processes Requests for Expedited Redetermination

(Rev. ~~98, 1/1/11~~1/1/10)

The plan must establish and maintain procedures for expediting redeterminations, including procedures that establish an efficient and convenient method for individuals to submit oral or written requests for expedited appeals, documenting oral requests (e.g., entering oral requests into an internal tracking system), and maintaining the documentation in the case file. The Part D plan sponsor must designate an office and/or department to receive both oral or written requests and a telephone number for oral

requests, and may include a facsimile number to facilitate receipt of requests for expedited appeals.

A Part D plan sponsor must promptly determine if a request must be expedited. If the oral or written request is made by a physician or other prescriber, or supported by a physician's or other prescriber's oral or written statement, the Part D plan sponsor must grant the request to expedite if the physician or other prescriber indicates that the enrollee's life, health, or ability to regain maximum function could be jeopardized by applying the standard time frame for processing the redetermination request. If a Part D plan sponsor denies a request for an expedited redetermination, it must automatically transfer the request to the standard redetermination process and provide the enrollee with prompt oral notice of the denial and the enrollee's rights. The oral notice must meet requirements 1-4 described below. The plan sponsor must subsequently deliver a written notice to the enrollee within 3 calendar days of the oral notification. The written notice must:

1. Explain that the Part D plan sponsor will automatically transfer and process the request using the 7-day time frame for standard redeterminations;
2. Inform the enrollee of the right to file an expedited grievance if he or she disagrees with the plan's decision not to expedite the redetermination;
3. Inform the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's or other prescriber's support, and explain that if the physician or other prescriber indicates that applying the standard time frame for making a determination could seriously jeopardize the enrollee's life, health or ability to regain maximum function, the request will be expedited automatically; and
4. Provide instructions about the grievance process and the applicable time frames.

CMS has developed a model notice that Part D plan sponsors can use to notify enrollees whenever a request to expedite is denied, (see [Appendix 3](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

If the Part D plan sponsor approves a request to expedite a redetermination, it must complete the expedited redetermination and give ~~the enrollee (and the 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. See the note in [§40.2](#) regarding when a request is deemed received by a plan sponsor.

~~Notice may be provided orally or in writing. However, Notice of completely favorable expedited redeterminations must be provided in writing in accordance with §70.9.4. Notice of adverse expedited redeterminations must be provided in writing in accordance with §70.9.32. (a~~

△ Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in [§70.8.2](#) instead).

A plan sponsor may not extend the applicable adjudication time frame by dispensing a temporary supply of the requested medication. For example, if a plan sponsor receives a request outside of its normal business hours, it cannot approve a 72-hour supply of the requested medication in dispute and defer issuing a decision for 72 hours; the plan sponsor must make its determination within the appropriate time frame.

If the Part D plan sponsor requires additional medical information, it must request the necessary information within 24 hours of receiving the initial request for an expedited redetermination. See the note in [§40.2](#) regarding when a request is deemed received by a plan sponsor. A prescribing physician, other prescriber, or other staff responsible for responding to a plan sponsor's request should make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the Part D plan sponsor in meeting the required time frame. Regardless of whether the Part D plan sponsor requests additional information, the Part D plan sponsor is responsible for meeting the time frame and notice requirements. CMS has developed a model notice that Part D plan sponsors can use to request additional information (see [Appendix 11](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

70.8.2 - Effect of Failure to Meet the Time Frame for Expedited Redetermination (Rev. 3, 2/1/07)

Although the Part D plan sponsor's failure to provide notice of a decision within the required timeframe constitutes an adverse decision, the plan sponsor must not send the adverse decision notice described in [§70.8.1](#) to the enrollee. Instead, if a Part D plan sponsor does not notify the enrollee within the required time frame set forth in [§70.8.1](#), the failure constitutes an adverse decision and the Part D plan sponsor must forward the complete file to the IRE and provide notice according to the procedures set forth in [§70.10](#). If CMS determines that the Part D plan sponsor has a pattern of not concluding its expedited redeterminations within the required time frames or not making reasonable and diligent efforts to gather and forward information to the independent review entity, then the Part D plan sponsor may be considered to be in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with [subpart O of 42 CFR Part 423](#).

Transition Period Note:

The "Transition Period Note" in [§40.4](#) also applies to this section.

70.9 - Notification of the Result of an Adverse Redetermination

70.9.1 - Adverse Standard Redeterminations

(Rev. ~~98, 1/1/11/1/10~~)

If a Part D plan sponsor's standard redetermination decision is adverse, in whole or in part, it must provide written notice of its decision ~~to the enrollee~~ as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date the Part D plan sponsor receives the request (see the note in §40.2 regarding when a request is deemed received by a plan sponsor).

- If an enrollee files the request, notice must be provided to the enrollee.
- If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).
- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must provide written notice to both the prescriber and the enrollee.

~~(a Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.7.1 instead). See the note in §40.2 regarding when a request or supporting statement is deemed received by a plan sponsor. As noted in §10.4.2, if an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of to the enrollee.~~

The plan sponsor may use the model notice language contained in [Appendix 4](#), or it may develop its own notice that meets the regulatory requirements in [42 CFR 423.590\(g\)](#). If a plan sponsor makes any substantive change to a model notice or develops its own notice that meets the regulatory requirements in [42 CFR 423.590\(g\)](#), the proposed change or notice must be approved through the appropriate CMS marketing procedures. The denial notice must be written in a manner that is understandable to the enrollee, and must:

1. State the specific reasons for the denial;
2. Inform the enrollee of his or her right to a reconsideration;
 - a. 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;
 - b. For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and

3. Contain the enrollee's HIC number, the plan name, the plan identification number, the contract identification number, and the formulary identification number.

Plan sponsors must complete the applicable sections of the model Request for Reconsideration form (see [Appendix 13](#)) and send it to the enrollee (and physician or other prescriber when appropriate) with each adverse redetermination notice. If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.7.1 instead.

70.9.2 - Favorable Standard Redeterminations **(Rev. 9, 1/1/11)**

If a Part D plan sponsor's standard redetermination decision is completely favorable, it must provide written notice of its decision as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date the Part D plan sponsor receives the request (see the note in §40.2 regarding when a request is deemed received by a plan sponsor).

- If an enrollee files the request, notice must be provided to the enrollee.
- If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).
- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must provide written notice to both the prescriber and the enrollee.

The approval notice must be written in a manner that is understandable to the enrollee, and must explain the conditions of the approval. The conditions of approval may include (but are not limited to):

- The duration of an approval;
- Limitations associated with an approval; and/or
- Any coverage rules applicable to subsequent refills.

The plan sponsor may develop its own notice that meets the regulatory requirements in 42 CFR 423.590(h).

A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.7.1 instead.

70.9.32 - Adverse Expedited Redeterminations (Rev. 98, 1/1/11+4/40)

If a Part D plan sponsor's expedited redetermination decision is adverse, in whole or in part, it must provide notice ~~to the enrollee of its determination~~ as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the date and time the Part D plan sponsor receives the request (see the note in §40.2 regarding when a request is deemed received by a plan sponsor). ~~(a Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.8.2 instead). See the note in §40.2 regarding when a request is deemed received by a plan sponsor. As noted in §10.4.2, if an enrollee has identified a representative, the plan sponsor must notify the enrollee's representative instead of the enrollee. Additionally, if an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify the enrollee and the enrollee's prescribing physician or other prescriber.~~

A plan sponsor may make its initial notification orally. However, if a plan sponsor issues an adverse expedited redetermination, in whole or part, it must provide written notice of the decision. Therefore, if a plan sponsor first makes its adverse notification orally, a follow-up written decision must be mailed within 3 calendar days of the oral notification ~~(note that a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with written notice of an expedited adverse redetermination after providing notice to the physician or other prescriber orally).~~

- If an enrollee files the request, notice must be provided to the enrollee.
- If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).
- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.

~~If a plan sponsor's decision is adverse, the oral (if provided) and written notices must satisfy the requirements stated below.~~The note in §40.3.2 regarding a good-faith effort to provide oral notice also applies to this section.

~~The plan sponsor may use the model notice language contained in Appendix 4, or it may develop its own notice that meets the regulatory requirements in 42 CFR 423.590(g). If a plan sponsor makes any substantive change to a model notice, or it develops its own notice that meets the regulatory requirements in 42 CFR 423.590(g), the proposed change or notice must be approved through the appropriate CMS marketing procedures. Any written notice must be written in a manner that is understandable to the enrollee. In addition, the oral (if provided) and written denial notice must be written in a manner that is understandable to the enrollee, and must:~~

1. State the specific reasons for the denial;
2. Inform the enrollee of his or her right to a reconsideration;
 - a. 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;
 - b. For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and
3. Contain the enrollee's HIC number, the plan name, the plan identification number, the contract identification number, and the formulary identification number.

~~The plan sponsor may use the model notice language contained in Appendix 4, or it may develop its own notice that meets the regulatory requirements in 42 CFR 423.590(g). If a plan sponsor makes any substantive change to a model notice, or it develops its own notice that meets the regulatory requirements in 42 CFR 423.590(g), the proposed change or notice must be approved through the appropriate CMS marketing procedures.~~

Plan sponsors must complete the applicable sections of the model Request for Reconsideration form (see [Appendix 13](#)) and send it to the enrollee (and physician or other prescriber when appropriate) with each adverse redetermination notice. If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

~~A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.8.2 instead.~~

70.9.4 - Favorable Expedited Redeterminations **(Rev. 9, 1/1/11)**

If a Part D plan sponsor's expedited redetermination decision is completely favorable, it must provide written notice of its decision as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the date and time the Part D plan sponsor receives the request (see the note in §40.2 regarding when a request is deemed received by a plan sponsor. A plan sponsor may make its initial notification orally. However, if a plan sponsor issues a completely favorable expedited redetermination, ~~in whole or part~~, it must provide written notice of the decision. Therefore, if a plan sponsor first makes its favorable notification orally, a follow-up written decision must be mailed within 3 calendar days of the oral notification.

- If an enrollee files the request, notice must be provided to the enrollee.
- If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).
- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.

The note in §40.3.2 regarding a good-faith effort to provide oral notice also applies to this section.

Any written notice must be written in a manner that is understandable to the enrollee. In addition, the oral (if provided) and written approval notice must explain the conditions of the approval. The conditions of approval may include (but are not limited to):

- The duration of an approval;
- Limitations associated with an approval; and/or
- Any coverage rules applicable to subsequent refills.

The plan sponsor may develop its own notice that meets the regulatory requirements in 42 CFR 423.590(h).

A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.7.1 instead.

70.10 - Forwarding Untimely Redeterminations to the Independent Review Entity

(Rev. 98, ~~1/1/11/4/10~~)

If a Part D plan sponsor does not provide notice of its standard or expedited redetermination within the required time frame, it must forward the complete case file to the IRE within 24 hours of the expiration of the adjudication time frame. The case file must satisfy the requirements in §70.30. The Part D plan sponsor must deliver a hard copy of the case file to the IRE by overnight delivery at its designated address, or by fax at its designated fax number. The Part D plan sponsor should refer to the IRE's Reconsideration Process Manual for additional instructions.

Note: If a plan sponsor makes a completely favorable decision soon after the adjudication timeframes expires (i.e., within 24 hours) and notifies the enrollee of the decision, the plan sponsor should not forward the case file to the IRE and provide the notice described in this section. Plan sponsors should use this exception sparingly. If a plan sponsor does not regularly meet the adjudication timeframe and CMS finds that the plan sponsor uses this exception frequently, CMS may consider the plan sponsor in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with [subpart O of 42 CFR Part 423](#).

Note: As indicated in §10.5, an enrollee's prescribing physician or other prescriber may request a coverage determination or redetermination on an enrollee's behalf, ~~but-~~ ~~Thus, an enrollee's physician or other prescriber~~ is prohibited from requesting a higher appeal without being the enrollee's representative. However, when a request for a coverage determination or redetermination that is initiated by an enrollee's physician or other prescriber is automatically forwarded to the IRE under §§50.6 or 70.10, the physician or other prescriber is not required to be the enrollee's representative for the IRE to review the forwarded request. If the IRE issues an adverse decision, the enrollee's physician or other prescriber must become the enrollee's representative, as indicated in §10.4, to file any further appeal on the enrollee's behalf.

Although the Part D plan sponsor's failure to provide notice of a decision within the required timeframe constitutes an adverse decision, the plan sponsor must not send the adverse decision notice described in §70.7 or §70.8.1 to the enrollee. Instead, the Part D plan sponsor must notify the enrollee that it has forwarded his or her request to the IRE for review. The plan sponsor must send the notification within 24 hours of the expiration of the adjudication time frame. The notice must advise the enrollee of his/her right to submit additional evidence to the IRE and must include information on how to contact the IRE. CMS has developed a model notice that Part D plan sponsors can use to notify enrollees whenever cases are forwarded to the IRE, (see [Appendix 6](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

If CMS determines that the Part D plan sponsor has a pattern of not concluding its redeterminations within the required time frames or not making reasonable and diligent effort to gather and forward information to the IRE, then the Part D plan sponsor may be considered to be in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with [subpart O of 42 CFR Part 423](#).

Transition Period Note:

The "Transition Period Note" in [§40.4](#) also applies to this section.

70.20 - Time Frame for Forwarding Case Files to the Independent Review Entity

(Rev. **93**, [1/1/112/4/07](#))

In cases where an enrollee has filed a reconsideration request and the IRE has requested the enrollee's file from the Part D plan sponsor, the plan sponsor must ensure that the IRE receives a hard copy of the case file and all of its contents within 24 hours (expedited requests) or 48 hours (standard requests) from the time it receives the IRE's request for the case file. The case file must contain the information described in [§70.30](#). The Part D plan sponsor may determine what method of delivery will ensure that the IRE will receive the case file within the applicable time frame (e.g., overnight delivery at the IRE's designated address or by fax at its designated fax number). The Part D plan sponsor should refer to the IRE's Reconsideration Process Manual for additional instructions.

Transition Period Note:

~~The "Transition Period Note" in [§40.4](#) also applies to this section. The memorandum "Next Steps on Formulary Transition Policies" dated March 17, 2006 explains the steps a plan sponsor must take to ensure a meaningful transition process for a new enrollee who has been, prior to enrollment, stabilized on a medication that is either not on the plan formulary or is subject to utilization management requirements. Two of the steps involve plan sponsors providing a temporary supply of the requested medication and sending the enrollee a written notice explaining when the supply will end and the procedures for requesting an exception. A transition process is not meaningful if an enrollee who is in the transition period files an exception request and the plan sponsor does not make a decision timely or does not forward the enrollee's request/case file to the IRE within the appropriate time frame. Therefore, as explained in the memorandum "Critical Steps As Transition Period Ends" dated March 30, 2006, **when an enrollee who is in the transition period files an exception request and the plan does not make its decision timely and/or fails to forward a request/case file to the IRE as required, the plan sponsor should provide the enrollee with a temporary supply of the requested prescription drug (when not medically contraindicated) until the case is resolved by the plan sponsor or the IRE issues a reconsideration decision.** The memoranda referenced above can be viewed on the HPMS Guidance History webpage: <http://www.cms.hhs.gov/PrescriptionDrugCovContra/HPMSGH/list.asp>.~~

For more information about the transition policy, see Chapter 6 (Part D Drugs and Formulary Requirements), §30.4 of the Prescription Drug Benefit Manual:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp

70.30 - Preparing the Case File for the Independent Review Entity (Rev. 8, 1/1/10)

Note: Part D plan sponsors should also refer to [§70.40](#) to determine what documents/items to send with the case file.

