

Part D QIC

Reconsideration Procedures
Manual

Maximus Federal

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1. INTRODUCTION

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) was enacted into law on December 8, 2003. Section 101 of Title I of the MMA amended Title XVIII of the Social Security Act and created the new Part D Voluntary Prescription Drug Benefit Program beginning January 1, 2006. The law requires the Federal government to contract with a Qualified Independent Contractor (QIC) to review and resolve prescription drug disputes and late enrollment penalty disputes between Part D plans and individuals enrolled in these entities. Part D plans include:

- Prescription Drug Plan (PDP) sponsors;
- Medicare Advantage (MA) organizations offering the Part D prescription drug benefit (MA-PDs);
- Programs of All-Inclusive Care for the Elderly (PACE) plans offering qualified prescription drug coverage; and
- Cost-based Health Maintenance Organizations (HMOs) and Competitive Medical Plans (CMPs) offering qualified prescription drug coverage.

The Centers for Medicare & Medicaid Services (CMS) has contracted with Maximus Federal to serve as the Part D QIC. Title 42 of the Code of Federal Regulations, Part 423, sets out the regulations enacting the Voluntary Prescription Drug Benefit Program. Throughout subparts M and U of Part 423 of the Medicare regulations, the phrase “independent review entity” (IRE) is used to describe the entity responsible for reviewing such appeals. The IRE is commonly referred to as the Part D Qualified Independent Contractor or Part D QIC. Maximus Federal, in its role as the Part D IRE, will be referred to as the Part D QIC or Maximus Federal throughout this manual.

Subpart B of Part 423 discusses the Late Enrollment Penalty (LEP) and the procedures Part D plans must follow regarding the determination of creditable coverage and assessment of an LEP. Individuals determined to be subject to a late enrollment penalty may request Reconsideration of this determination. This review will be conducted by the Part D QIC, in accordance with guidance issued by CMS. Decisions made through this review are not subject to appeal, but may be reviewed and revised at the discretion of CMS and the Part D QIC.

Subpart M of Part 423 sets forth the procedures Part D plans must follow with regard to prescription drug coverage issues, including grievances, coverage determinations, and appeals. In general, Part D plans must follow appeals requirements that are similar to those applicable to MA organizations regarding IRE review. Subpart M also discusses the reconsideration process conducted by the IRE, and plan requirements with respect to effectuation of reconsideration decisions.

Subpart U of Part 423 discusses post-adjudication procedures for Part D plans, the Part D QIC, Administrative Law Judges (ALJs) and the Medicare Appeals Council (the Council). This includes reopening review process at each level, as well as specific requirements for ALJ review and hearings, Council review and judicial review. Note that only the enrollee (or representative if applicable) has further appeal rights after a Reconsideration decision has been issued by the Part D QIC. While Part D plans may request reopening review by the Part D QIC, plans cannot appeal a reconsideration decision.

This Part D QIC Reconsideration Procedures Manual (manual) contains the procedures for the coordination between Part D plans and Maximus Federal in the processing of drug appeal Reconsiderations, related drug appeal post Reconsideration activities, and Reconsiderations of Late Enrollment Penalty (LEP) determinations. The procedures defined in this manual are applicable to all Part D plans (with the exception of organizations operating under a waiver per 42 C.F.R. §423.458) that are referenced above, and are effective January 1, 2006.

For drug appeals, the Part D QIC Reconsideration is one step in a larger multi-level Part D appeal process. For example, Part D plans are required to adhere to CMS rules for making coverage determinations and plan level redeterminations—steps that occur prior to the submission of a case file to the Part D QIC. Conversely, the only level of review for disputes related to the imposition of a LEP is at the Reconsideration level with the Part D QIC. There are no levels of appeal at the Part D plan level or beyond the Part D QIC. However, as previously noted, LEP decisions may be reviewed and revised at the discretion of CMS and the Part D QIC.

The focus of this manual is on the processes by which a Part D plan and Maximus Federal, in its role as the Part D QIC, interrelate for the Reconsideration level of Part D appeals. This manual will highlight many of the rules in subpart B, subpart M and subpart U of Part 423, but is not intended to serve as a complete resource of CMS rules and policy governing plan obligations for the appeal process. This manual complements the guidance promulgated by CMS in Chapters 4, 6 and Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance

The manual presumes that the reader has an in-depth command of the Medicare laws, rules and policy set forth in:

- Section 101 of the MMA of 2003, Pub. L. 108-73, which amended Title XVIII of the Social Security Act (the Act)
- Final Rule, “Medicare Program; Medicare Prescription Drug Benefit.” Federal Register, Vol. 70, No. 18, January 28, 2005. (Preamble contains industry comments and CMS responses, which provide in-depth explanation of the prescription drug benefit)
- Final Rule, “Medicare Program; Application of Certain Appeals Provisions to the Medicare Prescription Drug Appeals Process.” Federal Register, Vol. 74, No. 235, December 9, 2009
- 42 C.F.R. Part 423
- Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance
- CMS Prescription Drug Benefit Manual, Chapter 4
- CMS Prescription Drug Benefit Manual Chapter 5
- CMS Prescription Drug Benefit Manual Chapter 6
- CMS Prescription Drug Benefit Manual Chapter 7
- CMS Medicare Managed Care Manual Chapter 2
- CMS Medicare Managed Care Manual Chapter 3
- CMS Prescription Drug Coverage: General Information on <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/index>
- CMS Prescription Drug Coverage Contracting Overview <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index> (contains links to various special guidance materials for Part D plans)
- Medicare Advantage Prescription Drug Contracting (MA-PDs) <https://www.cms.gov/Medicare/Medicare-Advantage/MAPDContracting/index.html>
- Medicare Coverage Database for National Coverage Determinations (NCDs) issued by CMS, or Local Coverage Determinations (LCDs) issued by Medicare contractors (as appropriate for discerning the scope of the prescription drug benefit versus coverage under Part A and Part B of Medicare). <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>

Certain policies, procedures and operational documents discussed in this manual are mandatory, and complete compliance by Part D plans is expected. For such requirements, the term "must" or "mandatory" is used. In other areas, we have attempted to provide the Part D plan with flexibility, and may have offered suggestions for work methods that we believe will enhance the working relationship between Part D plans and Maximus Federal in its role as the Part D QIC. In these areas, the term "recommended" or "suggested" or "optional" is used.

Our hope is that Part D plans will find this manual clear and helpful. If not, please submit comments or suggestions to:

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2. DEFINITIONS

The following definitions are provided solely for use in this manual. These definitions do not address all the significant terms used in 42 C.F.R. Parts 422, 423 or Chapters 6, 14 and Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. In some instances, regulatory text is paraphrased or summarized. In the event of any discrepancy or inconsistency, the language of 42 C.F.R. Part 423 and CMS guidance overrides these definitions.

2.1 ADJUDICATOR

An appeal professional that is employed by the Part D QIC to manage Reconsideration case files for the Part D Reconsideration project. Adjudicators are trained to resolve disputes that do not require medical necessity determinations, e.g., disputes involving cost sharing issues, and LEPs. Adjudicators are responsible for issuing the Part D QIC Reconsideration decision letters for both types of appeal and do not make medical necessity determinations. Medical necessity determinations are made by fully credentialed board certified physicians on the Part D QIC.

2.2 ANNUAL ENROLLMENT PERIOD (AEP)

The Annual Enrollment Period (AEP), also known as the Open Enrollment Period and/or the Annual Election Period, is the time frame during which a Medicare eligible individual can enroll in a Part D plan or change Part D plans. The AEP is October 15 through December 7. If an individual does not enroll in a Part D plan (PDP or MA-PD) during his/her Initial Enrollment Period (IEP), the individual may have to wait until the AEP (October 15 through December 7) to enroll. Note that if a Medicare eligible individual also qualifies for Extra Help, he or she can change plans at any time. There is also a Special Enrollment Period (SEP) to switch into a 5 Star Prescription Drug Plan or Medicare Advantage Prescription Drug Plan at any time during the year. This may be used by those enrollees in a plan with less than a 5 Star rating, and may be used once during the calendar year.

2.3 APPEAL

Appeal means any of the procedures that deal with either the review of adverse drug coverage determinations made by Part D plans regarding benefits the enrollee believes he or she is entitled to receive, review of an “at risk” determination or the review of a disputed Late Enrollment Penalty (LEP).

The adverse drug coverage determinations include delay in providing or approving 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. The adverse drug coverage determination procedures include redeterminations by Part D plans, Reconsiderations by the Part D QIC, Administrative Law Judge (ALJ) hearings, reviews by the Medicare Appeals Council (the Council), and judicial reviews.

The review of a disputed Late Enrollment Penalty (LEP) made by Part D plan is the Reconsideration process managed by the Part D QIC.

2.4 APPEAL SYSTEM

The entire five level Part D appeal process addresses enrollee challenges to a Part D plan’s adverse drug coverage determination. The Part D QIC Reconsideration process is the second level in the broader Part D drug appeal system.

The appeal system for an LEP reconsideration consists of one level, i.e., the Reconsideration process managed by the Part D QIC.

2.5 APPOINTED REPRESENTATIVE

An individual either appointed by an enrollee in writing or authorized under state or other applicable law to act on behalf of the enrollee in obtaining a coverage determination or in dealing with any of the levels of the drug appeals process, or in seeking Reconsideration of the imposition of an LEP. A valid 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 drug appeals process, or in seeking Reconsideration of the imposition of an LEP.

2.6 CONTRACTED PHARMACY NETWORK

Pharmacies including retail, mail order, and institutional pharmacies under contract with a Part D plan to provide covered Part D drugs at negotiated prices to Part D enrollees.

2.7 COST-SHARING

The dollar or monetary amount that a beneficiary is responsible for paying with respect to obtaining a Part D benefit is cost-sharing. This includes deductibles, coinsurance and copayment amounts that may be the responsibility of the beneficiary under Medicare rules and Part D plan rules. Coinsurance is a fixed percentage of the total amount paid for a Part D benefit that can be charged to the beneficiary. Copayments are a fixed amount that can be charged to a beneficiary on a per-service basis.

2.8 COVERAGE DETERMINATIONS

The following are coverage determinations made by a Part D plan, all of which are subject to the appeals process described in subparts M and U of Part 423:

- (i) A decision not to provide or pay for a Part D drug that the enrollee believes may be covered by the Part D plan. Denial reasons include:
 - Drug not medically necessary;
 - Drug not on Plan formulary;
 - Drug furnished by out-of-network pharmacy;
 - Drug excludable under Section 1862(a) of the Act if applied to Medicare Part D;
 - Drug not prescribed for a medically accepted indication;
 - Drug not FDA approved; and
 - Drug eligible for coverage under Medicare Part A or Part B.
- (ii) A failure on the part of the Part D plan to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee.
- (iii) An adverse decision concerning an exceptions request to a Part D plan's tiered cost-sharing structure (e.g., the requested drug is not medically necessary because the Part D plan formulary contains a preferred drug at a lower cost-sharing tier that is medically appropriate for enrollee).
- (iv) An adverse decision concerning an exceptions request for a non-formulary Part D drug. Denial reasons include:
 - Non-formulary drug is not medically necessary because the Part D plan formulary covers drug(s) that are medically appropriate for enrollee;
 - Cost-utilization guidelines (e.g., prior authorization, dose restriction, step therapy, therapeutic substitution requirements) have not been met for the drug;
 - No coverage due to a Part D plan formulary change in coverage (e.g., previously covered drug has been removed from Plan formulary);

- (v) A decision on the amount of cost-sharing for a drug that the enrollee believes is incorrect; and
- (vi) A Part D plan's decision regarding whether an enrollee has satisfied cost-utilization guidelines (e.g., prior authorization, dose restriction, step therapy, therapeutic substitution requirements).

Note the difference between (iv) and (vi) above. In (iv) the enrollee may argue that cost-utilization guidelines should not apply to him for medical necessity reasons, whereas in (vi) the enrollee may argue that he has satisfied the cost-utilization guidelines.

2.9 COVERAGE DETERMINATION: DENIAL NOTICES

A written denial notice by a Part D plan that states the specific reasons for the denial and informs the enrollee of his or her right to a redetermination is the coverage determination notice. For drug coverage denials, the notice describes both the standard and expedited redeterminations processes and the rest of the appeals process. For payment denials, the notice describes the standard redetermination process and the rest of the appeals process.

2.10 COVERED PART D DRUG

A Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal, and obtained at a network pharmacy or an out-of-network pharmacy.

2.11 CREDITABLE COVERAGE

Creditable prescription drug coverage is coverage that meets Medicare's minimum standards since it is expected to pay, on average, at least as much as Medicare's standard prescription drug coverage. Creditable drug coverage includes, but is not limited to: some employer-based prescription drug coverage, qualified State Pharmaceutical Assistance Programs (SPAPs), military-related coverage (e.g., VA, TRICARE), and certain Medicare supplemental (Medigap) policies. See 42 C.F.R §423.56(b) for a complete list of types of prescription drug coverage that may be determined to be creditable.

2.12 CREDITABLE COVERAGE NOTICE

All entities that offer prescription drug coverage (except PDPs, Medicare Advantage Prescription Drug Plans (MA-PDs), PACE, or cost-based HMO or Civilian Marksmanship Program (CMP) organizations) must provide an annual disclosure notice to CMS and to current Medicare-eligible enrollees and/or their Medicare-eligible dependents. This notice must also be provided to Medicare-eligible individuals at the time of enrollment, and to individuals requesting enrollment information. The notice must state whether the coverage the entity provides is creditable prescription drug coverage. If it is not, the disclosure notice must convey that the coverage offered is not creditable, that there are limitations on when an individual may enroll in a Part D plan, and that the individual may be subject to a late enrollment penalty when enrolling in a creditable Part D plan. The CMS model creditable coverage disclosure form indicates that if an enrollee drops or loses coverage and does not have creditable coverage for a continuous period of 63 days or more, the enrollee may be subject to a late enrollment penalty.

2.13 DE NOVO REVIEW

A review or retrial of an individual dispute by a new and impartial reviewer. The reviewer does not give deference to any previous determinations made on the individual dispute. The reviewer evaluates all of the evidence from the beginning. Maximus Federal, as the Part D QIC, conducts de novo review for Reconsideration requests.

2.14 ENROLLEE

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

2.15 EVIDENCE OF COVERAGE

The document that sets forth the terms of Part D drug coverage for enrollees of stand-alone drug plans (PDPs) or Medicare Advantage plans offering the Part D prescription drug benefit (MA-PDs).

2.16 EXPEDITED RECONSIDERATION

A de novo review of an adverse prescription drug coverage determination/redetermination by a Part D plan that must be processed quickly by the Part D QIC to avoid endangering the life or health of the enrollee or the enrollee's ability to regain maximum function. The Part D QIC must complete an expedited Reconsideration and provide notice as soon as is medically indicated, but no longer than 72 hours after the Part D QIC receives a written request for Reconsideration from the enrollee or an appointed representative. The enrollee or the enrollee's prescribing physician or other prescriber may request an expedited Reconsideration. For requests made or supported by the prescribing physician or other prescriber, the Part D QIC will conduct an expedited Reconsideration if the physician or other prescriber indicates that applying the standard time frame for conducting a Reconsideration may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. Requests for payment for services already furnished may not be expedited.

2.17 FORMULARY

The entire list of Part D drugs covered by a Part D plan.

2.18 INITIAL ENROLLMENT PERIOD (IEP)

The initial enrollment period is the time frame during which an individual is first eligible to enroll in a Part D plan. An individual is eligible to enroll in a Part D plan when the individual has Part A coverage and/or is enrolled in Part B, and lives in the service area of a Part D plan. This time period runs from three months before becoming eligible for Part D, through the month of eligibility, to the last day of the third month following the month of eligibility. The Part D IEP is the same as the Part B IEP.

2.19 LATE ENROLLMENT PENALTY (LEP)

An additional charge that is billed to an enrollee who does not maintain creditable prescription drug coverage for a continuous period of 63 days or longer at any time following his/her initial enrollment period for the Medicare prescription drug benefit.

2.20 LATE ENROLLMENT PENALTY LETTER

The letter sent to the enrollee by the Part D plan if the plan determines the enrollee has had a continuous period of 63 days or more without creditable prescription drug coverage. The enrollee will receive an LEP letter, a reconsideration notice, and a reconsideration request form. The reconsideration notice provides the enrollee with an explanation of the right to ask Medicare to review (or reconsider) the late enrollment penalty.

2.21 LOW-INCOME SUBSIDY (LIS)

The low-income subsidy, also called Extra Help, helps pay Medicare prescription drug plan costs (e.g., plan monthly premiums, copayments, annual deductible) for enrollees who have limited income and resources. If the enrollee received the low-income subsidy (LIS) at any time prior to the end of his/her IEP, the enrollee is not subject to an LEP for any uncovered months the enrollee received the subsidy. If an enrollee was paying an LEP before qualifying for an LIS, the enrollee is **not exempt** from those payments.

2.22 MEDICARE APPEALS SYSTEM (MAS)

The CMS system used by the Part D QIC for processing and tracking Reconsideration appeals, and for collecting specific data elements from Reconsideration cases. The collection of data facilitates creating specific reports for CMS. This system is also used throughout the appeal process from the Part D QIC level of review through the Medicare Appeals Council level of review.

2.23 ELIGIBILITY AND ENROLLMENT MEDICARE ONLINE (ELMO)

The CMS database that is used by the Part D QIC to verify various enrollee information including; date of birth, date of death, current Medicare Part A/B entitlement, Medicare Part D eligibility, current and previous Part D plans with effective dates of enrollment/disenrollment, uncovered months assessed, Part D late enrollment penalty amount, and retiree drug data.

2.24 NON-PREFERRED PHARMACY

A network pharmacy that offers covered Part D drugs to Part D enrollees at higher cost-sharing levels than those that apply at a preferred pharmacy.

2.25 OUT-OF-NETWORK PHARMACY

A licensed pharmacy that is not under contract with a particular Part D plan to provide negotiated prices to the Part D plan's enrollees.

2.26 PART D DRUG

A Part D drug is a drug that:

- May be dispensed only by prescription;
- Is approved by the Food and Drug Administration (FDA) (or is exempt from approval);
- Is used and sold in the US;
- Is used for a medically accepted indication:
 - Includes FDA-approved uses;
 - Includes uses supported by one or more citations included or approved for inclusion in the American Hospital Formulary Service Drug Information, and DRUGDEX Information System;
 - For drugs used as part of an anti-cancer chemotherapeutic regimen, includes uses in additional compendia and approved peer reviewed literature as identified in Section 50.4.5 of the Medicare Benefit Policy Manual, Chapter 15;
 - Off -label uses described in peer-reviewed literature are insufficient on their own to establish a medically accepted indication for anti-cancer chemotherapeutic medications;

- Includes prescription drugs, biologic products, vaccines that are reasonable and necessary for the prevention of illness, insulin, and medical supplies associated with delivery of insulin into the body that are not covered under Parts A or B (syringes, needles, alcohol, swabs, gauze, and insulin delivery systems). See 42 C.F.R. §423.100.

