

Prescription Drug Benefit Manual

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

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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.

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. 2, 6-22-06)

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.

Appointed Representative: An individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in obtaining a grievance, 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 appointed 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.

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.

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.

10.2 - Responsibilities of the Part D Plan Sponsor

(Rev. 1, 11-30-05)

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.
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 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 - Appointed Representatives

10.4.1 - Appointed Representative Filing on Behalf of the Enrollee

(Rev. 2, 6-22-06)

An enrollee may appoint any individual (such as a relative, friend, advocate, attorney, physician, or an employee of a pharmacy, charity, state pharmaceutical assistance program, or other secondary payor) to act as his or her representative. A representative who is appointed by the court or who is acting in accordance with State law may also file a grievance or a request for a coverage determination, or appeal on behalf of an enrollee.

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.

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 the appointed representative is an attorney, only the enrollee needs to sign the appointment of representative form or similar statement.

The representative statement must include the enrollee's name and Medicare number. An enrollee may use Form CMS-1696. (See [Appendix 2](#)). The enrollee may also use an equivalent written notice. 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](#), §60.5.3, of the Medicare Claims Processing Manual for more information about whether a notice is an "equivalent written notice."

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 request for a 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 the 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 appointed representative must file a copy of the original form or other conforming written instrument with each new request for a coverage determination.

Except in the case of incapacitated or incompetent enrollees, a request for a coverage determination or redetermination from an appointed 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 request will not be considered until the appropriate documentation is provided.

When a request for a coverage determination or redetermination is filed by a person claiming to be an appointed 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 coverage

determination or redetermination request 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 the time frame the plan sponsor would have for making its coverage determination or redetermination if the request had been filed by the enrollee, the Part D plan sponsor should dismiss the request on the grounds that a valid request was not received. The plan sponsor should explain in the dismissal letter that it will process the request if the enrollee resubmits the request with a properly executed Form CMS-1696 or other equivalent notice.

If an appeal is initiated by an appointed 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 requests a standard coverage determination, expedited coverage determination, or an 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 is not required to submit a signed Form CMS-1696 or other equivalent notice to the IRE because a prescribing physician may request a standard coverage determination, expedited coverage determination, or an expedited redetermination on an enrollee's behalf without being an appointed representative.

10.4.2 - Authority of an Appointed Representative

(Rev. 2, 6-22-06)

Unless otherwise stated in the rules described in subpart M of part 423, the appointed representative has all of the rights and responsibilities of an enrollee in obtaining a

grievance, coverage determination, or in dealing with any of the levels of the Part D appeals process.

For instance, an appointed 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 an appointed 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 appointed 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 an appointed representative (who is representing an enrollee in regards to an MA claim) files a request for 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

(Rev. 2, 6-22-06)

A prescribing physician may act on behalf of an enrollee in requesting a standard or expedited coverage determination, or an expedited redetermination. An enrollee's prescribing physician is not an enrollee's appointed representative, as described in [§10.4.1](#), and therefore does not have all of the rights and responsibilities of an enrollee as described in [§10.4.2](#). However, an enrollee's prescribing physician is entitled to receive certain notifications, as described in §§[40.2](#), [40.3.2](#), [50.3](#), [50.4](#), and [70.8.1](#).

Note: The regulations do not prohibit an enrollee's prescribing physician from becoming an enrollee's appointed 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. 2, 6-22-06)

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. 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 a written explanation of the procedures the enrollee must follow to file a request for a standard coverage determination. 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. 2, 6-22-06)

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.

Example 2

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 3

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.

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 - Excluded Drug Complaints

(Rev. 2, 6-22-06)

A transaction with an enrollee or physician that involves a request for coverage of a drug that 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 excluded from coverage under section 1927(d)(2) of the Social Security Act are not Part D drugs. Thus, strictly interpreted, a decision by a plan sponsor not to cover a drug excluded under section 1927(d)(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 not statutorily excluded for a specific indication;**
- **A drug is covered by the plan as a supplemental benefit; or**
- **The plan sponsor incorrectly classified/identified a Part D drug as excluded from coverage.**

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

If a drug is excluded, it is never covered by Medicare, regardless of medical necessity. However, an appeal entity may overturn a plan's decision to not cover a drug because it is excluded if the appeal entity determines that the drug is a Part D drug and is not excluded under section 1927(d)(2) of the Act, the drug is being used for an indication that isn't excluded under section 1927(d)(2) of the Act, or the plan sponsor includes the excluded drug as a supplemental benefit.