All case files involving a completed coverage determination and redetermination **must include** the following documents:

- Reconsideration Case File Transmittal Form and Case Narrative Form.
- Request for a Coverage Determination and the Coverage Determination Notice.
- Request for a Redetermination and the Redetermination Notice.
- Redetermination evidence presented by the enrollee and/or the prescribing physician or other prescriber.
- Representation documentation for representative appeals.
- Expedited information regarding the Coverage Determination and Redetermination.
- A complete copy of the relevant Evidence of Coverage or other subscriber materials on a CD.

In addition to the documents that must be included with all case files sent to the IRE, case files involving an exceptions request should include:

- A statement from the prescribing physician or other prescriber addressing the medical necessity for an exceptions request in accordance with the standards set forth in 42 CFR 423.578(a)(4) and 423.578(b)(5). Any initial oral or written statement, and any subsequently submitted written statements, should be provided. Additionally, the name and specialty of the prescribing physician or other prescriber should be clearly identified, and contact numbers for office address, telephone, fax and email should be provided.
- A complete copy of the relevant plan formulary on a CD, including descriptions of any utilization management requirements relative to the drug in dispute.
- Exceptions process/criteria for determining medical necessity for the drug in dispute.
- Medical Records relevant to the drug in dispute.
- A detailed statement explaining the basis for the plan sponsor's denial. The plan sponsor's statement should mirror the steps of the plan sponsor's exceptions process/criteria, and indicate precisely which criteria were not met.
- Any internal plan sponsor medical reviews that were obtained during redetermination review with regard to the disputed drug benefit.
- A precise description of medical documentation that is missing from the case file if the plan sponsor's adverse decision is based on the failure of the prescribing physician or other prescriber to submit additional medical documentation as requested by the plan sponsor.

In addition to the documents that must be included with all case files sent to the IRE, case files involving a medical necessity issue (that is not an exceptions request) should include:

- A complete copy of the relevant plan formulary on a CD, including descriptions of any utilization management requirements relative to the drug in dispute.
- Written or oral statements provided by the prescribing physician or other prescriber. The name and specialty of the prescribing physician or other prescriber should be clearly identified, and contact numbers for street address, telephone, fax and email should be provided.
- Medical Records relevant to the drug in dispute.
- A detailed statement explaining the basis for the plan sponsor's denial.
- Any internal plan sponsor medical reviews that were obtained during redetermination review with regard to the disputed drug benefit.
- A precise description of medical documentation that is missing from the case file if the plan sponsor's adverse decision is based on the failure of the prescribing physician or other prescriber to submit additional medical documentation as requested by the plan sponsor.

Part D plan sponsors should refer to the most current version of the IRE's Reconsideration Process Manual for information concerning the Reconsideration Case File Transmittal Form and Case Narrative Form. These forms can be downloaded at <http://www.medicarepartdappeals.com>. Plan sponsors are expected to fully complete all appropriate sections of the Reconsideration Case File Transmittal Form in support of CMS' appeals data collection activities.

An enrollee is entitled to request a copy of his or her complete case file upon request. Although not required, a plan sponsor may charge a fee for providing the copy.

70.40 - Including the Evidence of Coverage and Formulary in Case Files (Rev. 8, 1/1/10)

CMS strongly recommends that Part D plan sponsors include complete copies of the relevant Evidence of Coverage (EOC) and formulary with any case files sent to the IRE for review (the EOC and formulary should be **copied onto a CD** which is sent to the IRE; **do not send paper copies of the EOC and formulary to the IRE**). The previous practice, with respect to EOCs and formularies, was to include relevant excerpts of these plan documents, rather than entire copies, in case files requested by an Administrative Law Judge (ALJ). However, the Office of Medicare Hearings & Appeals (OMHA) ALJs have indicated that these documents are needed in their entirety in order to properly adjudicate appeals. Additionally, the Medicare Appeals Council (MAC) has declined to review certain Part D cases referred for own motion review because the ALJ did not have access to a complete copy of the relevant Part D plan formulary and/or EOC at the time of the ALJ hearing. Therefore, it is in a plan's best interest to ensure that each case file sent to the Part D IRE includes a CD with complete versions of the EOC and formulary relevant to an enrollee's specific case. Failure to include this information could result in

an unfavorable appeals decision and/or CMS declining to refer an ALJ decision to the MAC for review.

If a plan sponsor chooses to implement this recommendation, the complete EOC and formulary (if applicable) that is relevant to the enrollee's appeal must be put on a CD and included with the case file that is sent to the Part D IRE. Plans may not mail or fax paper copies of the complete EOC and/or formulary to the IRE.

Plan sponsors choosing to include the CD with the case file must do so in the following manner:

- The CD must be properly labeled with the plan name and contract number, formulary ID, enrollee name/HICN, and appeal number;
- The CD must be securely affixed to the paper case file;
- All documents on the CD must be in PDF or Word format and should not be encrypted (none of the documents on the CD contain PHI); and
- The CD should only include the EOC and formulary applicable to the specific case being adjudicated (a plan must not place copies of all of its EOCs and formularies on the CD).

80 - Reconsiderations by the Independent Review Entity **(Rev. 2, 6/22/06)**

The IRE, which is commonly referred to as the Part D Qualified Independent Contractor (QIC), must conduct the reconsideration as expeditiously as the enrollee's health condition requires, but not exceed the time frames applicable for Part D plan sponsors when making redeterminations under §§[70.7](#) and [70.8.1](#).

When the IRE completes its reconsideration, it is responsible for mailing or otherwise transmitting notification of the decision to all the parties.

The reconsideration notice must be written in a manner that is understandable to the enrollee and that takes into account the enrollee's presenting medical condition(s), disabilities, or special language requirements, if any, and:

1. Include specific reasons for the entity's decision;
2. If the decision is adverse (i.e., does not completely reverse the plan's adverse determination), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the appropriate threshold requirement; and
3. Describe procedures that the enrollee must follow to obtain an ALJ hearing, including the filing location.

80.1 - Storage of Appeal Case Files by the Independent Review Entity **(Rev. 2, 6/22/06)**

The Part D QIC is responsible for maintaining reconsideration case files in accordance with CMS' Records Management Program. The inventory of case files includes the redetermination case files forwarded from the Part D plan sponsor and processed by the IRE which are not appealed further, and ALJ hearing case files returned to the IRE. Generally, reconsideration case files are retained for a period of seven (7) years from the end of the calendar year in which final action occurs. Final action means a decision on an appeal by the highest level of appeal, not the decision made by the Part D QIC.

Until further instructions are released by CMS, no reconsideration case files can be destroyed. However, in an effort to reduce associated costs for storing Medicare documents, electronic imaging is an acceptable method of storage. Therefore, if the IRE stores reconsideration case files electronically, it may destroy paper documents, as long as the following conditions are met:

- The IRE must certify the scanned image is an identical replication of the paper document in every way;
- The scanned image becomes the recordkeeping copy and is verified and documented as an identical replication of the paper document; and
- The IRE must maintain accessibility and the ability to read the document in accordance with changes in technology.

Reconsideration files will be made accessible to CMS and to any authorized party consistent with the Privacy Act regulations.

80.2 - Who May Request a Reconsideration

(Rev. ~~98, 1/1/11/4/10~~)

An enrollee or an enrollee's representative may request a reconsideration ~~or any appeal.~~

Note: As indicated in §[10.5](#), an enrollee's prescribing physician or other prescriber may request a coverage determination or redetermination on an enrollee's behalf, ~~but, Thus, an enrollee's physician or other prescriber~~ is prohibited from requesting a higher appeal without being the enrollee's representative. However, when a request for a coverage determination or redetermination that is initiated by an enrollee's physician or other prescriber is automatically forwarded to the IRE under §§[50.6](#) or [70.10](#), the physician or other prescriber is not required to be the enrollee's representative for the IRE to review the forwarded request. If the IRE issues an adverse decision, the enrollee's physician or other prescriber must become the enrollee's representative, as indicated in §[10.4](#), to file any further appeal on the enrollee's behalf (i.e., the physician or other prescriber would be responsible for becoming the enrollee's representative and submitting the proper representation documentation with the appeal request).

80.3 - How to Request a Reconsideration

(Rev. ~~98, 1/1/11+4/40~~)

An enrollee may request a standard or expedited reconsideration by filing a signed written request with the IRE. An enrollee must file the request for reconsideration within 60 calendar days from the date of the notice of the redetermination, unless the time frame is extended by the IRE as described in [§80.4](#) below.

A written request may be made on the model Request for Reconsideration contained in [Appendix 13](#), or on any other written document. As indicated in ~~§70.9~~[§§70.9.1 and 70.9.3](#), plan sponsors must complete the applicable sections of the model Request for Reconsideration form and send it to the enrollee with each adverse redetermination notice.

In order for an enrollee to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide a Part D drug that is not on the plan sponsor's 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.

80.4 - Good Cause Extension

(Rev. 1, 11/30/05)

If an enrollee misses the 60-day timeframe for requesting a reconsideration, he or she may request a good-cause extension. The extension request must be filed with the IRE, in writing, and include the reason why he or she did not request a reconsideration timely. If the enrollee shows good cause, the IRE may extend the time frame for filing a request for reconsideration. The IRE should consider the circumstance that kept the enrollee from making the request on time and whether any actions by the plan may have misled the enrollee. Examples of circumstances where good cause may exist include (but are not limited to) the situations described in [§70.3](#). The decision by the IRE on whether to grant an extension for good cause is final and not subject to appeal.

80.5 - Withdrawal of Request for Reconsideration

(Rev. 1, 11/30/05)

The enrollee who files a request for reconsideration may withdraw the request at any time by writing to the IRE and requesting the withdrawal before the IRE mails its decision.

80.6 - Effect of a Reconsideration Determination

(Rev. 1, 11/30/05)

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 before an ALJ.

80.7 - Other Determinations Subject to Independent Review

80.7.1 - Reconsideration of Late Enrollment Penalty Determinations (Rev. 8, 1/1/10)

Under §1860D-13(b) of the Social Security Act and 42 C.F.R. §§423.46 and 423.56(g), the Secretary or his or her designee imposes a late enrollment penalty (LEP) if there is a continuous period of 63 days or more at any time after the end of the individual's Part D initial enrollment period during which the individual was eligible to enroll in a Part D plan, but was not enrolled in a Part D plan and was not covered under any creditable prescription drug coverage. "Creditable prescription drug coverage" is coverage that meets Medicare's minimum standards since it is expected to pay, on average, at least as much as Medicare's standard prescription drug coverage.

Creditable drug coverage may include but is not limited to:

- Employer-based prescription drug coverage, including the Federal employees health benefits program (FEHBP);
- State Pharmaceutical Assistance Programs (SPAPs);
- Military-related coverage (for example, VA, TRICARE coverage); and
- Certain Medicare supplemental (Medigap) policies.

See 42 C.F.R §423.56(b) for a complete list of types of prescription drug coverage that may be determined to be creditable.

As outlined at 42 CFR 423.56(c) and (d), with the exception of Prescription Drug Plan Sponsors, Medicare Advantage Organizations, Section 1876 Cost-Based Contractors, and PACE organizations offering prescription drug plans, entities that offer prescription drug coverage must make an annual determination of creditable coverage status and provide a disclosure notice to Medicare eligible individuals (see the appropriate plan enrollment guidance for information related to Part D enrollment eligibility). See Chapter 4 of this manual for additional guidance regarding creditable coverage period determinations and the calculation and assessment of the LEP.)

Note: Prescription drug discount cards, free clinics, or drug discount websites do not constitute creditable prescription drug coverage. Also, the "certificate of creditable coverage" an enrollee may receive when his or her health coverage ends does not mean the prescription drug coverage met Medicare's minimum standards – unless the notice specifically mentioned the enrollee had "creditable" prescription drug coverage that expected to pay as much as Medicare's standard prescription drug plan pays. For additional guidance concerning creditable coverage-related requirements, see the material posted on the CMS website: <http://www.cms.hhs.gov/creditablecoverage/>

An enrollee, or his or her representative (as defined in [§10.4](#) of this chapter), may request a review, or reconsideration, of a decision to impose an LEP. An enrollee may only obtain review under the circumstances listed on the LEP Reconsideration Request Form ([Appendix 15](#)) and described under [§80.7.1.4](#) of this chapter. Unless otherwise stated in

§10.4 of this chapter, the enrollee’s representative has all of the rights and responsibilities of an enrollee under Part D LEP reconsideration procedures.

The LEP reconsideration is conducted by an Independent Review Entity (IRE) under contract with Medicare. At this time, the IRE is MAXIMUS.

80.7.1.1 - Summary of the LEP Reconsideration Process (Rev. 8, 1/1/10)

The LEP Reconsideration Process is described below:

- When a Part D plan sponsor sends a letter notifying an enrollee of the imposition of or increase in the LEP (“LEP letter”), and the increase is due to reporting additional uncovered months, except in a case where the number of uncovered months increases as a result of an IRE decision, the sponsor shall include the Part D LEP Reconsideration Notice: “Your Right to Ask Medicare to Review Your Medicare Part D Late Enrollment Penalty” and the LEP Reconsideration Request Form ([Appendix 14](#) and [Appendix 15](#), respectively).
- The LEP letter, Part D LEP Reconsideration Notice, and the LEP Reconsideration Request Form advise the enrollee that he or she has 60 calendar days from the date on the LEP letter to request reconsideration of the LEP, or the request may not be considered. If the 60-day timeframe for filing an LEP reconsideration has expired, the enrollee may request a good-cause extension, subject to the requirements described in §80.4 of this chapter. The enrollee must explain his or her reason for filing late on a separate sheet and send this explanation along with the LEP Reconsideration Request Form.
- The enrollee sends his or her signed, completed LEP Reconsideration Request Form to the IRE under contract with Medicare, in accordance with the filing instructions provided on the form ([Appendix 15](#)). Enrollees also may write a letter requesting an LEP reconsideration, provided the letter contains the elements on the LEP Reconsideration Request Form.
- The IRE shall request a copy of the case file from the Part D plan sponsor and make a reconsideration decision based on the case file, the information supplied by the enrollee, and any other information the IRE deems relevant.
- The IRE will inform the enrollee and the Part D plan sponsor of the final decision.
- The Part D plan sponsor, if applicable, shall report a revised creditable coverage determination to CMS and notify the enrollee in writing of the new LEP amount and any refund due. (Refer to Chapter 4 of this manual for more information.)

