

C2C Contact Information

C2C Part D QIC Website: <https://PartDAppeals.C2Cinc.com>

C2C Part D QIC Portal: <https://www.c2cinc.com/Appellant-Signup>

Drug Benefit Reconsideration and DMP At-Risk Appeals	
United States Postal Service (USPS):	UPS / FedEx ONLY:
C2C Innovative Solutions, Inc. Part D Drug Reconsiderations P.O. Box 44166 Jacksonville, FL 32231-4166	C2C Innovative Solutions, Inc. Part D Drug Reconsiderations 301 W. Bay St., Suite 1110 Jacksonville, FL 32202
Telephone for Part D Plans	(904) 394-4700
Telephone for Enrollees Only	(833) 919-0198 (Toll Free)
Fax for Part D Plan Expedited Appeals	(904) 539-4093
Fax for Part D Plan Standard Appeals	(904) 539-4097
Fax for Part D Plan Auto-Forwarded Appeals	(904) 539-4099
Fax for Part D Plan Drug Effectuations	(904) 539-4101
Fax for Enrollees Only – Expedited Appeals	(833) 710-0579 (Toll Free)
Fax for Enrollees Only – Standard Appeals	(833) 710-0580 (Toll Free)

LEP Reconsideration Appeals	
United States Postal Service (USPS):	UPS / FedEx ONLY:
C2C Innovative Solutions, Inc. Part D LEP Reconsiderations P.O. Box 44165 Jacksonville, FL 32231-4165	C2C Innovative Solutions, Inc. Part D LEP Reconsiderations 301 W. Bay St., Suite 1110 Jacksonville, FL 32202
Telephone for Part D Plans	(904) 394-4700
Telephone for Enrollees Only	(833) 919-0198 (Toll Free)
Fax for Part D Plans	(904) 539-4072
Fax for Enrollees Only	(833) 946-1912 (Toll Free)

C2C Part D QIC Plan Liaison:

MedicarePartDAppeals@C2Cinc.com	(904) 394-4700 (Phone)
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1. INTRODUCTION

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

- Prescription Drug Plan (PDP) sponsors
- Medicare Advantage (MA) organizations offering the Part D prescription drug benefit (MA-PDs)
- Programs of All-Inclusive Care for the Elderly (PACE) plans offering qualified prescription drug coverage
- 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 C2C to serve as the Part D QIC. Title 42 of the Code of Federal Regulations (CFR), Part 423, sets out the regulations enacting the Voluntary Prescription Drug Benefit Program. Throughout subparts M and U of Part 423 of the Medicare regulations, the phrase “independent review entity” (IRE) is used to describe the entity responsible for reviewing such appeals. The IRE is commonly referred to as the Part D Qualified Independent Contractor or Part D QIC. C2C, in its role as the Part D IRE, will be referred to as the Part D QIC or C2C throughout this manual.

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

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

Subpart U of Part 423 discusses post-adjudication procedures for Part D plans, the Part D QIC, Administrative Law Judges (ALJs) and the Medicare Appeals Council (Council). This

includes a reopening review process at each level, as well as specific requirements for ALJ review and hearings, Council review and judicial review. Note that only the enrollee (or representative, if applicable) has further appeal rights after a reconsideration decision has been issued by the Part D QIC. While Part D plans may request reopening review by the Part D QIC, plans cannot appeal a reconsideration decision.

This Part D QIC Reconsideration Procedures Manual (manual) contains the procedures for the coordination between Part D plans and C2C in the processing of drug appeal reconsiderations, related drug appeal post reconsideration activities, and the reconsiderations of LEP determinations. The procedures defined in this manual are applicable to all Part D plans (with the exception of organizations operating under a waiver per 42 CFR §423.458) that are referenced above.

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

The focus of this manual is on the processes by which a Part D plan and C2C, in its role as the Part D QIC, interrelate for the reconsideration level of Part D appeals. This manual will highlight many of the rules in subpart B, subpart M and subpart U of Part 423, but it is not intended to serve as a complete resource of CMS rules and policy governing plan obligations for the appeal process. This manual complements the guidance set forth by CMS in the Medicare Prescription Drug Benefit Manual and CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

The manual presumes that the reader has knowledge 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 Act
- Final Rule, “Medicare Program; Medicare Prescription Drug Benefit.” Federal Register, Volume (Vol.) 70, Number (No.) 18, January 28, 2005. (Preamble contains industry comments and CMS responses, which provide in-depth explanation of the prescription drug benefit)
- Final Rule, “Medicare Program; Application of Certain Appeals Provisions to the Medicare Prescription Drug Appeals Process.” Federal Register, Vol. 74, No. 235, December 9, 2009
- 42 CFR Part 423

- CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance Manual
- CMS Internet-Only Manual (IOM), Publication (Pub.) 100-18, Medicare Prescription Drug Benefit Manual
- CMS Prescription Drug Coverage: General Information on <https://www.cms.gov/> website
- CMS Prescription Drug Coverage Contracting Overview on <https://www.cms.gov/> website (contains links to various special guidance materials for Part D plans)
- Medicare Advantage Prescription Drug Contracting (MA-PDs) <http://www.cms.gov/Medicare/Medicare-Advantage/MA-PDContracting/index.html>
- Medicare Coverage Database for National Coverage Determinations (NCDs) issued by CMS, or Local Coverage Determinations (LCDs) issued by Medicare contractors (as appropriate for discerning the scope of the prescription drug benefit versus coverage under Part A and Part B of Medicare).

Certain policies, procedures and operational documents discussed in this manual are mandatory, and complete compliance of Part D plans is expected. For such requirements, the term "must" or "mandatory" or "required" or "should" is used. In other areas, we have attempted to provide the Part D plan with flexibility, and we offer suggestions for work methods we believe will enhance the working relationship between Part D plans and C2C in its role as the Part D QIC. In these areas, the term "recommended" or "suggested" or "optional" is used.