A Part D drug excludes:

- Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B; and
- Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid (with the exception of smoking cessation products):
 - Drugs for anorexia;
 - Drugs for weight loss or weight gain,;
 - Drugs to promote fertility;
 - Drugs for cosmetic purposes and hair growth;
 - Drugs for symptomatic relief of coughs and colds;
 - Vitamins and minerals (except for prenatal vitamins and fluoride preparations),
 - Non-prescription drugs;
 - Outpatient prescriptions for which manufacturers require the purchase of associated tests or monitoring services as a condition for getting the prescription (manufacturer tying arrangements); and
 - As of January 1, 2007 Erectile Dysfunction (ED) drugs unless used to treat a condition, other than sexual or erectile dysfunction will meet the definition of a Part D drug when prescribed for medically accepted indications approved by the FDA. However, ED drugs will not meet the definition of a Part D drug when used off-label, even when the off-label use is listed in one of the compendia found in Section 1927(g)(1)(B)(i) of the Act.

The Medicare Improvements for Patients and Providers Act of 2008 established that certain classes or categories of drugs would no longer be excluded from Part D coverage beginning January 1, 2013. As a result, effective January 1, 2013 the Medicare Part D program began providing coverage for benzodiazepines when used for a medically accepted indication. Effective January 1, 2013 the Medicare Part D program began providing coverage for barbiturates when used in the treatment of epilepsy, cancer, or a chronic mental health disorder. Effective January 1, 2014, the Medicare Part D program began providing coverage for barbiturates when used for a medically accepted indication. Please note that coverage among plans will vary, and plans may not provide coverage for all drugs within these classes. Plans may also implement utilization tools/restrictions, such as prior authorization, step-therapy, and quantity limits.

Not Excluded:

- Prescription drug products that otherwise satisfy the definition of a Part D drug are Part D drugs when used for AIDS wasting and cachexia due to a chronic disease, if these conditions are medically-accepted indications as defined by section 1927(k)(6) of the Act for the particular Part D drug. Specifically, CMS does not consider such prescription drug products being used to treat AIDS wasting and cachexia due to a chronic disease as either agents used for weight gain or agents used for cosmetic purposes;
- Part D drugs indicated for the treatment of psoriasis, acne, rosacea, or vitiligo are not considered cosmetic;
- Vitamin D analogs such as calcitriol, doxercalciferol, paricalcitol and dihydrotachysterol, when used for a medically-accepted indication as defined by section 1927(k)(6) of the Act, are not excluded because CMS interprets the exclusion of prescription vitamin D products as

- being limited to products consisting of ergocalciferol (vitamin D2) and/or cholecalciferol (vitamin D3);
- Prescription-only smoking cessation products;
 - Prescription Niacin Products (Niaspan, Niacor); and
 - Cough and cold medications are eligible to meet the definition of a Part D drug in clinically relevant situations other than those of symptomatic relief of cough and colds. For example, when cough medications are used for a medically-accepted indication that treats a cough produced by a medical condition unrelated to symptomatic cough and cold. In such circumstances, such as the treatment of cough to alleviate bronchospasm in asthma, CMS does not consider these cough medications as excluded drugs.

2.27 PART D PLAN

Means a stand-alone prescription drug plan (PDP), a Medicare Advantage (MA) plan offering the Part D prescription drug benefit (MA-PD), a PACE organization offering a PACE plan that includes qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage. Please note that throughout this manual Maximus Federal may refer to Part D plans as “Part D plan”, or simply as “Plan(s)” or “plan(s)”

2.28 QUALIFIED INDEPENDENT CONTRACTOR (QIC)

The entity under contract with CMS to perform Reconsiderations of adverse coverage determinations and redeterminations made by Part D Plans for enrollees who wish to continue the appeal process. This entity (currently Maximus Federal) also reviews Late Enrollment Penalty appeals (LEPs). The QIC is commonly referred to as the Part D QIC.

2.29 RECONSIDERATION PROCESS (LATE ENROLLMENT PENALTY)

The Part D QIC’s review of a disputed LEP, the evidence and findings upon which the plan’s creditable coverage determination was based, and any other evidence the enrollee submits or the Part D QIC obtains. LEP Reconsiderations must generally be completed, and notice provided, no later than 90 calendar days from the date the Part D QIC receives the request. The Part D QIC may take an additional 14 calendar days if the enrollee requests an extension or if the Part D QIC finds good cause to extend the timeframe. Good cause would include, for example, when the Part D QIC finds a need for additional information and considers the delay to be in the interest of the enrollee, such as receipt of additional information that may reduce the number of uncovered months upon which the LEP was based.

2.30 RECONSIDERATION PROCESS (PRESCRIPTION DRUG)

The Part D QIC’s review of an adverse coverage determination/redetermination by the Part D Plan, the evidence and findings upon which the Plan’s decision was based, and any other evidence the enrollee submits or the Part D QIC obtains. Prescription drug Reconsiderations may be standard or expedited, and may involve requests for covered benefits or requests for payment.

- Standard Reconsiderations for drug coverage requests must be completed, and notice provided, as expeditiously as the enrollee’s health requires, but no later than 7 calendar days from the date the Part D QIC receives the request.
- Standard Reconsiderations for prescription drug payment requests must be completed, and notice provided, no later than 14 calendar days from the date the Part D QIC receives the request.
- Expedited Reconsiderations must be completed, and notice provided, as expeditiously as the enrollee’s health requires, but no later than 72 hours after the Part D QIC receives the request.

Unlike the Part 422 appeals process, enrollees who wish to appeal an adverse redetermination must file a written request for Reconsideration with the Part D QIC within 60 calendar days of the adverse redetermination notice. There is no automatic escalation to the Part D QIC, except for those appeals involving Part D plan coverage determinations and redeterminations that are not completed within the prescribed time frames (i.e., auto-forwarded appeals).

2.31 LEP RECONSIDERATION DECISION (LEP RECONSIDERATIONS)

A written decision by the Part D QIC that sets forth the LEP Reconsideration determination. The decision letter is mailed to the enrollee if there is no valid representative appointed, and to the valid representative when one has been appointed. A copy of the decision letter is faxed to the Part D plan in either case. If the enrollee has enrolled in a new Part D plan subsequent to requesting an LEP reconsideration, the Part D QIC will fax the decision letter to both the former and the current Part D plan.

The decision letter states the specific reasons for the QIC's decision. The Part D QIC generally will notify the enrollee of the final LEP Reconsideration decision (including a decision to dismiss the Reconsideration request), within 90 calendar days of receiving a request for Reconsideration. The Part D QIC may take an additional 14 calendar days, as described under Section 2.29 of this manual.

2.32 RECONSIDERATION DECISION (PRESCRIPTION DRUG APPEAL)

A written decision by the Part D QIC that sets forth the prescription drug Reconsideration determination. The decision letter is mailed or faxed to the enrollee and valid representative (if applicable), and faxed to the Part D plan. The decision letter states the specific reasons for the QIC's decision, and if the determination continues to be adverse, informs the enrollee of his or her right to an ALJ hearing if the amount in controversy requirement is met, and describes the procedures to obtain an ALJ hearing. When the case is expedited, the Reconsideration determination is verbally communicated to the enrollee or authorized representative by a phone call, and the written notice follows in the mail within 3 calendar days of that call. If a fax number is available, the Reconsideration determination is faxed to the enrollee and authorized representative (if applicable), and the Part D plan.

2.33 REDETERMINATION PROCESS

A review of an adverse coverage determination by a Part D plan, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan obtains. Redeterminations may be standard or expedited, and may involve requests for coverage or requests for payment.

- Standard redeterminations for coverage requests must be completed, and notice provided, as expeditiously as the enrollee's health requires, but no later than 7 calendar days from the date the Part D plan receives the request for a standard redetermination.
- Standard redeterminations for payment requests must be completed, and notice provided, no later than 14 calendar days from the date the Part D plan receives the request for a standard redetermination.
- Expedited redetermination requests must be completed, and notice provided, as expeditiously as the enrollee's health requires, but no later than 72 hours after the Part D plan receives the request for redetermination.

2.34 REDETERMINATION: DENIAL NOTICE

An oral or written denial notice by a Part D plan that states the specific reasons for the denial and informs the enrollee of his or her right to a Part D QIC level Reconsideration. For adverse drug coverage determinations, the notice describes both the standard and expedited Reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited Reconsideration and appeal rights for

the rest of the appeals process. For adverse payment denials, the notice describes the standard Reconsideration process and the rest of the appeals process.

2.35 REOPENING

The process by which the Part D plan, Part D QIC, ALJ, or Medicare Appeals Council reviews its own decision that is otherwise final and binding. Reopening review may be undertaken by the entity that made the determination or decision under the rules in Part 423, subpart U. Part D QIC reopening review of completed Reconsiderations are undertaken at the sole discretion of the Part D QIC for the purpose of the following; 1) addressing a potential error in the determination; 2) addressing new and material evidence not available at the time the Reconsideration appeal was processed, and which may result in a different conclusion; or 3) addressing whether the decision was procured by potential fraud or similar fault. (See 42 C.F.R. §§ 423.1978-1986).

2.36 REQUEST FOR INFORMATION (RI)

A Part D QIC document submitted to the Part D plan or other entity requesting information to correct a case file deficiency or defect, or to obtain additional information required to adjudicate the appeal.

2.37 SPECIAL ENROLLMENT PERIOD (SEP)

A special enrollment period (SEP) is a time period outside of the IEP and AEP during which a Medicare enrollee is allowed to disenroll from or enroll in a Part D plan. An individual is eligible for an SEP in certain circumstances such as change of residence, dual eligibility, loss of coverage due to plan contract violation, or certain other reasons for involuntary loss of creditable coverage (e.g., change in employment status, change in marital status). There is also an annual SEP for enrollees to move into a 5 Star rated plan, even if their current plan is a 5 Star plan. Note that a 5 Star plan must be in the enrollee's service area in order for this SEP to be used, and it can be used once per calendar year. It is the Part D plan's responsibility to determine if an individual is eligible for an SEP.

2.38 TIERED COST-SHARING

A process of grouping Part D drugs into different cost-sharing levels within a Part D plan's formulary.

2.39 TROOP (TRUE OUT OF POCKET EXPENSE)

Incurred beneficiary expenses relative to the Part D benefit that count toward beneficiary spending toward the out-of-pocket limit as set forth in Medicare rules. "Incurred expenses" are defined in 42 C.F.R. § 423.100. The TrOOP calculation includes all out-of-pocket expenses paid by the enrollee for drugs under the plan, including those incurred from use of non-preferred or higher tiered drugs. The TrOOP calculation does not include the cost of a non-formulary drug that the enrollee purchases that is not paid for under the Plan on exception or appeal.

3. WORKING WITH MAXIMUS FEDERAL

This chapter explains the basic processes for communicating with Maximus Federal, the Part D QIC, under the following headings:

- 3.1 Sources of information about the Part D QIC Reconsideration Procedures
- 3.2 Establishing Points of Contact for Part D Plans
- 3.3 Seeking Information About Active Cases
- 3.4 Suggestions and Complaints
- 3.5 5-Day Period Notice Mailing Rule

Please note that the Part D QIC is not authorized by CMS to guide or instruct Part D plans on interpretation of CMS coverage rules and policies, or matters related to Part D plan compliance with CMS appeals system requirements. For example, the Part D QIC is not able to offer Part D plans advice on how a hypothetical case would be decided if presented. Policy inquiries of this type should be directed by the Part D plan to its designated CMS account manager.

The Part D QIC is responsible for:

- Adjudicating standard and expedited drug appeal Reconsiderations of plan decisions that are adverse, in whole or in part, to the enrollee, including at-risk determinations;
- Adjudicating drug appeal coverage determinations and redeterminations that have not been decided by the Part D plan within the prescribed adjudicatory time frame;
- Adjudicating Reconsiderations of adverse determinations related to prior creditable prescription drug coverage under the Medicare Part D program (Late Enrollment Penalty appeals.);
- Adjudicating reopening reviews for drug appeal and Late Enrollment Penalty appeal Reconsiderations that meet specified requirements set forth in Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance;
- Monitoring Part D plan compliance with effectuation of drug appeal Reconsideration decisions that reverse, in whole or in part, a plan's adverse determination;
- Participating and coordinating with other entities in the Medicare appeals process including: CMS and its contractors, Part D plans, the Office of Medicare Hearings and Appeals (OMHA), and the Medicare Appeals Council (Council);
- Reviewing ALJ decisions that reverse, in whole or part, the Part D QIC's drug appeal Reconsideration decision in order to determine whether a motion for review should be sent to the Council;
- Case file handling and storage; and
- Various administrative services related to the Part D appeals process, which includes review of data for statistical and analytic purposes, as requested by CMS.

3.1 SOURCES OF INFORMATION ABOUT PART D QIC RECONSIDERATION PROCEDURES

3.1.1 Medicare Part D QIC Project Website

The Part D QIC maintains a Part D QIC project website that contains the following information:

- Part D QIC Reconsideration Procedures Manual;
- Case File Transmittal forms (Drug and LEP reconsiderations) and instructions;
- Status of pending and processed appeals;

- Enrollee-specific FAQs and instructions;
- Prescriber/pharmacist-specific FAQs and instructions;
- Links to relevant laws and regulations;
- Links to resources/information from CMS;
- Publications/newsletters, as required by CMS;
- Conference Information and Presentations, as required by CMS; and
- Link to using the QIC Portal for Case File Submissions (see section 5.3.1 of this manual below).

The Part D QIC website can be found at <https://www.medicarepartdappeals.com>.

3.1.2 Maximus Federal Part D QIC Conferences

The Part D QIC may participate with CMS in hosting conferences regarding the Part D benefit schedules and locations. Conference information will be posted on the Maximus Federal Part D QIC website.

3.1.3 Part D QIC Newsletters

The Part D QIC may publish newsletters, as required by CMS, which address issues specific to Part D QIC Reconsideration appeals. Any newsletters published will be made available for downloading on the Part D QIC website.

3.2 ESTABLISHING POINTS OF CONTACT FOR PART D PLANS

3.2.1 Designation of a key Plan contact, phone number, fax number and email

The Part D QIC requests that each Part D plan complete a *Plan Contact Form* to submit to the Part D QIC. This form requires Part D plans to supply a phone number, fax number and an email address, and designate one key organization contact and an alternate for communications with the Part D QIC regarding appeals. The *Plan Contact Form* should be used to identify the Plan Contact as well as to change the Plan Contact identified in a prior submission. Part D plans that offer more than one plan must designate and maintain a Plan Contact for each CMS approved plan. The individual designated as Plan Contact will be the official management contact with the Part D QIC.

The Part D QIC will send the Plan Contact all materials that are important to the appeals process and will also contact this individual if there is a general issue in working with the Part D Plan, or an unusual and significant case-specific problem. The Part D plan should use the Part D QIC Plan Liaison to initiate contact with the Part D QIC to resolve any problems or concerns the Part D plan has with regard to the Reconsideration process.

3.2.2 Designation of an individual Reconsideration case contact

The Part D Plan must designate a Case Contact on the *Reconsideration Case File Transmittal Form* submitted by the Part D Plan pursuant to a case file request from the Part D QIC for Reconsideration appeals. The Part D Plan may, but is not required to, use its Plan Contact as the designated case specific contact. The Part D Plan may vary the Case Contact from case to case. The individual designated as Case Contact will be the individual to whom the Part D QIC directs case specific questions.

3.3 SEEKING INFORMATION ABOUT CASES

3.3.1 Hours of operation

The Part D QIC call center will be staffed Monday through Friday from 8:00 a.m. to 5:00 p.m. EST. Calls received after these hours will be directed to a voicemail message system, and calls will be returned the next business day. Case file requests may be made 7 days a week since case processing and review may also be conducted 7 days a week.

The Part D QIC's offices will be closed for all Federal holidays:

- New Year's Day;
- Martin Luther King, Jr. Day;
- Presidents' Day;
- Memorial Day;
- Independence Day;
- Labor Day;
- Columbus Day;
- Veterans Day;
- Thanksgiving Day; and
- Christmas Day

3.3.2 Questions on the status of a case (case tracking)

For Part D plan inquiries about the processing status of a specific case file, or group of cases, the Plan Contact should ask the Part D QIC operator for the Plan Liaison. Plan Contacts are encouraged to utilize the Plan Liaison for assistance on the Part D Reconsideration process, which includes untimely decisions at the coverage and redetermination levels. Plan Contacts are also encouraged to utilize the Medicare Part D QIC Project Website to determine the status of pending or processed appeals. The Part D QIC website can be found at <https://www.medicarepartdappeals.com>

For enrollee inquiries about the processing status of a specific case file, the caller should use the Part D QIC's toll-free numbers and ask for a Customer Service representative. Due to privacy issues, the Part D QIC will provide case status and limited information only to those authorized to obtain such information. An enrollee may also utilize the Part D QIC Project Website to determine the status of a pending or processed appeal.

The Part D QIC email address is also available to Plan Contacts and enrollees for Reconsideration information at: medicarepartdappeals@maximus.com. Please note Reconsideration appeals may **not** be requested via email.

Part D plans are responsible for supporting their enrollees in the Reconsideration process. Plans should not direct members to the Part D QIC for routine case status inquiries. Medicare enrollees may be referred to 1-800-MEDICARE (1-800-633-4227) or <https://www.medicare.gov> for general information regarding the Medicare appeals process and to locate resources for assistance in the appeals process.

3.4 SUGGESTIONS AND COMPLAINTS

Please feel free to provide any suggestions or complaints to any Maximus Federal staff member who is interacting with you, or to the Project Director or to any other Part D QIC Key Contact noted in this manual. Maximus Federal management endorses and follows a formal process for addressing complaints and suggestions. This process enables us to identify opportunities for continuous improvement and initiate corrective and preventive actions as necessary.

3.5 5 DAY PERIOD NOTICE MAILING RULE

The date of receipt of required mailings in any Part D drug appeal reconsideration, post drug appeal reconsideration or LEP reconsideration shall be presumed to be 5 calendar days after the date written on such mailed correspondence, unless there is evidence to the contrary as to date of receipt. Maximus Federal allows 5 days for mailing the appeals. If the appeal is received after 65 calendar days from the date of the plan notification, the case is considered late unless good cause has been established.

4. BACKGROUND – IMPORTANT CONSIDERATIONS FOR PLAN LEVEL DRUG APPEAL DETERMINATIONS

The responsibilities of Part D Plans relative to adverse medication coverage determinations and redeterminations are set forth in CMS regulations at 42 C.F.R. Part 423 subparts M and U, in Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, and in various policy and guidance documents issued by CMS and available on CMS's website at <https://www.cms.gov>.

This Part D QIC Reconsideration Procedures Manual presumes that Part D plans will conduct determinations in accordance with CMS rules and policies. The purpose of this Chapter is to highlight certain aspects of the Part D plan's appeal processing that directly impacts subsequent Part D QIC Reconsiderations. The topics addressed are:

- 4.1 Coverage Determinations
- 4.2 At-Risk Determinations
- 4.3 Exceptions Requests
- 4.4 Redeterminations
- 4.5 Notices of Formulary Changes
- 4.6 Validation of Appealing Party
- 4.7 Validation of Eligibility of Appeal
- 4.8 Identification of Appeal Classes and Types
- 4.9 Responsibility to Conduct a Full and Meaningful Determination

When conducting Reconsideration reviews, the Part D QIC will closely review all evidence pertinent to the appeal, including Plan level coverage determinations and redeterminations, and the various evidentiary materials in the case file. Information that should be part of the case file includes all oral and written evidence and facts submitted to and/or considered by the Part D plan relative to the disputed drug benefit, as well as any notices issued by the Part D plan. (See Section 5.3 of this manual for details regarding the required content of the case file submission to the Part D QIC). The Part D QIC will identify case files that do not contain complete information for Reconsideration review, and will report patterns of deficiency to CMS.