- The final LEP reconsideration decision is not subject to appeal (that is, is not subject to further review by an Administrative Law Judge (ALJ), Medicare Appeals Council (MAC), or in a district court of the U.S.).

80.7.1.2 - Part D Plan Sponsor Responsibilities Under the LEP Reconsideration Process (Rev. 8, 1/1/10)

The Part D plan sponsor shall become familiar with LEP procedures so it is able to assist enrollees throughout the LEP reconsideration process. For example, the Part D plan sponsor shall:

- Attempt to obtain a completed Declaration of Prior Prescription Drug Coverage from the enrollee at the beginning of the creditable coverage determination process, where the enrollee appears to have a qualifying break in creditable prescription drug coverage, as set forth in Chapter 4 of this manual. Obtaining the Declaration may avoid the assessment of a LEP and the need for reconsideration if the enrollee had prior creditable drug coverage for the uncovered months in question.
- Send the enrollee the Part D LEP Reconsideration Notice, “Your Right to Ask Medicare to Review Your Part D Late Enrollment Penalty” ([Appendix 14](#)), and the LEP Reconsideration Request Form ([Appendix 15](#)) at the same time the plan sends an enrollee his or her LEP letter.

Note: Part D plan sponsors shall only send the LEP reconsideration notice and form when notifying an enrollee of an imposition of or increase in the LEP where the increase is due to reporting additional uncovered months, except in a case where an increase in the number of uncovered months is a result of an IRE decision. While an increase in the number of uncovered months following an LEP reconsideration does not happen frequently, it can occur if the plan under-reported the number of uncovered months.

- Retain a copy of the LEP letter sent to an enrollee. The information included in the LEP letter about the end of the individual’s IEP and the dates of the potential gap in creditable coverage is important in the event the enrollee requests a reconsideration. If the Part D plan sponsor retains a copy of the LEP letter in the enrollee’s file, that information will be readily and easily available if the enrollee requests review of the LEP and the IRE requests this information.
- Assist the enrollee in completing the LEP Reconsideration Request Form upon request. For example, the Part D plan sponsor shall help an enrollee determine which checkbox to mark as his or her reason for seeking reconsideration.
- Send the IRE a copy of the enrollee’s case file, which includes copies of any information the plan used in making its creditable coverage determination for the

enrollee, including, but not limited to: the enrollee's Part D IEP or subsequent IEP end date (and how it was derived), the enrollee's creditable coverage attestation materials ("Declaration of Prior Prescription Drug Coverage" form), and any documentation from CMS of the enrollee's enrollment in a Part D plan or in a plan whose sponsor received the retiree drug subsidy. (See Chapter 4 of this manual for specific guidance on information retention requirements related to creditable coverage and the LEP.)

80.7.1.3 - Elements of an LEP Reconsideration Request (Rev. 8, 1/1/10)

The Part D plan sponsor shall inform the enrollee that his or her LEP reconsideration request must include the following elements:

- A completed, signed LEP Reconsideration Request Form ([Appendix 15](#)) or a signed, written request for reconsideration containing the elements on the LEP reconsideration request form; and
- If the enrollee has named a representative, proof that the individual has authority to represent the enrollee.

In addition to the items above, the Part D plan sponsor shall inform the enrollee that his or her LEP reconsideration request should include:

- Any additional information that may help the enrollee's case, including evidence that the IRE should consider (e.g., notice from an employer sponsored health plan indicating that prior drug coverage was creditable). See [§80.7.1.4](#).

80.7.1.4 - Reasons for Requesting LEP Reconsideration and Presentation of Evidence (Rev. 8, 1/1/10)

As listed on the LEP Reconsideration Request Form, enrollees may request review of their LEP decision for one of the following specific reasons:

- The individual had prior creditable prescription drug coverage that the enrollee believes may have not been considered.
- The individual had prior prescription drug coverage but didn't get a notice that clearly explained if the drug coverage was creditable. In this case, the enrollee should submit any evidence, such as a copy of an organization's letter or other material, for example, a Summary of Benefits that the enrollee found unclear or misleading.
- The individual believes the LEP is wrong because he or she was not eligible to enroll in a Medicare drug plan during the period stated by the Medicare drug plan.

- The individual believes the LEP is wrong because he or she was unable to enroll in a Medicare drug plan due to a serious medical emergency during the period the individual was eligible to enroll in a drug plan.
- The individual has/had extra help from Medicare to pay for prescription drug coverage; that is, the low-income subsidy for Medicare prescription drug coverage.
- The individual lived in an area affected by Hurricane Katrina at the time of the Hurricane (August 2005), and he or she joined a Part D plan before December 31, 2009. NOTE: Certain Medicare beneficiaries who were affected by Hurricane Katrina were allowed to enroll in a Medicare prescription drug plan with no penalty before December 31, 2006 if, at the time of the hurricane (August 2005), they resided in any of the parishes or counties declared as meeting the level of “individual assistance” by the Federal Emergency Management Agency (FEMA).
Refer to Chapter 4 for additional guidance on the opportunity for certain individuals to enroll in Medicare Part D without an LEP:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp

If additional information or evidence can help explain why an enrollee’s LEP is incorrect, he or she should submit such proof with the LEP Reconsideration Request Form. Enrollees are asked to send to the IRE any proof that helps support the request. Part D plan sponsors shall instruct enrollees to send this material to the IRE at the address or fax number shown on page 2 of the LEP Reconsideration Request Form, to include their Medicare Health Insurance Claim number on any separate materials, and to only send photocopies of their original documents.

80.7.1.5 - LEP Reconsideration Process Timeline
 (Rev. 8, 1/1/10)

Below is a summary of the timelines the IRE generally will follow during the LEP reconsideration process:

- Unless the IRE finds good cause to extend its decision-making timeframe, the IRE generally will notify the enrollee of the final LEP reconsideration decision (including a decision to dismiss the reconsideration request), within 90 calendar days of receiving an enrollee’s request for reconsideration.
- The IRE may take an additional 14 days if the enrollee requests an extension or if the IRE finds good cause to extend the timeframe. Good cause would include, for example, when the IRE finds a need for additional information and considers the delay to be in the interest of the enrollee, such as receipt of additional information that may reduce the number of uncovered months upon which the LEP was based.

- In cases where an individual other than the enrollee files for reconsideration, the reconsideration timeframe will not commence until the IRE receives documentation verifying that the individual is the enrollee’s representative or is authorized under state law to act on behalf of an enrollee, as described in §10.4 of this chapter. The IRE will attempt to cure any defect in an Appointment of Representative form (CMS-1696) or other equivalent written notice – e.g., the form or notice was not properly executed – by requesting information from the individual who filed the reconsideration. If the IRE cannot verify an individual’s status as the representative within a reasonable time period, not to exceed 30 calendar days after the date of the reconsideration request, the IRE will determine that the reconsideration request be dismissed.

Note: In all cases, the IRE strives to notify an enrollee of its final decision as quickly as possible. However, the IRE may take longer than the 90-day timeframe to process an LEP reconsideration decision in certain cases depending, among other issues, on the amount of research the IRE has to perform to verify whether an individual’s prior prescription drug coverage was creditable.

80.7.1.6 - Withdrawal of an LEP Reconsideration Request (Rev. 4, 6/8/07)

An enrollee may withdraw his or her LEP reconsideration request in writing at any time before the IRE mails the final decision. For purposes of a withdrawal, “enrollee” also includes a former enrollee or his or her representative.

80.7.1.7 - Dismissal of an LEP Reconsideration Request (Rev. 8, 1/1/10)

Instances in which the IRE may determine that a reconsideration request be dismissed include, but are not limited to, the following:

- An enrollee failed to request a timely LEP reconsideration and did not have good cause for missing the filing deadline;
- An enrollee dies while the reconsideration is pending and the enrollee’s surviving spouse or estate has no remaining financial interest in the reconsideration;
- An individual requesting the reconsideration is not the enrollee, and the authority of the individual seeking a reconsideration cannot be verified within a reasonable time period, not to exceed 30 calendar days after the date of the reconsideration request; or
- An enrollee requests a reconsideration of an issue that is ineligible for LEP reconsideration or is otherwise ineligible for review. For example, the IRE will not make actuarial determinations concerning whether an enrollee’s prescription drug coverage was creditable; that is, an enrollee may not use the LEP

reconsideration process to seek review of the decision that his or her coverage under an employer-sponsored prescription drug plan was not creditable coverage.

80.7.1.8 - Requests for Information
(Rev. 8, 1/1/10)

Upon request, the Part D plan sponsor shall forward to the IRE any information necessary to make a reconsideration decision, including all creditable coverage and LEP-related information received in accordance with Chapter 4 of this manual, such as information from a current or previous enrollee.

Upon request, the Part D plan sponsor delivers (by mail or fax) a hard copy of the requested information within 14 calendar days after receiving the request for information. Requested information may include, for example, an enrollee's attestation materials ("Declaration of Prior Prescription Drug Coverage" form), including forms received late.

In the event a Part D plan sponsor has no information to forward, the Part D plan sponsor shall deliver (by mail or fax) a brief letter to the IRE within 14 calendar days after receiving the request for information. The letter acknowledges that the requested information is unavailable and explains the reason; for example, the enrollee never submitted an attestation form (a "Declaration of Prior Prescription Drug Coverage" form).

80.7.1.9 - [Reserved]
(Rev. 4, 6/8/07)

80.7.1.10 - Dismissals
(Rev. 4, 6/8/07)

Dismissals are not appealable.

80.7.1.10.1 - Vacating a Dismissal
(Rev. 4, 6/8/07)

The dismissal is binding, unless the dismissal is vacated. If a Part D enrollee requests the dismissal be vacated and he or she shows good cause that the reconsideration request should not be dismissed, the dismissal of the reconsideration request may be vacated. The enrollee must request that the dismissal be vacated within 60 days after the date of the dismissal notice. The IRE will notify the enrollee and the Part D plan sponsor in writing if the dismissal is vacated.

80.7.1.11 - Requirements Following LEP Reconsideration

80.7.1.11.1 - IRE Responsibilities
(Rev. 8, 1/1/10)

The IRE will notify the enrollee and the Part D plan sponsor of the final reconsideration decision generally within 90 calendar days after receiving the enrollee's request for reconsideration. If an enrollee has identified a representative, the IRE will send any notice or other correspondence required under §80.7.1 to the individual's representative instead of to the enrollee.

80.7.1.11.2 - Part D Plan Sponsor Responsibilities (Rev. 8, 1/1/10)

If the IRE partially or fully reverses a Part D plan sponsor's creditable coverage determination, the Part D plan sponsor shall comply with the requirements described under Chapter 4 of this manual concerning adjustment or removal of an LEP.

80.7.2 - Low Income Subsidy (Rev. 1, 11/30/05)

[Reserved]

90 - Administrative Law Judge (ALJ) Hearings (Rev. 1, 11/30/05)

If the amount remaining in controversy meets the appropriate threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE's reconsideration decision has a right to a hearing before an ALJ.

90.1 - Request for an ALJ Hearing (Rev. ~~98, 1/1/11/1/10~~)

A request for an ALJ hearing must be ~~in writing and must be~~ filed with the entity specified in the IRE's reconsideration notice. A request for a standard ALJ hearing must be submitted in writing. A request for an expedited ALJ hearing may be submitted orally or in writing (an enrollee cannot request an expedited hearing if the only issue involves a request for payment of Part D drugs already furnished).

The oral or written request must include all of the following information:

1. The name, address, telephone number, and Medicare health insurance claim number of the enrollee;
2. The name, address, and telephone number of the appointed representative, if any;
3. The appeals case number assigned to the appeal by the IRE, if any;
4. The name of the prescription drug in dispute;
5. The plan name;
6. The reasons the enrollee disagrees with the IRE's reconsideration;
7. A statement of any additional evidence to be submitted and the date it will be submitted; and
8. A statement that the enrollee is requesting an expedited hearing, if applicable.

If a Part D plan sponsor receives a ~~written~~ request for an ALJ hearing from an enrollee, the Part D plan sponsor must immediately forward the enrollee's request to the appropriate ALJ hearing office. ~~When the IRE receives a request for a case file from the ALJ, the IRE is responsible for compiling the case file and forwarding it to the appropriate ALJ hearing office within 5 calendar days of receipt of the request.~~

Except when an ALJ extends the time frame as provided in [42 CFR 423.2014\(d\)](#), an enrollee must file a request for an ALJ hearing within 60 ~~calendar~~ days of the date of the ~~written~~ notice of a reconsideration. Any request for a "good cause" extension must be in writing and state the reasons why the request was late. If the enrollee shows good cause for missing the deadline, the ALJ may grant an extension. (See [42 CFR 405.942\(b\)\(2\)](#) and [\(b\)\(3\)](#) for the ALJ standards for good cause.)

90.2 - Determination of Amount in Controversy

(Rev. ~~89~~, 1/1/~~4011~~)

Beginning in January 2005, the amount in controversy (AIC) threshold for an ALJ hearing will increase by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved. Any amount that is not a multiple of \$10 will be rounded to the nearest multiple of \$10. If there is a change in the amount in controversy requirement, the new requirement will be published by the Office of Medicare Hearings and Appeals.

For ~~2010~~2011, the AIC threshold for an ALJ hearing is \$130.

The ALJ determines whether the amount remaining in controversy meets the appropriate threshold.

If the basis for the appeal is the Part D plan's refusal to provide prescription drug benefits, the amount remaining in controversy will be calculated by subtracting any allowed amount under Part D, and any deductible, co-payments, and coinsurance amounts applicable to the Part D drug at issue, from the projected value of the drug benefits in dispute. Projected value 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.

If the enrollee is seeking reimbursement for out-of-pocket costs incurred in obtaining a disputed Part D drug, the amount remaining in controversy will be calculated by subtracting any allowed amount under Part D, and any deductible, co-payments, and coinsurance amounts applicable to the Part D drug at issue, from the actual amount charged the enrollee or a third party for the Part D drug.

When necessary, the Part D plan sponsor is expected to cooperate with the ALJ in computing the amount remaining in controversy (e.g., the ALJ may need the Part D plan sponsor to provide information regarding the amount an enrollee was required to pay for a drug at the time the coverage determination request was made).

The hearing may be conducted on more than one claim. The enrollee may combine claims he or she is appealing to meet the threshold requirement if the following elements are met:

1. The claims involve the delivery of prescription drugs to a single enrollee;
2. The claims must each have received a determination through the IRE reconsideration process;
3. The 60-day filing time limit must be met for all claims involved; and
4. The hearing request identifies all claims.

In addition, more than one enrollee may combine claims they are appealing to meet the threshold requirement, if the following elements are met:

1. The claims involve the delivery of the same prescription drug to each enrollee;
2. The claims must each have received a determination through the IRE reconsideration process;
3. The 60-day filing time limit must be met for all claims involved; and
4. The hearing request identifies all claims.