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, the Medicare Prescription Drug Benefit Manual, CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance Manual and CMS Memos to Part D plans. In some instances, regulatory text and CMS policy guidance is paraphrased or summarized. In the event of any discrepancy or inconsistency, the regulatory language in 42 CFR Part 423 and CMS written policy guidance takes precedence over these definitions, as summarized.

2.1 ADJUDICATOR

Part D QIC adjudicators are comprised of Physician Reviewers, Appeal Professionals and Reconsideration Analysts that are trained to adjudicate Part D drug benefit and/or LEP reconsiderations. Part D drug benefit reconsiderations that require medical necessity review are processed by Appeals Professionals and adjudicated by fully licensed Physician Reviewers. Part D drug reconsiderations that do not require medical necessity review are processed and adjudicated by Appeals Professionals and/or Reconsideration Analysts. LEP reconsiderations are processed and adjudicated by Reconsideration Analysts.

2.2 ANNUAL ELECTION PERIOD (AEP)

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

2.3 APPEAL

For Prescription Drugs: As defined at 42 CFR §423.560, an appeal encompasses the procedures that deal with the review of adverse coverage determinations made by a Part D plan on drug benefits under Part D that the enrollee believes he or she is entitled to receive, including a delay in providing, arranging for or approving drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a drug as defined in 42 CFR §423.566(b). An appeal also encompasses at-risk determinations made by Part D plans under a Drug Management Program (DMP). The adverse drug coverage or at-risk determination procedures include redeterminations by Part D plans, reconsiderations by the Part D QIC, hearings conducted by ALJs, reviews by the Council, and judicial reviews in Federal Court.

For LEPs: An appeal is a request for review or reconsideration of a Part D plan's adverse determination related to the imposition of, or increase in, an LEP under the Part D program.

2.4 APPEAL SYSTEM

For Prescription Drugs: There are five levels to the Part D appeal process for enrollee challenges to a Part D plan's adverse drug coverage determination or at-risk determination. The Part D QIC reconsideration process is one level in the broader Part D drug appeal system; specifically the Part D QIC process is the second level of appeal

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

2.5 APPOINTED REPRESENTATIVE

An individual is either appointed by an enrollee in writing or authorized under state or other applicable law to act on behalf of the enrollee in obtaining a coverage determination or in dealing with any of the levels of the drug appeals process, or in seeking reconsideration of the imposition of, or increase in, an LEP by a Part D plan. A valid representative has all of the rights and

responsibilities of an enrollee in obtaining a coverage determination or in dealing with any of the levels of the drug appeals process, or in seeking reconsideration of the imposition of an LEP.

2.6 CONTRACTED PHARMACY NETWORK

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

2.7 COST-SHARING

Cost-sharing is the dollar or monetary amount that an enrollee is responsible for paying with respect to obtaining a Part D drug or benefit. This includes deductibles, coinsurance and copayment amounts that may be the responsibility of the enrollee under Medicare rules and policies and Part D plan subscriber materials, as approved by CMS. Coinsurance is a fixed percentage of the total amount paid for a Part D benefit that can be charged to the enrollee. Copayments are a fixed amount that can be charged to an enrollee on a per-service basis.

2.8 COVERAGE DETERMINATIONS

The following are coverage determinations made by a Part D plan, all of which are subject to the appeals process described in Subparts M and U of 42 CFR Part 423:

- (i) A decision not to provide or pay for a Part D drug that the enrollee believes may be covered by the Part D plan. Denial reasons may include:
 - Drug not medically necessary
 - Drug not on plan formulary
 - Drug does not meet the definition of a Part D drug
 - Drug furnished by out-of-network pharmacy
 - Drug excludable under § 1862(a) of the Act if applied to Medicare Part D
 - Drug not prescribed for a medically accepted indication
 - Drug not FDA approved
 - Drug may be eligible for coverage under Medicare Part A or Part B
- (ii) A failure on the part of the Part D plan to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee.
- (iii) An adverse decision concerning an exceptions request to a Part D plan's tiered cost-sharing structure (e.g., the requested drug is not medically necessary because the Part D plan formulary contains a preferred drug at a lower cost sharing tier that is medically appropriate for enrollee).
- (iv) An adverse decision concerning an exceptions request for a non-formulary Part D drug. Denial reasons include:

- Non-formulary drug is not medically necessary because the Part D plan formulary covers alternate drug(s) that are medically appropriate for enrollee
 - Cost-utilization guidelines (e.g., prior authorization, dose restriction, step therapy, therapeutic substitution requirements) have not been met for the drug
 - No coverage due to a Part D plan formulary change in coverage (e.g., a previously covered drug has been removed from the plan's formulary)
- (v) A decision on the amount of cost-sharing for a drug that the enrollee believes is incorrect.
- (vi) A Part D plan's decision regarding whether an enrollee has satisfied cost-utilization guidelines (e.g., prior authorization, dose restriction, step therapy, therapeutic substitution requirements).
- (vii) The enrollee disagrees with the Part D plan's at-risk determination made pursuant to the plan's DMP.

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

2.9 COVERAGE DETERMINATION: DENIAL NOTICES

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

2.10 COVERED PART D DRUG

A covered Part D drug 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 under 42 CFR §§ 423.566, 423.580 and 423.600, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with 42 CFR §423.124.

2.11 CREDITABLE COVERAGE

Creditable prescription drug coverage is coverage that meets Medicare's minimum standards, i.e., coverage expected to pay, on average, at least as much as Medicare's standard prescription drug coverage. Examples may include group health plans, union/employer-sponsored coverage, military related coverage, such as VA and TRICARE, Indian Health Service, a Tribe or Tribal organization, or an Urban Indian organization (I/T/U). See 42 CFR § 423.56(b) for procedures to determine and document creditable status of prescription drug coverage offered by various entities and a list of types of prescription drug coverage that may be determined to be creditable.

2.12 CREDITABLE COVERAGE NOTICE

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

2.13 DE NOVO REVIEW

Review or adjudication of an individual dispute by a new and impartial reviewer. The reviewer does not give deference to any previous determinations made on the individual dispute. The reviewer evaluates all of the evidence from the beginning. C2C, as the Part D QIC, conducts de novo review for reconsideration requests.