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

Inquiry

Not all transactions that involve excluded drugs should be classified as grievances or coverage determinations. In general, an initial transaction involving an excluded drug should be treated as an inquiry unless the enrollee or the enrollee's physician complains about the exclusion of the requested drug from coverage (i.e., files a grievance), or argues that the plan sponsor incorrectly classified/identified a Part D 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 (i.e., makes a request for a coverage determination). **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 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 excluded from coverage under section 1927(d)(2) the Social Security Act;
2. The plan sponsor must explain that the requested drug is one of the statutorily excluded drugs and the plan does not offer the drug as a supplemental benefit;
3. The plan sponsor must emphasize that, because the drug is excluded from coverage and is not offered as a supplemental benefit, the enrollee may not obtain it through the coverage determination, exceptions, or appeals processes.
4. The plan sponsor must explain that the enrollee should work with his or her physician 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 or physician has the right to contact the plan sponsor and request a coverage determination if he or she believes that:
 - The plan sponsor incorrectly classified/identified the requested drug as excluded under section 1927(d)(2) of the Act;
 - The drug is not excluded under section 1927(d)(2) of the Act for the purpose for which it was prescribed; or
 - The drug is covered by the plan as a supplemental benefit.

The plan sponsor must also explain how the enrollee or physician 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.

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**.

Grievance

If an enrollee is not disputing that a drug is an excluded drug, but he/she is complaining about the exclusion of the requested drug from coverage, 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 or physician. 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**.

Coverage Determination

If an enrollee or physician argues that a plan sponsor incorrectly classified/identified a requested drug as excluded from coverage, a drug is not excluded for the purpose for

which it was prescribed, or a drug is covered by the plan as a supplemental benefit, the plan sponsor must process the complaint as a coverage determination, which is subject to appeal. This complaint may occur after an inquiry is made, or it may be the initial transaction with the enrollee or physician. 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 excluded from coverage, it must issue an adverse coverage determination explaining that certain drugs are excluded from coverage under Part D and the requested drug is one of excluded 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 excluded from coverage. If it 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 excluded, is excluded 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 coverage under Part D, 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, 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 coverage because it is not being used to treat a medically accepted off-label use, it must issue an adverse coverage determination explaining that the requested drug is excluded from coverage. See the Valium example in section 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. If the IRE determines that the requested drug is not being used to treat a medically accepted off-label use, 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. 2, 6-22-06)

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 2 of this manual.

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 §[140.1](#) 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 issue 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. 2, 6-22-06)

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.

A case where an enrollee/physician is attempting to satisfy a PA requirement (i.e., the enrollee/physician 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 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 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 with the necessary PA form. A physician 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.

Where an enrollee or an enrollee's prescribing physician is seeking an exception to a PA or other UM requirement (e.g., a physician indicates that an enrollee would suffer adverse effects if he or she were required to satisfy the PA requirement), the prescribing physician must submit a statement to support the request consistent with the requirements set forth in 42 CFR 423.578(b)(5). A physician 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 to make a written request or submit a supporting statement on a specific form.** As with other exception requests, the plan must notify the enrollee (and the prescribing physician involved, as appropriate) of its decision no later than 24 hours after

receiving the physician's supporting statement for expedited cases, or no later than 72 hours after receiving the physician's supporting statement for standard cases.

Finally, if an enrollee/physician asks for coverage for a non-formulary drug, the plan should contact the enrollee/physician and explain the need for a supporting statement in order to process the request. A physician 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.

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 or physician 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 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 calls the plan sponsor to ask about the UM requirement and the plan sponsor explains the procedures that the enrollee/physician 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 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 calls the plan sponsor and the plan sponsor explains the procedures that the enrollee/physician must follow for the PA requirement to be satisfied.
4. The enrollee/physician 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 has attempted to satisfy the UM requirement.

30.2 - Exceptions

(Rev. 2, 6-22-06)

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 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.

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, the notice must:

- Explain that the exception will not be extended, and
- Provide the date that coverage will end (e.g., on December 31, 2006).

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.

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. 2, 6-22-06)

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 provides a supporting statement. A supporting statement provided by a physician is entitled to great weight when reviewing the exception or other coverage determination request. The physician may provide either a written or an oral supporting statement.

Written Supporting Statements

If the physician 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 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, as appropriate, within 24 hours (expedited requests) or 72 hours (standard requests) after receiving the 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 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.

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

Oral Supporting Statements

If the physician 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 to subsequently provide a written supporting statement indicating factors (1) and (2) discussed below.

If the plan sponsor requires a written statement, it must request it immediately. The plan sponsor's request must explicitly state that the physician 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 to provide additional supporting medical documentation as part of the written follow-up. If the plan sponsor requires the prescribing physician 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. If the plan sponsor requires the prescribing physician 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 written follow-up supporting statement indicating factors (1) and/or (2) discussed 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, 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 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 drug; and/or
- (2) Would have adverse effects.

A physician 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.