When claims are combined to meet the AIC threshold, the projected value of those benefits may be used to determine whether the requirement has been satisfied.

The ALJ dismisses cases if the AIC threshold is not met. If, after a hearing is initiated, the ALJ finds that the AIC threshold has not been satisfied, he/she will discontinue the hearing and will not rule on the substantive issues raised in the appeal. An enrollee may request review of the dismissal of a hearing through the Medicare Appeals Council (MAC) review. The MAC's decision is final and not subject to review.

90.3 - Submitting Evidence Before an ALJ

(Rev. ~~91, 1/1/1111/30/05~~)

~~Parties must submit all written evidence they wish to have considered at the hearing with the request for hearing (or within 10 days of receiving the notice of hearing). An enrollee may submit written evidence that he or she wishes to have considered at an ALJ hearing in accordance with the following:~~

Standard Hearings

A represented enrollee must submit all written evidence he or she wishes to have considered at the hearing with the request for hearing, or within 10 calendar days of receiving the notice of hearing. If a represented enrollee submits written evidence later than 10 calendar days after receiving the notice of hearing, the period between the time the evidence was required to have been submitted and the time it is received does not count toward the adjudication deadline specified in §90.4. These requirements do not apply to unrepresented enrollees, or to oral testimony given at a hearing.

Expedited Hearings

An enrollee must submit all written evidence he or she wishes to have considered at the expedited hearing with the request for expedited hearing, or within 2 calendar days of receiving the notice of hearing. If an enrollee submits written evidence later than 2 calendar days after receiving the notice of hearing, the period between the time the evidence was required to have been submitted and the time it is received does not count toward the adjudication deadline specified in §90.4. These requirements do not apply to oral testimony given at a hearing.

Evidence of a Change in Medical Condition

If an enrollee's medical condition changes after the coverage determination decision was made, the ALJ will not consider that evidence at the hearing. If an enrollee wishes such evidence to be considered, the ALJ will remand the case to the Part D IRE.

90.4 – Time Frame for Deciding an Appeal Before an ALJ

(Rev. 9, 1/1/11)

Standard Hearing

The ALJ must generally issue a decision, dismissal order, or remand, as appropriate, within 90 calendar days from the date the ALJ receives the request for a standard ALJ hearing.

Expedited Hearing

If an ALJ grants a request for an expedited review, the ALJ must generally issue a decision, dismissal order, or remand, as appropriate, as expeditiously as the enrollee's health condition requires, but no later than 10 calendar days from the date the ALJ receives the request for an expedited ALJ hearing.

100 - Medicare Appeals Council (MAC) Review

(Rev. 8, 1/1/10)

An enrollee who is dissatisfied with an ALJ's hearing decision may request that the MAC review the ALJ's decision or dismissal. Where applicable, the regulations located at [42 CFR Part 423, subpart U](#) apply to MAC review for matters addressed in this chapter.

The MAC may grant or deny the request for review. If it grants the request, it may either issue a final decision or dismissal, or remand the case to the ALJ with instructions on how to proceed with the case.

100.1 - Filing a Request for MAC Review

(Rev. ~~94, 1/1/1111/30/05~~)

A request for a MAC review must be submitted to the entity specified in the notice of the ALJ's action~~filed by writing a letter to the MAC~~. A request for a standard MAC review must be submitted in writing. A request for an expedited MAC review may be submitted orally or in writing (an enrollee cannot request an expedited MAC review if the only issue involves a request for payment of Part D drugs already furnished).

The enrollee ~~may~~**must** file a written request to the Department of Health and Human Services by ~~either~~ completing Form DAB-101, Request for Review of Administrative Law Judge (ALJ) Medicare Decision/Dismissal, which is available at ~~<http://www.hhs.gov/dab/divisions/dab101.pdf>~~~~<http://www.hhs.gov/dab/DAB101.pdf>~~, or by submitting a written request that includes the following:

- ~~1. The enrollee's name and address;~~
- ~~2. The enrollee's Medicare HIC number;~~
- ~~3. The item(s) in dispute;~~
- ~~4. The date(s) of the item(s);~~
- ~~5. Date of the ALJ's final action (if any); and~~
- ~~6. Name and signature of the enrollee or representative of the enrollee.~~

A written request not made on Form DAB-101, or an oral request for an expedited review, must include all of the following information:

1. The name, address, telephone number, and Medicare health insurance claim number of the enrollee;
2. The name of the appointed representative, if any;
3. The appeals case number assigned to the appeal by the ALJ, if any;
4. The prescription drug in dispute;
5. The plan name;
6. The reasons the enrollee disagrees with the IRE's reconsideration;
7. A statement that the enrollee is requesting an expedited hearing, if applicable; and
8. The signature of the enrollee or the representative of the enrollee, if any.

The appeal request must identify the parts of the ALJ's decision with which the enrollee disagrees, and explain why the enrollee disagrees. For example, if an enrollee believes that the ALJ's decision is inconsistent with a statute, regulation, Medicare agency ruling,

or other authority, the enrollee should explain why the ALJ's decision is inconsistent with that authority.

~~The w~~Written requests must be submitted directly to the MAC at the following address:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Alternatively, ~~a written~~ appeal request may be faxed to the MAC at (202) 565-0238~~0227~~. If the request is faxed, the enrollee should not also mail a copy of the request to the MAC.

~~Oral requests for expedited MAC review can be made by calling 202-565-0200.~~

An enrollee who files an appeal request with the MAC should send a copy of the ALJ's decision with the appeal request.

100.2 - Time Limit for Filing a Request for MAC Review

(Rev. ~~91, 1/1/1111/30/05~~)

The request for a MAC review must be filed within 60 calendar days of the date of receipt of the written ALJ hearing decision or dismissal. The MAC assumes the ALJ decision was received within 5 days of the date of the decision, unless evidence indicates otherwise. The MAC may grant an extension of the request for a review if the enrollee can show "good cause" for missing the deadline. (See [42 CFR 405.942\(b\)\(2\) and \(b\)\(3\)](#) for the standards applicable for determining good cause.)

100.3 - MAC Initiation of Review

(Rev. ~~91, 1/1/1111/30/05~~)

The MAC may initiate a review on its own motion or at the request of CMS or one of its contractors within 60 calendar days after ~~the date of~~ an ALJ's written hearing decision or dismissal is issued. If the MAC initiates a review, it mails notice of this action to the enrollee at his or her last address of record.

100.4 - MAC Review Procedures

(Rev. ~~91, 1/1/1111/30/05~~)

~~The MAC will review a case if it determines that:~~

- ~~1. There appears to be an abuse of discretion by the ALJ;~~

- ~~2. There is an error of law material to the outcome of the case;~~
- ~~3. The decision or dismissal of the ALJ is not supported by the preponderance of the evidence in the record; or~~
- ~~4. There is a broad policy or procedural issue that may affect the general public interest.~~

As noted in §100.1, the appeal request must identify the parts of the ALJ's decision with which the enrollee disagrees, and explain why the enrollee disagrees. The MAC will limit its review to those exceptions raised by the enrollee in the request for review, unless the enrollee is not represented.

The MAC limits its review of the evidence to the evidence contained in the record of the proceedings before the ALJ, and any new evidence that relates to the period before the coverage determination. However, under [42 CFR 423.2122](#), the MAC may also consider new evidence submitted for the first time to the MAC if:

1. The ALJ's decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level; or
2. The MAC determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence.

The MAC will not consider any new evidence submitted regarding a change in condition of an enrollee after a coverage determination is made. If an enrollee wishes to have such information considered, the MAC will remand the case to the Part D IRE for review.

Upon request, the MAC will give the enrollee requesting review a reasonable opportunity to file a brief or other written statement about the facts and law relevant to the case. Unless the enrollee requesting review files the brief or other statement with the request for review, the time that elapses between the date the MAC receives the request to submit the brief and the date the brief is received by the MAC will not count toward the adjudication timeframe set forth in §100.5.

~~A copy of the MAC's decision will be mailed to the enrollee at his or her last known address.~~

100.5 – Time Frame for Deciding an Appeal Before the MAC
(Rev. 9, 1/1/11)

The MAC will issue a decision, dismissal order, or remand in accordance with the following:

Standard Hearing

The MAC must generally issue a decision, dismissal order, or remand, as appropriate, within 90 calendar days from the date the MAC receives the request for a standard MAC review.

Expedited Hearing

If the MAC grants a request for an expedited review, the MAC must generally issue a decision, dismissal order, or remand, as appropriate, as expeditiously as the enrollee's health condition requires, but no later than 10 calendar days from the date the MAC receives the request for an expedited MAC review.

A copy of the MAC's decision will be mailed to the enrollee at his or her last known address, CMS, the IRE, and the Part D plan sponsor.

110 - Judicial Review
(Rev. 89, 1/1/1011)

An enrollee may request judicial review of an ALJ's decision if:

1. The MAC denied the enrollee's request for review; and
2. The amount remaining in controversy meets the appropriate threshold established annually by the Secretary.

In addition, an enrollee may request judicial review of a MAC decision if:

1. It is the final decision of the Secretary; and
2. The amount remaining in controversy meets the appropriate threshold established annually by the Secretary.

For ~~2010~~2011, the AIC threshold for judicial review is \$~~1,260~~300.

110.1 - Requesting Judicial Review
(Rev. 8, 1/1/10)

An enrollee must file a civil action in a district court of the United States in accordance with §205(g) of the Act (see the procedures outlined in 42 CFR Part 423, subpart U, for a description of the procedures to follow in requesting judicial review). The action should be initiated in the judicial district in which the enrollee lives or where the Part D plan

sponsor has its principal place of business. If neither the plan nor the member is in such a judicial district, the action should be filed in the United States district court for the District of Columbia.

110.2 – Expedited Access to Judicial Review **(Rev. 9, 1/1/11)**

In certain situations, an enrollee may request expedited access to judicial review (EAJR) in place of an ALJ hearing or MAC review. An enrollee may make a request for EAJR only once with respect to a question of law or regulation for a specific matter in dispute in an appeal.

110.2.1 - Conditions for Making the Request **(Rev. 9, 1/1/11)**

An enrollee may request EAJR if all of the following conditions are met:

1. A review entity (i.e., an entity of up to three reviewers who are ALJs or members of the Departmental Appeals Board, as determined by the Secretary) must certify that the MAC does not have the authority to decide the question of law or regulation relevant to the matters in dispute and that there is no material issue of fact in dispute (see §110.2.4);
2. An IRE has made a reconsideration determination and the enrollee has filed a request for an ALJ hearing in accordance with §90 and a final decision, dismissal order, or remand order of the ALJ has not been issued, or an ALJ has made a decision and the enrollee has filed a request for MAC review in accordance with §100 and a final decision, dismissal order, or remand order of the MAC has not been issued;
3. The amount remaining in controversy meets the threshold requirements established annually by the Secretary (see §110.1); and
4. If there is more than one enrollee to the hearing or MAC review, each enrollee concurs, in writing, with the request for the EAJR.

110.2.2 - Content of the Request **(Rev. 9, 1/1/11)**

The request for EAJR must:

1. Allege that there are no material issues of fact in dispute and identify the facts that the enrollee considers material and that are not disputed; and
2. Assert that the only factor precluding a decision favorable to the enrollee is:

a. A statutory provision that is unconstitutional, or a provision of a regulation that is invalid and specify the statutory provision that the enrollee considers unconstitutional or the provision of a regulation that the enrollee considers invalid; or

b. A CMS Ruling that the enrollee considers invalid;

3. Include a copy of the IRE reconsideration and of any ALJ hearing decision that the enrollee has received;

4. If the IRE reconsideration or ALJ hearing decision was based on facts that the enrollee is disputing, state why the enrollee considers those facts to be immaterial; and

5. If the IRE reconsideration or ALJ hearing decision was based on a provision of a law, regulation, or CMS Ruling in addition to the one the enrollee considers unconstitutional or invalid, state why further administrative review of how that provision applies to the facts is not necessary.

110.2.3 - How to File a Request **(Rev. 9, 1/1/11)**

The enrollee may include an EAJR request in his or her request for an ALJ hearing or MAC review. If an appeal is already pending with an ALJ, the enrollee may file the EAJR request with the ALJ at any time before receipt of the notice of the ALJ's decision. If an appeal is already pending with the MAC, the enrollee may file the EAJR request with the MAC at any time before receipt of notice of the MAC's decision.

The ALJ hearing office or MAC forwards the request to the review entity within 5 calendar days of receipt.

110.2.4 – Review Entity Determination **(Rev. 9, 1/1/11)**

Within 60 calendar days after the date the review entity described in §110.2.1 receives an EAJR request (and accompanying documents and materials) meeting the conditions stated in §§110.2.1, 110.2.2, and 110.2.3, the review entity will issue either a certification or a denial of the EAJR request.

Note: If the review entity fails to make a determination within the 60 day timeframe, the enrollee may bring a civil action in Federal District Court within 60 calendar days of the end of the timeframe.

If the review entity issues a certification, the enrollee has 60 calendar days (beginning on the date of the review entity's certification) to bring the civil action in Federal District Court.

Note: The enrollee must satisfy the requirements under section 205(g) of the Act, as well as the requirements for filing a civil action in a Federal District Court under 42 CFR 423.2136.

Note: The enrollee that requested the EAJR is considered to have waived any right to completion of the remaining steps of the administrative appeals process regarding the matter certified.

If the review entity denies a request for EAJR, it advises the enrollee in writing that the request has been denied, and returns the request to the ALJ hearing office or the MAC, which will treat it as a request for hearing or for MAC review, as appropriate.

Note: Whenever a review entity forwards a rejected EAJR request to an ALJ hearing office or the MAC, the appeal is considered timely filed and the 90 calendar day decision making timeframe begins on the day the request is received by the hearing office or the MAC.

A determination by the review entity either certifying that the requirements for EAJR are met or denying the request is not subject to review by an ALJ or the MAC.

120 - Reopening and Revising Determinations and Decisions (Rev. 2, 6/22/06)

A reopening is a remedial action taken to change a final determination or decision even though the determination or decision was correct based on the evidence of record. That action may be taken by:

1. A Part D plan sponsor to revise a coverage determination or redetermination;
2. An IRE to revise a reconsideration;
3. An ALJ to revise a hearing decision; or
4. The MAC to revise an ALJ hearing or review decision.

A Part D plan sponsor must process clerical errors (which include minor errors and omissions) as reopenings, instead of redeterminations. A clerical error may occur, for example, when a plan sponsor miscalculates the amount paid by the enrollee towards satisfying the catastrophic coverage threshold. The plan sponsor has discretion in determining what meets the definition of clerical error, and therefore, what could be corrected through a reopening. It should be noted that there are few clerical errors that should be handled through reopening. If the plan sponsor receives a request for reopening and does not agree that the issue is a clerical error, the plan sponsor must dismiss the reopening request and advise the enrollee of any appeal rights, provided the

time frame to request an appeal on the original denial has not expired. For purposes of this section, clerical error includes human and mechanical errors on the part of the plan sponsor such as:

1. Mathematical or computational mistakes;
2. Inaccurate data entry; or
3. Denials of claims as duplicates.

When an enrollee has filed a valid request for an appeal of a coverage determination, redetermination, reconsideration, ALJ hearing, or MAC review, the previous adjudicator no longer has jurisdiction to reopen and modify its decision until all appeal rights are exhausted, or a subsequent request to withdraw has been granted. Once the appeal rights have been exhausted or a subsequent request to withdraw has been granted, the Part D plan sponsor, IRE, ALJ, or MAC may conduct a reopening as set forth in this section.