4.1 COVERAGE DETERMINATIONS

For a complete discussion on coverage determinations, the Part D plan should refer to Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

4.1.1 Definition of a coverage determination

The rules require Part D plans to have procedures for making timely coverage determinations regarding the prescription drug benefits an enrollee is entitled to receive under the plan, supplemental benefits as specified in the rules, and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. It is crucial that Part D plans have a clear understanding of what constitutes a coverage determination.

42 C.F.R. §423.566 identifies actions that are coverage determinations, and hence are allowable appeals subject to the rules under Part 423 subparts M and U. These include the following plan decisions:

1. A decision not to provide or pay for a Part D drug that the enrollee believes may be covered by the plan. Denial reasons include:
 - a. Drug not medically necessary;
 - b. Drug not on plan formulary;
 - c. Drug furnished by out-of-network pharmacy;
 - d. Drug excludable under Section 1862(a) of the Act if applied to Medicare Part D; and
 - e. The enrollee did not satisfy a drug utilization management requirement.

2. A failure on the part of the Part D plan to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee.
3. An adverse decision concerning an exceptions request to a plan's tiered cost-sharing structure.
4. An adverse decision concerning an exceptions request for a non-formulary Part D drug. Denial reasons include:
 - a. Non-formulary drug is not medically necessary because the plan formulary covers drugs that are medically appropriate for enrollee;
 - b. Cost-utilization guidelines, including coverage rules, have not been met for the requested drug. These may include prior authorization rules, dose restriction rules, step therapy coverage rules, and therapeutic substitution requirements; and
 - c. No coverage due to a plan formulary change in coverage, e.g., previously covered drug has been removed from the plan formulary.
5. A decision on the amount of cost-sharing for a drug that the enrollee believes is incorrect.

4.1.2 Who can request a coverage determination?

Individuals or entities that can request a coverage determination, whether standard or expedited, are:

1. The enrollee;
2. The enrollee's appointed representative;
3. The prescribing physician or other prescriber including their respective authorized staff on behalf of the enrollee; and
4. Entity authorized under state or other applicable law to represent Medicare beneficiaries in the appeals process.

The enrollee may appoint any individual or entity to act as his or her representative for purposes of requesting a coverage determination or appeal. Moreover, an incompetent or incapacitated enrollee may request a coverage determination through a surrogate authorized under state law. (See Section 4.6 of this manual for additional details regarding appeals made by appointed representatives).

A prescribing physician or other prescriber may request a standard or expedited coverage determination on behalf of an enrollee. "Other prescriber" means a health care professional other than a physician who is authorized under state law or other applicable law to write prescriptions (e.g., nurse practitioner). A prescribing physician or other prescriber acting on behalf of an enrollee is not an appointed representative, and therefore is not required to complete an Appointment of Representation (AOR) form in order to make such a request. However, since the prescribing physician or other prescriber is not an appointed representative, he or she does not have all of the rights and responsibilities of an enrollee. The prescribing physician or other prescriber is entitled to receive only certain notifications from the Part D plan related to coverage determinations, redeterminations, and denials for standard and expedited review requests.

4.1.3 Standard requests

Standard requests include both a request for coverage of a drug benefit (prospective request) and a request for payment for a drug benefit that has already been furnished (retrospective request).

For prospective coverage requests, the Part D Plan must notify the enrollee (and the prescribing physician or other prescriber involved as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the enrollee's request. For requests involving formulary or tiering exceptions, the 72-hour time frame begins when the Part D Plan receives the prescribing physician or other prescriber's (written or oral) supporting statement.

A plan must notify the enrollee of its determination and make payment (when applicable) no later than 14 calendar days after receipt of the request. For requests involving formulary or tiering exceptions, the 72-hour time frame begins when the Part D plan receives the prescribing physician's or other prescriber's (written or oral) supporting statement.

If a Part D Plan makes a coverage determination that is adverse to the enrollee, in whole or in part, it must give the enrollee, or the enrollee's appointed representative, written notice of the determination. If an enrollee's prescribing physician or other prescriber files a request on behalf of the enrollee, and the Plan does not notify the prescribing physician or other prescriber orally, then the Plan must provide written notice to both the enrollee and the prescribing physician or other prescriber. The notice that is issued by the Part D Plan must comply with all CMS requirements set forth in 42 C.F.R. §423.568(c) and (d) and in Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

4.1.4 Expedited coverage requests

The rules require Part D Plans to have procedures for making determinations in situations where applying the standard time frames may seriously jeopardize the enrollee's life, health, or ability to regain maximum function. These are known as expedited requests. Expedited requests do not include requests for payment of a Part D benefit that has already been furnished.

An enrollee or an enrollee's prescribing physician or other prescriber acting on behalf of the enrollee can ask for an expedited coverage determination by submitting an oral or written request directly to the Part D Plan. For requests submitted by enrollees, the prescribing physician or other prescriber may, but is not required to, provide oral or written support for such a request.

For expedited requests made by an enrollee, the Part D plan must provide an expedited coverage determination if it determines that the time frame for making a standard determination may seriously jeopardize the enrollee's life, health, or ability to regain maximum function.

For expedited requests made by an enrollee's prescribing physician or other prescriber, the Part D plan must provide an expedited determination if the physician "indicates" and provides a supporting statement explaining that applying the standard time frame may seriously jeopardize the enrollee's life, health, or ability to regain maximum function. The term "indicates" should not be limited in scope to mean "shows" or "demonstrates" in a definitive manner, but rather should be construed more broadly to mean to "suggest" the necessity of or to "give evidence of." The Part D plan is required to grant and provide an expedited coverage determination even if the Part D plan disagrees with the physician's statement that standard time frames may put the enrollee's health in jeopardy.

If a Part D plan denies a request to expedite a coverage determination, it must automatically transfer the request to the standard coverage determination process and give the enrollee and his or her prescribing physician or other prescriber prompt oral notice of the denial, which includes the enrollee's rights (described below), and subsequently deliver (i.e., send by mail) to the enrollee, within 3 calendar days, a written letter of such enrollee's rights that:

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

If a Part D plan approves a request for an expedited determination, it must provide a determination and notify the enrollee (and the prescribing physician or other prescriber as appropriate), whether favorable or unfavorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. For requests involving formulary or tiering exceptions, the 24-hour time frame begins when the Part D plan receives the physician's or other prescriber's (written or oral) supporting statement. The Part D plan may notify an enrollee of an adverse expedited determination orally, but if it does so, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification. If a Part D plan orally notifies an enrollee's physician or other prescriber of an adverse determination, it does not need to provide written notice to the physician or other prescriber. However, if the plan does not provide oral notice of an adverse determination to the physician or other prescriber, then the plan must provide written notice to both the enrollee and the enrollee's prescribing physician or other prescriber.

The content of the notice of an expedited coverage determination must comply with CMS requirements set forth in 42 C.F.R. §423.572(c) and Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

A grievance is any complaint or dispute, other than one that involves a coverage determination or at-risk determination, which expresses dissatisfaction with any aspect of a Part D plan's operations, activities, or behavior, regardless of whether remedial action is requested. Part D plans are required to have procedures to ensure that grievances are heard and resolved in a timely manner. The grievance process is separate and distinct from the appeals process.

The Part D QIC will examine each appeal request that is received to determine if the request is for review of an adverse coverage determination. The Part D QIC will dismiss those appeal requests that do not involve adverse coverage determinations or redeterminations, and will remand those disputes to the Part D plan for proper processing under the plan's grievance procedures. Complaints or disputes that do not involve coverage determinations are not properly appealable under Part 423.

The Part D plan should refer to Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for further instruction and guidance on distinguishing between complaints that should be processed as grievances and complaints that should be processed as coverage determinations

4.1.5 Requests that are auto-forwarded to the Part D QIC

If the Part D plan fails to notify the enrollee within the time frames specified for standard coverage determinations or expedited coverage determinations, the Part D plan must forward the enrollee's request and the case file to the Part D QIC within 24 hours of the expiration of its adjudicatory time frame. The

Part D plan may send these records by fax, overnight mail or by any other means that ensures timely delivery.

Please note that it is crucial for Part D plans to send a copy of the case file, even though the case file may be incomplete, since the Part D QIC is obligated to render a determination on the enrollee's request. The Part D plan should explain why it was not able to timely complete the determination, and should identify missing information and any outstanding information requests.

4.2 AT-RISK DETERMINATIONS

The Comprehensive Addiction and Recovery Act (known by the acronym CARA) established a framework for Part D plans to voluntarily adopt drug management programs for beneficiaries who are at-risk of misusing or abusing frequently abused drugs.

If a Part D plan chooses to establish a drug management program for at-risk beneficiaries enrolled in their prescription drug benefit plans then such a drug management program must meet all the rules found in 42 C.F.R §423.153(f) regarding the identification of an individual as at-risk and making an at-risk determination decision. The definition for an at-risk beneficiary and other terms used in the drug management program rules mentioned in 42 C.F.R §423.153(f) and used in this section can be found in 42 C.F.R. §423.100.

At-risk determination decisions are subject to the existing Part D benefit appeals process and timeframes as redeterminations. If an enrollee disagrees with an at-risk determination made by a plan, the enrollee has the right to request a redetermination and potentially higher levels of appeal. For additional information and requirements on plan drug management programs see Chapter 6 of the Prescription Drug Benefit Manual.

4.3 EXCEPTIONS REQUESTS

Exceptions requests are coverage determination requests pursuant to 42 C.F.R. §423.578. There are two general types of exceptions requests: (1) a request for a tiering exception, and (2) a request for a non-formulary drug. Exceptions requests may be decided within standard or expedited adjudicatory time frames and may involve a request for a benefit not received (prospective request) or a request for payment for a benefit already furnished (retrospective request).

The Medicare rules provide that a written or oral statement from the prescribing physician or other prescriber must accompany and support all requests for a tiering or a non-formulary drug exception.

If the enrollee submits an exceptions request without a prescribing physician's or other prescriber's supporting statement, the Part D plan must contact the prescribing physician or other prescriber, or both and request the supporting statement. A Part D plan is not required to begin processing an enrollee's exceptions request until the enrollee's prescribing physician or other prescriber provides a supporting statement. However, the Part D plan is not required to wait an indefinite period of time before issuing its decision. If the Part D plan does not receive the supporting statement within a reasonable period of time, the Part D plan should not dismiss the request, but rather should issue an unfavorable determination based on insufficient evidence.

For Reconsideration review, the Part D plan must submit to the Part D QIC any and all exceptions procedures and criteria relative to the drug in dispute and the Part D plan's determination of non-coverage for the exceptions request. The procedures and criteria submitted must include a description of the process by which the Part D plan evaluates a determination of medical necessity by the enrollee's prescribing physician or other prescriber. The Part D plan must submit any internal medical reviews that are obtained relative to its determination. The Part D plan must also submit the oral or written statement obtained from

the prescribing physician or other prescriber, as well as any additional evidence submitted by the enrollee or prescribing physician or other prescriber during redetermination review. The Part D QIC will examine the record de novo to determine whether: (1) the Part D plan properly applied its own exceptions process/criteria in evaluating the exceptions request, and (2) made an appropriate determination of medical necessity in accordance with its criteria. The Part D QIC will conduct its own independent medical review when making a determination of medical necessity.

4.3.1 Tiering exception requests

Part D plans that manage the Part D benefit through the use of a tiered formulary are required to establish and maintain exceptions procedures that are subject to CMS's approval. A Part D plan is required to grant an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the provisions contained in 42 C.F.R. §423.578(a)(4).

The supporting statement submitted by the prescribing physician or other prescriber must indicate that the preferred drug(s) for the treatment of the enrollee's condition would not be as effective for the enrollee as the requested drug or would have adverse effects for the enrollee, or both.

While the initial supporting statement may be oral, a Part D plan may require the prescribing physician or other prescriber to submit a written statement demonstrating medical necessity in accordance with 42 C.F.R. §423.578(a)(4) if the oral statement is not sufficient and additional medical documentation as follow-up to any oral statements that are made. If the Part D plan requires a written statement, it must request this statement immediately. The Part D plan's request must explicitly state that the prescribing physician or other prescriber is required to demonstrate one of the factors discussed in 42 C.F.R. §423.578(a)(4). The Part D plan may also request additional supporting medical documentation as part of the written follow-up. If the Part D plan requires additional supporting medical documentation, the plan must clearly identify the type of information that must be submitted. If the Part D plan requires the prescribing physician or other prescriber to submit a written supporting statement following the oral statement, the adjudication time frame begins when the Part D plan receives the physician's or other prescriber's written supporting statement. If the Part D plan does not request a written supporting statement, the time frame begins when the oral supporting statement is received.

4.3.2 Formulary exceptions requests

Part D plans that manage the Part D benefit through the use of a formulary are required to establish and maintain exceptions procedures, subject to CMS approval, to ensure that enrollees have access to Part D drugs that are not included on the Plan formulary. A Part D plan is required to grant an exception whenever it determines that the drug is medically necessary, consistent with the prescribing physician's or other prescriber's statement as detailed in 42 C.F.R. §423.578(b)(5), and that the drug would be covered but for the fact that it is an off-formulary drug.

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

1. A dose restriction, including the 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 rules are met; or
3. A therapeutic substitution requirement.

Pursuant to 42 C.F.R §423.578(b)(5) the prescribing physician or other prescriber is required to submit a supporting statement to the Part D plan that addresses the medical necessity for the exceptions request. The statement may be written or oral. The content of the statement will vary, depending on the circumstances underlying the exceptions request.

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

1. All covered drugs on any tier of the formulary would not be as effective as the non-formulary drug, and/or would have adverse effects for the enrollee;
2. The number of doses available under a dose restriction for the prescription drug:
 - a. Has been ineffective in treating the enrollee, or
 - b. Based on sound clinical, medical and scientific evidence, and the known physical or mental characteristics of the enrollee and the 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 alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:
 - a. Has been ineffective in treating the enrollee's disease or condition, or based on sound clinical, medical and scientific evidence and the known physical or mental characteristics of the enrollee and the 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, medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee.

The Part D plan may require the prescribing physician or other prescriber to submit a written statement demonstrating medical necessity in accordance with Section 423.578(b)(5) following any oral statements that are made if the oral statement is not sufficient, and to provide additional medical documentation as part of the written follow-up. If the Part D plan requires a written statement, it must request the statement immediately. The plan's request must explicitly state that the physician or other prescriber is required to demonstrate one of the factors discussed in 42 C.F.R. §423.578(b)(5). The Part D plan may also request additional supporting medical documentation as part of the written follow-up. If the plan requires additional supporting medical documentation, the plan must clearly identify the type of information that must be submitted. If the plan requires the prescribing physician or other prescriber to submit a written supporting statement following the oral statement, the adjudication time frame begins when the Part D plan receives the physician's or other prescriber's written supporting statement. If the Part D plan does not request a written supporting statement, the time frame begins when the oral supporting statement is received.

4.4 REDETERMINATIONS

For a complete discussion on Part D plan level redeterminations, the Part D plan should refer to Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

An enrollee who has received an adverse coverage determination has the right to request that it be redetermined. Redetermination requests may be standard (a prospective request for a drug benefit or a retrospective request for payment) or expedited (prospective only).

A request for redetermination is the first level of the appeals process. At this level, the Part D plan is afforded an opportunity to take a second look at its original coverage determination. One or more individuals not involved in making the initial coverage determination are required to make the redetermination. If a lack of medical necessity formed the basis of the coverage denial, then a physician with expertise in the field of medicine appropriate for the services at issue must make the redetermination. In addition, the Part D plan is required to provide the enrollee or the prescribing physician or other prescriber, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law related to the issues in dispute, in person (i.e., hand delivery to the plan's physical location) as well as in writing (i.e., by mail or fax).

4.4.1 Standard redeterminations

To request a standard redetermination, the enrollee or the enrollee's representative must file a written request with the Part D plan, or an oral request if permitted by the plan, within 60 calendar days from the date of the notice of the coverage determination. The prescribing physician or other prescriber may appeal on behalf of the enrollee for a standard and expedited redetermination request. Note that under 42 C.F.R. §423.580, a prescribing physician or other prescriber may request a *standard* redetermination on an enrollee's behalf only after he or she has provided notice to the enrollee that he or she is making the appeal request. For standard redetermination requests that are prospective, whether the redetermination is favorable or adverse to the enrollee, the Part D plan must notify the enrollee in writing of its redetermination (and for favorable redeterminations must effectuate) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date the plan receives the request for a standard redetermination.

For adverse standard redetermination requests involving payment for services already furnished, the Part D plan must notify the enrollee of its redetermination in writing no later than 7 calendar days from the date it receives the request for a standard redetermination. For favorable standard redetermination requests involving payment, the Part D plan must issue its redetermination no later than 7 calendar days from the date it receives the request for a standard redetermination involving payment.

The notice of a standard adverse redetermination issued by a Part D plan must comply with CMS requirements set forth in 42 C.F.R. §423.590(g) and Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance

4.4.2 Expedited redeterminations

Requests to Part D plans for expedited redeterminations must be filed with the plan within 60 calendar days from the date of the notice of the coverage determination. These requests may be written or oral, and may be requested by the enrollee, the enrollee's representative, or the prescribing physician or other prescriber acting on behalf of the enrollee. As noted in the previous section, the prescribing physician or other prescriber does not need to obtain an AOR for a redetermination request. For expedited requests submitted by the enrollee, the prescribing physician or other prescriber may, but is not required to, provide oral or written support on behalf of the enrollee.

When an enrollee requests an expedited redetermination, the Part D plan is required to provide an expedited redetermination if the plan determines that the time frame for making a standard redetermination may seriously jeopardize the enrollee's life, health, or ability to regain maximum function.

For a request made or supported by a prescribing physician or other prescriber, the Part D plan must provide an expedited redetermination if the physician or prescriber "indicates" that applying the time frame for making a standard redetermination may seriously jeopardize the enrollee's life, health, or ability to regain maximum function. The term "indicate" should not be limited in scope to mean to "show" or "demonstrate" in a definitive manner, but rather should be construed more broadly to mean to "suggest" the necessity of or to "give evidence of." The Part D plan is required to grant and provide an expedited coverage determination even if the plan disagrees with the physician's statement indicating that standard time frames may put the enrollee's health in jeopardy.

If a Part D plan denies a request to expedite a redetermination, it must automatically transfer the request to the standard coverage determination process and give the enrollee and his or her prescribing physician or other prescriber prompt oral notice of the denial, which includes the enrollee's rights (described below), and subsequently deliver (i.e., send by mail) to the enrollee, within 3 calendar days, a written letter of such enrollee's rights that:

1. Explains that the Part D 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 Part D plan's decision not to expedite the determination;
3. Informs the enrollee of the right to resubmit a request for an expedited determination and that if the enrollee gets his or her prescribing physician's or other prescriber's support indicating that applying the standard time frame for making determinations could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain to maximum function, the request will be expedited automatically; and
4. Provides instructions about the expedited grievance process and its time frames.

If a Part D plan approves a request to expedite, it must notify the enrollee of its redetermination as expeditiously as the enrollee's health requires, but not later than 72 hours from the date the plan receives the request for an expedited redetermination. The Part D plan may notify the enrollee of its decision orally, so long as it sends an equivalent written notice to the enrollee within 3 calendar days of the oral notice.