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

As previously noted, the adjudication time frame does not begin until the plan receives the prescribing physician'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 supporting statement, or the physician's supporting statement does not indicate factors (1) and/or (2), the plan must contact the enrollee's prescribing physician, or the enrollee and the enrollee's prescribing physician, and request the supporting statement. The plan sponsor's request must explicitly state that the physician is required to indicate one of the two factors in the written supporting statement. A plan must provide the prescribing physician with a reasonable opportunity to provide the supporting statement before making its determination. If the plan does not receive the physician'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 submitted the prescribing physician's supporting statement with the request. The adjudication time frame does not begin until the prescribing physician'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 in an attempt to obtain the prescribing physician's supporting statement.

1/3/06: The plan sponsor again contacts the enrollee and the enrollee's prescribing physician in an attempt to obtain the prescribing physician'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 supporting statement before making a decision.

1/5/06: If the plan sponsor has not received the physician'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 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 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 did not produce the necessary supporting statement. The enrollee then has the right to appeal the denial.

A plan must grant a tiering exception when it determines that the preferred drug for treatment of the enrollee's condition would not be as effective for the enrollee as the requested 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 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 preferred drugs. Tiering exceptions are limited to obtaining a non-preferred drug at the cost-sharing level that applies to drugs in a plan's preferred tier. Thus, an enrollee can not request a tiering exception to obtain a preferred drug at the cost-sharing level that applies to drugs in a plan's generic tier. 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.

30.2.2 - Formulary Exception

(Rev. 2, 6-22-06)

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 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.

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

Written Supporting Statements

If the physician provides a written statement, 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, as appropriate, within 24 hours (expedited requests) or 72 hours (standard requests) after receiving the 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 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.

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

Oral Supporting Statements

If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement indicating 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. The plan sponsor's request must explicitly state that the physician is required indicate one of the three factors discussed below in the written supporting statement. The plan sponsor may also request the prescribing physician to provide additional supporting medical documentation as part of the written follow-up. If the plan sponsor requires the prescribing physician 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. If the plan sponsor requires the prescribing physician to submit a written supporting statement after the prescribing physician submits an oral supporting statement, the adjudication time frame begins when the plan receives the physician's written follow-up supporting statement indicating 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, 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 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 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.

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

As previously noted, the adjudication time frame does not begin until the plan receives the prescribing physician'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 supporting statement, or the physician's supporting statement does not indicate one of the three factors, the plan must contact the enrollee's prescribing physician, or the enrollee and the enrollee's prescribing physician, and request the supporting statement. The plan sponsor's request must explicitly state that the physician is required to indicate one of the three factors in the written supporting statement. A plan must provide the prescribing physician with a reasonable opportunity to provide the supporting statement before making its determination. If the plan does not receive the physician'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 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). Neither the enrollee nor the enrollee's prescribing physician submitted the prescribing physician's supporting statement with the request. The adjudication time frame does not begin until the prescribing physician'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 in an attempt to obtain the prescribing physician's supporting statement.

1/3/06: The plan sponsor contacts the enrollee and the enrollee's prescribing physician in an attempt to obtain the prescribing physician'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 supporting statement before making a decision.

1/5/06: If the plan sponsor has not received the physician'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 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 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 did not produce the necessary supporting statement. The enrollee then has the right to appeal the denial.

A plan must grant a formulary exception when it determines that 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.

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 single level of cost sharing will apply for all non-formulary drugs approved under the exceptions process. However, a plan sponsor is limited to choosing a cost-sharing level that applies to one of its existing formulary tiers, including the cost-sharing level that applies to the high-cost tier (if applicable) if it does not exceed 25-percent of the actual costs of the drugs contained in that tier. For example, a plan sponsor may apply the non-preferred level of cost sharing for all non-formulary drugs approved under the exception process.

30.3 - Procedures for Handling Misclassified Coverage Determinations

(Rev. 1, 11-30-05)

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.

30.3.1 - Quality of Care

(Rev. 1, 11-30-05)

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).

30.3.2 - Service Accessibility

(Rev. 1, 11-30-05)

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).

30.3.3 - Employer-Sponsored Benefits

(Rev. 1, 11-30-05)

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. 2, 6-22-06)

An enrollee, an enrollee's appointed representative, or an enrollee's prescribing physician may request a standard coverage determination 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](#), the model [Medicare Part D Coverage Determination Request Form for physicians](#) (a/k/a model Part D Exception & Prior Authorization Request Form), 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 an enrollee's appointed representative) **and are prohibited from requiring an enrollee or physician 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 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 coverage determinations 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 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 explain the procedures the enrollee must follow to file a written request for a standard coverage determination. If an enrollee or prescribing physician 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. 2, 6-22-06)

When a party has made a request for coverage or payment of a Part D drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician 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.