A plan sponsor cannot reopen and modify its decision if additional information is received after an enrollee files a request for an IRE reconsideration or the adjudication time frame at the coverage determination or redetermination levels have expired and the plan is required to forward the enrollee's request to the IRE, unless a subsequent request to withdraw has been granted. If an enrollee has not requested a review by the IRE (or the applicable adjudication time frame has not expired) and the plan sponsor receives additional information that would change the plan's decision, the plan may reopen its decision and modify it as described under [42 CFR 423.1978](#).

The decision by the Part D plan sponsor, IRE, ALJ, or MAC on whether to reopen is final and not subject to appeal or mandamus.

The filing of a request for a reopening with the IRE, ALJ, or MAC, does not relieve the Part D plan sponsor of its obligation to make payment for, authorize, or provide benefits as specified in this chapter.

120.1 - Guidelines for Reopening (Rev. 1, 11-30-05)

A request for reopening must:

1. Be made in writing;
2. Be clearly stated;
3. Include the specific reason for requesting the reopening (a statement of dissatisfaction is not grounds for a reopening); and
4. Be made within the time frames permitted for reopening (as set forth in [§120.2](#)).

120.2 - Time Frames and Requirements for Reopening

(Rev. ~~91, 1/1/11-1/30/05~~)

A Part D plan sponsor may reopen a coverage determination or redetermination on its own initiative:

1. Within 1 year from the date of the coverage determination or redetermination for any reason.
2. Within 4 years from the date of the coverage determination or redetermination for good cause as defined in §120.3.
3. At any time if there exists reliable evidence (i.e., relevant, credible, and material) that the coverage determination or redetermination was procured by fraud or similar fault.
- ~~4. At any time if the coverage determination or redetermination is unfavorable, in whole or in part, but only for the purpose of correcting a clerical error on which a determination was based.~~

A Part D plan sponsor may reopen a coverage determination or redetermination at the request of an enrollee under the following conditions:

1. A party may request that a Part D plan sponsor reopen its coverage determination or redetermination within 1 year from the date of the coverage determination or redetermination for any reason.
2. A party may request that a Part D plan sponsor reopen its coverage determination or redetermination within 4 years from the date of the coverage determination or redetermination for good cause in accordance with §120.3.
- ~~3. A party may request that a Part D plan sponsor reopen its coverage determination or redetermination at any time if the coverage determination or redetermination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which a determination was based.~~

Reopening IRE reconsiderations, ALJ hearing decisions, and MAC reviews.

1. An IRE may reopen a reconsideration on its own motion, or at an enrollee's or plan sponsor's request, within 180 calendar days from the date of the reconsideration for good cause in accordance with §120.3. If the IRE's reconsideration was procured by fraud or similar fault, the IRE may reopen at any time on its own motion.

2. An ALJ may reopen a hearing decision on his or her own motion, or at an enrollee's or plan sponsor's request, within 180 calendar days from the date of the decision for good cause in accordance with §120.3. If the ALJ's decision was procured by fraud or similar fault, the ALJ may reopen at any time on its own motion.
3. The MAC may reopen a review decision on its own motion or at an enrollee's or plan sponsor's request, within 180 calendar days from the date of the review decision for good cause in accordance with §120.3. If the MAC's decision was procured by fraud or similar fault, the MAC may reopen at any time on its own motion.

120.3 - Good Cause for Reopening- (Rev. ~~91, 1/1/1111/30/05~~)

Good cause for reopening may be established when:

1. There is new and material evidence that was not available or known at the time of the determination or decision, and may result in a different conclusion; or
2. The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.

Change in Substantive Law or Interpretative Policy

~~Note~~—A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening a determination or hearing decision under this section. This provision does not preclude Part D plan sponsors from conducting reopenings to effectuate coverage determinations.

An adjudicator may reopen a determination or decision to apply the current law or CMS or the Part D plan sponsor policy rather than the law or CMS or the Part D plan sponsor policy at the time the coverage determination is made in situations where the enrollee has not yet received the drug and the current law or CMS or the Part D plan sponsor policy may affect whether the drug should be received.

Third Party Payer Error

A request to reopen a claim based upon a third party payer's error in making a primary payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form does not constitute good cause for reopening.

120.4 - Definition of Terms in the Reopening Process

120.4.1 - Meaning of New and Material Evidence

(Rev. 1, 11/30/05)

The mere submission of additional evidence that was not a basis for reopening in and of itself. “New and material evidence” is evidence not considered when making the previous decision. This evidence must show facts not previously available, which could possibly result in a different decision. New information also includes a new interpretation of existing information (e.g., a different interpretation of a benefit). New and material evidence may include medical evidence not available at the time of decision, but does not include medical, clinical, or other scientific evidence that was, or reasonably could have been, available to the decision-maker at the time the decision was made.

120.4.2 - Meaning of Clerical Error

(Rev. 1, 11/30/05)

A clerical error includes human and mechanical errors such as mathematical or computational mistakes, inaccurate coding, and computer errors.

120.4.3 - Meaning of Obvious Error on the Face of the Evidence

(Rev. 1, 11/30/05)

An obvious error on the face of the evidence exists if the determination or decision is clearly incorrect based on all the evidence present in the case file. For example, a piece of evidence could have been contained in the file, but misinterpreted or overlooked by the person making the determination.

120.5 - Notice of a Revised Determination or Decision

120.5.1 - Reopenings Initiated by Adjudicators

(Rev. ~~91~~, ~~1/1/11-11/30/05~~)

When any determination or decision is reopened and revised as provided in [§120](#), the Part D plan sponsor, IRE, ALJ, or MAC must mail its revised determination or decision to the enrollee at his or her last known address, and to the Part D plan sponsor. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

120.5.2 - Reopenings Initiated at the Request of a Party

(Rev. ~~91~~, ~~1/1/11-11/30/05~~)

The Part D plan sponsor, IRE, ALJ, or MAC must mail a revised determination or decision to the enrollee at his or her last known address, and to the Part D plan sponsor.

An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

120.6 - Effect of a Revised Determination or Decision **(Rev. 9, 1/1/11)**

A revised determination or decision is binding unless it is appealed or otherwise reopened.

If an enrollee wishes to appeal a revised determination or decision, only the portion of the determination or decision revised by the reopening may be appealed.

130 - Effectuating Favorable Decisions **(Rev. 8, 1/1/10)**

In general, a favorable coverage determination or appeal decision is retroactive to the date of the earliest request or prescription purchase approved in a coverage determination or appeal decision.

Since exceptions are valid for the remainder of the plan year, all prescriptions purchased between the date of the earliest prescription approved under a coverage determination or appeal decision (that involves an exception) and the end of the plan year are reimbursable.

Example: UM requirement allows a 30-day supply for Drug X if a certain requirement is satisfied. The enrollee purchases a 30-day supply of Drug X on 6/1/07. On 9/1/07, the enrollee submits a request for reimbursement for the 6/1/07 purchase and asks the plan not to apply the UM requirement for reasons of medical necessity (i.e., files a formulary exception request). On 9/15/07, the plan approves the request on appeal. The 9/15/07 decision is retroactive to the 6/1/07 purchase, and all subsequent purchases for Drug X in 2007 are approved (i.e., the plan cannot require the enrollee to go through the coverage determination process for approval of Drug X from 6/1/07 until the end of the plan year).

If a request involves a UM requirement (and the member is not requesting an exception), the favorable decision is retroactive to the date of the earliest prescription purchase approved under a coverage determination or appeal decision, but does not extend beyond the terms of the UM requirement for any purchase not approved in the decision.

Example 1: A UM requirement allows a 30-day supply for Drug X if a certain requirement is satisfied. The enrollee purchases a 30-day supply of Drug X on 6/1/07. On 9/1/07, the enrollee submits a request for reimbursement for the 6/1/07 purchase and attempts to show that the UM requirement has been met. On 9/15/07, the plan approves the request on appeal. The 9/15/07 decision is retroactive to the 6/1/07 purchase. The member is required to complete the coverage determination/UM process for Drug X purchases made after 6/1/07.

Note: A plan may choose not to require enrollees to submit subsequent requests once a coverage determination involving a UM is approved.

Example 2: A UM requirement allows a 30-day supply for Drug X if a certain requirement is satisfied. The enrollee purchases a 30-day supply of Drug X on 6/1/07, and a 30-day supply of Drug X on 7/1/07. On 9/1/07, the enrollee submits a request for reimbursement for the 6/1/07 and 7/1/07 purchases and attempts to show that the UM requirement has been met for both dates. On 9/15/07, the plan approves the request on appeal. The 9/15/07 decision is retroactive to the 6/1/07 purchase and also covers the 7/1/07 purchase. The member is required to complete the coverage determination/UM process for Drug X purchases made after 7/1/07. **Note:** A plan may choose not to require enrollees to submit subsequent requests once a coverage determination involving a UM is approved.

130.1 - Effectuating Coverage Determinations

(Rev. ~~98, 1/1/11~~ 4/10)

If a plan sponsor approves a standard request for benefits, it must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request for coverage determination or physician's or other prescriber's supporting statement (for an exception request). See the note in §40.2 regarding when a request or supporting statement is deemed received by a plan sponsor.

If a plan sponsor approves a standard request for payment, it must ~~make~~ authorize payment ~~for the benefit~~ within ~~14 calendar days~~ 72 hours* after receiving the ~~coverage determination request or physician's or other prescriber's supporting statement (for an exception request), and make (i.e., mail) payment no later than 30 calendar days* after receiving the coverage determination request or physician's or other prescriber's supporting statement.~~ See the note in §40.2 regarding when a request ~~or supporting statement~~ is deemed received by a plan sponsor.

~~*Note: The reimbursement processing timeframes contained in this section of Chapter 18 reflect the current requirements contained in §423.568 of the regulations. However, plan sponsors should ensure enrollees' requests for reimbursement are processed in accordance with the processing timeframes contained in the Compliance/Monitoring section of the 2010 Parts C and D Combined Call Letter, which is located on the Prescription Drug Coverage Contracting webpage: <http://www.cms.hhs.gov/PrescriptionDrugCovContra/>~~

If a plan sponsor approves an expedited request for benefits, it must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the coverage determination request or physician's or other prescriber's supporting statement (for an exception request). See the note in §40.2 regarding when a request or supporting statement is deemed received by a plan sponsor.

130.2 - Effectuating Determinations Reversed by the Part D Plan Sponsor

130.2.1 - Standard Requests for Benefits (Rev. 2, 6/22/06)

If the Part D plan sponsor reverses its initial adverse coverage determination (i.e., initial benefit denial), the plan 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. See the note in [§40.2](#) regarding when a request is deemed received by a plan sponsor.

130.2.2 - Expedited Requests for Benefits (Rev. 2, 6/22/06)

If, on appeal of an expedited request for benefit, the Part D plan sponsor reverses its initial 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. See the note in [§40.2](#) regarding when a request is deemed received by a plan sponsor.

130.2.3 - Payment Requests (Rev. 2, 6/22/06)

If the Part D plan sponsor reverses its initial adverse coverage determination (i.e., initial payment denial), the plan must authorize payment for the benefit within 7 calendar days from the date it receives the request for redetermination, and make payment (i.e., mail the payment) no later than 30 calendar days after the date the plan sponsor receives the request for redetermination. See the note in [§40.2](#) regarding when a request is deemed received by a plan sponsor.

130.3 - Effectuating Decisions by All Other Review Entities

130.3.1 - Standard Requests for Benefits (Rev. 6, 1/1/09)

If the Part D plan sponsor's decision is reversed in whole or in part by any other appeal entity, the Part D plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice from the appeal entity reversing the determination. The Part D plan sponsor must inform the IRE that the Part D plan sponsor has effectuated the decision.

CMS has developed a model notice that Part D plan sponsors can use to notify the IRE when it has effectuated a decision (see [Appendix 9](#)).

130.3.2 - Expedited Requests for Benefits (Rev. 6, 1/1/09)

If the Part D plan sponsor's decision is reversed in whole or in part by any other appeal entity, 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 IRE that the Part D plan sponsor has effectuated the decision.

CMS has developed a model notice that Part D plan sponsors can use to notify the IRE when it has effectuated a decision (see [Appendix 9](#)).

130.3.3 - Payment Requests (Rev. 6, 1/1/09)

If the Part D plan sponsor's decision is reversed in whole or in part by any other appeal entity, the Part D plan sponsor must authorize payment for the benefit within 72 hours, and make payment (i.e., mail the 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 IRE that the Part D plan sponsor has effectuated the decision.

CMS has developed a model notice that Part D plan sponsors can use to notify the IRE when it has effectuated a decision (see [Appendix 9](#)).

130.4 - Independent Review Entity Monitoring of Effectuation Requirements (Rev. 1, 11/30/05)

CMS requires its IRE to monitor Part D plan sponsor's compliance with determinations or decisions that fully or partially reverse a Part D plan sponsor's adverse coverage determination. The process is as follows:

1. The IRE forwards a copy of the fully or partially favorable decision and other information necessary to effectuate the decision to the Part D plan along with a Notice of Requirement to Comply.
- 2 Pursuant to the compliance notice, the Part D plan sponsor is required to mail the IRE a statement attesting to compliance with the decision by the IRE, ALJ, MAC, or Federal court. This documentation must state when and how compliance occurred (e.g., benefit authorization, payment made, etc.). Notification to the IRE that the Part D plan sponsor intends to pay for or provide the benefit **will not** be considered appropriate compliance with the effectuation requirements. The Part D plan sponsor must provide the IRE with affirmative notice of effectuation (see

[Appendix 9](#)). The Part D plan sponsor's notice of compliance should be forwarded to the IRE concurrent with the Part D plan sponsor's effectuation.

3. If the IRE does not obtain the compliance notice, it must mail the Part D plan sponsor a reminder notice.
4. If the IRE does not receive the Part D plan sponsor's compliance notice within 30 days of the reminder notice, the IRE must report the Part D plan sponsor's failure to comply to CMS. The Part D plan sponsor is not copied on the notice to CMS.