The written (and oral) notice of an adverse expedited redetermination issued by a Part D plan must comply with CMS requirements set forth in 42 C.F.R. §423.590(g) and Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

4.4.3 Redetermination requests that are auto-forwarded to the Part D QIC

If the Part D Plan fails to notify the enrollee within the time frames specified for standard redeterminations or expedited redeterminations, the Part D plan must forward the enrollee's request and the case file to the Part D QIC within 24 hours of the expiration of its adjudicatory time frame. The Part D plan may send these records by fax, overnight mail or by any other means that ensures timely delivery to the Part D QIC.

Please note that it is crucial for Part D plans to send a copy of the case file, even though the case file may be incomplete, since the Part D QIC is obligated to render a determination on the request. The plan should explain why it was not able to timely complete the determination, and should identify missing information and any outstanding information requests. The Part D QIC strongly recommends that plans notify the Plan Liaison when submitting 20+ auto-forwarded case files for review

4.4.4 Dismissal of a standard pre-benefit redetermination

Where an enrollee requests a standard pre-benefit redetermination and the Part D plan learns that the enrollee has obtained the drug in dispute before the plan has completed its redetermination, the plan must stop processing the claim as prospective and instead process the claim as a retrospective request for payment.

In the event that the Part D plan does not discover that an initially filed prospective request has become retrospective, and the plan continues to deny the request and sends the case file to the Part D QIC for Reconsideration review, the Part D QIC will stop processing the claim as prospective and will process the claim as a retrospective request for payment if it receives information that the drug has been obtained.

4.5 NOTICE FOR FORMULARY CHANGES

Whenever a Part D plan removes a covered Part D drug from its formulary, or makes any changes in the preferred or tiered cost-sharing status of a covered drug, the Part D plan must provide notice in accordance with CMS rules.

The Part D plan is required to provide direct written notice to "affected" enrollees at least 60 calendar days prior to the change. An affected enrollee is a plan enrollee who is currently taking the covered Part D drug that is either being removed from the plan's formulary or is subject to a change in its preferred or tiered cost-sharing status. To the extent that the Part D plan does not give the mandatory 60-day (calendar day) advance notice, the plan will be required to provide the notice and provide a 60 day supply of the drug on the same terms as was provided by previous coverage when the affected enrollee requests a refill of his or her prescription. Once notice is provided, the enrollee will have a 60-day (calendar day) window either to switch to a therapeutically appropriate alternative medication, or access the Part 423 appeals process prior to the change becoming effective.

The written notice for formulary changes issued by a Part D plan must comply with CMS requirements in 42 C.F.R. §423.120(b)(5). Note that formulary changes from one (1) calendar year to the next are addressed in the member documents distributed in connection with the Annual Enrollment Period (AEP). Members receive the formulary for the following plan year and the Annual Notice of Changes (ANOC) in October.

For Reconsideration requests involving an affected enrollee alleging failure of the Part D plan to provide proper notice of a formulary change, and requesting coverage in accordance with rules in effect prior to the change, the Part D QIC will examine the record de novo to determine whether and when the plan gave direct written notice to the enrollee in accordance with CMS rules. A Part D plan may show that it furnished proper notice by producing the enrollee's signature indicating delivery and receipt of the mailed notice (i.e., return receipt requested mail). A Part D plan also may show that it furnished proper notice by producing a copy of the dated notice, providing records showing that the plan identified the enrollee as an

affected enrollee, and attesting in writing (or by other credible evidence) that notice was mailed to the enrollee on a specific date.

4.6 PART D PLAN VALIDATION OF APPEALING PARTY

Title 42 of the Code of Federal Regulations, Part 423 (Part 423) rules clearly identify the parties that may request a coverage determination and subsequently appeal a determination that is not fully favorable to the enrollee. Under the Part 423 rules, the enrollee, the enrollee's properly appointed representative, enrollee's prescribing physician, or other prescriber are permitted to make a request for a standard or expedited coverage determination, a standard or expedited redetermination, or a standard or expedited Reconsideration appeal with the Part D QIC.

The Part D plan must carefully evaluate whether the appealing party is a proper party for purposes of appeal under Part 423. It is a straightforward validation of the appellant when the enrollee is the individual who initiates the request for a coverage determination or redetermination. It is also a relatively straightforward validation when the appellant is the prescribing physician or other prescriber appealing a coverage determination or redetermination. Except for a prescribing physician or other prescriber who may appeal in the circumstances as described, it is not as straightforward to validate the appellant when a person other than the enrollee makes the request for a determination. Such appellants may properly appeal if they have been appointed by the enrollee (or a court) to act in a representative capacity or if they are authorized to act as a representative pursuant to state or other applicable law.

4.6.1 Appointed Representatives

An enrollee who is competent (i.e., has sufficient capacity to make informed decisions) may appoint any individual or entity to act as his or her representative for purposes of requesting a coverage determination or appeal. The enrollee may appoint a relative, friend, advocate, attorney, physician, pharmacy, or person working for a charity, SPAP, or other secondary payer. Moreover, a court of law may appoint an individual or entity to act on behalf of an incompetent enrollee (e.g., guardianship proceeding.)

An individual or entity that has been validly appointed by the enrollee to act as the enrollee's representative has the same rights as an enrollee. On behalf of an enrollee, an appointed representative may:

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

In order to appoint a representative, other than the prescribing physician, an enrollee must complete an Appointment of Representative (AOR) Form CMS-1696 or any other similar form or writing that meets the following requirements:

- Identifies the name, address, phone number of enrollee;
- Identifies the enrollee's Medicare number;
- Identifies the name, address, and telephone number of the individual being appointed;
- 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;
- Contains the signature of the enrollee making the appointment, and the date signed; and
- Contains the signature of the individual being appointed as representative, accompanied by a statement that the individual accepts the appointment, and the date signed.

Note that all of these fields must be completed in full. When a person claiming to be a representative files a request for a coverage determination or redetermination, he or she must include a signed form or statement showing valid representation status. There is an exception for the incompetent or incapacitated enrollee who has not previously executed an instrument of representation that is discussed in section 4.6.2. Once a signed form or statement is 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, the enrollee is not required to obtain a new signed form or statement for any new coverage determination request filed by the representative within one (1) calendar year from the date the representative form is properly executed. However, the representative filing a new coverage determination request under the authority of such a form or statement must file a copy of the original form at the time of the request.

When a person claiming to be a representative files a request without providing the requisite form or statement, the Part D plan is not required to undertake a substantive review until or unless the appropriate documents are provided. The plan should try to remedy the defect by asking the appealing party to provide an AOR that meets the above noted requirements. The Part D plan must document its reasonable efforts to obtain the requisite form or statement. The Plan's adjudicatory time frame does not begin until the plan receives a properly executed appointment form. However, the Part D plan may choose to begin the process for review, which may include requesting medical documentation in a case that will involve medical necessity review. If the plan does not receive a properly executed appointment document within a reasonable period of time, the plan should dismiss the request on the basis that the appealing party is not a proper party under Part 423.

Enrollees may also appoint representatives pursuant to state laws that permit the execution of legal instruments that delegate legal authority to other individuals to act in a representative capacity. Examples include Power of Attorney (POA) instruments and healthcare proxy instruments.

There are many different types of POAs, including durable and springing POAs. Durable POAs (DPOAs) typically enable the representative to act for the principal (the enrollee making the appointment) even after the principal is not mentally competent or physically able to make decisions. DPOAs typically are effective until and unless revoked by the principal, or until the principal's death. Springing POAs typically take effect only when the principal becomes mentally incompetent or physically unable to make decisions. Given the many different types of POAs, and the variability of each state's laws governing these instruments, the Part D plan must consult the applicable state law to ascertain the precise scope of a representative's authority under a POA and determine validity of representation for appeal purposes under Part 423. The Part D plan should not require a representative, who has validly been appointed as a POA in accordance with state law and has appropriate authority as a representative, to execute an AOR form that makes the same appointment.

Healthcare proxy instruments typically are springing instruments. These instruments are triggered when an individual loses competence or capacity to make healthcare decisions on his or her own behalf. Again, each state's laws differ, and the Part D plan must consult the applicable state law to determine whether the appellant who presents as a healthcare proxy is a valid representative under state law for appeal purposes under Part 423. As noted above, the Part D plan should not require a representative who is a valid healthcare proxy under state law to execute an AOR form that makes the same appointment. Conversely, it would not be appropriate for the Part D plan to permit the same individual (designated as a healthcare proxy) to initiate an appeal without obtaining an AOR if the enrollee remains competent to make his or her own healthcare decisions. This is because the triggering event of incompetency or incapacity has not yet occurred.

In response to a case file request from the Part D QIC, the Part D plan should submit any representation documentation it has obtained from non-enrollee appellants at the coverage determination and/or redetermination appeal level. Many of the same individuals who appealed as representatives at the plan

level, and received an adverse determination, will appeal to the Part D QIC for Reconsideration review. Occasionally, these individuals fail to submit representative documentation along with their requests for Reconsideration review. The Part D QIC is subject to the same representation rules as described above for Part D plans. The Part D QIC's Reconsideration time frame does not begin until and unless the Part D QIC receives a properly executed representation form or statement and is able to validate the appellant's representation. While the Part D QIC may contact the appellant and ask for the submission of representation documents, in many instances the defect will be remedied upon the Part D plan's submission of the case file, which may contain representation documents previously submitted by the same appellant at the plan determination level. However, as noted above, no AOR is required at the plan level if the enrollee's prescriber is submitting the appeal on behalf of the enrollee.

In the event the Part D QIC discovers an appealing party defect that was missed by the Part D plan at a prior level of appeal, the Part D QIC will contact the Part D plan and the appealing party and try to remedy the defect.

The *Reconsideration Case File Transmittal Form*, which is a form that must be completed by the Part D plan and submitted to the Part D QIC pursuant to a case file request, contains an attestation for Plans to complete to validate non-enrollee appellants who appeal pursuant to instruments conferring representative authority under state law. Part D plans will be asked to attest to the appealing party's validity as a representative on behalf of enrollee under state law. Unless there is evidence otherwise, this attestation, when accompanied by a copy of the instrument conferring representative authority, will serve as sufficient validation of the appellant's representative status at the coverage determination and redetermination level. Moreover, the Part D QIC will accept this as sufficient evidence for validation of representation at the Reconsideration level.

4.6.2 Individuals (or Entities) authorized under State Law to act as surrogates on behalf of incompetent or incapacitated enrollees

An individual who becomes incompetent or incapacitated, and has not previously executed an instrument of representation (and does not have a court-appointed guardian), does not lose the right to appeal adverse determinations regarding drug benefits under Part 423 simply by virtue of these circumstances. These individuals, though unable to act on their own behalf, are legally entitled to request coverage determinations and to appeal Part D plan denials for drug benefits. For these individuals, when a would-be representative initiates a request for a coverage determination or appeal, the Part D plan is required to ascertain whether the representative is a valid surrogate under state law, and hence a valid party for appeal purposes under Part 423 rules.

An enrollee may be considered incapacitated or incompetent when he or she cannot comprehend and sign an AOR document. If the enrollee has not previously executed a legal document (e.g., POA, healthcare proxy or AOR) authorizing another individual to act as his or her representative, the Part D plan is required to identify and apply state law regarding the legal representation of incapacitated or incompetent persons. State law includes both legislative and judicial case law.

Many jurisdictions have surrogacy statutes that permit a series of family members and other individuals to act on behalf of an incapacitated enrollee for purposes of healthcare decision-making. A spouse or child willing to act in a representative capacity typically is among those individuals listed as appropriate surrogates. The Part D plan should consult the applicable state's law to ascertain whether the non-enrollee appellant is an appropriate surrogate for the enrollee under state law. The Part D plan should consult with their legal counsel, as needed, to properly make these determinations.

As noted above, the *Reconsideration Case File Transmittal Form* contains an attestation for Part D plans to complete to validate the representation for individuals who appeal as surrogates on behalf of incompetent or incapacitated enrollees. Part D plans will be asked to attest to the appealing party's validity as a surrogate-representative for enrollee under state law. Unless there is evidence otherwise, this attestation will serve as sufficient validation of the appellant's status as representative at the coverage determination and redetermination level. Moreover, the Part D QIC will accept this attestation as validation of representation at the Reconsideration level.

4.6.3 Individuals (or Entities) who appeal on behalf of deceased enrollees

A coverage determination or redetermination request involving retrospective payment for a drug benefit furnished to a now deceased enrollee may properly be brought by a representative who is responsible for administering the deceased enrollee's estate. Such a representative may present as an "Executor" or "Executrix" having been named as a representative in the enrollee's will, or as an "Administrator" pursuant to appointment by a state court. Executors and Administrators typically are charged with a variety of powers and duties, which include the marshalling of the assets of the deceased individual. Each state has its own laws pertaining to estate administration and representation. The Part D plan must consult the laws of the applicable state to determine whether an individual (or entity) that appeals on a deceased enrollee's behalf is a proper and valid representative for purposes of appeal under Part 423.

As previously noted, the *Reconsideration Case File Transmittal Form* contains an attestation for Part D plans to complete that includes validation of representation for individuals who appeal as representatives on behalf of deceased enrollees. Plans will be asked to attest as to the appealing party's validity as a representative for the enrollee's estate. Unless there is evidence otherwise, this attestation, when accompanied by a copy of the instrument or document conferring representative authority, will serve as sufficient validation of the appellant's status as representative at the coverage determination and redetermination level. Moreover, the Part D QIC will accept this as sufficient evidence for validation of representation at the Reconsideration level.

4.6.4 Prescribing physician or other prescriber supporting the enrollee's appeal

A prescribing physician or other prescriber may "support" the enrollee's request for a coverage determination or redetermination by providing a written statement or oral testimony to the Part D plan. A prescribing physician or other prescriber may also support an enrollee's request for the Part D plan to expedite a request for a coverage determination or redetermination. Again, such support may be written or oral. Although a physician or other prescriber can provide support for an appeal without necessarily appealing on the enrollee's behalf, there is no requirement for execution of an AOR if the physician or other prescriber does wish to appeal on the enrollee's behalf at the Plan level or at the Reconsideration level with the Part D QIC.

The distinction between representation and support includes any of the following elements: (1) the person supporting the appeal generally has no standing to request the appeal proceeding, whereas the representative does; (2) the person supporting the appeal does not receive mandatory notices otherwise sent to the enrollee; whereas the representative does; (3) the person supporting the appeal cannot make decisions (for example, withdrawing the appeal), whereas the representative may do so, and (4) the person supporting the appeal does not otherwise "manage" the enrollee's participation in the appeal, whereas the representative may.

A prescribing physician or other prescriber may also, without being a representative, support a request to expedite a coverage determination or redetermination. The prescribing physician's or other prescriber's statement of support may be written or oral. The effect of such statement is to mandate expedited status for the appeal if the statement "indicates" that application of the standard decision time frame may seriously jeopardize the life or health of the enrollee, or the enrollee's ability to regain maximum functioning.

The Part D plan should note that it is not required to automatically expedite a request if the physician or other prescriber who submits the request is not the prescribing physician or other prescriber for the enrollee. In these cases, the Part D plan must independently determine if medical exigency exists, and must notify the enrollee of its decision as expeditiously as the enrollee's health requires.

4.7 VALIDATION OF ELIGIBILITY OF APPEAL

The Part D plan must determine whether a complaint or dispute is a request for a coverage determination or constitutes a grievance. Actions that constitute coverage determinations are defined in a previous Section (see Section 4.1.1 of this manual). Any complaint or dispute is a grievance if it does not meet definitional criteria for a coverage determination. The Part D plan should refer to Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, for a detailed discussion on distinguishing between complaints that are coverage determinations and complaints that are grievances. On Reconsideration review, the Part D QIC will examine the complaint to ensure that it constitutes an appealable issue. If the complaint does not present an appealable issue, the Part D QIC will dismiss the appeal request and remand the case to the Part D plan for processing under the plan's grievance procedures.

4.8 IDENTIFICATION OF APPEAL CLASSES AND TYPES

There are three classes of appeal requests: (1) standard requests for coverage for a drug benefit (prospective); (2) standard requests for payment for an already furnished drug benefit (retrospective); and (3) expedited requests for disputes where applying the standard time frames may seriously jeopardize the enrollee's life, health, or the ability to regain maximum function (prospective only).

The classification of a request for a coverage determination or redetermination as either expedited or standard is the responsibility of the Part D plan. The plan should not ask the Part D QIC to determine whether a given request for expedited review should be granted. The Part D plan should refer to Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, for instruction and guidance on making this decision.

For Reconsideration requests, the Part D QIC will independently determine whether a given expedited appeal request meets medical exigency standards and should be processed as an expedited or standard appeal. When making the decision whether or not to expedite, the Part D QIC will take into account whether the coverage determination or redetermination request was expedited. The Part D QIC will expect the Part D plan to include in the case file information concerning the Part D plan's decision with regard to determining medical exigency for expedited requests made at the Plan level.

4.9 RESPONSIBILITY TO CONDUCT A FULL AND MEANINGFUL DETERMINATION

The Part D QIC's primary responsibility is to adjudicate standard and expedited Reconsiderations in an accurate, efficient, timely and consistent manner. Part D plans play a vital role in helping the Part D QIC to accomplish this goal. A Part D plan that conducts full and meaningful review, clearly documents the results of its review in the case file, and timely furnishes the case file pursuant to a request from the Part D QIC, contributes significantly to promoting an efficient process that results in timely and accurate Reconsideration review.

The Part D plan is required to take an active role in evaluating requests for coverage determinations and redeterminations. It is not appropriate for a Part D plan to automatically deny or dismiss a request due to failure of the appealing party to submit medical or other documentation along with the request. The Part D plan should exercise best efforts with respect to gathering all of the information it needs for meaningful decision-making. For example, for a tiering or formulary exceptions request, the Plan must contact the enrollee and/or the prescribing physician or other prescriber to solicit a supporting statement, if such statement was not submitted with the original request. If the Part D plan requires additional medical documentation for an exceptions request, the Plan must clearly identify the records and documents it needs. For a medical necessity determination that does not involve an exceptions request (e.g., authorization for a covered Part D drug subject to completion of step therapy requirements), the Part D plan should contact the enrollee and/or prescribing physician or other prescriber to request statements and/or medical records, as needed, to make a meaningful decision regarding coverage.

If a Part D plan's adverse determination is based (fully or in-part) on incomplete medical documentation that the plan was unable to obtain, the plan should, in the case file, identify the information that is missing, explain its importance relative to the determination that is made, and document its reasonable attempts to obtain the information, including identifying whether it contacted the enrollee and/or the prescribing physician or other prescriber, and noting the telephone numbers for telephone calls attempted, fax numbers and email addresses for faxes or email sent, and/or street addresses for any mailings sent. Including this type of information in the case file helps narrow the issues for Reconsideration review, and facilitates a meaningful review by the Part D QIC.