Note: Plan sponsors must have processes in place to accept requests and physicians' 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 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 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 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, either the treating physician 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 or staff-person and the physician determines what course of action is appropriate (e.g., the physician 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 appointed representative) and the enrollee's treating physician 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. 1, 11-30-05)

A plan sponsor may make its initial notification orally. 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 with written notice of an adverse determination after providing oral notice to the physician. If a plan sponsor's decision is adverse, the oral (if provided) and written notices must satisfy the requirements in §[40.3.3](#).

If an enrollee has appointed a representative, the plan sponsor must notify the enrollee's appointed representative instead of the enrollee. Additionally, if an enrollee's prescribing physician files a request on behalf of an enrollee, the plan sponsor must notify the enrollee and the enrollee's prescribing physician.

40.3.3 - Written Notification by Part D Plan Sponsors

(Rev. 2, 6-22-06)

If the Part D plan sponsor denies, in whole or in part, a Part D benefit or payment for a prescription drug purchased by an enrollee, it must provide written notice of its determination. As noted in §[10.4.2](#), if an enrollee has identified an appointed representative, the plan sponsor must send the written notice to the enrollee's appointed representative instead of the enrollee. If an enrollee's prescribing physician files a request on behalf of an enrollee and the plan sponsor does not notify the prescribing physician 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.

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):

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 have 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.

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 or is being used for an indication that isn't excluded. See [§20.2.4](#)]

40.4 - Effect of Failure to Provide Timely Notice

(Rev. 2, 6-22-06)

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 does not begin until the plan sponsor receives the physician's supporting statement as indicated in §§[30.2.1](#) and [30.2.2](#), plan sponsors must not automatically forward case files to the IRE if a physician 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](#).

The case file must contain the enrollee's request and any oral and/or written evidence obtained by the plan sponsor. 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.

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](#).

50 - Expedited Coverage Determinations

(Rev. 1, 11-30-05)

An enrollee, his or her appointed representative, or the enrollee's prescribing physician, may request that a Part D plan sponsor expedite a coverage determination when the enrollee or his/her physician 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. 2, 6-22-06)

When asking for an expedited coverage determination, the enrollee or prescribing physician 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](#), the model [Medicare Part D Coverage Determination Request Form for physicians](#) (a/k/a model Part D Exception & Prior Authorization Request Form), 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 an enrollee's appointed representative) **and are prohibited from requiring an enrollee or physician to make a written request on a specific form.** A prescribing physician 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, and the physician 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 need not be the enrollee's appointed 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. 2, 6-22-06)

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

1. Establish efficient and convenient means for enrollees and/or their prescribing physicians 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 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. 1, 11-30-05)

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), give the enrollee and his or her prescribing physician, 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 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. 2, 6-22-06)

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 notify the enrollee and the physician 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 notify the enrollee and the physician 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 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.

50.5 - Notification of the Result of an Adverse Expedited Coverage Determination

(Rev. 1, 11-30-05)

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

A plan sponsor may make its initial notification orally. However, if a plan sponsor issues an adverse expedited 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 with written notice of an adverse determination after providing oral notice to the physician. 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).

50.6 - Effect of Failure to Provide Timely Notice

(Rev. 2, 6-22-06)

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 does not begin until the plan sponsor receives the physician's supporting statement as indicated in [§§30.2.1](#) and [30.2.2](#), plan sponsors must not automatically forward case files to the IRE if a physician 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](#).

The case file must contain the enrollee's request and any oral and/or written evidence obtained by the plan sponsor. 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.

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](#).

60 - Appeals

60.1 - Parties to the Coverage Determination for Purposes of an Appeal

(Rev. 2, 6-22-06)

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

Only the enrollee or the enrollee's appointed representative may request an appeal, with the exception that the enrollee's prescribing physician may request an 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 appointed 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. 1, 11-30-05)

An enrollee or an enrollee's appointed representative may request any appeal. In addition, the enrollee's prescribing physician may request an expedited redetermination without being the enrollee's appointed representative. However, this is the only appeal that an enrollee's prescribing physician may request on an enrollee's behalf unless he or she is the enrollee's appointed representative.

70.2 - How to Request a Standard Redetermination

(Rev. 1, 11-30-05)

A party 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 of the notice of the coverage determination (i.e., the date printed or written on the notice).

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 or prescribing physician 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. 1, 11-30-05)

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, appointed or authorized representative, or prescribing physician incorrect or incomplete information about when and how to request a redetermination;
5. The enrollee, appointed representative, or prescribing physician did not receive notice of the determination or decision; or
6. The enrollee, appointed representative, or prescribing physician 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 that denial to the IRE.

70.4 - Withdrawal of Request for Redetermination

(Rev. 1, 11-30-05)

The party 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. 1, 11-30-05)

The Part D plan sponsor must provide the enrollee or the prescribing physician, 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 appointed representative to obtain the material at a plan location or mailing the material to any address specified by the enrollee or appointed 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 benefits at issue.