2.14 ENROLLEE

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

2.15 EVIDENCE OF COVERAGE

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

2.16 EXPEDITED RECONSIDERATION

A de novo review of an adverse Part D drug benefit coverage determination/redetermination by a Part D plan that must be processed expeditiously by the Part D QIC is an expedited reconsideration. It is conducted by the QIC if applying the standard timeframe may seriously jeopardize the enrollee's life, health or 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 valid and complete written request for reconsideration from the enrollee, the enrollee's appointed representative, or the enrollee's treating prescriber. The enrollee, his or her representative, or the treating prescriber may request an expedited reconsideration. For requests made or supported by the enrollee's treating physician or other prescriber, the Part D QIC will conduct an expedited reconsideration if the prescriber indicates that applying the standard timeframe 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 are not subject to processing as an expedited reconsideration.

2.17 FORMULARY

The entire list of Part D drugs covered by a Part D plan and as approved by CMS.

2.18 INITIAL ENROLLMENT PERIOD (IEP)

The Initial Enrollment Period (IEP) is the timeframe during which an individual is first eligible for Part D. An individual is eligible for Part D when they have Part A coverage and/or they are enrolled in Part B and live in the service area of a Part D plan. This time period runs from three months before the month of becoming eligible for Part D, through the month of eligibility, to the last day of the third month following the month of eligibility. The Part D IEP timeframe is the same as the Part B IEP timeframe.

2.19 LATE ENROLLMENT PENALTY (LEP)

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

2.20 LATE ENROLLMENT PENALTY LETTER

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

2.21 LOW-INCOME SUBSIDY (LIS)

The low-income subsidy, (LIS) also called Extra Help, helps pay Medicare prescription drug plan costs (e.g., plan monthly premiums, copayments, annual deductible) for enrollees who have limited income and resources. If the individual has LIS at the time of enrollment or becomes eligible for LIS while they are enrolled in the plan, they are not subject to an LEP. LIS-eligible months do not count toward the late penalty. If an enrollee was paying an LEP before qualifying for an LIS, the enrollee is **not exempt** from those payments.

2.22 MEDICALLY ACCEPTED INDICATION

A drug or biological must be prescribed for a medically accepted indication to be eligible for coverage as a Part D drug. Section 1860D-2(e)(4) of the Act defines "medically-accepted

indication,” in part by reference to §1927(k)(6) of the Act, to any use of a covered Part D drug, which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in §1927(g)(1)(B)(i) of the Act. The recognized compendia are: American Hospital Formulary Service Drug Information (AHFS-DI) and DRUGDEX® Information System.

The definition of medically accepted indication also means, in the case of a covered Part D drug used in an anticancer chemotherapeutic regimen, the definition of ‘medically accepted indication’ as set forth in §1861(t)(2)(B) of the Act. This means that Part D sponsors are required to thoroughly understand and apply Part B’s definition of an anti-cancer chemotherapeutic regimen, utilize Part B compendia, and consider peer reviewed medical literature when necessary. The Part B rules for ‘medically accepted indication’ for drugs used in an anticancer chemotherapeutic regimen are set forth in CMS IOM Pub. 100-02, Medicare Benefit Policy Manual (MBPM), Chapter 15, §50.4.5.

Medically-accepted indication refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication. Part D plans may have dose limitations based on FDA labeling, but an enrollee may request (and be granted) an exception to a dose restriction through the formulary exception process based on medical necessity criteria.

Additionally, a Part D drug must be used for a medically-accepted indication that facilitates the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (except for Part D vaccines). Therefore, if a drug is used as part of a medical device to facilitate use of the device, versus prescribed for a medically-accepted indication of therapeutic value on the body, the drug does not satisfy the definition of a Part D drug. For example, heparin is used in a heparin flush to prevent or dissolve blood clots to maintain patency in an intravenous infusion line. Heparin would not satisfy the definition of a Part D drug in this instance.

Part D plans are responsible for ensuring that covered Part D drugs are prescribed for medically-accepted indications using the tools and data available to them to make such determinations. Part D plans must reference all CMS recognized compendia to determine whether there are any supportive citations, prior to determining that a drug is not being used for a medically-accepted indication.

2.23 MEDICARE APPEALS SYSTEM (MAS)

This CMS system is used by the Part D QIC for processing and tracking reconsiderations, and for collecting specific data elements from reconsideration cases. The data collected by the QIC is used to create specific reports for CMS. MAS is also used throughout the Part 423 appeal process from the Part D QIC level of review through the Council level of review.

2.24 ELIGIBILITY AND ENROLLMENT MEDICARE ONLINE (ELMO)

CMS database that is used by the Part D QIC to verify various enrollee information including: date

of birth, date of death, current Medicare Part A/B entitlement, Medicare Part D eligibility, current and previous Part D plans with effective dates of enrollment/disenrollment, uncovered months assessed, Part D late enrollment penalty amount, and retiree drug data.

2.25 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.

2.26 OUT-OF-NETWORK PHARMACY

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

2.27 PART D DRUG

A Part D drug is a drug that:

- May be dispensed only by prescription
- Is approved by the Food and Drug Administration (FDA) (or is exempt from approval)
- Is used and sold in the US
- Is used for a medically accepted indication
 - Includes FDA-approved uses
 - Includes uses supported by one or more citations included or approved for inclusion in the American Hospital Formulary Service Drug Information (AHFS-DI, and DRUGDEX Information System
 - For drugs used as part of an anti-cancer chemotherapeutic regimen; includes uses in additional compendia and peer reviewed literature as identified in the MBPM Chapter 15, §50.4.5.
- Includes prescription drugs, biologic products, vaccines that are reasonable and necessary for the prevention of illness, insulin, and medical supplies associated with delivery of insulin into the body that are not covered under Parts A or B (syringes, needles, alcohol, swabs, gauze, and insulin delivery systems). See 42 CFR §423.100

A Part D drug excludes:

- Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B

- 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)
 - 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 § 1927(g)(1)(B)(i) of the Act.