5. SUBMITTING THE CASE FILE TO THE PART D QIC FOR DRUG APPEAL RECONSIDERATION REVIEW

This Chapter defines the requirements for Part D plan preparation and submission of case files to the Part D QIC for QIC level Reconsideration under the following headings:

- 5.1 Cases That Must Be Submitted to the Part D QIC
- 5.2 Time Standards For Submission of Cases to the Part D QIC
- 5.3 Preparation and Submission of the Case File to the Part D QIC for Drug Appeals

5.1 CASES THAT MUST BE SUBMITTED TO THE PART D QIC

An enrollee who has received an adverse redetermination for a medication has the right to request that it be reconsidered by the Part D QIC. Requests for Reconsideration review may be standard (either prospective or retrospective), or expedited (prospective only). The enrollee or the enrollee's representative, or an enrollee's prescribing physician or other prescriber may submit a request for Reconsideration by filing a signed written request with the Part D QIC within 60 calendar days from the date of the notice of the redetermination. The 60-day time frame for filing may be extended if the Part D QIC finds that the appealing party has demonstrated good cause for the late filing. Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, sets forth examples of circumstances that constitute good cause. The decision of the Part D QIC whether or not to grant an extension for good cause is final and not subject to appeal. Please see section 3.5 for more information regarding mailing

The Part D QIC, upon receipt of a request for Reconsideration review, will fax a *Reconsideration Case File Request Form* to the Part D plan. This form constitutes a formal request by the Part D QIC for the Part D plan to produce and deliver a copy of the case file for the issue on Reconsideration appeal. The form contains various identifiers, which will permit the plan to accurately identify the associated case file. In the event that the Part D plan cannot identify the appeal and associated case file, the Part D plan must immediately contact the Part D QIC at the telephone number provided on the fax to report the problem.

The Part D QIC may also request a case file by telephone or email in the event that fax transmission is not possible or successful. However, the preferred method for requesting case files is by fax.

Please note that requests for case files may be made on any day of the week including Saturdays and Sundays. The Medicare law and rules mandate that drug appeal Reconsideration reviews generally be completed no later than 72 hours for expedited requests and 7 calendar days for standard requests. Given the very short decision-making time frames, and the fact that substantive review cannot be undertaken without the case file, the Part D QIC will request a case file as soon as possible after it receives a request for Reconsideration review.

The *Reconsideration Case File Request Form* is "received" by the Part D plan when the fax is successfully transmitted to the Part D plan's fax machine or when telephone contact is made or an email is sent. The Part D plan must submit any case for which it made a coverage determination or redetermination when that case is requested by the Part D QIC pursuant to the process described above. If the enrollee has not exhausted prior levels of appeal or was not enrolled in the Plan at the time of the benefit request, the Part D plan must provide this information to the Part D QIC on the *Reconsideration Case File Request Form*.

The Part D plan also must submit drug appeal cases in which it has not made a decision within the applicable decision time frame. These cases are auto-forwarded by the plan and are not requested by the Part D QIC. Cases subject to auto-forwarding, if not completed in a timely manner by the plan, include requests for coverage determinations and requests for redeterminations.

The Part D plan also must submit any additional information that it receives that is relevant to a Reconsideration appeal in process at the Part D QIC. The Part D QIC will consider any additional information that is received at a reasonable point in time prior to the expiration of the adjudicatory time frame for the appeal. However, the Part D QIC will not delay its review, and makes no guarantee that information submitted late in the process will be considered for Reconsideration review.

5.2 TIME STANDARDS FOR SUBMISSION OF CASES TO THE PART D QIC

The Part D QIC must receive case files for expedited drug appeal Reconsideration requests within 24 hours from the time that the Part D plan receives a request to produce and forward a specific case file. The Part D QIC must receive case files for standard drug appeal Reconsideration requests within 48 hours from the time that the Part D plan receives a request to produce and forward a specific case file. As noted above, the Part D plan receives a request for a case file when it receives a successfully transmitted fax at its office, or a telephone call or email. The Part D plan may forward the case file by fax, overnight mail, or any other means that will ensure timely delivery to the Part D QIC.

For coverage determinations and redeterminations that the Part D plan has failed to timely decide within its adjudicatory time frame, the Part D plan must forward both the request and the case file within 24 hours of the expiration of the plan's adjudicatory time frames. The Part D plan may forward the case file by fax, overnight mail, or any other means so long as the plan is able to track the shipment.

Part D plans are urged to submit case files as expeditiously as possible to facilitate timely and meaningful Reconsideration review by the Part D QIC. The Part D QIC's adjudicatory time frame begins when it receives a valid request for Reconsideration. The Medicare law does not permit the Part D QIC to extend its decision-making time frames for case files that are not submitted timely. When the case file is not submitted timely, the Part D QIC must make its decision based on the information on hand. For drug appeals, this may include the Reconsideration request, any additional information submitted by the appealing party or prescribing physician or other prescriber, statements the Part D QIC has solicited from the prescribing physician or other prescriber, and information in the Health Plan Management System (HPMS).

5.3 PREPARATION AND SUBMISSION OF THE REQUESTED CASE FILE FOR DRUG APPEALS

Addressed below are instructions for the Part D plan on the required content of a case file and methods for physical construction of a case file submitted to Part D QIC. The topics are addressed under the following subheadings:

- 5.3.1 Content and Organization of the Case File
- 5.3.2 Additional Guidance on Selection and Inclusion of Records

5.3.1 Content and Organization of the Case File

There are 2 forms that the Part D plan must complete and attach to each case file that it submits to the Part D QIC. These forms are the *Reconsideration Case File Transmittal Form* and the *Case Narrative Form*. Both of these forms are available for downloading from our website. These forms are the Part D plan's main working tools for submitting case files to the Part D QIC.

The *Case File Transmittal Form* is self-explanatory and must be completed in full by the Part D plan. Information that must be provided on the form includes the plan contract number, plan ID number or formulary ID number, and the plan type. The Part D QIC will need this information to access the Part D plan's formulary in the HPMS. Additionally, the form requires the Part D plan to provide information about the appeal at the Plan level of review. The Part D QIC will need this information to facilitate proper entry of data into the Medicare Appeals System (MAS).

When sending case files by fax, the Part D plan should complete the *Reconsideration Case File Transmittal Form* and use this form as the cover letter to identify each case file that is submitted. The Part D QIC dedicates fax machines for receiving documents and records from Part D plans. For auto-forwarded case files where the Part D plan has failed to decide within its adjudicatory time frame, the plan is asked to use the fax number for the Pittsford office: (720)462-7575. These fax machines are “secure,” meaning that they are only available to Reconsideration personnel working on the Part D QIC project. It is permissible to send records to our designated fax machines without redacting personally identifiable information. Our office is open to accept faxes 7 days a week. When faxing, please note that each case files **must** be sent in separate fax transmissions. Faxes are received and processed electronically, and multiple case files submitted in one fax transmission will process as receipt of only one case file. Therefore multiple case files cannot be included in 1 fax transmission to the Part D QIC.

When sending case files through the QIC Portal website (<https://qicappeals.cms.gov/my.policy>), the Part D plan should refer to the *Portal User Guide* linked on the web page’s home page for ease of access. QIC Portal account administrators may add and remove users and contract numbers as applicable.

All users identified by a Portal administrator as a Part D user should use the appropriate Part D Drug Submit Case tab within the website to complete the required fields in responding to a case file request from Maximus Federal. Exhibits, Evidences of Coverage, and Formularies may be submitted with the case file as PDF attachments in lieu of mailing a CD-ROM. Upon completion of a case file submission the QIC Portal user will receive a confirmation email including a reference ID number and the date and time a case file is determined to be received by the QIC.

Submissions may be made through the QIC Portal website 24/7. Technical issues with QIC Portal user accounts should be addressed to QICPortalHelp@maximus.com. Questions regarding the submissions process whose answers cannot be found within the *Portal User Guide* should be addressed to QICPortalSupport@maximus.com.

When sending cases files by overnight mail, the Part D plan should similarly use the *Reconsideration Case File Transmittal Form* as the case file cover letter. The Part D plan should place the associated documents and records in an envelope or container for shipping. Our office is open to accept case files sent by overnight mail on Monday through Saturday and most holidays. Unless indicated otherwise, packages should be addressed to:

**Maximus Federal
Medicare Part D QIC
3750 Monroe Ave. Suite 703
Pittsford, NY 14534-1302**

If the Part D plan wishes to send more than one case file in an overnight package, it must include a cover letter that identifies the contents of the package and must clearly separate each case file submission with separate *Reconsideration Case File Transmittal Forms*. For multiple submissions, the Part D plan should adhere to the following recommendations:

- Complete and place the *Reconsideration Case File Transmittal Form* on top of the case file package;
- Place each case in the package in a separate envelope;
- Do not staple or permanently bind case file material. Use of clips or binders that can be removed without special equipment is permissible; and
- Do not include any material in a "new" case file package submitted to the Part D QIC that is not related to a new case.

The organization of the case file should include the following applicable sections, each separately and clearly labeled, and should be placed in the following order, "top" of file to "bottom" of file:

Procedural Documents for Drug Appeal Case Files

A. Reconsideration Case Narrative Form

- The Case Narrative is where the Part D plan presents the Part D QIC with an overview of the issues on appeal, identifies arguments presented in favor of and against coverage, and explains the plan's reasons for denying coverage as requested by the appellant. The Part D plan also may include a brief chronology or timeline in this section addressing pertinent facts and findings.

B. Request for Coverage Determination and Coverage Determination Notice

- The request for a coverage determination may include any submitted written requests from an appropriate party or oral requests that are documented and transcribed by the plan. If the request for coverage was initiated with the presentation of a prescription drug at a pharmacy (i.e., the plan treats the presentation of the prescription at the pharmacy as a request for a coverage determination), then this should be indicated by the plan.
- The Coverage Determination Notice is the CMS mandated notice (see 42 C.F.R. §423.568(c) and (d)) that is sent to the appealing party when the Part D plan makes an adverse coverage determination (i.e., denies a drug benefit in whole or in part).
- The Part D plan should also indicate if the appellant requested an expedited coverage determination, and whether the plan in fact expedited the request. If the plan declined to expedite the request, the plan should include information explaining its decision to handle in accordance with standard decision-making time frames.

C. Request for Redetermination and Redetermination Notice

- The request for a redetermination may include any submitted written requests from an appropriate party or oral requests that are documented and transcribed by the Part D plan.
- The Redetermination Notice is the CMS mandated notice (see 42 C.F.R. §423.590(g)) that is sent to the appealing party when the Part D plan makes an adverse redetermination.
- The Part D plan should also indicate if the appellant requested an expedited redetermination, and whether the plan in fact expedited the request. If the plan declined to expedite the request, the plan should include information explaining its decision to handle in accordance with standard decision-making time frames.

D. Prescriber Statement

- For appeals involving an exceptions request, the Part D plan must submit oral and written statements provided by the prescribing physician or other prescriber and/or solicited by the plan during the appeal. We will accept oral statements that have been transcribed by the Part D plan as well as phone logs documenting telephone conversations.
- If the Part D plan has not been able to obtain a statement from the prescribing physician or other prescriber, the plan must document its attempts in the record.
- The Part D plan must include the prescribing physician's or other prescriber's office address, telephone and fax numbers, and email address, if available. If the case file provided by the Part D plan is insufficient, the Part D QIC is required by law to solicit the comments of the prescribing physician or other prescriber, and will need contact numbers for the prescriber.

E. Representation Documents

- For appeals initiated by representatives at the plan level, the Part D plan must include documentation showing that the representative is a valid party for purposes of Part 423 appeals.
- Documents or instruments showing valid representation may include the following:
 - AOR document (CMS-1696 form or other similar writing in compliance with 42 C.F.R. § 405.910;

- Instrument executed by an enrollee that confers representative authority in accordance with state law, e.g., POA or DPOA, health care proxy appointment, or other estate documentation naming an executor to handle a deceased enrollee's estate;
 - Representative authority conferred by state law that authorizes a designated individual to act on behalf of an incapacitated or incompetent enrollee, e.g., surrogacy statute;
 - Representative appointment made for an incapacitated or incompetent enrollee pursuant to a court of law, e.g., guardianship appointment; and
 - Representative appointment made by a court of law on behalf of a deceased enrollee that has not named an executor to handle his or her estate.
- If the Part D plan has not been able to validate a party who appeals as a representative, the plan should include this information in the record and document its attempts to correct the defect.
 - For representative authority conferred pursuant to state law, the Part D plan should complete the attestation on the *Reconsideration Case File Transmittal Form* indicating that it has determined that the appellant is a proper representative under state law.

F. Other Procedural Documents

- The Part D plan must submit any screen shots from the ABII system for applicable cases.
- The Part D plan should include any other documents or information that it believes is relevant to the disputed drug benefit.

Evidentiary Documents

G. Applicable Formulary Rules/Exceptions Criteria

- For determinations involving a tiering exception request or a formulary exception request, the Part D plan must provide the applicable exceptions procedures/criteria for determining whether the exceptions request should be granted. The plan must explain its basis for not granting an exceptions request, and should include a copy of any internal medical review that it obtained relative to its determination.
- The Part D plan must also provide a description of any cost-utilization tools applicable to the drug in dispute, e.g., dose restrictions, step therapy requirements, and therapeutic substitution.
- CMS strongly recommends that Part D plans include complete copies of the relevant formulary with any case files sent to the Part D QIC for review copied onto a CD, or as an attachment to a case file submission through the QIC Portal. For further instructions, please refer to Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

H. Evidence of Coverage or Other Subscriber Materials

- The Part D plan should include a complete copy of the relevant Evidence of Coverage (EOC), comprehensive formulary or other subscriber materials as applicable to the disputed drug benefit. CMS strongly recommends that plans supply a complete EOC on CD-ROM, or as an attachment to a case file submission through the QIC Portal. For further explanation, please refer to Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

I. Cost-Sharing/TrOOP Calculations

- The Part D plan should include any and all internal plan or pharmacy documents or screens showing calculations relevant to the disputed cost-sharing amount as well as any documentation submitted by the appellant.

J. Medical Records

- For medical necessity appeals and exceptions request appeals, the Part D plan should include medical records, including claims history, that are relevant to the disputed drug benefit.
- Medical records should be clearly tabbed and identified, legible and organized, submitted with the most recent records on top. Part D plans are encouraged to flag parts of the record that are pertinent to the disputed benefit.
- If the Part D plan requested, but was not able to obtain, medical records necessary for review, the plan should indicate this in the case file, document the precise records requested, and record its attempts to obtain the records.

K. Medicare Rules

- The Part D plan case file should reference Medicare law, regulations, or other CMS special guidance material, as relevant to the disputed drug benefit.

L. Redetermination Evidence

- The Part D plan should include any additional evidence and/or facts presented by the enrollee and/or the prescribing physician or other prescriber at the plan redetermination level including screen shots from the ABII system for applicable cases.

M. Other Evidentiary Information/Documents

- The Part D plan should include any other documents or information that it believes is relevant to the drug benefit in dispute.

Part D plans should note that the above sections as labeled correspond with the Exhibits box of the *Reconsideration Case File Transmittal Form*. Part D plans are required to provide only those lettered Exhibits that are pertinent to a given case file that is being submitted. If a lettered Exhibit does not apply to a particular case file, the plan should omit the Exhibit, but should not re-letter the other Exhibits to achieve chronological order.

5.3.2 Additional Guidance on Selection and Inclusion of Records

For denials that are based, in whole or part, on medical necessity, the Part D plan is required to provide a "peer defensible" rationale for the denial. Medical records that relate to the case issues must be included. If the Part D plan has made an unsuccessful attempt to obtain records, any such attempt should be documented. For example, the Part D plan may include a statement within the Case Narrative detailing the attempts made to obtain the records, and the basis for the Part D plan's decision.

Part D plans are required to submit the (oral or written) prescribing physician or other prescriber statement whenever the case involves a tiering exception or formulary exception request. If the prescribing physician's or other prescriber's statement is missing from the case file in cases involving formulary exceptions, the Part D QIC's adjudication time frame is tolled until the defect can be remedied. The Part D QIC will attempt to correct such defect by faxing a request for a statement to the prescribing physician or other prescriber. If the prescribing physician or other prescriber is contacted by telephone, his or her statements will be transcribed into the case file's record. The Part D QIC will also contact the Part D plan to ascertain whether there exists a statement that was inadvertently omitted from the case file. It is critical that the prescribing physician's or other prescriber's contact information is provided by the Part D plan when submitting a case file. If the Part D QIC is unable to obtain the prescribing physician's or other prescriber's statement, the case will be decided without such evidence.

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

- *Reconsideration Case File Transmittal Form* and *Case Narrative Form*;
- Request for a Coverage Determination and the Coverage Determination Notice;
- Request for a Redetermination and the Redetermination Notice;

- Redetermination evidence presented by the enrollee and/or the prescribing physician;
- Representation documentation for representative appeals;
- Expedited information regarding the Coverage Determination and Redetermination; and
- The relevant Evidence of Coverage or other subscriber materials.

In addition to the standard inclusions noted above, case files involving an exceptions request should include the following:

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

In addition to the standard inclusions noted above, case files involving a medical necessity issue (that is not an exceptions request) should include the following:

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

An example of a medical necessity issue that is not an exceptions request is as follows:

Enrollee requests coverage for a drug on the plan's formulary, and argues that he has met the plan's step therapy requirements for the drug. The plan disagrees and denies coverage on the basis that step therapy requirements have not been met. This is not an exceptions request since enrollee is not asking for a drug that is not on the formulary and is not asking for coverage at the preferred or lower cost-sharing tier.

In addition to the standard inclusions noted above, case files involving a cost-sharing request should include the following:

- All internal plan documents and/or plan or pharmacy screens used by the plan to calculate cost sharing amounts or TrOOP, as relevant to the dispute.
- Any documents submitted by the appellant.
- A detailed statement explaining the basis for the Part D plan's denial. The statement should also address and respond to the appealing party's arguments in favor of alternate cost-sharing amounts.

6. PART D QIC DRUG APPEAL RECONSIDERATION PROCESS

The purpose of this Chapter is to provide the Part D Plan with an overview of the procedures and approach that the Part D QIC follows in rendering the QIC level Reconsideration for the Part D QIC drug appeals. The topics addressed are:

- 6.1 The Part D QIC Case Processing Time Standards
- 6.2 Administrative Case Intake
- 6.3 Policies on Communication with Part D plans and Appellant during Case Processing
- 6.4 Adjudicator Case Review
- 6.5 Physician Review
- 6.6 Requests to Part D plans for Additional Information
- 6.7 The Part D QIC Determination Notices
- 6.8 Enrollee Requests for Case Files
- 6.9 Low Income Subsidy (LIS) Appeals

6.1 THE PART D QIC CASE PROCESSING TIME STANDARDS

The Part D QIC is responsible for completing the Reconsideration and notifying the enrollee of its decision within the same timeframes and standards that apply to Part D plans for redeterminations.

CASE CLASS	MAXIMUM TIME STANDARD
Expedited	72 hours
Standard	7 calendar days (14 days for Retrospective)

The Part D QIC's adjudicatory time frame begins when a valid and complete Reconsideration request is "received" at the Part D QIC's office. Requests for Reconsideration review may be submitted in writing sent by fax or by mail; email requests will not be accepted. The Part D QIC receives a request that is faxed when the fax is successfully transmitted to the Part D QIC's fax machine. The Part D QIC receives a request that is mailed when the mail is delivered to and received by the Part D QIC's Operations Department.

A request for Reconsideration is generally valid and complete when it contains the following information:

1. Enrollee's name;
2. Enrollee's Medicare number;
3. Identification of the item for which Reconsideration is requested, e.g., the prescription drug, including dose and quantity;
4. Name of the authorized representative, if applicable, and documentation of valid appointment; and
5. Name of the Part D plan that made the determination.

