

Part D QIC

Reconsideration Procedures Manual

MAXIMUS FEDERAL SERVICES

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PART D QIC
RECONSIDERATION PROCEDURES MANUAL

Part D QIC: Prescription Drug Benefit

Effective January 2006
(revised July 2008)

MAXIMUS Federal Services

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Appendix A: Part D QIC Reconsideration Case Forms

- Reconsideration Case File Transmittal Form
- Reconsideration Case Narrative Form
- Appointment of Representation Form
- Mail Transmittal Cover Sheet
- Part D Plan Contact Information Form-
- Notice of Effectuation form

Appendix B: Part D QIC Newsletters

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 created a new Part D: the 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 between Part D Plan sponsors and individuals enrolled in these entities. Part D Plan sponsors include:

- Prescription Drug Plan (PDP) sponsors (including fallback entities);
- 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 Services to serve as the Part D QIC. Throughout subpart M 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 Services, in its role as the Part D IRE, will be referred to as the Part D QIC or MAXIMUS Federal Services throughout this manual.

Subpart M of Part 423 sets forth the procedures Part D Plan sponsors must follow with regard to grievances, coverage determinations, and appeals. In general, Part D Plan sponsors must follow appeals requirements that are similar to those applicable to MA organizations regarding IRE review, Administrative Law Judge (ALJ) hearings, Medicare Appeals Council (MAC) review, and judicial review, respectively, as set forth in Part 423.

This manual contains the procedures for the coordination of Part D Plan sponsors with MAXIMUS Federal Services, the Part D QIC, in the processing of Part D QIC reconsiderations, and related post reconsideration activities for Part D appeals. The procedures defined in this manual are applicable to all Part D Plan sponsors (with the exception of organizations operating under a waiver per 42 CFR 423.458) that are referenced above, and are effective January 1, 2006.

The Part D QIC reconsideration is one step in a larger multi-level Part D appeal process. For example, Part D Plan sponsors 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. The focus of this manual is on the processes by which a Part D Plan sponsor and MAXIMUS Federal Services, in its role as Part D QIC, interrelate for the reconsideration level of Part D appeals. This manual will highlight many of the rules in subpart M 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 overall. This manual complements the guidance promulgated by CMS in Chapter 18 of the Prescription Drug Benefit Manual.

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)
- [42 CFR Part 423](#)
- 42 CFR Part 422, subpart M and any interpretative rules/policy applicable to the subpart. (These apply to Part 423 subpart M, as appropriate, unless provided otherwise in Part 423).
- [CMS Prescription Drug Benefit Manual, Chapter 18](#)
- [CMS Prescription Drug Coverage: General Information](#)
- [CMS Prescription Drug Coverage Contracting Overview](#) (contains links to various special guidance materials for Part D Plan Sponsors)
- [Medicare Advantage Prescription Drug Contracting](#) (MA-PDs)
- [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).

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

Our hope is that 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 CFR Part 423 or chapter 18 of the Prescription Drug Benefit Manual and in some instances paraphrase or summarize regulatory text. In the event of any discrepancy or inconsistency, the language of 42 CFR Part 423 and chapter 18 of the Prescription Drug Benefit Manual overrides these definitions.

2.1 APPEAL

Appeal means any of the procedures that deal with the review of adverse coverage determinations made by Part D Plans regarding benefits the enrollee believes he or she is entitled to receive, including 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. These procedures include redeterminations by Part D Plans, reconsiderations by the Part D QIC, Administrative Law Judge (ALJ) hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

2.2 APPEAL SPECIALIST

An appeal professional employed by the Part D QIC to manage reconsideration case files for the Part D reconsideration project. Appeal Specialists are trained to resolve disputes that do not require medical necessity determinations, e.g., disputes involving cost sharing issues. Appeal Specialists are responsible for issuing the Part D QIC reconsideration decision letter. Appeal Specialists do not make medical necessity determinations. Medical necessity determinations are made by fully credentialed board certified physicians under contract with the Part D QIC.

2.3 APPEAL SYSTEM

The entire five level Part D appeal process for addressing enrollee challenges to a Part D Plan's adverse coverage determination. The Part D QIC reconsideration process is one level in the broader Part D appeal system.

2.4 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 appeals process. 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 appeals process.

2.5 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.

2.6 COST-SHARING

The dollar or monetary amount that a beneficiary is responsible for paying with respect to obtaining a Part D benefit. 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.

2.7 COVERAGE DETERMINATIONS

The following are coverage determinations made by a Part D Plan, all of which are subject to the appeals process described in subpart M 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 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.
- (ii) A failure on the part of the 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 plan's tiered cost-sharing structure (e.g., the requested drug is not medically necessary because the 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 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 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.
- (vi) A plan's decision regarding whether an enrollee has satisfied a plan sponsor's 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.

2.8 COVERAGE DETERMINATION: DENIAL NOTICES

A written denial notice by a Part D Plan sponsor that states the specific reasons for the denial and informs the enrollee of his or her right to a redetermination. 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.

2.9 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.

2.10 CREDITABLE COVERAGE

Prescription drug coverage available to an individual that is actuarially equivalent to the standard drug coverage available to an eligible beneficiary through enrollment in a Medicare Part D Plan. Creditable drug coverage includes but is not limited to: Employer-based prescription drug coverage, some Medicaid coverage, State Pharmaceutical Assistance Programs (SPAPs), military 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.

2.11 DE-NOVO REVIEW

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

2.12 ENROLLEE

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

2.13 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).

2.14 EXPEDITED RECONSIDERATION

A de-novo review of an adverse 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 may request an expedited reconsideration. For requests made or supported by the prescribing physician, the Part D QIC will conduct an expedited reconsideration if the physician 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.

2.15 FORMULARY

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

2.16 QUALIFIED INDEPENDENT CONTRACTOR (QIC)

The entity under contract with CMS to perform reconsiderations of adverse coverage determinations and redeterminations made by Part D Plan sponsors for enrollees who wish to continue their appeals. The QIC is commonly referred to as the Part D QIC.

2.17 MEDICARE APPEALS SYSTEM (MAS)

The CMS system used by the Part D QIC for collecting specific data elements from reconsideration cases. This system is used to help facilitate creating reconsideration determinations and specific reports for CMS. This system is also used throughout the appeal process from the QIC level of review through the MAC level of review.

2.18 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.

2.19 OUT-OF-NETWORK PHARMACY

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

2.20 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);
- 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, US Pharmacopoeia-Drug Information, and DRUGDEX Information System
 - Off label uses described in peer-reviewed literature are insufficient on their own to establish a medically accepted indication.
- Includes prescription drugs, biologic products, vaccines that are reasonable and necessary for the prevention of illness, insulin, and medical supplies associated with insulin that are not covered under Parts A or B (syringes, needles, alcohol, swabs, gauze, and insulin delivery systems).