70.6.1 - Meaning of Physician With Expertise in the Field of Medicine

(Rev. 1, 11-30-05)

The physician need not, in all cases, be of the same specialty or subspecialty as the enrollee's prescribing physician. 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 sub-specialty to review the adverse coverage determination.

70.7 - Time Frames and Responsibilities for Conducting Standard Redeterminations

(Rev. 2, 6-22-06)

The Part D plan sponsor must 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. If the decision is adverse, plan sponsors must process the decision in accordance with [§70.9.1](#). In addition, if the Part D plan sponsor overturns its adverse coverage determination, it must effectuate it in accordance with [§130.1.1](#) or [§130.1.3](#).

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. 1, 11-30-05)

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](#).

70.7.2 - Dismissal of a Standard Pre-Benefit Redetermination

(Rev. 1, 11-30-05)

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.

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.

If the enrollee submits the bill for payment to the Part D plan sponsor, the plan should make a determination on whether to pay for the prescription drug. If the Part D plan sponsor denies payment, it will issue an adverse coverage determination notice and appeal rights will be available.

70.8 - Expediting Certain Redeterminations

(Rev. 2, 6-22-06)

An enrollee, the enrollee's appointed representative, or an enrollee's prescribing physician 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. The Part D plan sponsor may extend the time frame for filing an expedited request as noted in §70.3. An enrollee may withdraw his or her request as described in §70.4.

The enrollee's prescribing physician 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 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 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. 2, 6-22-06)

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, 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 supported by a physician's oral or written statement, the Part D plan sponsor must grant the request to expedite if the physician 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 support, and explain that if the physician 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 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, adverse expedited redeterminations must be provided in writing in accordance with [§70.9.2](#). 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 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. 1, 11-30-05)

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](#).

70.9 - Notification of the Result of an Adverse Redetermination

70.9.1 - Adverse Standard Redeterminations

(Rev. 2, 6-22-06)

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 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 or supporting statement is deemed received by a plan sponsor. As noted in [§10.4.2](#), if an enrollee has identified an appointed representative, the plan sponsor must send the written notice to the enrollee's appointed 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 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.

70.9.2 - Adverse Expedited Redeterminations

(Rev. 2, 6-22-06)

If a Part D plan sponsor's expedited redetermination decision is adverse, in whole or in part, it must provide notice 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. As noted in [§10.4.2](#), if an enrollee has identified an appointed representative, the plan sponsor must notify the enrollee's appointed representative instead of the enrollee. Additionally, if an enrollee's prescribing physician files a request on behalf of an enrollee, the plan sponsor must notify the enrollee and the enrollee's prescribing physician.

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 with written notice of an expedited adverse redetermination after providing notice to the physician orally). If a plan sponsor's decision is adverse, the oral (if provided) and written notices must satisfy the requirements stated below.

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. 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 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.

70.10 - Forwarding Untimely Redeterminations to the Independent Review Entity

(Rev. 2, 6-22-06)

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

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](#).

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

(Rev. 1, 11-30-05)

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.

70.30 - Preparing the Case File for the Independent Review Entity

(Rev. 1, 11-30-05)

Give each file a separate folder, labeled with the enrollee's name and Health Insurance Claim (HIC) number and the Part D plan's name and contract number.

The actual case file will contain:

1. An Appeal Transmittal Cover Sheet on top of the case file, so that the IRE can clearly differentiate new cases from other incoming materials;
2. Reconsideration Background Data Form, which is a standard data collection document with supplementary narrative description and attachments;

3. Case Narrative;
4. The appointment of representation form, equivalent written notice, other similar documentation required under state or other applicable law (e.g., a durable power of attorney), and an attestation by the plan sponsor verifying that a surrogate is acting in accordance with a state's authorized representative requirements, if filed;
5. All written and oral evidence submitted by the enrollee and/or the enrollee's prescribing physician (evidence submitted orally must be transcribed by the plan sponsor and included in the enrollee's case file);
6. Any written or oral attempts made by the plan sponsor to obtain medical evidence or other documentation from the enrollee and/or the enrollee's prescribing physician (attempts made orally must be documented by the plan sponsor and included in the enrollee's case file); and
7. A copy of the plan sponsor's coverage determination and/or redetermination notices, if applicable.

Part D plan sponsors should refer to the most current version of the IRE's Reconsideration Process Manual for information concerning the Appeal Transmittal Cover Sheet and the Reconsideration Background Data Form. Plan sponsors are expected to fully complete all appropriate sections of the Reconsideration Background Data Form in support of CMS' appeals data collection activities.

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. 2, 6-22-06)

An enrollee or an enrollee's appointed representative may request any appeal.