For appeals initiated by representatives that are not accompanied by documentation of valid representation, the Part D QIC's adjudicatory time frame begins when the Part D QIC receives documentation of valid representation. In these circumstances, the Part D QIC will request the case file from the Part D plan in anticipation that the defect may be remedied when the case file is received, since the same individual may have appealed at the plan redetermination level. The Part D QIC may also attempt to remedy the defect by contacting the appellant and asking for the submission of representation documentation.

For appeals involving a formulary exceptions request, the Part D QIC's adjudicatory time frame begins when the Part D QIC receives a valid and complete Reconsideration request. In these cases, the prescribing physician's or other prescriber's supporting statement must be submitted with the enrollee's request (i.e., the Reconsideration request is not valid and complete unless the supporting statement is included with the Reconsideration request). The Part D QIC will request the case file from the Part D plan, and assume that the prescribing physician or other prescriber statement will be submitted as part of the case file from the Part D plan. The Part D QIC's adjudication time frame for a request that involves a formulary exception shall be tolled in the event that the plan submits a case file without a supporting statement from the prescribing physician or other prescriber. In this circumstance, the Part D QIC will attempt to remedy the defect by soliciting the prescribing physician's or other prescriber's statement via the contact numbers (street address, telephone number, fax number and/or email address) provided by the Part D plan. In the event that the Part D QIC is unable to obtain a prescribing physician or other prescriber statement, and the Reconsideration request involves a formulary exception, the Part D QIC will wait at least 24 hours after the expiration of the applicable time frame before making a decision. The Part D QIC may wait longer if reasonable under the circumstances of the case.

For appeals involving auto-forwarded case files that have not been completed timely by the Part D plan, the Part D QIC's adjudicatory time frame begins when the Part D QIC receives the case file from the Part D plan. The case file sent by the Part D plan must contain the following information:

1. Enrollee's name;
2. Enrollee's Medicare number;
3. Identification of the item for which Reconsideration is requested, e.g., the prescription drug, including dose and quantity;
4. Name of the authorized representative, if applicable, and documentation of valid appointment;
5. Name and contact information of the prescriber; and
6. Name of the Part D plan that made the determination.

If an auto-forwarded request for reimbursement is so lacking in key information (for example, disputed drug, prescriber contact information) that it is impossible for the Part D QIC to process the case after making reasonable attempts to obtain the information, the case will be dismissed. When dismissing this type of case, the dismissal notice to the enrollee will include specific instructions on what information is needed to have the case reviewed by the Part D QIC.

The adjudicatory time frame will be tolled if the case file does not contain representation documentation for appeals initiated by a representative and/or a prescriber statement for appeals involving a formulary exceptions request (unless the appeal is retrospective). The Part D QIC will take reasonable steps to remedy any defects in the case file, including contacting the enrollee, the enrollee's representative, or the prescriber. The Part D plan's case file must contain accurate contact information for the enrollee, the representative and the prescriber.

The **first step** in case intake will be verification of the request for Reconsideration. The Part D QIC will examine the request to determine if it is valid and complete. The adjudicatory time frame will begin if the request contains the various identifiers described above. If the request is defective, the Part D QIC will take reasonable steps to remedy the defect as expeditiously as possible. For defects that the Part D QIC is not able to remedy, the Part D QIC will wait at least 24 hours after the expiration of the applicable time frame before dismissing the case (but may wait for a longer period of time if it is reasonable under the circumstances of the case).

The **second step** in case intake will be verification and validation of the appealing party. The adjudicatory time frame will begin when the Part D QIC verifies that the requesting party is the enrollee or a valid representative for the enrollee. The Part D QIC will take reasonable steps to validate the appealing party. If the Part D QIC is not able to validate the appealing party, the Part D QIC will wait at least 24 hours after the expiration of the applicable time frame before dismissing the case (but may wait for a longer period of time if it is reasonable under the circumstances of the case).

The **third step** in case intake is specific to **formulary exceptions requests**. The Part D QIC will determine whether a prescribing physician or other prescriber statement has been submitted with the request for Reconsideration review. The Part D QIC's adjudicatory time frame will begin if the appellant has submitted a prescribing physician or other prescriber statement. If a statement has not been submitted, the Part D QIC will take reasonable steps to remedy the defect as expeditiously as possible. These steps include requesting the case file from the Part D plan and attempting to solicit the statement from the prescribing physician or other prescriber. If the Part D QIC is not able to obtain a prescriber statement (and there is no credible medical evidence in the case file, e.g., medical records), the Part D QIC will wait at least 24 hours after the expiration of the applicable time frame before rendering a decision (but may wait for a longer period of time if it is reasonable under the circumstances of the case).

The Part D QIC completes Reconsideration review when it notifies the enrollee or the enrollee's representative of the Reconsideration decision. For expedited Reconsiderations, the Part D QIC will make reasonable efforts to notify the enrollee or representative orally by telephone (or by other means as indicated in the case file). If the Part D QIC first notifies the enrollee or the representative of its decision orally, the Part D QIC will fax or mail a written notice to both the enrollee and, if applicable, to the representative, within three calendar days after oral notice is made.

For standard Reconsiderations, the Part D QIC will notify the enrollee and the enrollee's representative of the Reconsideration decision via a hard copy mailing or fax. For these Reconsiderations, the Part D QIC is required to notify the enrollee and the enrollee's representative in writing within 7 calendar days after receiving a valid and complete request for Reconsideration review. The Part D QIC will use the most cost-efficient and effective means to ensure that the enrollee receives the written notice of the decision within the 7-day time frame.

6.2 ADMINISTRATIVE CASE INTAKE

The tasks involved in administrative case intake are as follows:

1. Opens the mail and sorts new case files and appeal requests;
2. Creates a case file in the MAS;
3. Sends the Part D plan a request for the case file; and
4. Assigns the case to a Part D QIC Adjudicator.

The Part D QIC will request the case file from the Part D plan as soon as possible from the moment of receipt of the request for Reconsideration. The Part D QIC will initiate this process by faxing to the Part D plan the *Reconsideration Case File Request Form*. The Part D plan is required to deliver the case file to the Part D QIC within 24 hours (of receipt of the fax) for Expedited requests and within 48 hours (of receipt of the fax) for Standard requests.

Note: Due to the short time frames for Reconsideration review, the Part D QIC expects to send requests for case files, and receive case files forwarded by Part D plans, on a daily basis, including holidays and weekends. Part D plans are expected to be able to receive and process case file requests 7 days a week in accordance with the noted time frames for submission of Expedited and Standard cases.

6.3 POLICIES ON COMMUNICATION WITH THE PART D PLAN AND APPELLANT DURING CASE PROCESSING

6.3.1 All evidence should be in writing

Federal regulations define the Part D QIC level Reconsideration as a de novo determination based upon the documented case file. The Part D QIC level Reconsideration does not provide for in-person or telephonic hearings. Any telephonic evidence will be transcribed into the record. However, Part D plans are encouraged to submit evidence in writing whenever possible.

6.3.2 Communications regarding potential Part D QIC determination are not permitted

The Part D QIC personnel are not permitted to engage in written or phone communication with parties, where the subject of such communication is any discussion or projection of outcome of the Reconsideration decision that the Part D QIC may make. Discussions are limited to review of the Part D QIC process, including instructions regarding the procedures for submitting written information to the Part D QIC.

6.4 ADJUDICATOR CASE REVIEW

An "Adjudicator" is a professional trained by the Part D QIC to: (1) manage the Part D QIC case Reconsideration and (2) issue Reconsideration decisions. The Adjudicator is not permitted to make medical necessity determinations. Physician reviewers staffed on the Part D QIC project and panel medical consultants, if utilized, make medical necessity determinations for appeals that require medical review. The Adjudicator is responsible for issuing the final decision letter.

The tasks that the Adjudicator may complete in Reconsideration review include:

1. Determine if the contested issue is subject to appeal, i.e., constitutes an adverse coverage determination. If the contested issue is not subject to appeal, the Adjudicator will dismiss the appeal and remand it to the Part D plan to be processed under its grievance procedures;
2. Determine if the appealing party is a valid party for purposes of appeal. For non-enrollee appellants, the Adjudicator will determine if there is sufficient representation documentation. If representation documentation is not sufficient, the Adjudicator will take steps to remedy the defect;
3. Determine if additional information is needed from the Part D plan to correct a case file deficiency. If so, the Adjudicator may request additional information if time permits, but also has discretion to decide the case based upon the contents of the file;

4. Determine if the case may be decided based upon coverage only (e.g., cost-sharing dispute), or if a medical necessity determination is required;
5. Complete and forward a referral to an appropriate Part D QIC medical consultant for cases requiring medical necessity review;
6. Receive and evaluate the Part D plan's response to any requests for additional information and/or the independent medical consultant's report. As necessary, the Adjudicator will seek clarification from the Part D plan or the independent medical consultant.;
7. Determine if the case should be referred to the Part D QIC's legal counsel or other designated staff for policy or coverage clarification;
8. Issue a final Reconsideration determination and
9. Enter appeal data into the MAS.

6.5 INDEPENDENT PHYSICIAN REVIEW

The Medicare rules state that a physician must make determinations of medical necessity. The Part D QIC's has staff medical consultants in addition to an affiliation with panel medical consultants, who are board-certified by the American Board of Medical Specialties.

The medical consultant's report is carefully reviewed by the Adjudicator and, if necessary, by the Part D QIC Medical Director. Special emphasis is placed on ensuring that the consultant's determination is consistent with Medicare rules and Part D plan rules, including subscriber materials, formulary coverage rules, and exceptions criteria provided by the plan as well as material posted on the HPMS. When additional information is required of the prescriber, a request for the information may be faxed to the prescriber or obtained by a phone call.

6.6 REQUESTS TO THE PART D PLAN FOR ADDITIONAL INFORMATION

"Request for Information" (RI) is the formal process by which the Part D QIC asks the Part D plan to supply written information to answer a question or remedy a deficiency in the Reconsideration case file.

6.6.1 Request for additional information is at the Part D QIC's discretion

The Part D QIC Reconsideration process is designed as an "on the record" review rather than an "in person" proceeding. Therefore, the Part D plan case file must include all materials relevant to the coverage determination and redetermination, as previously specified in this manual.

The Part D QIC is under no obligation to seek additional information from the Part D plan, and may decide a case at any time based upon the information available. The Part D QIC will rarely be able to use this process for appeals involving expedited Reconsiderations due to the abbreviated appeal time frames. However, the Part D QIC will seek additional information and/or attempt to clarify information in the case file if needed whenever possible.

6.6.2 Request for Information process

The process used by the Part D QIC to make a Request for Information is as follows:

- The Adjudicator (or medical consultant) identifies a deficiency and checks the case file to verify that the information is, in fact, absent;
- The Adjudicator requests the information by faxing a Request for Information (RI) Form to the fax number provided for the Case Contact on the *Reconsideration Case File Transmittal Form* or by calling the Case Contact;
- The Part D plan Case Contact calls the Part D QIC if there are any questions about the RI;
- The Part D plan Case Contact develops the RI response and submits the response to the Part D QIC within the timeframe specified on the RI form;

- The Adjudicator reviews the RI response and incorporates the information into the Reconsideration case file; and
- If the RI response is insufficient, the Adjudicator contacts the Plan Contact if time permits.

6.6.3 Part D Plan submission of the response to a Request for Information

The Part D plan may transmit personally identifiable health information to the Part D QIC if the plan transmits the information to one of our dedicated and secure fax machines. Alternatively, the Part D plan may send documents containing such information by overnight mail. The Part D plan should not send confidential information by email. Please note that due to the abbreviated time frames for Reconsideration review, fax transmission is the preferred method of receipt.

For faxes and overnight mailings, the Part D plan should place the *Request for Information Form* on top of the plan's RI response. For mailings, if the Part D plan places more than one RI response in a package, it should separate each response with the appropriate RI Form.

6.7 THE PART D QIC RECONSIDERATION NOTICES

6.7.1 The Part D QIC Reconsideration determination definitions

Upon completion of its Reconsideration, the Part D QIC issues a "Reconsideration determination" notice to the appealing party and the enrollee if the enrollee has a representative, with a copy to the Part D plan. The general categories of the Part D QIC Reconsideration determination notices include:

"Unfavorable"

The Part D QIC concurs with the Part D plan redetermination. The Part D QIC decides fully in favor of the Part D plan and against the appealing party requesting the Reconsideration.

"Favorable"

The Part D QIC disagrees with the Part D plan redetermination. The Part D QIC decides against the Part D plan and fully in favor of the appealing party requesting the Reconsideration.

"Partially Favorable"

The Part D QIC disagrees with a portion of the Part D plan redetermination. The Part D QIC partially decides against the Part D plan and partially decides in favor of the Part D plan.

"Dismissal: Enrollee Requests Withdrawal"

The appealing party may withdraw its request for Reconsideration at any time prior to the issuance of a Reconsideration decision. Withdrawal requests must be submitted in writing to the Part D QIC before the case will be withdrawn.

"Dismissal: No AOR or Invalid AOR, Untimely Filing, or Invalid Appeal"

As part of its evaluation of the submitted Reconsideration case file, the Part D QIC determines if the case qualifies for Reconsideration. If the Part D QIC determines that the case does not meet CMS qualifying criteria, and if a deficiency cannot be corrected, the Part D QIC will report "dismissal" as the disposition.

"Dismissal: Grievance"

If the Part D QIC has determined that one or more of the issues in dispute are grievances with the Part D Plan or other entity, as defined by CMS in the Prescription Drug Benefit Manual, then the QIC does not have jurisdiction to make a decision. In these cases, the issues are remanded back to the Plan for handling through their internal grievance process.

“Dismissal: Dismiss Request to Reopen”

The Part D QIC has determined that there was no new information provided or other good cause for the QIC to perform a new Reconsideration review.

6.7.2 General characteristics of the Part D QIC Reconsideration notices

All the Part D QIC Reconsideration determination notices that are not fully in the enrollee's favor or dismiss the enrollee's appeal contain an explanation of the enrollee's right to request further review by an Administrative Law Judge.

A Part D QIC Reconsideration determination notice that reverses a Part D plan determination contains an explanation of how the enrollee can obtain the disputed payment or drug benefit. The enrollee is directed to the Part D plan to obtain the drug benefit or claim payment.

A Part D QIC Reconsideration determination notice that partially reverses a Part D plan determination explains the enrollee's further appeal rights and advises how the enrollee can obtain the disputed payment or covered drug benefit.

Although a Part D QIC Reconsideration determination may address or discuss medical care and treatments relative to a drug benefit, the Part D QIC Reconsideration determination is not an assessment of quality of care, nor is it medical advice or instruction. A Part D QIC determination is a ruling on the Part D plan's obligation for coverage for a drug benefit.

For a fully or partially favorable determination, the Part D QIC also issues a *Notice of Requirement to Comply* to the Part D plan. This document references the determination notice and advises the Part D plan of its obligation to effectuate the Reconsideration decision.

6.8 ENROLLEE REQUESTS FOR CASE FILES

Under instruction from CMS, and subject to the provisions of the Privacy Act and Freedom of Information Act, the Part D QIC will release a copy of a Reconsideration case file to an enrollee or other authorized individual when requested in accordance with CMS rules.

The Part D QIC may only release to a Part D plan copies of documentation the Part D plan has submitted in the case file.

7. CREDITABLE COVERAGE/LATE ENROLLMENT PENALTY RECONSIDERATIONS

Under the Social Security Act, a late enrollment penalty (LEP) is imposed if there is a continuous period of 63 days or more at any time after the end of the individual's Part D initial enrollment period during which the individual was eligible to enroll in a Part D plan, but was not enrolled in a Part D plan and was not covered under any creditable prescription drug coverage

An enrollee who has received notice of the imposition of an LEP or an increase in the LEP, where the increase is due to reporting additional uncovered months (except in a case where the number of uncovered months increases as a result of a Part D QIC reconsideration decision), has the right to request that the Part D QIC reconsider the LEP. There is no expedited review process for LEPs. The enrollee or the enrollee's representative may submit a request for LEP Reconsideration by filing a signed written request with the Part D QIC within 60 calendar days from the date of the notice of the LEP. The 60-day time frame for filing may be extended if the Part D QIC finds that the appealing party has demonstrated good cause for the late filing. Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, sets forth examples of circumstances that constitute good cause. The decision of the Part D QIC whether or not to grant an extension for good cause is final and not subject to appeal.

7.1 PREPARATION AND SUBMISSION OF THE REQUESTED CASE FILE FOR LEP RECONSIDERATIONS

7.1.1. Timeframe for Case File Submission

Upon request for a case file from the Part D QIC, the Part D plan shall forward an enrollee's LEP case file containing all creditable coverage and LEP related information received by the Part D plan. This may include the Reconsideration request and any accompanying documents, and additional information the Part D plan has solicited from relevant sources regarding the enrollee's creditable prescription drug coverage. The Part D plan shall deliver (by mail or fax) a hard copy of the requested information within 14 calendar days after receiving the request for information.

In the event a Part D plan has no information to forward, the Part D plan shall deliver (by mail or fax) a brief letter to the Part D QIC within 14 calendar days after receiving the request for information. The letter should acknowledge that the requested information is unavailable and explain the reason.

7.1.2. Content and Organization of the Case File

There is one form that the Part D plan must complete and attach to each case file that it submits to the Part D QIC. The form is the *LEP Reconsideration Case File Transmittal Form*. Submission of the *LEP Case Narrative Form* is preferred, but not required. Both of these forms are available for downloading from Maximus' website.

The *LEP Case File Transmittal Form* is self-explanatory and must be completed in full by the Part D plan. Information that must be provided on the form includes the enrollee's name, enrollee's address and phone number, Medicare MBI Number, Part D plan contract number, and plan ID number. The Part D plan is also required to complete the *Plan Level LEP Information* and *Enrollee Coverage Information* sections of the *LEP Case File Transmittal Form*, which address specific LEP Determination information and current Part D plan information. If the Part D plan has rescinded an LEP, the Part D plan shall indicate on the *Case File Transmittal Form* the date the LEP was rescinded and the date the enrollee was notified of the rescission.

When sending LEP case files, the Part D plan should use the *LEP Reconsideration Case File Transmittal Form* as the cover letter to identify each case file that is submitted. The Part D QIC's fax number is located on the *LEP Case File Request Form*. The Part D QIC dedicates a fax machine for receiving documents from Part D plans for LEP reconsiderations. The Plan fax number for the LEP file submission is (720) 462-7577. The fax machine is "secure," meaning that they are only available to Reconsideration personnel working on the Part D project. It is permissible to send evidentiary documentation to our designated fax machine without redacting personally identifiable information. The Part D QIC accepts faxes 7 days a week. When faxing, please send each case file as a separate fax transmission. Faxes are received and processed electronically, and multiple case files submitted in one fax transmission will process as receipt of only one case file. Therefore multiple case files cannot be included in one fax transmission to the Part D QIC.

When sending LEP case files by mail, the Part D plan should similarly use the *LEP Reconsideration Case File Transmittal Form* as the case file cover letter. The Part D plan shall return the completed case file to the Part D QIC. The Part D QIC's address is identified on the *LEP Case File Request Form*. The Part D plan should place the associated documents and records in an envelope or container for proper mailing.