130.5 - Effectuation Requirements for Former Part D Plan Sponsor Members (Rev. 1, 11/30/05)

If a Part D plan sponsor terminates its contract with CMS, appeals that are pending with the Part D plan sponsor, IRE, or any higher appeal level after such termination must be effectuated if the plan sponsor, IRE, or other higher appeal entity overturns the Part D plan sponsor's initial adverse coverage determination. Since the Part D contract and the regulations at [42 CFR 423.505\(b\)\(4\)](#) require Part D plan sponsors to provide basic prescription drug coverage (and to the extent applicable, supplemental coverage) for the duration of their contracts, Part D plan sponsors are obligated to process and effectuate any appeals from coverage determinations (in connection with both prescription drug benefits and/or payment of benefits) that are determined to be covered, and which should have been provided or paid for while Medicare enrollees were enrolled in the plan. Thus, if appeals are pending at the time a plan sponsor terminates its contract with CMS, the plan must effectuate any favorable determinations that are issued following the date of termination in accordance with [§130](#).

140 - Data (Rev. 3, 2/1/07)

Part D plan sponsors are responsible for reporting certain data related to grievances, exceptions, and appeals. Information about the reporting requirements can be obtained on CMS' Plan Reporting and Oversight webpage:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp

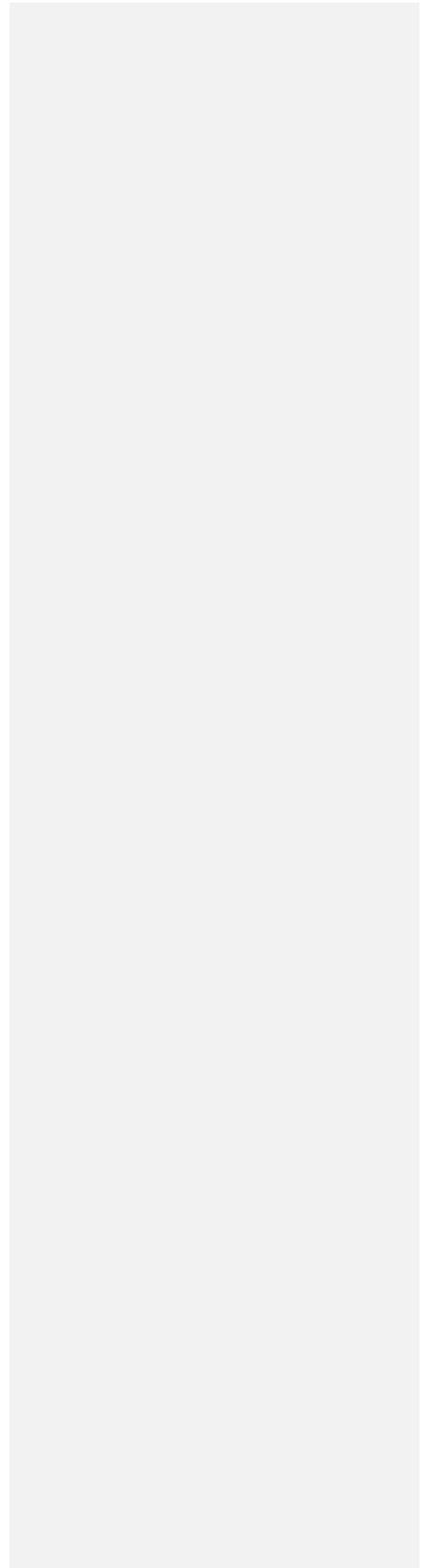
Appendices

(Rev. 8, 1/1/10)

Pursuant to CMS marketing guidance, plan sponsors are responsible for translating marketing materials into any language that is the primary language of more than ten percent of a plan sponsor's PBP service area. The notices contained in this appendix are considered post-enrollment marketing materials, and therefore must be translated in accordance with CMS marketing guidance. See Chapter 3 of the Managed Care Manual (§§30.7 and 20) for additional information. Chapter 3 can be located at: http://www.cms.hhs.gov/ManagedCareMarketing/03_FinalPartCMarketingGuidelines.asp or http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp (designated "Chapter 2" in the Prescription Drug Benefit Manual).

**Appendix 1 - Notice of Denial of Medicare Prescription Drug Coverage
(Rev. 3, 2/1/07)**

The form, [Notice of Denial of Medicare Prescription Drug Coverage - Form CMS-10146](#), and the form's [instructions](#) can be found on the Part D Grievances and Appeals Plan Sponsor Notices and Other Documents page:
http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/14_PlanNoticesAndDocuments.asp.



Appendix 2 - Appointment of Representative - Form CMS-1696

(Rev. ~~91, 1/1/11~~~~1/30/05~~)

The form, [Appointment of Representative - Form CMS-1696](#) can be found on the CMS forms page: <http://www.cms.hhs.gov/CMSForms/CMSForms/list.asp>. If an appointment is made using Form CMS-1696 or an equivalent written notice, the plan sponsor must accept it. Plan sponsors are prohibited from requiring the use of a specific form (other than Form CMS-1696 or an equivalent written notice) for appointments.

Appendix 3 - (Model) Notice of Right to an Expedited Grievance
(Rev. ~~98, 1/1/11+4/40~~)

[INSERT NAME OF MEDICARE PART D PLAN]

Date:

Patient Name:

Patient ID Number:

<Street Address>

<City, State Zip Code>

Notice of Right to an Expedited Grievance

_____ You are receiving this notice because we are denying your request to expedite (put on a fast track) your initial request for a Part D drug.

_____ You are receiving this notice because we are denying your request to expedite (put on a fast track) your appeal for a Part D drug.

Your request has been transferred to our regular processing time frame.

Initial requests will be processed no later than **72 hours** and appeal requests will be processed no later than **7 calendar days** from the day we received your request.

You may resubmit your request.

You may **resubmit your request** to expedite (put on a fast track) your initial request or appeal. If your prescribing physician or other prescriber tells us that applying the standard time frame could put your life or health at risk, we will automatically expedite your request.

You may file an expedited grievance.

If you disagree with our decision not to give you a fast decision, you may file an **expedited grievance** with us. We must decide within **24 hours** if our decision to deny making a fast decision puts your life or health at risk.

If we determine that we should have expedited your request, we will do so immediately and notify you of our decision.

Please call us at {insert phone number of health plan contact} if you want to file an expedited grievance, or want more information.

You can also call 1-800-MEDICARE for more information about the expedited grievance process.

Appendix 4 - (Model) Notice of Redetermination

(Rev. 98, 1/1/11+4/40)

[LOGO]

**Redetermination Notice
Denial of Medicare Prescription Drug Coverage**

Date:

Enrollee's name: <Insert Name>

Enrollee's Medicare (HIC) number: <Insert HICN>

<Street Address>

<City, State Zip Code>

Plan Name: <Insert Plan Name>

Contract ID: <Insert Contract ID>

Formulary ID: <Insert Formulary ID>

Plan ID: <Insert Plan ID>

We agree with our initial coverage determination and are denying the following prescription drug(s) that you or your physician or other prescriber requested: _____

We denied this request because: _____

What If I Don't Agree With This Decision?

You have the right to ask for an independent review (appeal) of our decision. If your case involves an exception request and your physician or other prescriber did not already provide your plan with a statement supporting your request, **your physician or other prescriber must provide a statement to support your exception request and you should attach a copy of this statement to your appeal request.** If you want to appeal our decision, you must request your appeal in writing within 60 calendar days after the date of this notice. You must mail or fax your written request to the independent reviewer at:

<Insert appropriate Part D QIC contact information>

Requests from PDP and MA-PD Plans:
MAXIMUS Federal Services, Medicare Part D QIC
860 Cross Keys Office Park
Fairport, NY 14450

Fax Numbers Customer Service:
Toll-free: (877) 456-5302
(585) 425-5300
~~(585) 425-5304~~
~~(585) 425-9404~~

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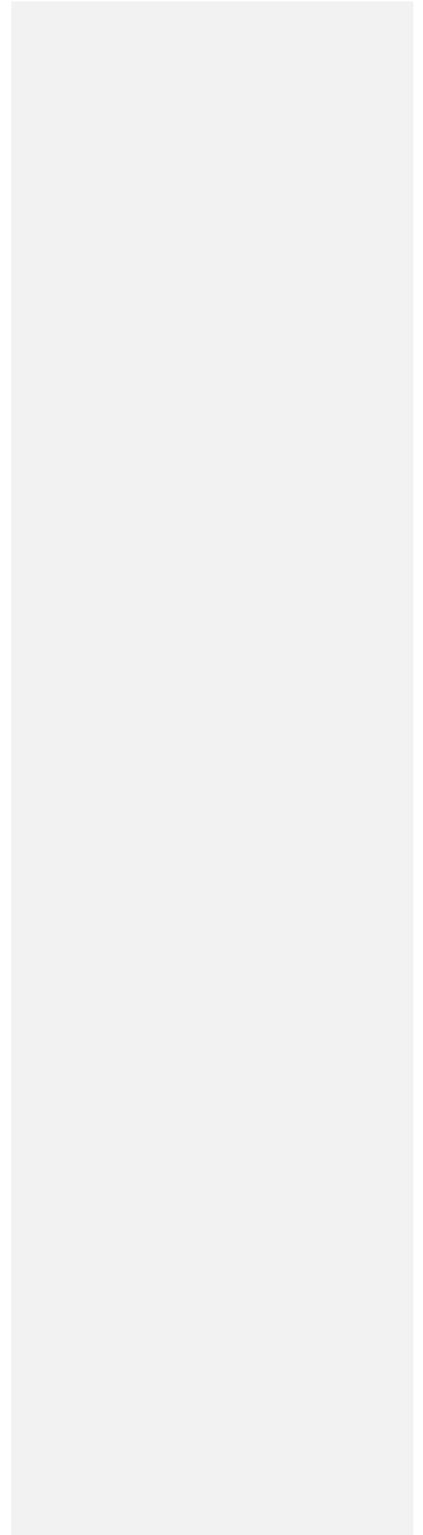
Fax Numbers:
Toll-free: (866) 825-9507
(585) 425-5390

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Who May Request an Appeal?

You or someone you name to act for you (your **representative**) may request an appeal. **A doctor or other prescriber may request an appeal ONLY if you appoint him or her to act for you.** You can name a relative, friend, advocate, attorney, doctor, or someone else to act for you. An Appointment of Representation is not needed if the person appealing is authorized under State law to act for you (for example, through a health care power of attorney or health care proxy).

You can call us at: (_____)_____ to learn how to name your representative. If you have a hearing or speech impairment, please call us at TTY (_____)_____.



IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

For more information about your appeal rights, call us or see your Evidence of Coverage.

There Are Two Kinds of Appeals You Can Request

Expedited (72 hours) - You can request an expedited (fast) appeal for cases that involve coverage, if you or your doctor believes that your health could be seriously harmed by waiting up to 7 days for a decision. If your request to expedite is granted, the independent reviewer must give you a decision no later than 72 hours after receiving your appeal (the timeframe may be extended in limited circumstances).

- **If the doctor who prescribed the drug(s)** asks for an expedited appeal for you, or supports you in asking for one, and the doctor indicates that waiting for 7 days could seriously harm your health, **the independent reviewer will automatically expedite the appeal.**
- If you ask for an expedited appeal without support from a doctor, the independent reviewer will decide if your health requires an expedited appeal. If you do not get an expedited appeal, your appeal will be decided within 7 days.
- Your appeal will not be expedited if you've already received the drug you are appealing.

Standard (7 days) - You can request a standard appeal for a case involving coverage or payment. The independent reviewer must give you a decision no later than 7 days after receiving your appeal (the timeframe may be extended in limited circumstances).

When the Independent Reviewer Can Extend the Timeframe for Making a Decision – The timeframe may be extended if your case involves an exception request and we have not received the supporting statement from your doctor or other prescriber supporting the request. The timeframe also may be extended when the person acting for you files an appeal request but does not submit proper documentation of representation. In both situations, the independent reviewer may toll (or stop the clock) for up to 14 days to get this information.

What Do I Include with My Appeal?

You should include your name, address, HIC number, the reasons for appealing, and any evidence you wish to attach. If the appeal is made by someone other than the enrollee (**for example, the enrollee's doctor or other prescriber**), the person must submit a document appointing him or her to act for you. If your appeal relates to a decision by us to deny a drug that is not on our list of covered drugs (formulary) or if you are asking for an exception to a prior authorization (PA) or other utilization management (UM) requirement, your prescribing doctor or other prescriber must submit a statement with your appeal request indicating that all the drugs on any tier of our formulary (or the PA/UM requirement) would not be as effective to treat your condition as the requested drug, or would harm your health.

How Do I Request an Appeal?

You or your representative should mail or fax your written appeal request to:

[Insert Part D QIC address and fax number]

What Happens Next? If you appeal, the independent reviewer will review your case and give you a decision. If any of the prescription drugs you requested are still denied, you can appeal to an administrative law judge (ALJ) if the value of your appeal is at least \$130. If you disagree with the ALJ decision, you will have the right to further appeal. You will be notified of your appeal rights if this happens.

Contact Information:

If you need information or help, call us at:

Toll Free:

TTY:

Other Resources To Help You:

Medicare Rights Center

Toll Free: 1-888-HMO-9050

TTY:

Elder Care Locator

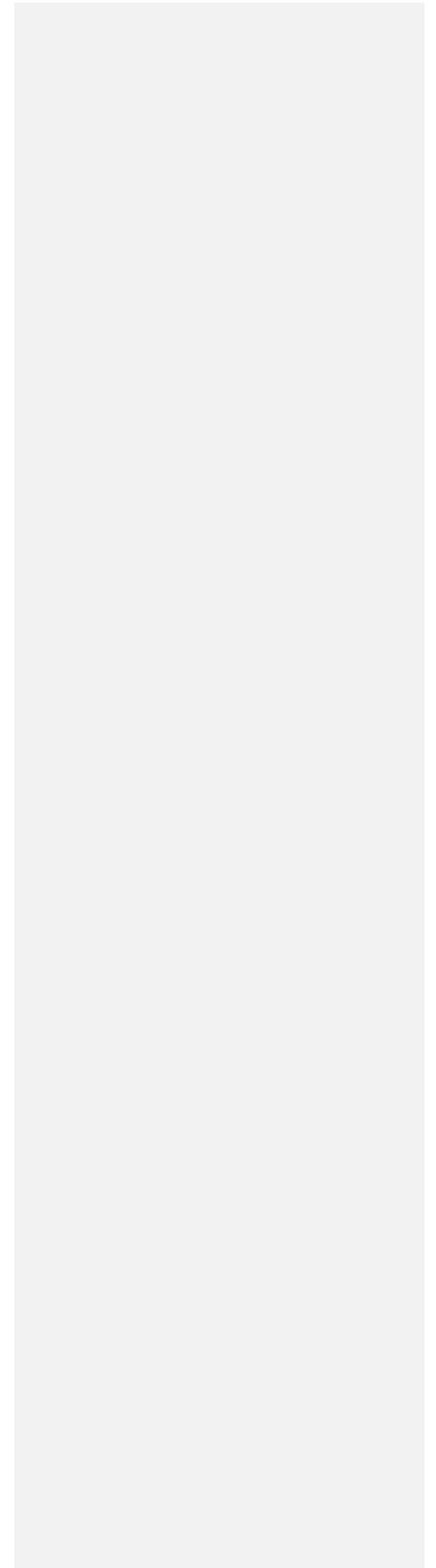
Toll Free: 1-800-677-1116

1-800-MEDICARE (1-800-633-4227)

TTY: 1-877-486-2048

Appendix 5 - Medicare Prescription Drug Coverage and Your Rights
(Rev. 3, 2/1/07)

The form, [Prescription Drug Coverage and Your Rights - Form CMS-10147](#), and the form's [instructions](#) can be found on the Part D Grievances and Appeals Plan Sponsor Notices and Other Documents page: http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/14_PlanNoticesAndDocuments.asp.