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;
- 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),
- Barbiturates, and
- Benzodiazepines (e.g. Xanax).
- 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 used is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act

2.21 PART D PLAN SPONSOR

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 Services may refer to Part D Plan sponsors as “Part D Plans” or simply as “Plans.”

2.22 RECONSIDERATION

A review of an adverse coverage determination/redetermination by the Part D QIC, the evidence and findings upon which it was based, and any other evidence the enrollee submits or the Part D Plan obtains. 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 QIC receives the request.
- Standard reconsiderations for payment requests must be completed, and notice provided, no later than 7 calendar days from the date the 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 receiving 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 QIC within 60 days of the adverse redetermination notice. There is no automatic escalation to the Part D QIC, except for those appeals involving Plan coverage determinations and Plan redeterminations that are not completed within the prescribed time frames.

2.23 RECONSIDERATION NOTICE

A written notice by the Part D QIC that sets forth the reconsideration determination. The notice is mailed to the enrollee or valid representative, and the Part D Plan sponsor. The notice 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 communicated to the enrollee or authorized representative by a phone call, and the notice follows in the mail within 3 days of that call.

2.24 REDETERMINATION

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 sponsor receives the request for a standard redetermination.
- Standard redeterminations for payment requests must be completed, and notice provided, no later than 7 calendar days from the date the Part D Plan sponsor 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.

2.25 REDETERMINATION: DENIAL NOTICE

An oral or written denial notice by a Part D Plan sponsor 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.

2.26 REOPENING

The process by which the Part D Plan, Part D QIC, ALJ, or MAC 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 422, subpart M. Part D QIC reopening review of completed reconsiderations are undertaken at the sole discretion of the Part D QIC for the purpose of addressing a potential error in the determination. (See 42 CFR §422.616).

2.27 REQUEST FOR INFORMATION (RI)

A Part D QIC document submitted to the Part D Plan or other party requesting information to correct a case file deficiency or defect.

2.28 TIERED COST SHARING

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

2.29 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 CFR section 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. The enrollee must incur \$3600 in 2006 in true out-of-pocket expenses before they can benefit from the Medicare catastrophic coverage.

3. WORKING WITH MAXIMUS FEDERAL SERVICES

This Chapter explains the basic processes for communicating with MAXIMUS Federal Services, 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

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, we are not able to offer Plans advice on how a hypothetical case would be decided if presented to us. Policy inquiries of this type should be directed by the Part D Plan to its designated CMS plan manager.

The Part D QIC is responsible for:

- Adjudicating standard and expedited reconsiderations of Plan decisions that are adverse, in whole or in part, to the enrollee.
- Adjudicating Plan coverage determinations and redeterminations that have not been decided by the Plan within the prescribed adjudicatory time frame.
- Adjudicating reconsiderations of CMS adverse low-income subsidy determinations under the Medicare Part D program.
- Adjudicating reconsiderations of adverse determinations related to prior creditable prescription drug coverage under the Medicare Part D program.
- Adjudicating reopening reviews for reconsiderations that meet specified requirements set forth in Chapter 18, section 120 of the Prescription Drug Benefit Manual.
- Monitoring Plan compliance and effectuation of 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 (MAC).
- Reviewing ALJ decisions that reverse, in whole or part, the Part D QIC's decision in order to determine whether a motion for review should be sent to the MAC.
- Case file handling and storage.
- 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 Reconsideration Manual

The Part D QIC maintains, and makes available on its website, a procedures manual for Part D QIC Reconsiderations that contains information for the coordination of Part D Plans with the Part D QIC in the processing of Part D QIC reconsiderations.

3.1.2 Medicare Part D QIC Project Web Site

The Part D QIC maintains a Part D QIC project website that, in addition to the Part D QIC Reconsideration Procedures Manual, contains the following information:

- Links to the MMA of 2003, the Social Security Act, federal regulations, CMS manuals, and CMS special guidance materials related to Part D appeals
- Updated Project Organization and Contact information
- Publications/newsletters, as required by CMS
- Conference Information and Presentations, as required by CMS

The Part D QIC website can be found at www.MedicarePartDAppeals.com.

3.1.3 MAXIMUS Federal Services Part D QIC Conferences

At schedules and locations set by CMS, the Part D QIC may participate with CMS in hosting conferences regarding the Part D benefit. Conference information will be posted on the MAXIMUS Federal Services Part D QIC website.

3.1.4 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. We will make any newsletters we publish available for downloading on our 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 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. 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. We will also contact this individual if we encounter 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 Key Contact to initiate contact with the Part D QIC to resolve any problems or concerns the Plan has with regard to the reconsideration process. 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.

3.2.2 Designation of an individual reconsideration case contact

The Part D Plan must designate a contact person on the *Reconsideration Case File Transmittal Form* submitted by the Part D Plan pursuant to a case request from the Part D QIC for reconsideration appeal. The Part D Plan may, but is not required to, use its Key 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 case specific questions are addressed by Part D QIC appeal specialist staff.

3.3 SEEKING INFORMATION ABOUT CASES

3.3.1 Hours of operation

Our switchboards will be staffed Monday through Friday from 8:00 am to 5:30 pm EST. Calls received after these hours will be asked to leave a message that will be answered as soon as possible. Case requests will be made 7 days a week, and case processing and review will also take place 7 days a week.

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

- New Year's Day
- Birthday of Martin Luther King, Jr.
- Washington's Birthday
- Memorial Day
- Independence Day
- Labor Day
- Columbus Day
- Veterans Day
- Thanksgiving Day
- Christmas Day

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

The Part D QIC will operate out of two locations: Rochester, New York and King of Prussia, Pennsylvania. The New York location will be responsible for handling reconsideration appeals involving prescription drugs. For Part D Plan inquiries about the processing status of a specific case file, or group of cases, the Plan 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 and procedures.

For enrollee inquiries about the processing status of a specific case file, or group of cases, the caller should ask the Part D QIC operator for "Case Tracking Support."

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 or 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 Services staff member who is interacting with you, or to the Project Director or to any other Part D QIC contact noted in this manual. MAXIMUS Federal Services management endorses and follows a formal process for addressing complaints and suggestions; this process enables us to identify opportunities for corrective and preventive action or continuous improvement.