Note: As indicated in §[10.5](#), an enrollee's prescribing physician may request a standard coverage determination, expedited coverage determination, or expedited redetermination on an enrollee's behalf. Thus, an enrollee's physician is prohibited from requesting a standard redetermination or higher appeal without being the enrollee's appointed representative. However, when a request for a coverage determination or expedited

redetermination that is initiated by an enrollee's physician is automatically forwarded to the IRE under §§[50.6](#) or [70.10](#), the physician is not required to be the enrollee's appointed representative for the IRE to review the forwarded request. If the IRE issues an adverse decision, the enrollee's physician must become the enrollee's appointed representative, as indicated in §[10.4](#), to file any further appeal on the enrollee's behalf.

80.3 - How to Request a Reconsideration

(Rev. 2, 6-22-06)

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](#), 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 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)

An enrollee requesting a good-cause extension may file the request with the IRE, in writing, and include the reason why the request was not filed 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 - Creditable Coverage / Late Enrollment Penalty

(Rev. 1, 11-30-05)

[Reserved]

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. 1, 11-30-05)

A request for an ALJ hearing must be in writing and must be filed with the entity specified in the IRE's reconsideration notice. 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 405.1014\(c\)](#), an enrollee must file a request for an ALJ hearing within 60 days of the date of the 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. 2, 6-22-06)

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 2006, the AIC threshold for an ALJ hearing is \$110.

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. 1, 11-30-05)

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).

100 - Medicare Appeals Council (MAC) Review

(Rev. 1, 11-30-05)

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 405, subpart I](#) 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. 1, 11-30-05)

A request for a MAC review must be filed by writing a letter to the MAC. The enrollee 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/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.

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

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. 1, 11-30-05)

The request for a MAC review must be filed within 60 days of the date of receipt of the 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. 1, 11-30-05)

The MAC may initiate a review on its own motion or at the request of CMS or one of its contractors within 60 days after the date of an ALJ hearing decision or dismissal. 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. 1, 11-30-05)

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.

The MAC limits its review of the evidence to the evidence contained in the record of the proceedings before the ALJ. However, under [42 CFR 405.1122](#), 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.

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

110 - Judicial Review

(Rev. 1, 11-30-05)

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 2006, the AIC threshold for judicial review is \$1,090.

110.1 - Requesting Judicial Review

(Rev. 1, 11-30-05)

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 405, subpart I](#), 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.

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 423.634](#).

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. 22, 05-09-03)

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. 1, 11-30-05)

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 request within 180 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.
2. An ALJ may reopen a hearing decision on his or her own motion or at an enrollee's request within 180 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.

3. The MAC may reopen a review decision on its own motion or at an enrollee's request within 180 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.

120.3 - Good Cause for Reopening.

(Rev. 1, 11-30-05)

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.

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.

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 decisionmaker 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. 1, 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. 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. 1, 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. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

130 - Effectuating Redeterminations or Decisions

130.1 - Effectuating Coverage Determinations

(Rev. 2, 6-22-06)

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 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 authorize payment for the benefit within 72 hours after receiving the coverage determination request or

physician's supporting statement (for an exception request), and make payment no later than 30 calendar days after receiving the coverage determination request or physician's supporting statement. 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 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 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. 1, 11-30-05)

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 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](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

130.3.2 - Expedited Requests for Benefits

(Rev. 1, 11-30-05)

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](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

130.3.3 - Payment Requests

(Rev. 1, 11-30-05)

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](#)). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

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

140.1 – Reporting Requirements for Grievances

(Rev. 1, 11-30-05)

Part D plan sponsors are responsible for reporting data related to grievances received (PACE Organizations are exempt from this reporting requirement). Part D plan sponsors are required by the regulations to track and maintain records on all grievances received, both orally and in writing. Grievance data, requested herein by CMS, should be reported based on the date the grievance was received by the Part D Plan, not the date of the event or incident that is the subject of the grievance. Multiple grievances by a single complainant should be tracked and followed as separate grievances.

Reporting timeline:

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Reporting Period	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
Data due to CMS/HPMS	May 31	August 31	November 30	February 28

The following data elements are to be directly entered into the Health Plan Management System at the Plan level:

- A. For the time period identified above, provide the number of fraud and abuse grievances received related to Part D. A fraud grievance is a statement, oral or written, alleging that a provider, pharmacy, pharmacist, PBM, Part D Plan, or beneficiary engaged in the intentional deception or misrepresentation that the individual knows to be false or does not believe to be true, and the individual makes knowing that the deception could result in some unauthorized benefit to himself/herself or some other person. An abuse grievance is a statement, oral or written, alleging that a provider, pharmacy, pharmacist, PBM, Part D Plan, or beneficiary engaged in behavior that the individual should have known to be false, and the individual should have known that the deception could result in some unauthorized benefit to himself/herself or some other person. This should be a numeric field. Note that although Part D plan sponsor reporting

requirements are separate from requirements included in a Part D plan sponsor's compliance program, an overlap in the two sets of data requirements may exist.