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

Not Excluded:

- Prescription drug products that otherwise satisfy the definition of a Part D drug are Part D drugs when used for AIDS wasting and cachexia due to a chronic disease, if these conditions are medically-accepted indications as defined by section 1927(k)(6) of the Act for the particular Part D drug. Specifically, CMS does not consider such prescription drug products being used to treat AIDS wasting and cachexia due to a chronic disease as either agents used for weight gain or agents used for cosmetic purposes

- Part D drugs indicated for the treatment of psoriasis, acne, rosacea, or vitiligo are not considered cosmetic
- Vitamin D analogs such as calcitriol, doxercalciferol, paricalcitol and dihydrotachysterol, when used for a medically-accepted indication as defined by § 1927(k)(6) of the Act, are not excluded because CMS interprets the exclusion of prescription vitamin D products as being limited to products consisting of ergocalciferol (vitamin D2) and/or cholecalciferol (vitamin D3)
- Prescription-only smoking cessation products
- Prescription niacin products (Niaspan, Niacor)
- Cough and cold medications are eligible to meet the definition of a Part D drug in clinically relevant situations other than those of symptomatic relief of cough and colds. For example, when cough medications are used for a medically accepted indication that treats a cough produced by a medical condition unrelated to symptomatic cough and cold. In such circumstances, such as the treatment of cough to alleviate bronchospasm in asthma, CMS does not consider these cough medications as excluded drugs.

2.28 PART D PLAN

Means a stand-alone prescription drug plan (PDP), a Medicare Advantage (MA) plan offering the Part D prescription drug benefit (MA-PD), a PACE organization offering a PACE plan that includes qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage. Please note that throughout this manual C2C may refer to Part D plans as “Part D plan” or simply as “Plan(s)” or “plan(s).”

2.29 QUALIFIED INDEPENDENT CONTRACTOR (QIC)

The entity under contract with CMS to perform reconsiderations of DMP At-Risk Determinations and adverse coverage determinations and redeterminations made by Part D Plans for enrollees who wish to continue the appeal process. This entity (currently C2C Innovative Solutions, Inc.) also conducts LEP reconsiderations. The QIC is commonly referred to as the Part D QIC, but may also be referred as the Part D Independent Review Entity or IRE.

2.30 RECONSIDERATION PROCESS (LATE ENROLLMENT PENALTY)

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

enrollee, such as receipt of additional information that may reduce the number of uncovered months upon which the LEP was based.

2.31 RECONSIDERATION PROCESS (PRESCRIPTION DRUG)

The Part D QIC's review of an adverse coverage determination/redetermination by the Part D Plan, the evidence and findings upon which the Plan's decision was based, and any other evidence the enrollee submits or the Part D QIC obtains. Prescription drug reconsiderations may be standard or expedited and may involve requests for covered benefits or requests for payment. Prescription drug reconsiderations may also involve DMP At-Risk Determinations and requests to review Part D plan Dismissals.

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

Enrollees who wish to appeal an adverse redetermination must file a written request for reconsideration with the Part D QIC within 65 calendar days of the adverse redetermination notice. There is no automatic escalation to the Part D QIC, except for those appeals involving Part D plan coverage determinations and redeterminations that are not completed within the prescribed timeframes, and partially favorable or unfavorable DMP At-Risk Determination appeals.

2.32 RECONSIDERATION DECISION (LEP APPEAL)

A written decision by the Part D QIC that sets forth the LEP reconsideration determination. The decision letter is mailed to the enrollee or his/her appointed representative (if applicable) and faxed to all impacted Part D plans. If the enrollee has enrolled in a new Part D plan subsequent to requesting an LEP reconsideration, the Part D QIC will fax the decision letter to both the former and the current Part D plan.

The LEP reconsideration states the specific reasons for the Part D QIC's decision to uphold, reverse or partially reverse the imposition of a LEP. The QIC generally will notify the enrollee of the final LEP reconsideration decision (including a decision to dismiss the reconsideration request), within 90 calendar days of receiving a request for reconsideration. The QIC may take an additional 14 calendar days, as described under § 2.30 of this manual.

2.33 RECONSIDERATION DECISION (DRUG BENEFIT APPEAL)

A written decision by the Part D QIC that sets forth the prescription drug reconsideration determination. The reconsideration is mailed or faxed to the enrollee, his/her treating prescriber, and/or the enrollee's appointed representative, as applicable, and faxed to the Part D plan. The reconsideration letter identifies the issue in dispute and the applicable CMS rules and/or CMS and plan policies, and sets forth the reasons for the QIC's decision. If the reconsideration is unfavorable or partially favorable, the letter informs the enrollee of his or her right to an ALJ hearing if the amount in controversy requirement is met, and describes the procedures for filing for ALJ review. For expedited appeals, the reconsideration may be verbally communicated to the enrollee, the treating prescriber, or the enrollee's authorized representative by a phone call, and the written notice is mailed or faxed to the appropriate parties within three calendar days of the call. The written notice is also faxed to the Part D plan. For appeals filed by a treating physician or prescriber, the QIC will send written notice to the prescriber and send a copy to the enrollee.

2.34 REDETERMINATION PROCESS (DRUG BENEFIT APPEAL)

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

2.35 REDETERMINATION: DENIAL NOTICE (DRUG BENEFIT APPEAL)

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

2.36 REOPENINGS

The process by which the Part D plan, Part D QIC, ALJ, or Council reviews its own decision that is otherwise final and binding. Reopening review at the QIC level may be initiated by the QIC or pursuant to a request from the appellant, Part D plan, or other parties under the rules in 42 CFR Part 423, Subpart U. Reopening review at the QIC level is undertaken at the sole discretion of the QIC. The QIC may reopen a reconsideration and issue a revised reconsideration for the following reasons; 1) To address a potential error in the QIC decision; 2) To address new and material evidence not available or known at the time the reconsideration was processed and which may result in a different conclusion; or 3) To address its reconsideration findings because the decision was procured by potential fraud or similar fault. (See 42 CFR §§ 423.1978-1986)

2.37 REQUEST FOR INFORMATION (RI)

A Part D QIC document submitted to the Part D plan (or other entity), the enrollee, his or her treating prescriber, or an appointed representative requesting information to correct a case file deficiency or defect, or to obtain additional information required to adjudicate the appeal.