4. BACKGROUND – IMPORTANT CONSIDERATIONS FOR PLAN LEVEL DETERMINATIONS

The responsibilities of Part D Plans relative to adverse coverage determinations and redeterminations are set forth in CMS regulations at 42 CFR Part 423 subpart M (and 42 CFR Part 422 subpart M for issues not addressed in Part 423), in Chapter 18 of the Prescription Drug Benefit Manual, and in various policy and guidance documents issued by CMS and available on CMS's website www.cms.hhs.gov

This Part D QIC Reconsideration Procedures Manual presumes that Part D Plans will conduct determinations in accordance with CMS rules and policies. This manual is not intended to be an instruction guide for them.

The purpose of this Chapter is to highlight certain aspects of the Part D Plan's appeal processing that directly impact on subsequent Part D QIC reconsiderations. The topics addressed are:

- 4.1 Coverage Determinations
- 4.2 Exceptions Requests
- 4.3 Redeterminations
- 4.4 Notices of Formulary Changes
- 4.5 Validation of Appealing Party
- 4.6 Validation of Eligibility of Appeal
- 4.7 Identification of Appeal Classes and Types
- 4.8 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 Sections 5.3.1 and 5.3.2 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 Chapter 18 of the Prescription Drug Benefit Manual, sections 30 (Coverage determinations), 40 (Standard coverage determinations) and 50 (Expedited coverage determinations).

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 Plans have a clear understanding of what constitutes a coverage determination.

42 CFR section 423.566 identifies actions that are coverage determinations, and hence are subject to appeal under Part 423 subpart M rules. 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.
 - e. The enrollee did not satisfy a cost utilization management requirement.
2. A failure on the part of the 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 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;
 - c. No coverage due to Plan formulary change in coverage, e.g., previously covered drug has been removed from Plan formulary.
5. A decision on the amount of cost sharing for a drug that the enrollee believes is incorrect.

A grievance is any complaint or dispute, other than one that constitutes a coverage determination, which expresses dissatisfaction with any aspect of a Plan's operations, activities, or behavior, regardless of whether remedial action is requested. 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 back to the 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 Chapter 18 of the Prescription Drug Benefit Manual sections 20.1 and 20.2 for further instruction and guidance on distinguishing between complaints that should be processed as grievances and complaints that should be processed as coverage determinations.

4.1.2 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, and
3. The prescribing physician on behalf of the enrollee.

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 4.5 for additional detail regarding representative appeals).

A prescribing physician may request a coverage determination on behalf of an enrollee. A prescribing physician acting on behalf of an enrollee is not a representative, and therefore is not required to obtain an Appointment of Representation (AOR) in order to make such a request. However, since the prescribing physician is not an appointed representative, he or she does not have all of the rights and responsibilities of an enrollee. The prescribing physician is entitled to receive only certain oral notifications from the Part D Plan related to coverage determinations, redeterminations, and denials for 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 Plan must notify the enrollee (and the prescribing physician involved as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the enrollee's request. For requests involving formulary or tiering exceptions, the 72-hour time frame begins when the Plan receives the prescribing physician's (written or oral) supporting statement.

For retrospective payment requests, the Part D Plan must notify the enrollee no later than 72 hours after receiving the request. The medical exigency standard has no application in these cases since the services have already been furnished. For requests involving formulary or tiering exceptions, the 72-hour time frame begins when the Plan receives the physician'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 written notice of the determination. The notice that is issued by the Part D Plan must comply with all CMS requirements set forth in 42 CFR 423.568(c) and (d) and in Chapter 18 of the Prescription Drug Benefit Manual, section 40.2.

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

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 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 Plan receives the physician's (written or oral) supporting statement. The Plan may notify an enrollee of an adverse expedited determination orally, but if it does so, must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

The content of the notice of an expedited coverage determination must comply with CMS requirements set forth in 42 CFR 423.572(c) and Chapter 18 of the Prescription Drug Benefit Manual section 50.5.

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 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 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 EXCEPTIONS REQUESTS

Exceptions requests are coverage determination requests, as per 42 CFR 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. The latter exceptions request, as described below, includes a variety of circumstances, not just those circumstances involving a request for a Part D drug not covered under a Plan's formulary. Exceptions requests may be decided within standard or expedited adjudicatory time frames, depending on the factors noted previously, 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 must accompany and support all requests for a tiering exception or a non-formulary drug.

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

For reconsideration review, the Plan must submit to the Part D QIC any and all exceptions procedures and criteria relative to the drug in dispute and the Plan's determination of noncoverage for the exceptions request. The procedures and criteria submitted must include a description of the process by which the Plan evaluates a determination of medical necessity by the enrollee's prescribing physician. The Plan must submit any internal medical reviews that are obtained relative to its determination. The Plan must also submit the oral or written prescribing physician statement, as well as any additional evidence and facts submitted by the enrollee or prescribing physician during redetermination review. The Part D QIC will examine the record de-novo to determine whether: (1) the 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 obtain independent medical review when making its determination.

4.2.1 Tiering Requests

Part D Plans that manage their 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 CFR 423.578(a)(4).

The supporting statement that is submitted by the prescribing physician must provide that the preferred drug 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.

While the initial supporting statement may be oral, a Plan may require the prescribing physician to submit a written statement (demonstrating medical necessity in accordance with section 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 Plan requires a written statement, it must request this statement immediately. The Plan's request must

explicitly state that the physician is required to demonstrate one of the factors discussed in 42 CFR 423.578(a)(4). The 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 to submit a written supporting statement following the oral statement, the adjudication time frame begins when the Plan receives the physician's written supporting statement. If the Plan does not request a written supporting statement, the time frame begins when the oral supporting statement is received.

4.2.2 Non-Formulary exceptions requests

Plans that manage their 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 provisions in 42 CFR 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.

The prescribing physician is required to submit a supporting statement to the 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 supporting statement must indicate that the requested drug is medically required 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 Plan may require the prescribing physician 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 plan sponsor requires a written statement, it must request the statement immediately. The Plan's request must explicitly state that the physician is required to demonstrate one of the factors discussed in 42 CFR 423.578(b)(5). The 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 to submit a written supporting statement following the oral statement, the adjudication time frame begins when the Plan receives the physician's written supporting statement. If the Plan does not request a written supporting statement, the time frame begins when the oral supporting statement is received.

4.3 REDETERMINATIONS

For a complete discussion on Plan level redeterminations, the Part D Plan should refer to Chapter 18 of the Prescription Drug Benefit Manual, section 70.

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, 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).

4.3.1 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. Note that the prescribing physician may not appeal on behalf of the enrollee for a standard redetermination request; the prescribing physician who wishes to appeal in this circumstance must appeal as a representative.