For LEP reconsiderations, mail should be addressed to the Part D QIC:

**Maximus Federal
Part D QIC, LEP
3750 Monroe Ave. Suite 704
Pittsford, NY 14534-1302**

For multiple LEP submissions, the Part D plan should adhere to the following recommendations:

- Complete and place the *LEP Reconsideration Case File Transmittal Form* on top of the case file package;
- Place each case in the package in a separate envelope;
- Do not staple or permanently bind case file material. Use of clips or binders that can be removed without special equipment is permissible; and
- Do not include any material in a "new" case file package submitted to the Part D QIC that is not related to specific new case.

The organization of the case file may include the following documents:

A. LEP Case Narrative Form

- The LEP Case Narrative is where the Part D plan provides an overview of the issues under reconsideration, identifies arguments in favor of the Part D plan's creditable coverage determination, and explains the Part D plan's reasons for making the determination. The Part D plan may include a chronology or timeline in this section addressing pertinent dates, facts, and/or findings concerning the creditable coverage determination leading to the LEP.

B. Beneficiary Declaration of Prior Prescription Coverage (Attestation Form)

- The Declaration or Prior Prescription Drug Coverage (Attestation Form) asks the beneficiary to attest whether s/he had creditable prescription drug coverage and to identify the source(s) and date(s) of his/her previous coverage. If the Part D plan was able to obtain a written or telephonic Declaration of Prior Prescription Drug Coverage (Attestation Form) from the appealing party, the Part D plan shall include a copy of the Declaration of Prior Prescription Drug Coverage (Attestation Form) as a part of the case file.

C. Beneficiary Notice of Late Enrollment Penalty

- The Beneficiary Notice of Late Enrollment Penalty advises the enrollee of the LEP amount, the date on which the member's adjusted premium will start and the number of uncovered months upon which the LEP is based. In cases where an LEP increase is due to reporting additional uncovered months (except in a case where the number of uncovered months increases as a result of a Part D QIC reconsideration decision), the Beneficiary Notice of Late Enrollment Penalty further advises the enrollee of the right to ask for Reconsideration of the LEP. The Part D plan shall include a copy of the Beneficiary Notice of Late Enrollment Penalty as a part of the case file.

D. Other Important Documents

- The Part D plan should include any other documents or information that it believes is relevant to the enrollee's case file.
- If applicable, the Part D plan shall include as part of the case file any representation documents that may have been acquired by the Part D plan during its attempts to ascertain prior creditable prescription drug coverage.
- Documents or instruments showing valid representation may include the following:
 1. AOR Document (CMS-1696 form or other similar writing).
 2. Instrument executed by an enrollee that confers representative authority appointment, or other estate documentation naming an executor to handle a deceased enrollee's estate.
 3. Representative authority conferred by state law that authorizes a designated individual to act on behalf of an incapacitated or incompetent enrollee, i.e., surrogacy statute.
 4. Representative appointment made for an incapacitated or incompetent enrollee pursuant to a court of law, i.e., guardianship appointment.
 5. Representative appointment made by a court of law on behalf of a deceased enrollee that has not named an executor to handle his or her estate.

E. Part D Plan Enrollment Application

- The Part D plan shall include a copy of the enrollee's Part D plan enrollment application. The Part D plan enrollment application should indicate the enrollee's name, the particular Part D plan elected, the date with which the application was signed, and whether the

enrollee elected direct bill or withdrawal of premiums from his or her Social Security payments.

F. Notice Informing Beneficiary of Part D Enrollment Effective Date

- The Part D plan shall include a copy of this notice, which indicates the effective date of the enrollee's Part D coverage with the Part D plan.

G. BEQ/MARx Screens

- The Part D plan shall provide copies of BEQ/MARx screens verifying the enrollee's Part D Entitlement and Part D Plan Enrollment and Creditable Prescription Drug Coverage history.

H. Notice of LEP Amount Reported to Part D Plan by CMS

- The Part D plan shall include in the case file any documentation or notice received by the Part D plan from CMS advising of the imposition of or increase in an LEP (i.e., number of uncovered months reported, and/or amount of LEP assessed).

I. Evidence of Special Circumstances

- This may include proof an enrollee lived abroad and did not reside in a Part D service area during his/her Part D initial enrollment period.

It would also be helpful to the Part D QIC's adjudication of the LEP for the Part D plan to include the following documents in an LEP Case File:

Notice of Creditable or Non-Creditable Prescription Drug Coverage

- If an enrollee provides the Part D plan with a Notice of Creditable or Non-Creditable Prescription Drug Coverage, the Part D plan shall include a copy of the Notice in the case file. Additionally, if the enrollee provides any additional prior prescription drug coverage information to the Part D plan, this information and/or documentation shall be provided to the Part D QIC for investigation.

Enrollment with Commercial, Group Health Plan, or Medigap/Medicare Supplement plan

- If an enrollee was previously enrolled with a commercial, group health plan, or Medigap/Medicare Supplement Plan provided by the same company as the Part D plan (i.e., parent company, subsidiary, etc.), the Part D plan shall include in the case file any necessary prior prescription drug coverage information. This would include dates of prior prescription drug coverage; whether the prior prescription drug coverage provided was considered creditable prescription drug coverage, and if possible a copy of the Notice of Creditable or Non-Creditable Prescription Drug Coverage.

7.2 LEP RECONSIDERATION PROCESS

The purpose of this section is to provide the Part D plan with an overview of the procedures and approach that the Part D QIC follows in rendering the QIC level Reconsideration for Part D QIC LEP reconsiderations. The enrollee will send his or her signed completed LEP Reconsideration Request Form to Maximus Federal, the current Part D QIC, in accordance with the instructions provided on the form. Enrollees also may send a letter to request a Reconsideration of an LEP, provided the letter contains the elements on the LEP Reconsideration Request Form.

The Part D QIC shall request a copy of the enrollee's case file from the Part D plan, and draft a Reconsideration decision based on the case file, the information supplied by the enrollee, and any other information that the Part D QIC obtains from its own investigation. The Part D QIC will inform the enrollee and the Part D plan of the final decision, generally within 90 calendar days of receipt of the

enrollee's Reconsideration request, subject to a possible 14 calendar day extension of this timeframe, as described under Section 2.29 of this manual. The Reconsideration decision is not subject to further appeal (i.e., is not subject to further review by an Administrative Law Judge (ALJ), Medicare Appeals Council (Council), or in a U.S. District Court).

7.2.1 Elements of an LEP Reconsideration Request

The Part D plan shall inform the enrollee that his or her LEP Reconsideration Request must include the following elements:

- A completed, signed, LEP Reconsideration Request Form or a signed, written request for Reconsideration containing the elements on the LEP Reconsideration Request Form. If an enrollee submits a Reconsideration request that is not signed, the Part D QIC will attempt to cure this deficiency by contacting the enrollee, by phone, to obtain verbal confirmation of the enrollee's intent to proceed with the reconsideration. If the Part D QIC is unable to obtain verbal confirmation, the Part D QIC will mail the enrollee a request for a signed Reconsideration Request Form or equivalent signed, written document in order to proceed with the LEP Reconsideration process. The Part D QIC will allow for a reasonable timeframe not exceeding 14 calendar days for the enrollee to return a valid Reconsideration request. If the Part D QIC is unable to cure this deficiency within a reasonable timeframe, the Part D QIC will issue a "Dismissal" notice to the enrollee and appropriate Part D plan(s) advising of the dismissal for no signed Reconsideration request. The enrollee may request a new Reconsideration if s/he provides a signed, complete LEP Reconsideration Request Form or equivalent documentation.
- If the enrollee has named a representative, representation documents as described above must be submitted to prove that the individual has the authority to represent the enrollee.

In addition, the Part D plan shall inform the enrollee that his or her LEP Reconsideration Request should include any additional information that may help the enrollee's case.

7.2.2 Reasons for Requesting LEP Reconsideration

As listed on the LEP Reconsideration Request Form, an enrollee may request review of the LEP for one of the following specific reasons:

1. The individual had prior creditable prescription drug coverage that the enrollee believes may have not been considered;
2. The individual had prior prescription drug coverage but did not get a notice that clearly explained if the drug coverage was creditable. In this case, the enrollee should submit any evidence, such as a copy of an organization's notice regarding prescription drug coverage, or other material, such as, a Summary of Benefits that the enrollee found unclear or misleading;
3. The individual believes the LEP is wrong because he or she was not eligible to enroll in a Medicare drug plan during the period stated by the plan;
4. The individual believes the LEP is wrong because he or she was unable to enroll in a Medicare drug plan due to a serious medical emergency during the time period the individual was eligible to enroll in a drug plan;
5. The individual has/had extra help from Medicare to pay for prescription drug coverage; that is, the low-income subsidy for Medicare prescription drug coverage; and
6. The individual lived in an area affected by Hurricane Katrina at the time of the Hurricane (August 2005), and he or she joined a Part D plan before December 31, 2006. NOTE: Certain Medicare beneficiaries who were affected by Hurricane Katrina were allowed to enroll in a Medicare prescription drug plan with no penalty before December 31, 2006 if, at the time of the hurricane

(August 2005), they resided in any of the parishes or counties declared as meeting the level of “individual assistance” by the Federal Emergency Management Agency (FEMA).

Refer to the Medicare Prescription Drug Benefit Manual Chapter 4. Creditable Coverage Period Determinations and the Late Enrollment Penalty for additional guidance on the opportunity for certain individuals to enroll in Medicare Part D without an LEP.

If additional information or evidence can help explain why an enrollee’s LEP is incorrect, he or she should submit such proof with the LEP Reconsideration Request Form. Enrollees are asked to send to the Part D QIC any proof that helps support the request. Part D plans shall instruct enrollees to send this material to the Part D QIC to the address or fax number shown on the LEP Reconsideration Request Form, to include the enrollee’s “Medicare number” (as shown on the red, white and blue Medicare card) on any separate materials, and only to send photocopies of any original documents.

7.2.3 LEP Reconsideration Process Timeline

The Part D QIC will notify the enrollee of the final LEP reconsideration decision generally within 90 calendar days of receiving an enrollee’s request for Reconsideration, subject to a possible 14 calendar day extension as described 2.29 of this manual. In cases where an individual other than the enrollee requests a Reconsideration, the Part D QIC will not begin the Reconsideration review until it receives documentation verifying that the individual is the enrollee’s representative or is authorized under state law to act on behalf of an enrollee. The Part D QIC will attempt to obtain representative documentation by requesting information from the individual who filed the Reconsideration request. If the Part D QIC cannot obtain verification of an individual’s status as the representative within a reasonable time period, the Part D QIC will dismiss the Reconsideration request.

7.2.4 Requests for Information

The Part D QIC may find it necessary to obtain additional information from the appropriate Part D plan or from other entities that it determines appropriate when adjudicating an enrollee’s Reconsideration request. The Part D QIC may request additional information via telephone or in writing by fax or mail.

7.3 LEP RECONSIDERATION DECISIONS

Adjudication of a Late Enrollment Penalty (LEP) reconsideration requires the Part D QIC to determine if an enrollee had a qualifying break in creditable prescription drug coverage prior to enrolling with the Part D plan. The Part D QIC will make this determination based on information contained in the enrollee’s LEP Reconsideration Request, the Part D plan’s LEP case file, and an independent investigation of the enrollee’s prior prescription drug coverage conducted by the Part D QIC.

Note: Multiple Part D plans: If the Part D QIC learns during its Reconsideration review that the enrollee has enrolled with a new Part D plan, the Part D QIC will also provide the new Part D plan with a copy of its Reconsideration decision letter.

7.3.1 Favorable Decision

If the Part D QIC determines that an LEP should not be imposed, the Part D QIC will issue a “Favorable” decision reversing the Part D plan’s imposition of the LEP to the appealing party and the appropriate Part D plan(s). The “Favorable” decision letter advises the Part D plan of its obligation to effectuate the Reconsideration decision.

7.3.2 Partially Favorable Decision

If the Part D QIC determines that a LEP should be partially reversed, the Part D QIC will issue a “Partially Favorable” decision reversing the Part D plan’s creditable coverage determination based on the Part D QIC’s review of the Reconsideration request. The Part D QIC will uphold the Part D plan’s decision for any remaining uncovered months based on the Part D QIC’s review of the Reconsideration

request. In this circumstance, the enrollee may owe an LEP, but if so, it will be less than the LEP assessed by the Part D plan.

In some circumstances, the Part D QIC will determine that the Part D plan miscalculated the number of uncovered months by including months that were part of the enrollee's Initial Enrollment Period. In these instances, the Part D QIC will also issue a "Partially Favorable" decision.

Note: Favorable and Partially Favorable Reconsideration Decision Letters

- If the Part D QIC issues a final decision letter that reverses or partially reverses the Part D plan's creditable coverage determination, the final decision letter shall contain an explanation of how the enrollee can obtain reimbursement of the disputed LEP, if applicable. The enrollee is further directed to contact 1-800-MEDICARE (1-800-633-4227) should there be any additional questions and/or concerns.

7.3.3 Unfavorable Decision

If the Part D QIC agrees with the Part D plan's creditable coverage determination, the Part D QIC will uphold the LEP. The Part D QIC will issue an "Unfavorable" Reconsideration decision letter to the appealing party and the appropriate Part D plan(s).

In some circumstances, the Part D QIC will determine that the Part D plan miscalculated the number of uncovered months by not including additional uncovered months that an enrollee did not have creditable prescription drug coverage prior to enrolling with the Part D plan. In these instances, the Part D QIC will include any additional uncovered months found during its Reconsideration review to the total number of uncovered months assessed by the Part D plan.

7.3.4 Dismissal of an LEP Reconsideration Request

Occasionally the Part D QIC will determine that a request for LEP Reconsideration should be dismissed. Instances in which the Part D QIC may determine that a Reconsideration request be dismissed include, but are not limited to, the following:

- An enrollee failed to request a timely LEP Reconsideration and did not have good cause for missing the filing deadline;
- An enrollee dies while the Reconsideration is pending and the enrollee's surviving spouse or estate has no remaining financial interest in the Reconsideration;
- An individual requesting the Reconsideration is not the enrollee, and the authority of the individual seeking a Reconsideration cannot be verified within a reasonable time period, not to exceed 30 calendar days after the date of the Reconsideration request;
- An enrollee requests a Reconsideration of an issue that is ineligible for LEP Reconsideration. For example, the Part D QIC will not make actuarial determinations concerning whether an enrollee's prescription drug coverage was creditable; i.e., an enrollee may not use the LEP Reconsideration process to seek review of the decision that his or her coverage under an employer-sponsored prescription drug plan was not creditable coverage;
- Upon a determination that an LEP was not imposed by the Part D plan. The Part D QIC will issue a "Dismissal" notice to the appealing party and the appropriate Part D plan(s) advising of the dismissal for no pending LEP;

Upon a determination that an LEP was rescinded by the Part D plan, the Part D QIC will issue a "Dismissal" notice to the appealing party and Part D plan(s) advising of the dismissal for the rescinded LEP;

- If the Reconsideration request is not signed, and neither verbal authorization confirming intent to appeal nor a signed Reconsideration request can be obtained; and
- If appropriate representation documentation from the party requesting Reconsideration on behalf of an enrollee was not provided by the requesting party and could not be obtained by the Part D QIC.

7.3.5 Vacating a Dismissal

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

7.3.6 Withdrawal of an LEP Reconsideration Request

An enrollee may withdraw his or her LEP Reconsideration request, in writing, at any time before the Part D QIC renders its final decision. For purposes of a withdrawal, “enrollee” also includes a former enrollee or his or her appointed representative.

7.4 LEP EXCLUSIONS

The Part D QIC will consider the following circumstances when determining if the enrollee should be subject to a LEP:

7.4.1 Low Income Subsidy Eligible Enrollees

If the enrollee received the Low Income Subsidy (LIS) at any time since January 1, 2006, the enrollee is not subject to an LEP for any uncovered months during which the enrollee received the subsidy. The Part D QIC will issue a “Favorable” decision to the enrollee and the Part D plan.

If an enrollee was paying an LEP before qualifying for an LIS, the enrollee is not exempt from that payment. If an enrollee who is currently paying an LEP becomes LIS eligible, he/she is still responsible for any unpaid LEP amount owed prior to the LIS eligibility effective date. The Part D QIC will issue a “Partially Favorable” decision requiring the enrollee to pay any LEP amount that he or she may have owed up until the LIS eligibility date. The enrollee is not responsible for any LEP amount assessed after he or she became LIS eligible. In addition, any amount paid by the enrollee following his or her LIS eligibility date must be reimbursed by the Part D plan. The Part D plan must report a revised creditable coverage period determination indicating zero (0) uncovered months to CMS effective with the LIS eligibility date.

7.4.2 Individuals affected by Hurricane Katrina

Medicare enrollees affected by Hurricanes Katrina were allowed to enroll in a Part D plan without penalty if at the time of Hurricane Katrina they resided in any of the parishes or counties declared as meeting the level of “individual assistance” by the Federal Emergency Management Agency (FEMA). However, to qualify for this exemption, beneficiaries must have enrolled in a Part D plan with an effective date no later than January 1, 2007. If the effective enrollment date is later than January 1, 2007, any uncovered months in 2006 are included in the uncovered months’ calculation, and this exemption does not apply.

7.4.3 PACE (Program of All Inclusive Care for the Elderly) Enrollees

A PACE enrollee who is a dual-eligible member (has Medicare and qualifies for Medicare Savings Program or Medicaid) is not subject to the LEP, as long as he or she remain enrolled in Part D. The Part D QIC will issue a “Favorable” decision for this enrollee if at the time of the uncovered months, he or she was a dual eligible member.

7.4.4 Serious Medical Emergency

If the enrollee indicates on the LEP Reconsideration Request Form, that s/he incurred a lapse in creditable prescription drug coverage of 63 calendar days or more due to a serious medical emergency (i.e., unexpected hospitalization), the enrollee must submit proof of the medical emergency to the Part D QIC. The documentation submitted must support that the medical emergency affected the enrollee's ability to timely enroll with a Part D plan.

7.4.5 Subsequent Initial Enrollment Periods

If an individual is eligible for Medicare prior to turning age 65 (for example, based on disability), the individual will be assigned a new Medicare Initial Enrollment Period upon turning age 65. Therefore, if an enrollee is issued an "Unfavorable" Reconsideration decision by the Part D QIC, the enrollee will continue to pay this LEP while enrolled in a Part D plan. However, this LEP ends on the day before the new Medicare Initial Enrollment Period begins. The day before the enrollee's new IEP begins, the Part D plan must report a revised creditable coverage period determination indicating zero (0) uncovered months to CMS, in accordance with Medicare guidelines.

If the enrollee enrolled in a Medicare Part D plan prior to turning age 65, but has subsequently turned age 65 prior to the Part D QIC rendering a reconsideration determination, and the Part D QIC cannot verify that the enrollee had prior creditable prescription drug coverage, the Part D QIC will issue a "Partially Favorable" decision. The Part D plan is required to bill the enrollee for an LEP based on the uncovered months beginning with the effective date of his or her enrollment in a Medicare Part D plan. However, the LEP should end on the day before the enrollee's new Medicare Initial Enrollment Period begins. At that time, the Part D plan must report a revised creditable coverage determination indicating zero (0) uncovered months to CMS in accordance with Medicare guidance. The Part D plan is responsible for reimbursing the enrollee for any amounts the enrollee may have paid after the enrollee's new Medicare Initial Enrollment Period began.