2.38 SPECIAL ENROLLMENT PERIOD (SEP)

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

2.39 TIERED COST SHARING

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

2.40 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 §423.100 and further described in CMS IOM Pub. 100-08, Medicare Prescription Drug Benefit Manual, Chapter 5, §30. 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 as an exception or as a result of an appeal.

3. WORKING WITH C2C

This chapter explains the basic processes for communicating with C2C, 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 Five-day Period Notice Mailing Rule
- 3.5 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, the Part D QIC is not able to offer Part D plans advice on how a hypothetical case would be decided if presented. Policy inquiries of this type should be directed by the Part D plan to its designated CMS account manager.

The Part D QIC is responsible for:

- Adjudicating standard and expedited drug benefit reconsiderations of plan decisions that are adverse, in whole or in part, to the enrollee.
- Adjudicating drug appeal coverage determinations and redeterminations that have not been timely decided by the Part D plan within CMS prescribed adjudicatory timeframes.
- Adjudicating DMP At-Risk Determinations that are auto-forwarded to the QIC for review.
- Adjudicating requests to review dismissals issued by Part D plans.
- Adjudicating adverse determinations related to prior creditable prescription drug coverage under the Medicare LEP appeal program.
- Adjudicating reopening reviews for drug benefit reconsiderations and LEP appeal reconsiderations that meet specified requirements set forth in 42 CFR Part 423 Subpart U and CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.
- Monitoring Part D plan compliance with effectuation of drug benefit reconsiderations, OMHA decisions and Council 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 OMHA, and the Council.

- Reviewing ALJ decisions that reverse, in whole or part, the Part D QIC's drug benefit reconsiderations to determine whether a motion for review should be sent to the Council.
- Case file handling and storage.
- Various administrative services related to the Part D appeals process, which includes developing reports for CMS for program oversight and review of data for analytic purposes, pursuant to CMS direction.

3.1 SOURCES OF INFORMATION ABOUT PART D QIC RECONSIDERATION PROCEDURES

3.1.1 Medicare Part D QIC Project Website

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

- Part D QIC Reconsideration Procedures Manual
- Prescription Drug and LEP Reconsideration Request Forms
- Prescription Drug and LEP Case File Transmittal Forms and Case Narrative Forms
- Status of pending and processed appeals
- Enrollee-specific FAQs and instructions
- Prescriber/pharmacist-specific FAQs and instructions
- Plan-specific FAQs and instructions
- Links to relevant laws, regulations and policies
- Links to resources/information from CMS
- Publications/newsletters, as required and approved by CMS
- Conference Information and Presentations, as required by CMS
- Link to a searchable website database of Part D QIC Drug Benefit reconsideration decision rationales
- Link to the QIC portal for submission of appeal requests, plan case files and appeal related documents

The C2C Part D QIC website can be found at <https://PartDAppeals.C2Cinc.com>

3.1.2 C2C Part D QIC Conferences

The Part D QIC may participate with CMS in hosting annual or periodic conferences regarding the Part D benefit and administrative appeals. Conference information will be posted on the C2C Part D QIC website.

3.1.3 Part D QIC Newsletters

The Part D QIC may publish newsletters, as required and approved by CMS, which address issues specific to Part D QIC reconsiderations. Any newsletters published will be made available for downloading on the C2C Part D QIC website.

3.2 ESTABLISHING POINTS OF CONTACT FOR PART D PLANS

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

The Part D QIC requires each Part D plan to complete, update as needed, and submit to the QIC a *Plan Contact Form* identifying POCs for Drug Benefit appeals and LEP appeals. This form requires Part D plans to supply information, such as phone numbers, fax numbers and email addresses, and designate one key organization contact and an alternate for communications with the Part D QIC regarding Drug Benefit appeals and LEP appeals. If the plan has different POCs for Drug Benefit appeals or LEP appeals the plan should complete a separate *Plan Contact Form* identifying a POC for each of these departments. Part D plans that offer more than one plan must complete a separate *Plan Contact Form* for each CMS approved plan.

The Part D plan POC designated in the *Plan Contact Form* for Drug Benefit and/or LEP appeals is the individual C2C will request case files from for reconsiderations that are filed with the QIC and the individual to whom decisions letters will be faxed. This is the individual C2C will contact if there are general issues in working with the plan or significant case-specific issues. The Part D plan should use the Part D QIC Plan Liaison to initiate contact with the Part D QIC to resolve any problems or concerns the Part D plan has with regard to the reconsideration process.

Instructions for completing the *Plan Contact Form*: This form is housed on the C2C Part D QIC website and is available for downloading. It is a PDF fillable form. Entries should be typed in the provided fields; freehand should not be used. Any updated forms should be submitted by email to C2C at the email address at the bottom of the form - MedicarePartDAppeals@c2cinc.com no more than 14 days prior to the date the changes will go into effect. No changes will be made without the submission of a completed Contact Form.

3.2.2 Designation of an individual reconsideration case contact

The Part D plan must designate a Case Contact on the *Part D QIC Drug Appeal Case File Transmittal Form (Drug Case File Transmittal Form)* submitted by the plan pursuant to a case file request from the Part D QIC. The plan may but is not required to use the POC identified in the *Plan Contact Form* as the designated Case Contact for the specific case file submitted for each appeal. The plan may vary the Case Contact from case to case. The individual designated as Case Contact will be the individual to whom the Part D QIC directs case specific questions during the adjudication process.