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 it 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

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 CFR 423.590(g) and Chapter 18 of the Prescription Drug Benefit Manual, section 70.9.

4.3.2 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 acting on behalf of the enrollee. Note that the prescribing physician does not need to obtain an AOR for an expedited redetermination request. For expedited requests submitted by the enrollee, the prescribing physician 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 it 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, the Part D Plan must provide an expedited redetermination if the physician "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 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 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 Plan will automatically transfer and process the request using the 72-hour time frame for standard determinations;
2. Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the Plan's decision not to expedite the determination;
3. Informs the enrollee of the right to resubmit a request for an expedited determination and that if the enrollee gets his or her prescribing physician's support indicating that applying the standard time frame for making determinations could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain to maximum function, the request will be expedited automatically; and
4. Provides instructions about the expedited grievance process and its time frames.

If a 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 it receives the request for an expedited redetermination. The 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 CFR 423.590(g) and Chapter 18 of the Prescription Drug Manual, section 70.9.

4.3.3 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 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

4.3.4 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.

4.4 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 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 advance notice, the Plan will be required to provide the notice AND provide a 60 day supply of the drug at the same terms covered previously when the affected enrollee requests a refill of his or her prescription. Once notice is provided, the enrollee will have a 60-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 CFR 423.120(b)(5).

For reconsideration requests involving an affected enrollee alleging failure of the 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 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 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 enrollee on a specific date.

4.5 PART D PLAN VALIDATION OF APPEALING PARTY

The 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. The enrollee or the enrollee's representative may request a coverage determination, and may appeal an adverse determination, at any level in the appeals process. The prescribing physician acting on behalf of the enrollee may request a coverage determination, and may subsequently appeal only for an expedited Plan level redetermination. The prescribing physician is not permitted to appeal for a standard redetermination, and is not permitted to appeal at any subsequent level in the appeals process, in the absence of providing an AOR to show that he or she is a representative of the enrollee.

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 straightforward validation when the appellant is the prescribing physician appealing a coverage determination or expedited redetermination. Except for a prescribing physician who may appeal in the limited 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 law.

4.5.1 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, a 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.

An enrollee may appoint a representative by completing an Appointment of Representation (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 HICN;
- 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.

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 that is discussed below). 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 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 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 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 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. It is anticipated that some of these individuals will 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, it is our assumption that, 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.

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 that addresses validation of non-enrollee appellants who appeal pursuant to instruments conferring representative authority under state law. Plans will be asked to attest as 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.

4.5.2 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 Plan denials for drug benefits. For these individuals, when a purported 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 Plan should consult with legal counsel, as needed, to properly make these determinations.

The *Reconsideration Case File Transmittal Form* contains an attestation for Plans to complete that addresses validation of representation for individuals who appeal as surrogates on behalf of incompetent or incapacitated enrollees. Plans will be asked to attest as 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.

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

A coverage determination or redetermination request involving payment for a drug benefit furnished to an 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," 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.

The *Reconsideration Case File Transmittal Form* contains an attestation for Plans to complete that addresses 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.

4.5.4 Prescribing physician ‘supporting’ the enrollee’s appeal

A prescribing physician 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 may also support an enrollee’s request for the Plan to expedite a request for a coverage determination or redetermination. Again, such support may be written or oral. There is no requirement for execution of an AOR in these circumstances if the physician is simply providing evidence in support of an enrollee’s request for coverage or request for expeditious handling.

The distinction between representation and support includes any of the following elements: (1) the person supporting the appeal 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 may also, without being a representative, support a request to expedite a coverage determination or redetermination. The prescribing physician’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 ability to regain maximum functioning.

The Part D Plan should note that it is not required to automatically expedite a request if the physician who submits the request is not the prescribing physician. 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.

4.6 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 4.1.1). 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 Chapter 18 of the Prescription Drug Benefit Manual, section 20, 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 back to the Plan for processing under the Plan’s grievance procedures.

MA-PDs should note that the Part D appeals process, though modeled in part after the Part C appeals process, differs from Part C in that appeals may be initiated even if there is no further financial liability for a Part D benefit on the part of the enrollee. In Part C, an enrollee (or his or her representative) is prohibited from appealing when he or she has no further financial liability for the services in dispute. This requirement does not pertain to Part D appeals. Therefore, a secondary payer, who covers an enrollee’s additional cost-

sharing amounts for a covered Part D drug(s), may dispute a Plan's decision regarding the amount of cost sharing by initiating an appeal as an enrollee's representative.

4.7 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 Plan should refer to Chapter 18 of the Prescription Drug Benefit Manual, sections 50 and 70.8, 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 Plan to include in the case file information concerning the Plan's decision with regard to determining medical exigency for expedited requests made at the Plan level.

4.8 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 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 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 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 non-formulary exceptions request, the Plan must contact the enrollee and/or the prescribing physician to solicit a supporting statement, if such statement was not submitted with the original request. If the 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 Plan should contact the enrollee and/or prescribing physician to request statements and/or medical records, as needed, to make a meaningful decision regarding coverage.

If a 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, 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 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:

- Cases That Must Be Submitted to the Part D QIC
- Time Standards For Submission of Cases to the Part D QIC
- Preparation and Submission of the Case File to the Part D QIC

5.1 CASES THAT MUST BE SUBMITTED TO THE PART D QIC

An enrollee who has received an adverse redetermination 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 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. Chapter 18 of the Prescription Drug Benefit Manual, section 70.3, 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.

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 a 7-day per week basis. The Medicare law and rules mandate that reconsideration reviews 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. In most instances, we anticipate that we will request a case file within 1 hour of receiving a request for reconsideration.

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.

The Part D Plan also must submit 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 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 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. This may include the reconsideration request, any additional information submitted by the appealing party or prescribing physician, statements the Part D QIC has solicited from the prescribing physician, and information in the Health Plan Management System (HPMS).

5.3 PREPARATION AND SUBMISSION OF THE REQUESTED CASE FILE

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
- 5.3.3 Confirmation of Part D QIC Case Receipt

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 at: www.MedicarePartDAppeals.com. 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 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 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 at both of its locations for receiving documents and records from Part D Plans. The fax number for the King of Prussia office is (484) 688-5601. The fax number for the Victor office is (585) 425-5301. These fax machines are "secure," meaning that they are only available to reconsideration personnel working on the Part D project. It is permissible to send records to our designated fax machines without redacting personally identifiable information. Our offices are open to accept faxes 7 days a week.