- B. For the time period identified above, provide the number of enrollment/disenrollment grievances received related to Part D. Examples include, but are not limited to, discrimination in the enrollment process, enrollment information and/or identification cards not being received by beneficiaries in a timely manner, and disenrollment requests not being processed in a timely manner. This should be a numeric field.
- C. For the time period identified above, provide the number of benefit package grievances received related to Part D (benefit package grievances includes formulary and pricing/co-insurance issues). Examples include, but are not limited to, drugs not on formulary and beneficiary cost sharing. This should be a numeric field.
- D. For the time period identified above, provide the number of pharmacy access/network grievances received related to Part D. Examples include, but are not limited to, network pharmacy refusing to accept a beneficiary's card and network/non-network pharmacy concerns. This should be a numeric field.
- E. For the time period identified above, provide the number of marketing grievances received related to Part D. Examples include, but are not limited to, marketing materials or promotional messages by sales representatives that include misrepresentations or false/misleading information about plans and benefits and discriminatory practices identified in marketing materials or through oral/written promotional messages. This should be a numeric field.
- F. For the time period identified above, provide the number of customer service grievances received related to Part D. Examples include, but are not limited to, grievances regarding services provided by the pharmacist/pharmacy staff, plan or subcontractor representatives, or customer service representatives. This should be a numeric field.
- G. For the time period identified above, provide the number of confidentiality/privacy grievances received related to Part D. Examples include, but are not limited to, potential violations of medical information privacy standards by the plan or pharmacy. This should be a numeric field.
- H. For the time period identified above, provide the number of other grievances received related to Part D. Examples include, but are not limited to, quality issues, appeals not handled on a timely basis, and any grievances that do not fall into one of the categories described above. This should be a numeric field.

140.2 – Reporting Requirements for Non-Formulary Exceptions and Tier Exceptions

(Rev. 1, 11-30-05)

Part D Plan Sponsors are responsible for reporting several data elements related to non-formulary exceptions and tier exceptions. PACE Organizations utilizing formularies are also responsible for these reporting requirements (PACE Organizations not utilizing formularies are waived from this requirement).

Reporting timeline:

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Reporting Period	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
Data due to CMS/HPMS	May 31	August 31	November 30	February 28

The following data elements will be directly entered into the Health Plan Management System at the Plan level:

- A. Number of prior authorizations requested for non-formulary medications in the time period specified above (not including early refills). This will be a numeric field.
- B. Number of prior authorizations approved for non-formulary medications in the time period specified above (not including early refills). This will be a numeric field.
- C. Number of prior authorizations requested for tier exceptions in the time period specified above (not including first pass step therapy edits or early refills). This will be a numeric field.
- D. Number of prior authorizations approved for tier exceptions in the time period specified above (not including first pass step therapy edits or early refills). This will be a numeric field.

140.3 – Reporting Requirements for Appeals

(Rev. 1, 11-30-05)

CMS will request coverage determination appeal data as part of the monitoring of a Plan's availability, accessibility, and acceptability of its services.

Reporting timeline:

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
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Reporting Period	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
Data due to CMS/HPMS	May 31	August 31	November 30	February 28

The following data elements will be directly entered into the Health Plan Management System at the Plan level:

- A. Number of appeals submitted for **standard** redetermination in the time period specified above. This should be a numeric field.
- B. Number of appeals submitted for **expedited** redetermination in the time period specified above. This should be a numeric field.
- C. Number of appeals submitted for **expedited** redetermination that were granted **expedited** status. This should be a numeric field.
- D. Number of appeals submitted for **standard** redetermination withdrawn by the enrollee. This should be a numeric field.
- E. Number of appeals submitted for **expedited** redetermination withdrawn by the enrollee. This should be a numeric field.
- F. Number of standard redeterminations resulting in reversal (full or partial) of original decision. This should be a numeric field.
- G. Number of **expedited** redeterminations resulting in reversal (full or partial) of original decision. This should be a numeric field.
- H. Number of appeals submitted for IRE reconsideration due to inability to meet time frame for **coverage determination**. This should be a numeric field.
- I. Number of appeals submitted for IRE reconsideration due to inability to meet time frame for **redetermination**. This should be a numeric field.
- J. Number of appeals submitted for **standard** reconsideration withdrawn by the enrollee. This should be a numeric field.
- K. Number of appeals submitted for **expedited** reconsideration withdrawn by the enrollee. This should be a numeric field.
- L. Number of IRE decisions for **standard** reconsideration resulting in reversal (full or partial) of original coverage determination or redetermination. This should be a numeric field.