3.2.3 Parent plans responsibility for inactive plans

Parent plans are responsible for maintaining and submitting case files for plan contracts that are no longer operational. For example, the Part D QIC may request a case file for a LEP imposed by an inactive plan, to the parent plan. This includes LEP Notification Letters from any inactive plan, which is necessary for the Part D QIC to make a timeliness of appeal calculation.

3.3 SEEKING INFORMATION ABOUT CASES

3.3.1 Hours of operation

The Part D QIC will respond to inquiries and return calls to enrollees and plans on Monday through Friday from 8:00 AM to 4:30 PM EST. Messages left will be returned within 24 business hours of receipt. Case file requests may be made seven days a week since reconsiderations may be processed seven days a week.

The Part D QIC's offices will be closed on the following holidays:

- New Year's Day (first weekday in January)
- Memorial Day (last Monday in May)
- Independence Day
- Labor Day (first Monday in September)
- Thanksgiving Day (fourth Thursday in November)
- Friday after Thanksgiving Day
- Christmas Eve (December 24)
- Christmas Day (December 25)

If Independence Day falls on a Saturday, it is observed the preceding Friday; if it falls on a Sunday, it is observed the following Monday.

If Christmas falls on a Saturday, the two weekdays prior are observed. If it falls on a Sunday, the two weekdays following are observed.

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

For inquiries about the processing status of a specific case, or group of cases, the plan POC or plan Case Contact should email the Part D QIC Plan Liaison. Alternatively, plans can use the Medicare Part D QIC website to determine the status of pending or processed appeals. The Part D QIC website can be found at <https://PartDAppeals.C2Cinc.com>.

Plans are encouraged to use the Plan Liaison for assistance on any issues concerning the processing of Part D reconsiderations. Plans are encouraged to reach out to the Plan Liaison to inform and coordinate with the QIC when submitting auto-forwarded appeals due to untimely decisions at the coverage or redetermination levels. Providing the QIC with advance notice of a

large number of auto-forwarded cases helps the QIC plan for seamless processing.

For enrollee inquiries about the processing status of a specific case file, the caller may use the QIC website to determine to the status of a pending or processed drug benefit appeal or call the Part D QIC's toll-free telephone number and leave a message. The QIC typically returns calls within 24 business hours.

Due to privacy issues, the Part D QIC will provide case status and limited information only to those authorized to obtain such information.

Part D plans are responsible for supporting their enrollees in the reconsideration process. Plans should not direct their enrollees to the Part D QIC for routine case status inquiries. Plans may assist their enrollees by providing information on the status of a given case by querying the QIC website on their behalf. Enrollees seeking general information regarding the Medicare appeals process or resources for assistance in the appeals process may be referred to 1-800-MEDICARE or <https://www.medicare.gov>.

The Part D QIC email address is also available to plans for reconsideration processing issues and/or information at: MedicarePartDAppeals@C2Cinc.com.

Please note that reconsiderations may **not** be requested via email or phone call. Appeal requests must be submitted in writing by mail, fax, or the C2C web portal.

3.4 FIVE-DAY PERIOD NOTICE MAILING RULE

For purposes of timely filing for LEP reconsiderations, C2C allows five days from the date of the plan notification letter beyond the 60-day requirement for timely filing. Therefore, in the absence of evidence to the contrary as to date of receipt, C2C allows five days for mailing of appeal requests. If an appeal request is received after 65 calendar days from the date of the plan notification, the appeal is considered late unless good cause is established.

The five-day mailing rule does not apply to prescription drug benefit appeals. For purposes of timely filing for prescription drug benefit appeals, C2C must receive the appeal request within 65 calendar days of the date of the plan written notice unless there is good cause.

3.5 SUGGESTIONS AND COMPLAINTS

Please feel free to provide any suggestions for improvement or complaints to any C2C staff member who is interacting with you, or to the C2C Program Director or to any other Part D QIC Key Contact noted in this manual. C2C management endorses and follows a formal process for addressing complaints and suggestions. This process enables us to identify opportunities for continuous improvement and initiate corrective and preventive actions as necessary.

4. BACKGROUND – IMPORTANT CONSIDERATIONS FOR PLAN LEVEL DRUG APPEAL 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 subparts M and U, in CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, and in various policy and guidance documents issued by CMS and available in the Health Plan Management System (HPMS) and/or on CMS's website at <https://www.cms.gov/>

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

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

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

4.1 COVERAGE DETERMINATIONS

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

4.1.1 Definition of a coverage determination

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

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

1. A decision not to provide or pay for a Part D drug that the enrollee believes may be

- covered by the plan. Denial reasons include:
- a. Drug not medically necessary
 - b. Drug not on plan formulary
 - c. Drug furnished by out-of-network pharmacy
 - d. Drug excludable under § 1862(a) of the Act as applied to Medicare Part D
 - e. The enrollee did not satisfy a drug utilization management requirement
2. A failure on the part of the Part D plan to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee.
 3. An adverse decision concerning an exceptions request to a plan's tiered cost-sharing structure.
 4. An adverse decision concerning an exceptions request for a non-formulary Part D drug. Denial reasons include:
 - a. Non-formulary drug is not medically necessary because the plan formulary covers drugs that are medically appropriate for the 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 a plan formulary change in coverage, e.g., previously covered drug has been removed from the plan formulary
 5. A decision on the amount of cost sharing for a drug that the enrollee believes is incorrect.