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 offices are open to accept case files sent by overnight mail on Monday through Saturday and most holidays. Packages should be addressed to:

MAXIMUS Federal Services
Medicare Part D QIC Project
860 Cross Keys Office Park
Fairport, New York 14450
(585) 425-5301 (Fax)

MAXIMUS Federal Services
Medicare Part D QIC Project
1040 First Ave., Suite 200
King of Prussia, PA 19406
(484) 688-5601 (Fax)

(For all Drug Appeal Submissions)

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.
- 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

A. *Reconsideration Case Narrative Form*

- The Case Narrative is where the 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 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 CFR 423.568(c) and (d)) that is sent to the appealing party when the Plan makes an adverse coverage determination (i.e., denies a drug benefit in whole or in part).
- The 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 Plan.
- The Redetermination Notice is the CMS mandated notice (see 42 CFR 423.590(g)) that is sent to the appealing party when the Plan makes an adverse redetermination.
- The 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. Prescribing Physician Statement

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

by law to solicit the comments of the prescribing physician, and will need contact numbers for the physician.

E. Representation Documents

- For appeals initiated by representatives at the Plan level, the 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)
 - Instrument executed by an enrollee that confers representative authority in accordance with State law, e.g., POA or DPOA, health care proxy appointment, or a will 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.
 - 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 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 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 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 non-formulary exception request, the 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 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.

H. Evidence of Coverage or Other Subscriber Materials

- The Plan should include a copy of relevant portions of the Evidence of Coverage or other subscriber materials as applicable to the disputed drug benefit.

I. Cost-Sharing/TrOOP Calculations

- The Plan should include any and all internal Plan or pharmacy documents or screens showing calculations relevant to the disputed cost-sharing amount.

J. Medical Records

- For medical necessity appeals and exceptions request appeals, the Plan should include medical records 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. Plans are encouraged to flag parts of the record that are pertinent to the disputed benefit.
- If the 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 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 Plan should include any additional evidence and/or facts presented by the enrollee and/or the prescribing physician at the Plan redetermination level.

M. Other Evidentiary Information/Documents

- The 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. Medical records that do not relate to the case should not 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 statement whenever the case involves a tiering exception or non-formulary exception request. If the prescribing physician's statement is missing from the case file in cases involving non-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 contacting the prescribing physician by telephone (or other means of contact if available) and transcribing his or her statements 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. If the Part D QIC is unable to obtain the prescribing physician'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.
- Applicable portions of the 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 addressing the medical necessity for an exceptions request in accordance with the standards set forth in 42 CFR 423.578(a)(4) and 423.578(b)(5). Any initial oral or written statement, and any subsequently submitted written statements, should be provided. Additionally, the name and specialty of the prescribing physician should be clearly identified, and contact numbers for office address, telephone, fax and email should be provided.
- Relevant portions of the 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 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 Plan medical reviews that were obtained during redetermination review with regard to the disputed drug benefit.
- A precise description of medical documentation that is missing from the case file if the Plan's adverse decision is based on the failure of the prescribing physician 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.

- Relevant portions of the Plan formulary, including descriptions of any cost-utilization tools relative to the drug in dispute.
- Written or oral statements provided by the prescribing physician. The name and specialty of the prescribing physician should be clearly identified, and contact numbers for street address, telephone, fax and email should be provided.
- Medical Records relevant to the drug in dispute.

- A detailed statement explaining the basis for the Plan's denial.
- Any internal Plan medical reviews that were obtained during redetermination review with regard to the disputed drug benefit.
- A precise description of medical documentation that is missing from the case file if the Plan'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.
- A detailed statement explaining the basis for the 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 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 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 Appeal Specialist Case Review
- 6.5 Physician Review
- 6.6 Requests to Plans for Additional Information
- 6.7 The Part D QIC Determination Notices
- 6.8 Enrollee Requests for Case Files
- 6.9 Creditable Coverage (CC)/Late Enrollment Penalty (LEP) Appeals
- 6.10 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

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 Claim Number;
3. Identification of the item for which reconsideration is requested, e.g., the prescription drug;
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 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 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 remains tolled in the event that the Plan submits a case file without a supporting statement from the prescribing physician. In this circumstance, the Part D QIC will attempt to remedy the defect by soliciting the prescribing physician's statement via the contact numbers (street address, telephone number, fax number and/or email address) provided by the Plan. In the event that the Part D QIC is unable to obtain a prescribing physician 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 dismissing the appeal. 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. However, 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 prescribing physician statement for appeals involving a formulary exceptions request. 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 prescribing physician. The Part D Plan's case file should contain contact information for the enrollee, the representative and the prescribing physician.

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 **non-formulary exceptions requests**. The Part D QIC will determine whether a prescribing physician 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 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. If the Part D QIC is not able to obtain a prescribing physician 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 dismissing the case (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 mail a written notice within three calendar days after oral notice is made.

With regard to telephone notification, the Part D QIC will attempt to verify the enrollee as the proper receiver by asking for the enrollee's name and date of birth. The Part D QIC will exercise discretion, taking care to protect the enrollee's privacy and confidentiality. If the Part D QIC encounters an answering machine or an individual other than the enrollee, it will leave a message regarding the general disposition of the case (e.g., favorable or unfavorable) without noting the drug in dispute or otherwise divulging personal health information. If the decision is adverse, the message left will advise the enrollee to contact the Part D QIC for more information about the specific reasons for the denial and the enrollee's right to appeal the decision. Moreover, the message will advise that enrollee will receive a written decision in the mail, including an explanation of appeal rights for an adverse decision. For messages left with an individual other than the enrollee, the Part D QIC will document the name of the individual or the individual's relationship to the enrollee.

For standard reconsiderations, the Part D QIC will notify the enrollee or the enrollee's representative of the reconsideration decision via a hard copy mailing. For these reconsiderations, the Part D QIC is required to notify the enrollee or 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. Determines if the appealing party is valid, including validating a representative.
3. Sends the Part D Plan a request for the case file.
4. Creates a case file in MAS.
5. Images the case file and associates with the case file in MAS.
6. Assigns the case to a Part D QIC Appeal Specialist.

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 Saturdays and Sundays. 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 the 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 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 APPEAL SPECIALIST CASE REVIEW

An "Appeal Specialist" is a professional trained by the Part D QIC to: (1) manage the Part D QIC case reconsideration and (2) issue reconsideration decisions. Appeal Specialists are not permitted to make medical necessity determinations. Physicians affiliated with the Part D QIC make medical necessity determinations for appeals that require medical review. The Appeal Specialist is responsible for issuing the final decision letter.

The tasks that the Appeal Specialist may complete in reconsideration review are:

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 Appeal Specialist will dismiss the case and remand it to the 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 Appeal Specialist will determine if there is sufficient representation documentation. If representation documentation is not sufficient, the Appeal Specialist will take steps to remedy the defect.