- M. Number of IRE decisions for **expedited** reconsideration resulting in reversal (full or partial) of original coverage determination or redetermination. This should be a numeric field.
- N. Number of IRE decisions for **standard** reconsideration resulting in upholding of original coverage determination or redetermination. This should be a numeric field.
- O. Number of IRE decisions for **expedited** reconsideration resulting in upholding of original coverage determination or redetermination. This should be a numeric field.

Appendices

Appendix 1 - Notice of Denial of Medicare Prescription Drug Coverage

(Rev. 1, 11-30-05)

The form, [Notice of Denial of Medicare Prescription Drug Coverage](#), and the form's [instructions](#) can be found on the [Part D Enrollment and Appeals Guidance](#) page.

Appendix 2 - Appointment of Representative - Form CMS-1696

(Rev. 1, 11-30-05)

The form, [Appointment of Representative - Form CMS-1696](#) can be found on the [CMS forms page](#).

Appendix 3 - (Model) Notice of Right to an Expedited Grievance

(Rev. 1, 11-30-05)

[INSERT NAME OF MEDICARE PART D PLAN]

Date:

Patient Name:

Patient ID Number:

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 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. 2, 6-22-06)

[LOGO]

Redetermination Notice Denial of Medicare Prescription Drug Coverage

Date:

Enrollee's name: <Insert Name>

Enrollee's Medicare (HIC) number: <Insert HICN>

Plan Name: <Insert Plan Name>

Contract ID: <Insert Contract ID>

Formulary ID: <Insert Formulary ID>

Plan ID: <Insert Plan ID>

We have affirmed our initial coverage determination denying the following prescription drug(s) that you or your physician 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 did not already provide your plan with a statement supporting your request, **your physician 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 Plans:

MAXIMUS

1040 First Avenue, Suite 200

King of Prussia, PA 19406

Fax: (484) 688-5601

Requests from MA-PD Plans:

MAXIMUS

50 Square Drive, Suite 120

Victor, NY 14564

Fax: (585) 425-5301

Who May Request an Appeal?

You or someone you name to act for you (your **appointed representative**) may request an appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to act for you. Others may already be authorized under State law to act for you.

You can call us at: (_____)_____ to learn how to name your appointed 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.

- **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.

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 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 physician 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 appointed 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 \$110. 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. 1, 11-30-05)

The form, [Medicare Prescription Drug Coverage and Your Rights - Form CMS-10147](#), and the form's [instructions](#) can be found on the [Part D Enrollment and Appeals Guidance](#) page.

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. 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 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 doctor if one of these drugs is right for you. If your doctor 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 doctor 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 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.

Thank you.

<Plan name>

Appendix 11 - (Model) Request for Additional Information

(Rev. 1, 11-30-05)

<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>* 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 <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.

<Plans must specifically describe the type of written documentation they require from the physician.>

For formulary exceptions: Plans may require a statement that the drug is medically necessary to treat the enrollee’s condition because 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; 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, 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 Regarding an Excluded Drug

(Rev. 2, 6-22-06)

<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 1927(d)(2) the Social Security Act (the Act), certain drugs are excluded from Medicare coverage or are excluded from coverage if they are used to treat certain medical conditions.

<Insert name of drug> is one of the drugs that is excluded from Medicare coverage by law, and we do not offer the drug as a supplemental benefit.

You should work with your physician to determine if a drug on our list of covered drugs (our formulary) is medically appropriate for treating your condition.

If, after reading this letter, you have reason to believe that we incorrectly classified/identified <insert name of drug> as excluded from coverage under section 1927(d)(2) of the Act, the drug is not excluded under section 1927(d)(2) of the Act for the purpose for which it was prescribed, or the drug is covered by the plan as a supplemental benefit, you or your physician 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. 2, 6-22-06)

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 Plans:

MAXIMUS

1040 First Avenue, Suite 200

King of Prussia, PA 19406

Fax: (484) 688-5601

Requests from MA-PD Plans:

MAXIMUS

50 Square Drive, Suite 120

Victor, NY 14564

Fax: (585) 425-5301

Note about Appointed 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 appointed representative. Contact your Medicare drug plan to learn how to name an appointed 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) _____

The person making this request (if not the enrollee) must include the following information:

Requestor's Name _____

Requestor's Relationship to Enrollee _____

Address _____

City _____ State _____ Zip Code _____

Phone () _____

Attach documentation that shows authority to represent enrollee, such as a completed Form CMS-1696, if it was not submitted to the plan at the coverage determination or redetermination level.

Prescription drug you asked your plan to cover: _____

Prescribing Physician's Information

Name _____

Address _____

City _____ State _____ Zip Code _____

Office Phone: () _____ Fax: () _____

Office Contact Person _____

Expedited Decisions

If you or your prescribing physician 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 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. If you do not obtain your physician's support, 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, attach it to this request)

Please attach any additional information you have related to your appeal such as a statement from your prescribing physician 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.

Enrollee's/Requestor's Signature: _____ **Date:** _____