4.1.2 Who can request a coverage determination?

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

1. The enrollee
2. The enrollee's appointed representative
3. The prescribing physician or other prescriber on behalf of the enrollee
4. Staff of prescribing physician's office acting on physician's behalf
5. An entity authorized under state or other applicable law to represent Medicare beneficiaries in the appeals process

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

A prescribing physician or other prescriber may request a standard or expedited coverage

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

4.1.3 Standard requests

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

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

For retrospective requests, the Part D plan must notify the enrollee of its determination and make payment (when applicable) no later than 14 calendar days after receipt of the request

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

4.1.4 Expedited coverage requests

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

An enrollee or an enrollee’s prescribing physician or other prescriber acting on behalf of the

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

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

For expedited requests made by an enrollee's prescribing physician or other prescriber, the Part D plan must provide an expedited determination if the physician "indicates" and provides a supporting statement explaining that applying the standard timeframe may seriously jeopardize the enrollee's life, health or ability to regain maximum function. The term "indicates" should not be limited in scope to mean "shows" or "demonstrates" in a definitive manner, but rather should be construed more broadly to mean to "suggest" the necessity of or to "give evidence of." The Part D plan is required to grant and provide an expedited coverage determination even if the Part D plan disagrees with the physician's statement that standard timeframes 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. The plan must give the enrollee and his or her prescribing physician or other prescriber prompt oral notice of the denial, which includes the enrollee's rights (described below), and subsequently deliver (i.e., send by mail) to the enrollee, within three calendar days, a written letter of the enrollee's rights that:

1. Explains that the Part D plan will automatically transfer and process the request using the 72-hour timeframe for standard determinations
2. Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the plan's decision not to expedite the determination
3. Informs the enrollee of the right to resubmit a request for an expedited determination and that if the enrollee gets his or her prescribing physician's or other prescriber's support indicating that applying the standard timeframe 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
4. Provides instructions about the expedited grievance process and its timeframes

If a Part D plan approves a request for an expedited determination, it must provide a determination and notify the enrollee (and the prescribing physician or other prescriber as appropriate), whether favorable or unfavorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. For requests involving formulary or tiering exceptions, the 24-hour timeframe begins when the Part D plan receives the physician's or other prescriber's (written or oral) supporting statement. The Part D plan may notify an enrollee of an adverse expedited determination orally, but if it does so, it must mail

written confirmation to the enrollee within three calendar days of the oral notification. If a Part D plan orally notifies an enrollee's physician or other prescriber of an adverse determination, it does not need to provide written notice to the physician or other prescriber. However, if the plan does not provide oral notice of an adverse determination to the physician or other prescriber, then the plan must provide written notice to both the enrollee and the enrollee's prescribing physician or other prescriber.

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

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

The Part D QIC will examine each appeal request that is received to determine if the request is for review of an adverse coverage determination or At-Risk Determination. The Part D QIC will dismiss those appeal requests that do not involve adverse coverage determinations, redeterminations or At-Risk Determinations, and will remand those disputes to the Part D plan for proper processing under the plan's grievance procedures. Complaints or disputes that do not involve coverage determinations are not properly appealable under 42 CFR Part 423.

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

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

If the Part D plan fails to notify the enrollee within the timeframes 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 timeframe. The Part D plan may send these records by fax, overnight mail or by any other means that ensures timely delivery.

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

policies, as applicable, and subscriber materials detailing the benefits offered. Please refer to §6.1 of this manual for direction on requirements for auto-forwarded case files.

4.2 DMP AT-RISK DETERMINATIONS

The Comprehensive Addiction and Recovery Act (CARA) of 2016 contained provisions permitting Part D plans to establish DMPs for beneficiaries who are at-risk of misuse or abuse of frequently abused drugs (FADs). In a final rule (CMS-4182-F) published in the Federal Register on April 16, 2018, CMS established the framework under which Part D plans may implement a DMP. This rule codified the retrospective Part D Opioid Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) with adjustments as needed to comply with CARA by integrating them with the DMP provisions at 42 CFR §423.153(f). While DMPs are currently voluntary, the CMS regulations place requirements on DMPs when established by Part D plans.

The goal of all DMPs is to address overutilization of FADs while maintaining access to such drugs as medically necessary. DMPs will review potential at-risk beneficiaries (PARBs) who meet OMS criteria. Under the DMP program, plans will engage in case management of PARBs through contact with their prescribers to determine if a beneficiary is at-risk. After providing notification to beneficiaries who are determined to be at-risk, plans may then limit the at-risk beneficiaries' (ARBs') access to coverage of FADs for their safety to a selected network prescriber(s) (when applicable) and/or network pharmacy(ies), or through a beneficiary specific point of sale (POS) claim edit for the safety of the ARB. In general, the beneficiary may select the prescriber and pharmacy.

At-Risk Determinations includes decisions made under a Part D plan's DMP under the rules contained in 42 CFR §423.153(f). At-risk determination decisions involve:

1. Identification of an individual as an at-risk enrollee for prescription drug abuse
2. A limitation, or the continuation of a limitation, on access to coverage for FADs (i.e., an enrollee specific point-of-sale (POS) edit or the selection of a prescriber and/or pharmacy for purposes of lock-in)
3. Information sharing for subsequent Part D plan enrollments

At-Risk Determination decisions are subject to the existing Part D drug appeals process and timeframes as described in the CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance §40 and 42 CFR §423.153(f). If an enrollee disagrees with an At-Risk Determination made by a plan, the enrollee has the right to request a redetermination.

Beginning January 1, 2021, if a Part D plan upholds its At-Risk Determination on appeal, the plan is required to automatically forward the case to the Part D QIC for review. For additional information and requirements on Part D plan DMPs, including the beneficiary notification process and appeals process, see the 2021 Part D Drug Management Program Guidance, issued by CMS on December 23, 2020, with an implementation effective date of January 1, 2021, and subsequent

guidance issued via CMS Health Plan Management System (HPMS) memo.

4.3 EXCEPTIONS REQUESTS

Exceptions requests are coverage determination requests pursuant to 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. Exceptions requests may be decided within standard or expedited adjudicatory timeframes. In addition, exceptions requests may involve a request for a benefit not received (prospective request) or a request for payment for a benefit already furnished (retrospective request).

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

If the enrollee submits an exceptions request without a prescribing physician's or other prescriber's supporting statement, the Part D plan must contact the prescribing physician or other prescriber, or both, and request the supporting statement. A Part D plan is not required to begin processing an enrollee's exceptions request until the enrollee's prescribing physician or other prescriber provides a supporting statement. If the Part D plan does not receive the supporting statement within 14 calendar days after receipt of the request, the Part D plan should not dismiss the request, but rather should issue an unfavorable determination based on insufficient evidence.