3. Determine if the case file contains a sufficient prescribing physician statement for appeals involving a formulary exceptions request. If the statement is missing from the case file, the Appeal Specialist will attempt to remedy the defect by soliciting a statement from the prescribing physician.
4. Determine if additional information is needed from the Plan to correct a case file deficiency. If so, the Appeal Specialist *may* request additional information if time permits, but also has discretion to decide the case based upon its original contents.
5. Determine if the case may be decided based upon coverage only (e.g., cost-sharing dispute), or if a medical necessity determination is required.
6. Complete and forward a referral to an appropriate Part D QIC medical consultant for cases requiring medical necessity review.
7. Receive and evaluate the Plan's response to any requests for additional information and/or the independent medical consultant's report. As necessary, the Appeal Specialist will seek clarification from the Plan or the independent medical consultant.
8. Determine if the case should be referred to Legal Counsel for policy or coverage clarification.
9. Issue a final reconsideration determination.
10. Abstract data from the case file for entry into MAS for subsequent reporting to CMS and for possible future appeals.

6.5 INDEPENDENT PHYSICIAN REVIEW

The Medicare rules state that a physician must make determinations of medical necessity. The Part D QIC maintains a panel of medical consultants, who are fully credentialed to the standards of our accrediting body, American Accreditation HealthCare Commission (URAC). These medical consultants are located throughout the United States.

The Part D QIC medical consultants cover all specialties and all relevant sub-specialties recognized by the American Board of Medical Specialties (ABMS) and the American Osteopathic Association (AOA) Specialty Board. Physicians are matched to cases based upon the case clinical issue.

The physician consultant's report is reviewed by the Appeal Specialist and, if necessary, by a Part D QIC Medical Director. Special emphasis is placed on ensuring that the consultant's determination is consistent with Medicare rules and Plan rules, including subscriber materials, formulary coverage rules, and exceptions criteria.

6.6 REQUESTS TO THE PART D PLAN FOR ADDITIONAL INFORMATION

"Request for Additional 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 discretion

The Part D QIC reconsideration 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 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 for Request for Information is as follows:

- The Appeal Specialist (or physician consultant) identifies a deficiency and checks the case file to verify that the information is, in fact, absent.
- The Appeal Specialist completes a *Request for Information Form*.
- The Appeal Specialist faxes the Request for Information Form to the fax number provided for the Case Contact on the *Reconsideration Case File Transmittal Form*.
- The Part D Plan Contact confirms receipt of the Request for Information to the Part D QIC.
- The Part D Plan Contact calls the Part D QIC if the Contact has any questions about the RI.
- The Part D Plan Contact develops the RI Response and submits the response to the Part D QIC.
- The Appeal Specialist reviews the RI response and incorporates the information in the reconsideration case file.
- If the RI response is insufficient, the Appeal Specialist 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 Plan may send documents containing such information by overnight mail. The 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 approach.

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 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, 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 a 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: No Prescribing Physician Statement"

The Part D QIC dismisses a non-formulary exceptions request for reconsideration review when the Part D QIC is unable to obtain a prescribing physician statement and there is no other credible medical information in the case file (e.g., medical records).

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 contain an explanation of the enrollee's right to request further appeal before 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 to the Part D Plan a *Notice of Requirement to Comply*. 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.

6.9 CREDITABLE COVERAGE/LATE ENROLLMENT PENALTY APPEALS

(Section to be added at a later date based on future CMS guidance).

6.10 LOW INCOME SUBSIDY APPEALS

(Section to be added at a later date based on future CMS guidance).

7. POST RECONSIDERATION DETERMINATION PROCESSING

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

- 7.1 The Part D QIC Monitoring of Part D Plan Compliance with Determinations that have been Reversed on Appeal
- 7.2 The Part D QIC Reopening Process
- 7.3 Administrative Law Judge (ALJ) Process
- 7.4 Medicare Appeal Council (MAC) Process

7.1 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 Chapter 18 of the Prescription Drug Benefit Manual, section 130.

7.1.1 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 CFR §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 CFR §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 CFR §423.636(b)(2)

If a Plan has questions regarding a Part D QIC determination, the Plan should contact the appropriate 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 7.2), whether granted by the Part D QIC or not, does not stay or pend the date of the Part D Plan's compliance obligation.

7.1.2 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, MAC, or Federal court. The documentation must state when and how compliance occurred (e.g., benefit authorization, payment made, etc.).
 - 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 Chapter 18 of the Prescription Drug Benefit Manual, Appendix 9. 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 2 weeks, it will mail the Part D Plan a reminder notice.
4. If the Part D QIC does not receive the compliance notice within 30 days of the reminder notice, the Part D QIC will report the Plan's failure to comply to CMS. The Part D Plan is not copied on this report to CMS.

If 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. Thus, 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 the attention of:

MAXIMUS Federal Services
Medicare Part D QIC Project
860 Cross Keys Office Park
Fairport, New York 14450
(585) 425-5301 (Fax)
(For all Drug Appeal Submissions)

MAXIMUS Federal Services
Medicare Part D QIC Project
1040 First Ave., Suite 200
King of Prussia, PA 19406
(484) 688-5601 (Fax)

7.2 THE PART D QIC REOPENING PROCESS

For a complete discussion on Reopenings, the Part D Plan should refer to Chapter 18 of the Prescription Drug Benefit Manual, section 120.

7.2.1 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 MAC 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 an enrollee's request within 180 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 Chapter 18 of the Prescription Drug Benefit Manual, section 120.4.1); 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 Chapter 18 of the Prescription Drug Benefit Manual, section 120.4.3).

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 must:

1. Be made in writing;
2. Be clearly stated;
3. Include the specific reasons for requesting the reopening (a statement of dissatisfaction is not grounds for a reopening); and
4. 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 additional information not previously available or known, the Part D Plan may submit a written statement to its designated Plan Liaison that sets forth this information. If a 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 Plan alleges new and additional 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 statement submitted by the 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 Plan about its decision not to reopen. If the Part D Plan 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 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 MAC, 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 noncoverage decision.

7.2.2 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 Plan Liaison (or an Appeal Specialist not involved in the reconsideration decision) reviews the reopening request and determines whether to grant reopening review.
3. If reopening review is not granted, the Plan Liaison (or an Appeal Specialist not involved in the reconsideration decision) notifies the requestor of its decision not to reopen.