Appendix 6 - (Model) Notice of Case Status
(Rev. 1, 11/30/05)

NOTICE OF CASE STATUS

<Date>

Member Name
Street Address
City, State Zip Code

Member ID Number: <111-11-1111A>
Case Number: <insert number>

Dear <insert name>:

This letter is to inform you that your request for a ["standard initial decision"] ["fast initial decision"] ["standard" appeal] ["fast" appeal] was forwarded to an independent organization for review on <insert date>.

[For a "standard initial decision" request: Your case file was forwarded to an independent review organization because we did not provide you with an answer within 72 hours after receiving your request.]

[For a "fast initial decision" request: Your case file was forwarded to an independent review organization because we did not provide you with an answer within 24 hours after receiving your request.]

[For a "standard" appeal: Your case file was forwarded to an independent review organization because we did not provide you with an answer within 7 calendar days after receiving your appeal.]

[For a "fast" appeal: Your case file was forwarded to an independent review organization because we did not provide you with an answer within 72 hours after receiving your appeal.]

The law requires us to forward your case file to an independent review organization within 24 hours if we do not provide you with an answer within the required time frame.

The independent review organization has a contract with the Centers for Medicare & Medicaid Services (CMS), the government agency that runs the Medicare program. The independent review organization has no connection to us. You have the right to ask us for a copy of your case file that we sent to this organization. *[Plans must indicate if there is a charge for the copy.]*

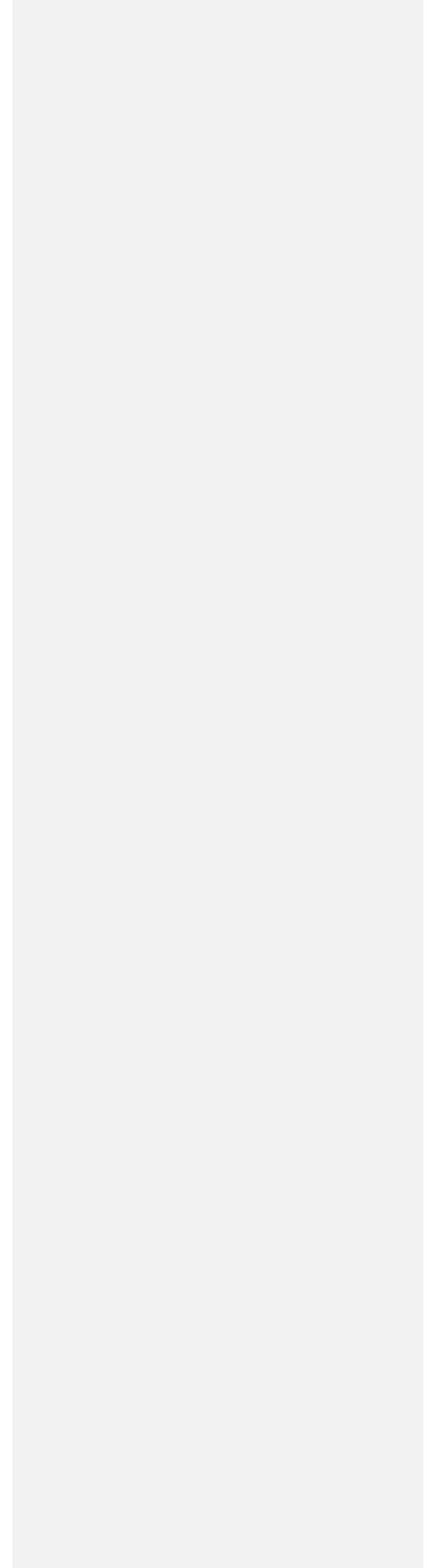
You have the right to submit additional evidence about your case. If you choose to submit additional evidence, you should send it promptly to the independent review organization at <address><fax>.

If you have any questions, or if you would like to request a copy of your case file, please contact Customer Services at <toll-free number> <days and hours of operation>. TTY users should call <toll-

free TTY number>.

Thank You.

<Plan name>



Appendix 7 - (Model) Notice of Plan's Decision to Extend the Deadline for Making a Decision Regarding a Grievance
(Rev. 1, 11/30/05)

<Date>

Member Name
Street Address
City, State Zip Code

Member ID Number: <111-11-1111A>

Dear <Insert name>:

This letter is in response to your grievance (complaint) that you filed with us on <insert date>.

Based upon our review, we are extending the time frame for making a decision until <insert date> because <Plan should list reason for extension, i.e., if the enrollee requested the extension **or** if the Plan needs more information. If the Plan needs more information, the Plan **must** also detail how the delay is in the best interest of the enrollee>.

If you have any questions, please contact Customer Services at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you for your concern.

<Plan name>

**Appendix 8 - (Model) Notice of Plan's Decision Regarding a Grievance
(Rev. 1, 11/30/05)**

<Date>

Member Name
Street Address
City, State Zip Code

Member ID Number: <111-11-1111A>

Dear <Insert name>:

This letter is in response to your grievance (complaint) that you filed with us on <insert date>.

Based upon our review, <Plan should insert decision>.

<For grievances related to quality of care, the notice to the enrollee must include a description of the enrollee's right to file a written complaint with the quality improvement organization (QIO)>.

If you have any questions, please contact Customer Services at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you for your concern.

<Plan name>

**Appendix 9 - (Model) Notice of Effectuation to Part D Independent Review
Organization
(Rev. 1, 11/30/05)**

<Date>

[Part D QIC]
Street Address
City, State Zip Code

Member ID Number: <111-11-1111A>
Case Number: <insert number>

Dear <insert name>:

[For requests for benefits:

We received notice of the decision made on <insert date> for Case Number <insert number>.

In accordance with this decision, the benefit(s) under dispute was/were provided to the enrollee on <insert date>.]

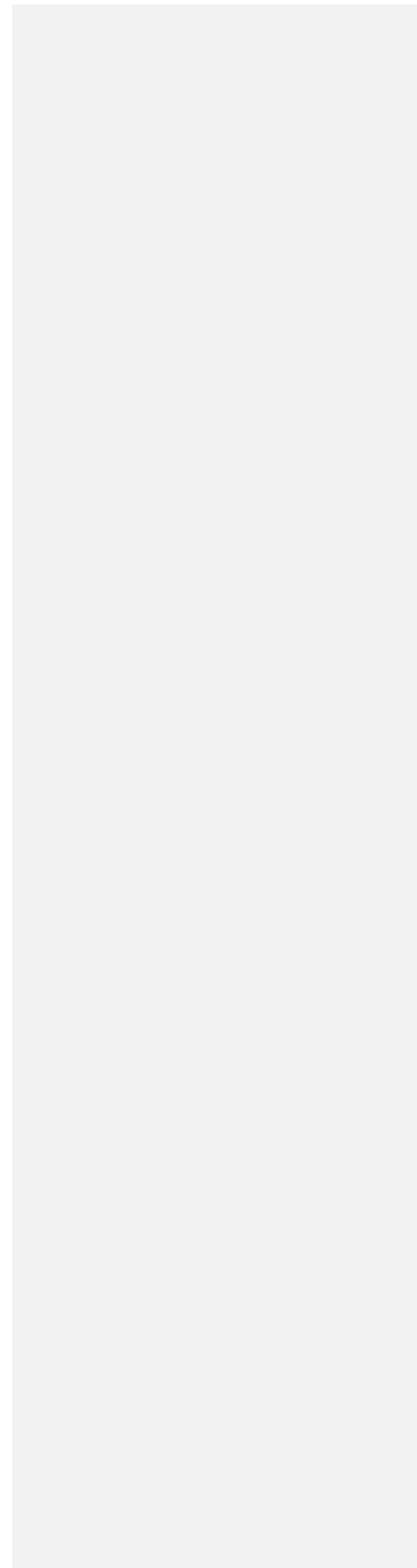
[For requests for payment:

We received notice of the decision made on <insert date> for Case Number <insert number>.

In accordance with this decision, payment for the benefit was made on <insert date>.]

Thank you.

<Plan name>



Appendix 10 - (Model) Notice of Formulary or Cost-sharing Change
(Rev. 8, 2/24/10)

<Date>

Member Name
Street Address
City, State Zip Code

Member ID Number: <111-11-1111A>

Dear <insert name>:

This letter is to inform you of a change to our formulary.

Effective on <insert date>, <insert name of drug> *<Plan must state if the drug is being removed from the formulary or if there has been a change to the drug's preferred or tiered cost-sharing status. >*

We are <removing or changing the tiering structure of> <insert name of drug> because <Plan must explain the reason for removal of the drug from the formulary or why there is a change to the drug's preferred or tiered cost-sharing status. >

You may be able to use another drug to treat your medical condition that <is on our formulary or is in the same drug tier as <insert drug name. > These drugs include *<Plan must indicate alternative drugs that are in the same therapeutic category/class or in the same cost-sharing tier. >* You should ask your prescriber if one of these drugs is right for you. If your prescriber prescribes one of these drugs for you, your expected cost will be *<Plans must indicate the expected cost of the alternative drug(s). >*

If your prescriber believes that none of the drugs listed above is right for you due to your medical condition, you may request <an exception to our formulary or a tiering exception. > To file a request, *<Plan must describe the process for filing an exception, including the need for the prescribing physician's or other prescriber's supporting statement, and refer the enrollee to the appropriate section(s) in the EOC for more information. >*

Or, you can call us at <insert toll-free number> for help in asking for this type of decision.

If you disagree with our decision to *<remove or change the tiering structure of> <insert name of drug>*, you may also file a grievance with us. Please call us at *<toll-free number>* if you want to file a grievance. You may also send your grievance to us in writing by *<Describe the process for filing a written grievance, and refer the enrollee to the appropriate section(s) in the EOC for more information>*.

Thank you.

<Plan name>

Appendix 11 - (Model) Request for Additional Information
(Rev. 8, 1/1/10)

<Date>

Member Name
Street Address
City, State Zip Code

Member ID Number: <111-11-1111A>
Case Number: <insert number>

Dear <insert name>:

This letter is in response to your request for a <indicate type of request, e.g., formulary or tiering exception, expedited redetermination> that <you **OR** your physician or other prescriber> filed with us on <insert date>. <A "formulary exception" request is when you ask for a drug that is not on <Plan name>'s list of covered drugs (called a "formulary"), or ask us not to apply a prior authorization or other requirement to a drug on our formulary >. **OR** <A "tiering exception" request is when you ask for a non-preferred drug at the preferred cost level>.

In order to process your request, we need additional information from your physician or other prescriber.

<Plans must specifically describe the type of written documentation they require from the physician. or other prescriber >

For formulary exceptions: Plans may require a statement that the drug is medically necessary to treat the enrollee's condition because: (1) all of the covered drugs on the Plan's formulary 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; (2) step therapy has been or is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance, or has caused or is likely to cause an adverse reaction to the enrollee; or (3) the number of doses that is available under a dose restriction for the drug has been or is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

For tiering exceptions: Plans may require a statement that the preferred drug for the treatment of the enrollee's condition would not be as effective as the requested drug and/or that the preferred drug would have adverse effects for the enrollee.

If applicable, for either type of exception request, Plans must also indicate if this letter is a request for additional supporting medical documentation>.

If you have any questions, please contact Customer Services at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you.

<Plan name>

Appendix 12 - (Model) Notice of Inquiry
(Rev. 8, 1/1/10)

<Date>

Member Name
Street Address
City, State Zip Code

Member ID Number: <111-11-1111A>

Dear <insert name>:

This letter is in response to your inquiry on <insert date>.

You asked if <insert name of drug> is covered for you.

< Under section 1860D-2(e)(1) of the Social Security Act (the Act), certain drugs are not covered Part D drugs or are not covered Part D drugs when used to treat certain medical conditions.> **or** <Under section 1860D-2(e)(2) of the Social Security Act (the Act), certain drugs are excluded from Medicare coverage or are excluded from coverage when used to treat certain medical conditions.> or <Under section 1860D-43 of the Social Security Act (the Act), certain drugs are excluded from Medicare coverage if the manufacturer did not sign an agreement to participate in the Medicare Coverage Gap Discount Program.>

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<Insert name of drug> is one of the drugs that is <not a covered Part D drug> **or** <excluded from Medicare coverage> by law, and we do not offer the drug as a supplemental benefit.

[If a drug is not a covered Part D drug or is excluded from coverage because of the indication, insert language explaining why the drug isn't covered and the indication(s) that the drug would be covered for. For example:

Under Medicare law, Actiq is a covered Part D drug only when it is prescribed for breakthrough cancer pain. Because your physician or other prescriber prescribed Actiq to relieve your back pain, it is not a covered Part D drug.]

You should work with your physician or other prescriber to determine if a drug on our list of covered drugs (our formulary) is medically appropriate for treating your condition.

[If the drug is excluded from coverage, insert the following language:] <If you receive Medicaid, you may be able to obtain coverage for this drug under the Medicaid program. Check with your state Medicaid office.>

If, after reading this letter, you have reason to believe that we made a mistake and <insert name of drug> is <a covered Part D drug under section 1860D-2(e)(1) of the Act> **or** <not excluded under section 1860D-2(e)(2) of the Act> or <not excluded under section 1860D-43 of the Act>

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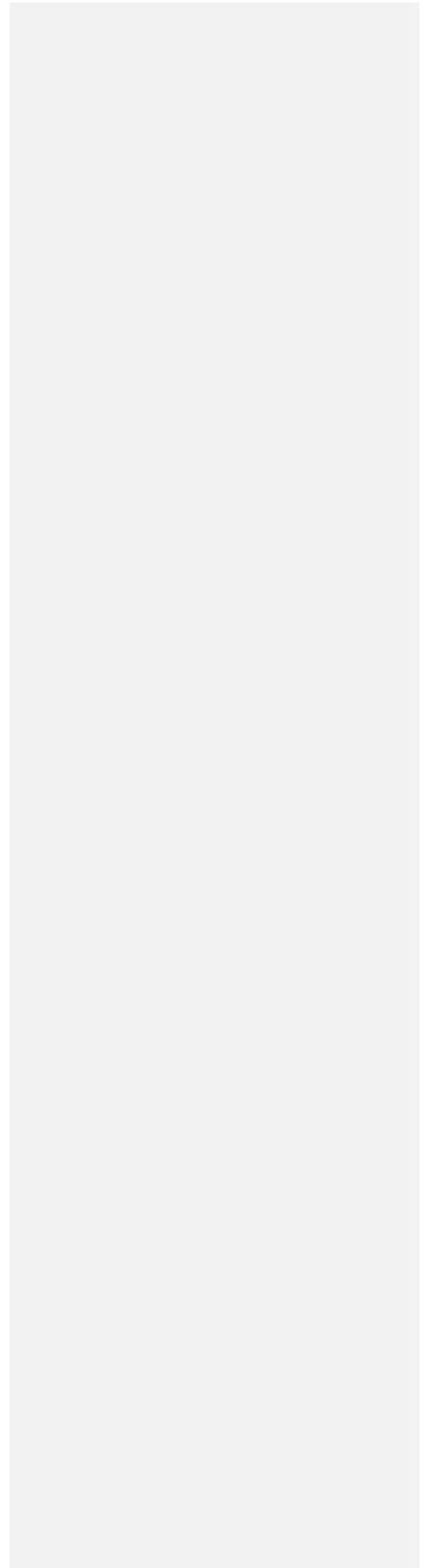
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or is covered by the plan as a supplemental benefit, you or your physician or other prescriber have the right to contact us and request a coverage determination. Contact us at the number below or refer to your evidence of coverage to find out how to ask us for a coverage determination.