7.5 CMS REVIEW

The Part D QIC at its discretion may recommend a Reconsideration decision for CMS review. The recommended decision letter is sent to a designee appointed by the Secretary of Health and Human Services. The Secretary's designee may adopt, modify, or reject the recommended decision letter. The Part D QIC must accept the decision of the Secretary's designee and generate a final Reconsideration decision letter. The Part D QIC will notify the enrollee and the appropriate Part D plan(s) of the final LEP Reconsideration decision.

8. POST RECONSIDERATION DETERMINATION PROCESSING FOR DRUG APPEALS

A number of processes may be invoked after the Part D QIC issues its Reconsideration determination notice for a drug appeal. This Chapter provides useful information on these various post determination processes. The topics addressed are:

- 8.1 The Part D QIC Monitoring of Part D Plan Compliance with Determinations that have been Reversed on Appeal
- 8.2 The Part D QIC Reopening Process
- 8.3 Administrative Law Judge (ALJ) Process
- 8.4 Medicare Appeals Council (the Council) Process

8.1 THE PART D QIC MONITORING OF PART D PLAN COMPLIANCE WITH DETERMINATIONS THAT HAVE BEEN REVERSED ON APPEAL (FAVORABLE AND PARTIALLY FAVORABLE DETERMINATIONS)

Compliance ("effectuation") is defined as the Part D plan's payment of a claim, or authorization and arrangement for a drug benefit, as instructed in the Part D QIC Reconsideration determination notice. For a complete discussion regarding effectuating redeterminations or decisions, the Part D plan should refer to Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

8.1.1 Part D Plan effectuation timeframes

The following table summarizes CMS requirements for timeliness of Part D plan effectuation for plan determinations that are reversed in whole or in part by other appeal entities:

APPEAL TYPE	TIME REQUIREMENT	REFERENCE
Standard Requests for Benefits	Authorize or provide within 72 hours from the date of receipt of the notice reversing the plan determination.	42 C.F.R. §423.636(b)(1)
Expedited Requests for Benefits	Authorize or provide the benefit in dispute as expeditiously as enrollee's health condition requires, but no later than 24 hours from the date it receives notice reversing the determination.	42 C.F.R. §423.638(b)
Retrospective Request for Payment	Authorize within 72 hours, but make payment no later than 30 calendar days from the date of receipt of the notice reversing the plan determination.	42 C.F.R. §423.636(b)(2)

If a Part D plan has questions regarding a Part D QIC determination, the plan should contact the Part D QIC Plan Liaison. Please note the Part D QIC is not authorized to waive compliance time frames with any final determination.

A Part D plan request for a reopening (see Section 8.2 of this manual), whether granted by the Part D QIC or not, does not stay the date of the Part D plan's compliance obligation.

8.1.2 The Part D QIC Reconsideration Compliance Monitoring

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

1. The Part D QIC provides the Part D plan with a copy of the fully or partially favorable decision and other information necessary to effectuate the decision. Included with the copy of the decision is a *Notice of Requirement to Comply*. This notice details the Part D plan's responsibilities, including the time frame by which a compliance notice must be received by the Part D QIC.
2. The Part D plan is required to submit to the Part D QIC a statement attesting to compliance (effectuation) with the decision by the Part D QIC, ALJ, Council or Federal court. The documentation must state when and how compliance occurred (e.g., benefit authorization, payment made, etc.) as follows:

- a. Notification to the Part D QIC that the Part D plan intends to pay for or provide the benefit will not be considered appropriate compliance with the effectuation requirements. The Part D plan must provide the Part D QIC with affirmative notice of effectuation.
 - b. The Part D plan should not submit unidentified internal computer screen prints as the statement of compliance.
 - c. The Part D plan is encouraged to use CMS's Model Notice of Effectuation in Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. However, the Part D plan may submit its own statement of compliance form, provided it contains all of the information set forth in the model notice and the notice is approved through the appropriate CMS marketing procedures.
3. If the Part D QIC does not receive the compliance notice within 30 calendar days of the reminder notice, the Part D QIC will report the plan's failure to comply with CMS. The Part D plan is not copied on this report to CMS.

In the event a Part D plan terminates its contract with CMS, appeals that are pending with the Part D plan, the Part D QIC, or any higher appeal level after such termination, must be effectuated if the adverse determination is reversed in whole or in part. Part D plans are required by Medicare rules to provide basic prescription coverage (and supplemental coverage as applicable) for the duration of their contracts. Part D plans are obligated to process and effectuate benefits and/or payment for benefits for which coverage has been denied by the Part D plan and found upon appeal to be services the enrollee was entitled to have furnished or paid for by the Part D plan while enrolled in the plan. Therefore, if appeals are pending at the time a Part D plan terminates its contract with CMS, the Part D plan must effectuate any favorable determinations that are issued following the date of termination.

The Part D plan's notice of compliance or effectuation must be mailed separately from other Part D plan documents and/or correspondence, and must be sent to:

**Maximus Federal
Medicare Part D QIC
3750 Monroe Ave. Suite 703
Pittsford, NY 14534-1302
(720) 462-7576 (Fax)**

8.2 THE PART D QIC REOPENING PROCESS FOR DRUG AND LEP APPEALS

For a complete discussion on the reopening process, the Part D plan should refer to Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. The reopening process is governed by the regulations set forth in 42 C.F.R. §423 subpart U.

8.2.1 Overview

A reopening is a remedial action taken to change a final determination or decision even though the determination or decision may be correct based on the evidence of record. A reopening action may be undertaken by each entity involved in the appeals process: a Part D plan may reopen to revise a coverage determination or redetermination; the Part D QIC may reopen to revise a Reconsideration, an ALJ may reopen to revise a hearing decision, and the Medicare Appeals Council may reopen to revise an ALJ hearing or review decision.

The Part D QIC may reopen a Reconsideration decision on its own motion or at the request of a Part D plan or enrollee within 180 calendar days from the date of the Reconsideration decision for good cause. 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 the evidence may result in a different conclusion (see Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance); 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 Reconsideration decision (see Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance).

The Part D QIC may also reopen its Reconsideration decision at any time if it discovers evidence that the decision was procured by fraud or similar fault.

A reopening is not an appeal right. The Part D QIC may accept or reject a request for a reopening at its sole discretion. The decision by the Part D QIC on whether to reopen is final and not subject to appeal.

The request for a reopening:

1. May be made verbally or in writing;
2. Should be clearly stated;
3. Should include the specific reasons for requesting the reopening (a statement of dissatisfaction is not grounds for a reopening); and
4. Must be made within the CMS time frames permitted for reopening.

When the Part D QIC receives a request for reopening from an enrollee (or the enrollee's representative), the Part D QIC will evaluate the request to determine if good cause exists. If good cause for reopening is not found, the Part D QIC will dismiss the request for reopening and notify the enrollee in writing of its decision not to reopen. If the Part D QIC does find good cause for reopening, the Part D QIC will process the request as described below and in accordance with CMS rules.

The Part D QIC may initiate reopening review on its own motion pursuant to information it receives from a variety of sources, including CMS, Part D plans, enrollees, and Part D QIC internal quality assessment reviews of Reconsideration decisions.

When a Part D plan believes that a Reconsideration decision is erroneous and/or should be modified due to new and material information not previously available or known, the Part D plan may submit a written or verbal statement to the Part D QIC that sets forth this information. If a Part D plan alleges error as a basis for reopening, the plan should clearly describe its rationale for concluding that the Reconsideration decision is erroneous on the face of the evidence. If a Part D plan alleges new and material information as a basis for reopening, the plan should clearly identify the new information it has received, explain why the information was not previously available, and explain how the new information may modify the Reconsideration decision. The Part D QIC will evaluate the written or verbal statement submitted by the Part D plan, and determine if there is good cause for reopening review. If the Part D QIC does not find good cause for reopening, the Part D QIC will notify the Part D plan about its decision not to reopen. If the Part D QIC does find good cause for reopening, the Part D QIC will reopen on its own motion and process the request as described below and in accordance with CMS rules.

Part D plans should note the Part D QIC is not permitted to reopen and modify a Reconsideration decision in circumstances where an enrollee (or an enrollee's representative) has filed a valid request for an appeal of the Reconsideration decision. The Part D QIC has no jurisdiction once an appeal request is filed with an ALJ, and must wait until all appeal rights are exhausted, or a subsequent request to withdraw at the higher appeal level has been granted.

The same reopening limitation applies to Part D plans. A Part D plan may not reopen and modify its decision if additional information is received after an enrollee files a request for a Part D QIC Reconsideration, unless a subsequent request to withdraw has been granted. Additionally, the Part D plan may not reopen and modify its decision if the plan's adjudication time frame at the coverage

determination or redetermination levels has expired and the Part D plan is required to auto-forward the case file to the Part D QIC, unless a subsequent request to withdraw has been granted.

Part D plans should note that the submission of a request for reopening review with the Part D QIC, ALJ, or Council does not relieve the Part D plan of its obligation to make payment for, authorize, or provide benefits pursuant to an appeal determination reversing a plan's non-coverage decision.

8.2.2 Process for conducting reopening review

The process by which the Part D QIC administers and adjudicates a reopening request is similar to the Reconsideration process:

1. The Part D QIC receives and logs the reopening request.
2. The Reopening Adjudicator reviews the reopening request and determines whether to grant reopening review. Notification is sent to the requestor and the Part D plan that a request for reopening has been received and notification indicating the outcome of the review will be forthcoming. If a reopening review is not granted, the Reopening Adjudicator notifies the requestor and the Part D plan of its decision not to reopen. Notification of the Part D QIC's decision whether or not to grant reopening shall be sent within 30 calendar days of the receipt of the reopening request.
3. If a reopening review is granted, the reopening review is conducted in accordance with the process and procedures described in Section 6 of this manual for Reconsideration review. Reopening Reconsiderations for both drug and LEP appeals must be completed, and notice provided, as expeditiously as the enrollee's health requires, but no later than 120 calendar days from the date the Part D QIC receives the request to reopen.
4. The reopening review is completed by issuing a Reopening Reconsideration decision in accordance with the notices described in Section 6.7 of this manual.
5. For both drug and LEP appeals, a Reopening Reconsideration may be dismissed due to no new and material evidence, and if no evidence of an error on the face of the Part D QIC's review is found. For Drug appeals, if outcome determinative new evidence is submitted by a requesting party and the appeal also requires a clinical review, it will then undergo a new and independent review by the Part D QIC's Medical Director. For LEP appeals, if outcome determinative new evidence is submitted by a requesting party the appeal will be reviewed by a Reopening Adjudicator.
6. If the Reopening Reconsideration reverses an unfavorable Reconsideration (that is, the Reopening Reconsideration finds in favor of the enrollee in whole or in part), a *Notice of Requirement to Comply* is also issued to the Part D plan. The Part D plan is then responsible for "effectuation" pursuant to Section 8.1 of this manual.

Part D plans should note that a request for a reopening does not relieve the Part D plan of the burden of compliance, and reporting of compliance, within the required time frames. The Part D plan is relieved of this burden only in the event that the Part D plan obtains a Reopening Reversal (of a Favorable or Partially Favorable Reconsideration) prior to the Part D plan compliance date.

8.3 ADMINISTRATIVE LAW JUDGE (ALJ) PROCESS

An enrollee or his/her appointed representative who is dissatisfied with the Part D QIC's Reconsideration decision and meets amount in controversy (AIC) requirements, may file a written request for an ALJ hearing or an Attorney Adjudicator on-the-record review within 60 calendar days of receipt of the notice of the Part D QIC's Reconsideration determination. An enrollee or his/her appointed representative also has the right to have the Part D QIC's dismissal of a Reconsideration request reviewed by the ALJ or Attorney Adjudicator if the enrollee meets amount in controversy (AIC) requirements, and files a written

request for an ALJ hearing or Attorney Adjudicator on-the-record review within 60 days of receipt of the notice of the Part D QIC's Reconsideration dismissal notice. The Part D QIC's Reconsideration decision and dismissal notice identifies the appropriate OMHA for filing. The appropriate OMHA with jurisdiction is determined by the appellant's address of record.

8.3.1 Notice of rights to hearing and submission of request for ALJ hearing

The right to request an ALJ hearing or Attorney Adjudicator on-the-record review and the process for filing is explained in the Part D QIC's Reconsideration notice. If an appellant is requesting that the hearing be expedited, the appellant may make the request for an ALJ hearing or Attorney Adjudicator on-the-record review orally, but only after receipt of the written Part D QIC's Reconsideration notice. The ALJ hearing office must document all oral requests in writing and maintain the documentation in the case file. A prescribing physician or other prescriber may provide oral or written support for an appellant's request for expedited review. The Part D QIC does not determine an appellant's right to a hearing, nor does it schedule, conduct or administer hearings.

If an appellant mistakenly sends a request for an ALJ hearing or Attorney Adjudicator on-the-record review to the Part D QIC, the Part D QIC will forward the request to the appropriate OMHA office with jurisdiction for the appeal and send notice to the appellant advising of such action. If an appellant mistakenly sends a request for an ALJ hearing or Attorney Adjudicator on-the-record to the Part D plan, the plan similarly should forward the request to the appropriate OMHA office for processing and send notice to the appellant advising of such action.

Once a hearing request is appropriately filed, the ALJ or Attorney Adjudicator to whom the appeal is assigned contacts the Part D QIC to request the enrollee's case file. The Part D QIC maintains an electronic copy of all case files. The Part D QIC will print a paper copy of the case file and forward to the ALJ or Attorney Adjudicator within 5 calendar days of receipt of the request for a standard ALJ review or Attorney Adjudicator on-the-record review. If an ALJ or Attorney Adjudicator has granted expedited review, the Part D QIC has 24 hours to forward the case file to the Cleveland, OH OMHA office.

8.3.2 Tracking and conduct of ALJ hearing

The Part D QIC does not schedule ALJ hearings and does not have direct access to ALJ scheduling information. The ALJ is responsible for contacting the appellant to schedule the matter before the ALJ. Therefore, appellants with questions or concerns regarding the process should be directed to the ALJ with jurisdiction of the appeal.

Generally, the Part D QIC does not communicate directly with Part D plans or the appellant during the ALJ process. However, the Part D QIC may contact a plan to request submission of a complete Evidence of Coverage and/or Formulary if these documents are missing from the case file.

8.3.3 Notices of Hearing (NOH)

The Part D QIC may review NOHs, and as it deems appropriate may request to participate in a given hearing. Typically, the Part D QIC will choose to participate as a non-party, which means that it will provide oral argument in support of its reconsideration decision at the hearing and respond to questions from the ALJ, but will not question the enrollee or other appellant, or any other participants at the hearing. When the Part D QIC participates in a hearing, it also may choose to submit written position papers regarding the issue on appeal.

8.3.4 ALJ determinations

Within 2 business days of receipt of the ALJ or Attorney Adjudicator decision, the Part D QIC's legal counsel (or other designated staff) will review those ALJ or Attorney Adjudicator decisions that overturn, in whole or in part, the Part D QIC's reconsideration decision. The Part D QIC will review the ALJ's or Attorney Adjudicator's decision for perceived errors in the application of Medicare statutes, regulations, and coverage guidelines, or as otherwise instructed by CMS. The Part D QIC, in conjunction with CMS, will determine if there are grounds for Council own motion referral, and as directed by CMS may prepare a referral memorandum requesting Council Own Motion Review. Once it is decided that an ALJ or Attorney Adjudicator decision will be referred to the Council, the Part D QIC will send a notification of the pending referral to both the enrollee (and appointed representative if applicable) and to the Part D plan. The Part D QIC will also send a "Notice to Comply with Administrative Law Judge (ALJ) Decision Pending Outcome of Referral to the Medicare Appeals Council" to the plan, along with a copy of the ALJ's or Attorney Adjudicator's decision, advising that the plan is required to effectuate the ALJ's or Attorney Adjudicator's favorable or partially favorable decision pending the Part D QIC's referral of the decision to the Council for own motion review. The plan receives direct notification of the Council's decision on the referral, and will adjust effectuation in accordance with the Council's decision. In the event that the Part D QIC determines there are no grounds for Council own motion referral, the Part D QIC will provide the Part D plan with the necessary effectuation information, which includes a copy of the ALJ's or Attorney Adjudicator's decision.

8.4 MEDICARE APPEALS COUNCIL (COUNCIL) PROCESS

8.4.1 Enrollee Requests for Council Review

As permitted by 42 C.F.R. §423.2100, an enrollee or his/her representative who is dissatisfied with an ALJ hearing or Attorney Adjudicator on-the-record decision and meets the amount in controversy (AIC) requirements, may request that the Council review the ALJ's or Attorney Adjudicator's decision or dismissal.

When the Part D QIC receives a request for a case file from the Council, the Part D QIC makes and retains a copy of the case file, and forwards the original case file to the Council within 5 calendar days of receipt of the request. The Part D QIC supplies the case file in the exact order and manner in which it was received from the OMHA. For expedited Council case file requests, the Part D QIC will provide the case file within 24 hours of the case file request.

Upon completion of Council review and receipt of a favorable decision, the Part D QIC provides the plan with an effectuation notice and a copy of the Council decision within 2 business days of receipt of the Council decision. The Part D QIC also serves as a repository for all completed Council cases and associated case files.

8.4.2 Referral to the Council for Own Motion Review

The Council may decide on its own motion to review a decision or dismissal by an ALJ or Attorney Adjudicator.

In addition, CMS or its contractors may refer a case to the Council for consideration under the Council's own motion authority if the referral is made anytime within 60 calendar days after the date of an ALJ's or Attorney Adjudicator's decision or dismissal. The process for requesting Council Own Motion Review is set forth in 42 C.F.R. §423.2110(b).

While the process established by 42 C.F.R. §423.2110 does not permit a Part D plan to refer a Part D case to the Council for own motion review, plans have the opportunity to communicate with the Part D QIC about cases that may warrant such a referral. Any such communications should be directed to the Part D QIC's legal counsel (or other designated staff).

42 C.F.R. §423.2110 sets forth the standards for referral and review of Part D cases for Own Motion Review by the Council. This regulation states that CMS or the Part D QIC may refer a Part D case to the Council if, in the view of CMS or the Part D QIC, the ALJ's or Attorney Adjudicator's decision or dismissal contains: (1) an error of law material to the outcome of the case; or (2) presents a broad policy or procedural issue that may affect the public interest. CMS or the Part D QIC may also request that the Council undertake Own Motion Review of a case if CMS or the Part D QIC participated or requested to participate in the appeal at the ALJ level, and in CMS's or the Part D QIC's view, the ALJ's or Attorney Adjudicator's decision or dismissal is not supported by a preponderance of the evidence in the record or the ALJ abused his or her discretion.

The Part D QIC's legal counsel (or other designated staff) reviews all favorable ALJ and Attorney Adjudicator decisions to determine if there is a perceived error of law material to the outcome of the case or a procedural issue that may affect the general public interest. The Part D QIC works closely with CMS in determining which cases are appropriate for Council referral. The Council generally chooses not to undertake Own Motion Review for those cases where the record does not contain a complete Evidence of Coverage and Formulary. Accordingly, the Part D QIC makes every effort to help ensure that these documents are provided to the ALJ or Attorney Adjudicator at the time of the ALJ hearing or Attorney Adjudicator review, and Part D plans should insure these documents are included with their Reconsideration case file submissions to the Part D QIC.