4. If reopening is granted, the Plan Liaison (or an Appeal Specialist not involved in the reconsideration decision) notifies the requestor and other parties to the reconsideration of its decision to reopen, and the Appeal Specialist initiates reopening review.
5. The Appeal Specialist conducts reopening review in accordance with the process and procedures described in section 6 above for reconsideration review.
6. The Appeal Specialist completes reopening review by issuing a Reopening Reconsideration Notice in accordance with the notices described in section 6.7 above.
7. 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" as per section 7.1 above.

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.

7.3 ADMINISTRATIVE LAW JUDGE (ALJ) PROCESS

The enrollee (or the enrollee's representative) may request an appeal of the Part D QIC reconsideration determination before an Administrative Law Judge (ALJ) if the amount in controversy requirement is satisfied. The Part D QIC does not determine an enrollee's right to a hearing, nor does it schedule, conduct or administer hearings.

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

The right to request an ALJ hearing is explained in the Part D QIC reconsideration determination notice. An enrollee may submit a written request for an ALJ hearing to the appropriate ALJ field office. **If the Part D Plan receives a request for an ALJ hearing, it will immediately forward the request to the appropriate ALJ field office for processing.** The appropriate ALJ field office is determined by the appellant's address of record.

The Part D QIC forwards the reconsideration case file to the appropriate ALJ field office. The Part D QIC does not communicate directly with Part D Plans or parties during the ALJ process. The Part D QIC role for this level of appeal is to provide complete case files to the ALJ field office.

7.3.2 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 enrollee to schedule the matter before the ALJ. The enrollee has the right to present testimony at the ALJ hearing. Any concerns regarding the ALJ hearing should be directed to the Office of Medicare Hearings and Appeals.

7.3.3 ALJ determination processing

When the Part D QIC receives a request for a case file from the ALJ, the Part D QIC will update MAS with the ALJ filing/request information, make and retain a copy of the case file, and forward the case file to the ALJ within five (5) calendar days of receipt of the request. After the ALJ has adjudicated the case, the case file will be sent back to the Part

D QIC. The Part D QIC will update MAS with the ALJ disposition data and act as a repository for all completed ALJ cases and associated files. The Part D QIC will notify the Part D Plan of the ALJ decision and provide the Plan with the necessary effectuation information including, but not limited to, a copy of the ALJ decision within two (2) calendar days.

Designated staff at the Part D QIC will determine whether a motion to review the ALJ disposition should be sent to the MAC. Within two (2) days of receipt of the ALJ decision, the Part D QIC will review those ALJ decisions that overturn, in whole or in part the Part D QIC reconsideration decision. The Part D QIC will review the ALJ decisions for perceived errors in application of Medicare statutes, regulations, and coverage guidelines, or as otherwise instructed by CMS. If errors are noted, the Part D QIC will prepare a referral memorandum and file a motion for review with the MAC as instructed by CMS. In this circumstance, effectuation information shall not be forwarded to the Part D Plan until the MAC decision is issued.

7.4 MEDICARE APPEALS COUNCIL (MAC) PROCESS

Federal regulations permit any party to an ALJ hearing to request a hearing before the MAC. See 42 CFR §423.620. If a hearing before the MAC is requested, the Part D QIC is contacted by the MAC to provide a copy of the entire case file in dispute. The Part D QIC does not communicate directly with Part D Plans or parties regarding the MAC hearing process.

When the Part D QIC receives a request for a case file from the MAC, the Part D QIC shall update MAS with MAC filing/request information, make and retain a copy of the case file and forward the case file information to the MAC within five (5) calendar days of receipt of the request. The Part D QIC shall comply with the MAC's request for the case file and supply the actual case file in the exact order and manner that it was sent from the ALJ Hearing Office.

Upon completion of a MAC review and receipt of a MAC decision, the Part D QIC shall update MAS with MAC disposition data and act as a repository for all completed MAC cases and associated case files. The Part D QIC shall notify the Part D Plan of the MAC decision and provide the Plan with the necessary effectuation information including, but not limited to, a copy of the MAC decision and a copy of the reconsideration decision within two (2) calendar days.

APPENDICES

Appendix A: Part D QIC Reconsideration Case Forms

- Reconsideration Case File Transmittal Form
- Reconsideration Case Narrative Form
- Appointment of Representation Form
- Mail Transmittal Cover Sheet
- Part D Plan Contact Information Form-
- Notice of Effectuation form

Name of Part D Plan: _____

Date of Redetermination Notice: _____

Appeal Information: (Check one for each line)

- a. Priority: Expedited Standard
b. Appeal Type: Prospective Retrospective
c. Auto-forward: Yes No

Appellant Name	Enrollee Name

Enrollee HIC/Medicare Claim Number	Date of Birth

Enrollee Address and Phone Number:

--

Part D Plan Information:

Plan Type: <input type="checkbox"/> PDP (S#) <input type="checkbox"/> MA-PD (H or R#) <input type="checkbox"/> Cost
Plan Contract# (H/S/R) _____ (Circle "H" "S" or "R" and list the 4 digit CMS Plan Contract #)
Plan ID # _____ Formulary Name/Formulary ID # _____
Plan Contact (Name/Title) _____
Phone # _____ Fax # _____ Email _____
Plan Address _____

Representative Appeals: (**NOTE: Representative documents MUST be included in case file**)

Name of Representative _____
Address _____
Phone # _____ Fax # _____ Email _____

PLAN ATTESTATION FOR VALIDITY OF REPRESENTATIVE

I attest on behalf of the Part D Plan sponsor that the above referenced representative appealed at the Plan level and is a valid representative of the enrollee under State law.

Signed _____ Print Name _____
Requested coverage at CD level <input type="checkbox"/> Appealed at RD level <input type="checkbox"/>

**If multiple drugs in dispute, print and complete a separate version of this page for each drug in dispute*

Plan Level Appeal Information:

Coverage Determination (CD):

Date Requested: _____ Decision Date: _____ Was CD Timely? YES NO
Did Appellant Ask Plan To Expedite? YES NO Did Plan Expedite? YES NO

Redetermination (RD):

Date Requested: _____ Decision Date: _____ Was RD Timely? YES NO
Did Appellant Ask Plan To Expedite? YES NO Did Plan Expedite? YES NO

For Determinations Involving an Exceptions Request:

Is the Prescribing Physician Statement in the Case File? YES NO

Drug Benefit in Dispute:

Name of Drug: _____
Quantity/Dosage (e.g. 20 mg BID) _____
Is Prescriber Requesting: Brand Generic Either Acceptable (Check one)
Off-Formulary? Yes No

Pre-Service Requests: Has Enrollee Purchased the Drug Pending Appeal? Yes No
If YES: Date Purchased: _____ Amount Paid: _____
Purchased From Network Pharmacy? Yes No.