If you have any questions, please contact Customer Services at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you.

<Plan name>



Appendix 13 - (Model) Request for Reconsideration

(Rev. ~~98, 1/1/11~~ 1/1/14)

Part D plans must include this Request for Reconsideration form with each adverse Redetermination Notice and must complete the following plan identifying information:

Plan Name: <Insert Plan Name>

Contract ID: <Insert Contract ID>

Formulary ID: <Insert Formulary ID>

Plan ID: <Insert Plan ID>

Request for Reconsideration of Medicare Prescription Drug Denial

Because your Medicare drug plan has upheld its initial decision to deny coverage of, or payment for, a prescription drug you requested, you have the right to ask for an independent review of the plan's decision. **You may use this form to request an independent review of your drug plan's decision.** You have 60 days from the date of the plan's Redetermination Notice to ask for an independent review. Please complete this form and mail or fax it to:

<Insert appropriate Part D QIC contact information>

Requests from PDP and MA-PD Plans:	Customer Service:	Fax Numbers:
MAXIMUS, Federal Services, Medicare Part D QIC	Toll-free: (877) 456-5302	Toll-free: (866) 825-9507
860 Cross Keys Office Park	(585) 425-5300	(585) 425-5304
Fairport, NY 14450		(585) 425-9404
		(585) 425-5390

Note about Representatives: If you want another individual, such as a family member, friend, or your doctor to request an independent review for you, that individual must be your representative. Contact your Medicare drug plan to learn how to name a representative.

Enrollee's Information

Enrollee's Name _____ Date of Birth _____

Enrollee's Address _____

City _____ State _____ Zip Code _____

Phone _____

Enrollee's Medicare (HIC) Number (as shown on your Medicare card) _____

Complete the following section ONLY if the person making this request is not the enrollee (make sure to attach documentation showing the person's authority to represent enrollee for purposes of this request):

Requestor's Name _____

Requestor's Relationship to Enrollee _____

Address _____

City _____ State _____ Zip Code _____

Phone () _____

Representation documentation for appeal requests made by someone other than enrollee:

Attach documentation showing the authority to represent the enrollee (a completed Form CMS-1696 or a written equivalent) if it was not submitted at the coverage determination or redetermination level. A physician or other prescriber may request an appeal ONLY if he or she is appointed by the enrollee to do so.

Prescription drug you asked your plan to cover: _____

Prescribing Physician's or Other Prescriber's Information

Name _____

Address _____

City _____ State _____ Zip Code _____

Office Phone: () _____ Fax: () _____

Office Contact Person _____

If the prescriber is appealing for enrollee, is an appointment of representation form attached Yes No

Expedited Decisions

If you or your prescribing physician or other prescriber believe that waiting for a standard decision (which will be provided within 7 days) could seriously harm your life, health, or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescribing physician or other prescriber indicates that waiting 7 days could seriously harm your life or health or ability to regain maximum function, the independent review organization will automatically give you a decision within 72 hours. This timeframe may be extended for up to 14 calendar days if your case involves an exception request and we have not received the supporting statement from your doctor or other prescriber supporting the request, OR the person acting for you files an appeal request but does not submit proper documentation of representation. If you do not obtain your physician's or other prescriber's support for an expedited appeal, the independent review organization will decide if your health condition requires a fast decision.

Check this box if you believe you need a decision within 72 hours (if you have a supporting statement from your prescribing physician or other prescriber, attach it to this request)

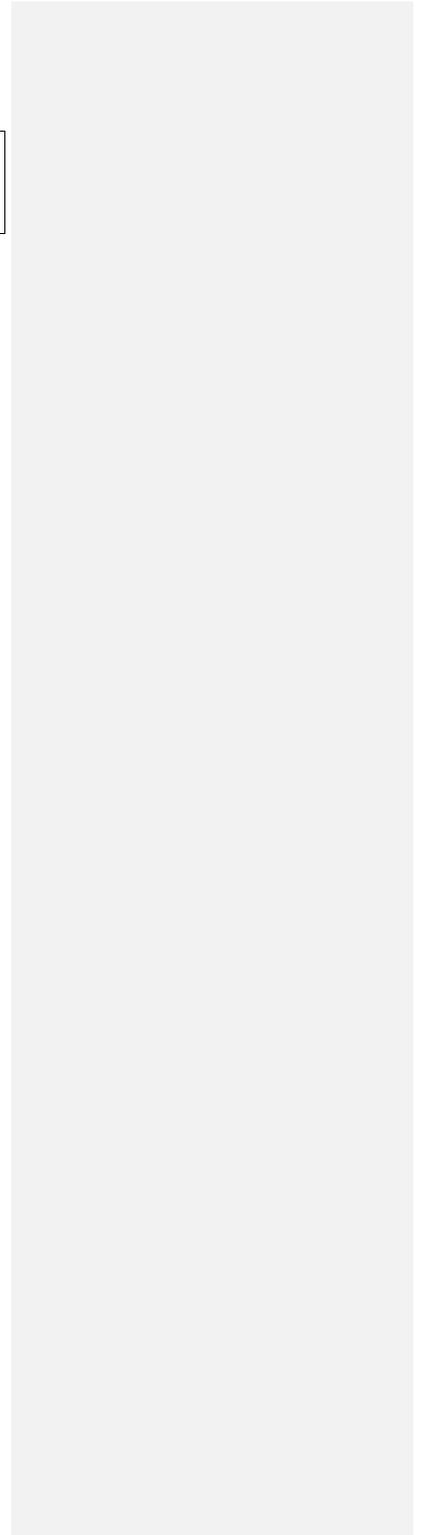
Please attach any additional information you have related to your appeal such as a statement from your prescribing physician or other prescriber and relevant medical records.

Additional information we should consider: _____

Important: Please include a copy of the Redetermination (denial) Notice you received from your drug plan with this request.

Signature of person requesting the appeal (the enrollee or the representative):

_____ **Date:** _____



Appendix 14 - (Model) Part D Late Enrollment Penalty Reconsideration Notice
(Rev. 8, 7/1/09)

**YOUR RIGHT TO ASK MEDICARE TO REVIEW
YOUR MEDICARE PART D LATE ENROLLMENT PENALTY**

What if I Don't Agree with Medicare's Late Enrollment Penalty Decision?

"Creditable prescription drug coverage" is coverage (for example from an employer or union) that meets Medicare's minimum standards since it is expected to pay, on average, at least as much as Medicare's standard prescription drug coverage. If you don't join a Medicare drug plan when you are first eligible, and you don't have other "creditable prescription drug coverage," you may have to pay a late enrollment penalty (LEP). In some cases you have the right to ask Medicare to review your late enrollment penalty decision. This is called a "reconsideration." For example, you could request a reconsideration if you think Medicare did not count all of your creditable coverage or if you didn't get a notice that clearly explained whether your previous prescription drug coverage was creditable. Other reasons for requesting a reconsideration are listed on the request form sent with this notice.

Who Can Ask for a Reconsideration?

You or someone you name to act for you (your representative) can ask for a reconsideration. If someone requests a reconsideration for you, he or she must send proof of his or her right to represent you with the request form. Proof could be a power of attorney form, a court order, or an "Appointment of Representative" form. This last form can be found at <http://www.medicare.gov/Basics/forms> on the web. You also can call the Medicare helpline (see below) and ask for Form CMS-1696.

How Do I Ask for a Reconsideration?

The reconsideration request form is sent with this notice. Complete the form. Mail it to the address or fax it to the number listed on the form within 60 days from the date on the letter you got stating you had to pay a late enrollment penalty. You should also send any proof that supports your case, like information about previous creditable prescription drug coverage. If you wait more than 60 days, you must explain why your request is late. Medicare will decide if you had good cause to send a late request.

What Do I Need to Include with My LEP Reconsideration Request?

1. A completed, signed LEP reconsideration request (keep a copy).
2. Copies of information you believe may help your case.
3. If you've named someone to act for you, a copy of the proof the individual can represent you.

NOTE: Do not send original documents.

Where Can I Get More Information?

Call <Plan Name> at <plan toll-free number> <days and hours of operation>. TTY users should call the plan at <plan TTY number>. <A plan also may include a URL to its website here to provide additional information.> Or, visit www.medicare.gov on the web or call 1-800-MEDICARE (1-800-633-4227) for help. TTY users should call Medicare at 1-877-486-2048.

Appendix 15 - (Model) Part D Late Enrollment Penalty Reconsideration Request Form
(Rev. 8, 1/1/10)

**LATE ENROLLMENT PENALTY
RECONSIDERATION REQUEST FORM**

Date: _____ **Enrollee Name:** _____
Address: _____
Phone: (____) _____

Medicare Health Insurance Claim #

(From red, white and blue Medicare card): _____

Name of Medicare Prescription Drug Plan: _____

IMPORTANT: Complete, sign and mail this request to the address or fax it to the number listed on the form within 60 days from the date on the letter you got stating you had to pay a late enrollment penalty. If it has been more than 60 days, explain your reason for delay on a separate sheet and send it with this form.

Send any additional information that may help your case. If applicable, please provide evidence of prior prescription drug coverage that was “creditable.” “Creditable prescription drug coverage” is coverage that meets Medicare’s minimum standards since it is expected to pay, on average, at least as much as Medicare’s standard prescription drug coverage. For example:

- If you had drug coverage from an employer or union plan, provide a copy of the Notice of Creditable Prescription Drug Coverage or Certificate of Prior Creditable Prescription Drug Coverage from the employer or union plan.
- If you had drug coverage with the Department of Veterans Affairs (VA), please provide any of the following: Notice of Creditable Prescription Drug Coverage; a copy of your VA Health Benefit Card; a letter from the VA certifying eligibility; or an Explanation of Benefits (EOB).

Check all boxes that apply to you. Your case will only be reviewed for one or more of the reasons listed on the next page.

<p><input type="checkbox"/> I had other creditable* prescription drug coverage. Please complete the following (use a separate sheet, if necessary):</p> <p>Plan Name: _____</p> <p>Dates of coverage (mm/dd/yyyy) from ____/____/____ to ____/____/____</p> <p>Plan Address & Phone: _____</p> <p>Name of former employer/union/other insurer: _____</p> <p>Contact name: _____ Phone: _____</p>
<p><input type="checkbox"/> I had prescription drug coverage but I didn’t get a notice that clearly explained if my drug coverage was creditable* coverage.</p> <p>Reminder: Most non-Medicare plans that offer prescription drug coverage, like employer or union coverage, must send enrollees a notice explaining how their prescription drug coverage compares to Medicare prescription drug coverage. Plans may provide this information in their benefits handbook or as a separate written notice.</p>

If you don't know if your prescription drug coverage was creditable:*

To help your case, you may want to send a letter to your previous plan and ask if your coverage was creditable. Attach your letter and any response to this form.

I believe the LEP is wrong because I was not eligible to enroll in a Medicare drug plan during the period stated by my current Medicare drug plan. Example: You lived outside of the United States during the initial enrollment period stated by your Medicare plan. You must submit proof why you believe the LEP is wrong, such as proof of overseas residency.

I believe the LEP is wrong because I was unable to enroll in a Medicare drug plan due to a serious medical emergency. You must submit proof that you experienced a serious medical emergency (for example, unexpected hospitalization) that affected your ability to enroll timely in a Medicare drug plan.

I have/had extra help from Medicare to pay for my prescription drug coverage.

Date(s) of extra help: from _____ to _____.

Use a separate sheet if necessary.

I lived in an area affected by Hurricane Katrina at the time of the hurricane (August 2005) and I joined a Medicare drug plan before December 31, 2006.

Name of Parish: _____

* **“Creditable” means that your prior coverage met Medicare’s minimum standards.**

To the best of my knowledge, the information on this form is true and correct. I understand that my signature (or the signature of my representative) on this document means that I have read and understand the contents of this request. By signing this form, I give permission to any entity to release information needed by Medicare to review my Medicare prescription drug late enrollment penalty.

Signature of Person Requesting Reconsideration
(Either Enrollee or Representative)

Date

Important: Prescription drug coverage is **insurance**. It's NOT doctor samples, discount cards/programs, free clinics, or drug discount websites.

Also, the “certificate of creditable coverage” that you may have received when your health coverage ended doesn't mean that your prescription drug coverage met Medicare's minimum standards – unless the notice specifically mentioned you had “creditable” prescription drug coverage that expected to pay as much as Medicare's standard prescription drug plan pays.

Note about Representatives: If you want another individual, such as a family member, friend, or your doctor to request a reconsideration for you, that individual must be your representative. Contact your Medicare drug plan to learn how to name a representative.

Complete this section only if the person making this request is NOT the enrollee:

Representative Name: _____

Address: _____ Phone: (____) _____

Relationship to Enrollee: _____

Attach documentation that shows authority to represent enrollee, such as a Form CMS-1696.

Send this form and any extra pages to MAXIMUS (Medicare's Appeals Contractor):

MAXIMUS Federal Services
Medicare Part D QIC
P.O. Box 991
Victor, NY 14564-0991
1040 First Avenue, Suite 200
King of Prussia, PA 19406
Fax: (484) 688-5604 (585) 869-3320
Toll-free fax: (866) 589-5241
Toll-free customer service: (877) 456-5302
Customer Service: (585) 425-5300

Be sure to include your Medicare Health Insurance Claim number on any materials you send. Do not send original documents.

Where Can I Get More Information? Call <Plan Name> at <plan toll-free number> <days and hours of operation>. TTY users should call the plan at <plan TTY number>. <A plan also may include a URL to its website here to provide additional information.> Or, visit www.medicare.gov on the web or call 1-800-MEDICARE (1-800-633-4227). TTY users should call Medicare at 1-877-486-2048.

STOP! DID YOU SIGN THIS FORM?