Retrospective Requests: Date(s) of Purchase: _____
Amount(s) Paid: _____ Drug Tier: _____
Purchased From Network Pharmacy? Yes No.
If NO, explain: _____

Drug Benefit Denial Rationale:

PA rules not met Step Therapy exception rules not met
 Dose/QL exception rules not met Brand/Generic Cost Differential
exception rules not met
 PA exception rules not met Off-Formulary exception rules not met
 Tiering exception rules not met Out-of-Network rules not met
 Excluded Drug Class/Use Covered Under A/B
 Cost-Sharing Dispute Not a Medically Accepted Indication
 Other _____

Prescriber Information:

Name/Specialty of Physician _____
Office Address _____
Phone # _____ Fax # _____ Email _____
Prior Authorization Form Submitted? Yes No

Exhibits: Label applicable exhibits with letters provided below, and place them in order by letter.

Procedural Documents	<input type="checkbox"/> A. Case Narrative cover page that presents an overview of the appeal: Describe the issue on appeal; Identify all relevant information; Identify the arguments presented in favor of coverage; and Explain the Plan rationale for denial. <input type="checkbox"/> B. Request for Coverage Determination and Plan Coverage Determination Decision Notice <input type="checkbox"/> C. Request for Redetermination and Plan Redetermination Decision Notice <input type="checkbox"/> D. Prescribing Physician Statement (for exceptions requests) <input type="checkbox"/> E. Representation Documents (AOR or other writing, DPOA/POA, Healthcare Proxy, Surrogate for an incompetent enrollee under State law, estate representative) <input type="checkbox"/> F. Other (describe or list additional exhibits the Plan considers important)
Evidentiary Documents	<input type="checkbox"/> G. Part D Plan Formulary (relevant exceptions and/or coverage criteria) <input type="checkbox"/> H. Part D Plan Evidence of Coverage or other Subscriber Materials (relevant portions) <input type="checkbox"/> I. Cost Sharing Information (copies of internal Plan documents/screens showing TrOOP or other cost-sharing information as relevant to the dispute). <input type="checkbox"/> J. Medical Records (separated by physician, labeled, and in chronological order with most recent on top). <input type="checkbox"/> K. Medicare Rules (Medicare law and regulations, CMS manuals, and/or CMS program guidance as relevant to the Part D Plan's determination). <input type="checkbox"/> L. Redetermination Evidence (evidence submitted by appellant and/or the prescribing physician, and internal Plan medical reviews conducted to evaluate medical necessity issues) <input type="checkbox"/> M. Other (describe or list additional exhibits the Plan considers important).

CASE NARRATIVE FORM

OVERVIEW OF ISSUES ON APPEAL

ENROLLEE ARGUMENTS IN FAVOR OF COVERAGE

PART D PLAN DENIAL RATIONALE
(INCLUDE PERTINENT CITATIONS TO MEDICARE LAW, RULES AND
MANUALS)

CHRONOLOGY/TIMELINE OF PERTINENT FACTS AND
FINDINGS

**Medicare PART D
APPOINTMENT OF REPRESENTATIVE STATEMENT**

**Section I: Appointment of Representative
To be completed by the enrollee:**

_____	_____
Enrollee Name	Medicare/HIC Number
_____	_____
Enrollee address	Phone number (area code)

City, State, Zip code	
_____	_____
Part D Plan	Date(s) of Service

I do hereby swear that I am the above-mentioned enrollee or have the legal authority to appoint a representative for the above-mentioned enrollee. I appoint the following individual _____ to act as my representative in requesting a coverage determination from the Part D Plan and/or further appeal subject to the appeals process for the Part D prescription drug program regarding the benefit(s) for which the above-referenced Part D Plan has denied payment or authorization. I authorize this individual to make any request; to present or to elicit evidence; to obtain appeals information; and to receive any notice in connection with my appeal, on my behalf. I understand that personal medical information related to my appeal may be disclosed to the representative indicated below.

_____	_____
Enrollee Signature	Date

**Section II: Acceptance of Appointment
To be completed by the representative:**

I, _____ hereby accept the above appointment.
(Name of Appointed Representative)

_____	_____
Signature of Appointed Representative	Date

(Address and telephone number of representative)



Medicare Part D QIC MAIL TRANSMITTAL COVER SHEET

For use with any mail transmittal of information on any appeal at MAXIMUS Federal Services Part D QIC

Attach one of these forms to each set of documents you send to MAXIMUS Federal Services for each Medicare Appeal number. Indicate what type of information you are sending on each case by checking the box for each type. If information is included on an existing appeal, list the Medicare Appeal Number opposite the appropriate heading. *If you are sending information on multiple cases in one package, include one of these transmittal sheets as the first sheet for each case.*

√	DOCUMENT TYPES	MEDICARE APPEAL NUMBER
	Prescribing Physician Statement	
	Appointment of Representative Form	
	Requested Information	
	Request for Reopening	
	Compliance Notification	

√	MISROUTED/MISFILED MATERIAL	MEDICARE APPEAL NUMBER
	Reconsideration Request	
	Reconsideration correspondence	
	Supporting Evidence	
	FOIA Request	



Medicare Part D QIC Reconsideration Project

Part D Plan Contact Information

PLAN CONTACT INFORMATION	
Company Name	
Plan Name	
Plan Type	
**Plan Contract ID #	
Formulary Name	
Formulary ID #	
Plan Contact Name	
Plan Contact Title	
Street Address	
Mail Stop	
City	
State	
Zip Code	
Phone Number	
Phone Extension	
Fax Number	
Email Address	
Alternate Contact name	
Alternate Contact Phone #	

The Part D Plan contact is the individual to whom all general appeal information is to be sent by MAXIMUS Federal Services. If the Plan selects another individual at the Plan to receive information about a specific case file that is submitted to MAXIMUS Federal Services pursuant to an appeal, the Plan must list this individual on the Case File Transmittal Form as the Plan contact person for that specific case.

**Please send this form by fax to:
Victor (585) 425-5301**

** If the Plan Contract ID # begins with "S" it is a PDP type
If the Plan Contract ID # begins with "H" or "R" it is an MA-PD type

MEDICARE PART D QIC RECONSIDERATION PROJECT

NOTICE OF EFFECTUATION

Medicare Appeal #	
Medicare ID # (HIC)	
Date Plan Received QIC Reconsideration Decision	
Effectuation Date	

Please note MAXIMUS Federal Services cannot waive compliance with a MAXIMUS Federal Services Reconsideration Determination. If you feel that you cannot comply with this Reconsideration Determination, you must notify your contact at the CMS Regional Office.