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

The Part D QIC will examine the record de novo to determine whether: 1) The Part D plan properly applied its own exceptions process/criteria in evaluating the exceptions request; and 2) Made an appropriate determination of medical necessity in accordance with its criteria and CMS rules. The Part D QIC will conduct an independent medical review when making its determination.

4.3.1 Tiering exception requests

Part D plans that manage the Part D benefit through the use of a tiered formulary are required to establish and maintain exceptions procedures that are subject to CMS's approval. A Part D plan is

required to grant an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the provisions contained in 42 CFR §423.578(a)(4).

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

4.3.2 Formulary exceptions requests

Part D plans that manage the Part D benefit through the use of a formulary are required to establish and maintain exceptions procedures, subject to CMS approval, to ensure that enrollees have access to Part D drugs that are not included on the plan formulary. A Part D plan is required to grant an exception whenever it determines that the drug is medically necessary, consistent with the provisions in 42 CFR §423.578(b)(5) and CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, 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
3. A therapeutic substitution requirement

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

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

1. All covered drugs on any tier of the formulary would not be as effective as the non-formulary drug, and/or would have adverse effects for the enrollee
2. The number of doses available under a dose restriction for the prescription drug:
 - a. Has been ineffective in treating the enrollee, or
 - b. Based on sound clinical, medical and scientific evidence, and the known physical or mental characteristics of the enrollee and the known characteristics of the drug

- regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or
3. The prescription alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:
 - a. Has been ineffective in treating the enrollee's disease or condition, or based on sound clinical, medical and scientific evidence and the known physical or mental characteristics of the enrollee and the known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance, or
 - b. Has caused, or based on sound clinical, medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee

4.3.3 Supporting statements for exceptions requests

The initial supporting statement from the prescribing physician or other prescriber may be oral. However, a Part D plan may require the prescriber to submit a written statement demonstrating medical necessity, in accordance with 42 CFR §423.578(a)(4) and (b)(5), if the plan determines the oral statement does not sufficiently demonstrate the medical necessity of the requested drug. The plan may also request additional supporting medical documentation as part of the follow-up written statement. If the Part D plan requires a written statement from the prescriber, it must request this statement immediately. The plan's request must explicitly state that the prescriber is required to indicate that the required drug is medically necessary pursuant to the exceptions criteria for tiering exceptions and/or formulary exceptions, as set forth 42 CFR §423.578(a)(4) and (b)(5). If the Part D plan requires the prescribing physician or other prescriber to submit a written supporting statement following the oral statement, the adjudication timeframe begins when the Part D plan receives the prescriber's written supporting statement. If the Part D plan does not request a written supporting statement, the timeframe begins when the oral supporting statement is received.

4.3.4 Prior Authorization (PA) and other Utilization Management (UM) Requests

When a plan processes a coverage request that involves a prior authorization (PA) or other utilization management (UM) requirement, such as step therapy for Part B drugs, the Part D plan's determination on whether to grant approval of a drug for an enrollee constitutes a coverage determination and is subject to appeal.

The rules require the Part D plan to determine whether a request that involves a PA edit or other UM requirement is either a coverage determination request where an enrollee is attempting to satisfy a PA requirement or an exceptions request where the enrollee is asking the plan to waive the PA or other UM requirement.

If a Part D plan denies coverage of a drug because the enrollee failed to seek PA or failed to comply with similar limits on coverage, the denial also constitutes an initial determination and is

subject to appeal. The adjudication timeframe, notice, and other requirements applicable to coverage determinations under 42 CFR Part 423 Subpart M apply to requests that involve a PA or other UM requirement in the same manner that they apply to all coverage requests.

If an enrollee requests coverage of a service, item or drug that involves PA, the Part D plan must accept and process the request as a coverage determination and should contact the physician or prescriber for information needed to satisfy the PA.

If an enrollee requests the Part D plan waive the PA or UM requirement, then the Part D plan must process the request as an exceptions request.

4.4 REDETERMINATIONS

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

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

For a complete discussion on Part D plan level redeterminations, the Part D plan should refer to CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance §50.

4.4.1 Standard redeterminations

To request a standard redetermination, the enrollee or the enrollee's representative must file a written request with the Part D plan, or an oral request if permitted by the plan, within 65 calendar days from the date of the notice of the coverage determination. Plans may accept a request for a standard or expedited redetermination after the 65-day timeframe if a filing party shows good cause. A request to file a redetermination after the timeframe must be in writing and state why the request for a redetermination was not filed on time. If an untimely appeal request does not include an explanation as to why the request wasn't filed timely, the plan may make an attempt to obtain information supporting good cause for the late filing.

The prescribing physician or other prescriber may appeal on behalf of the enrollee for a standard and expedited redetermination request. Note that under 42 CFR §423.580, a prescribing

physician or other prescriber may request a *standard* redetermination on an enrollee's behalf only after he or she has provided notice to the enrollee that he or she is making the appeal request. If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan must provide notice to the prescriber and written notice to the enrollee.

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 15 calendar days from the date the plan receives the request for a standard redetermination. For adverse standard redetermination requests involving payment for services already furnished, the Part D plan must notify the enrollee of its redetermination in writing no later than 14 calendar days from the date it receives the request for a standard retrospective redetermination. For favorable standard redetermination requests involving payment, the Part D plan must issue its redetermination no later than seven 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 CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

4.4.2 Expedited redeterminations

Requests to Part D plans for expedited redeterminations must be filed with the plan within 65 calendar days from the date of the notice of the coverage determination. Plans may accept a request for a standard or expedited redetermination after the 65-day timeframe if a filing party shows good cause. A request to file a redetermination after the timeframe must be in writing and state why the request for a redetermination was not filed on time. If an untimely appeal request does not include an explanation as to why the request wasn't filed timely, the plan may make an attempt to obtain information supporting good cause for the late filing.

These requests may be written or oral, and may be requested by the enrollee, the enrollee's representative, or the prescribing physician or other prescriber acting on behalf of the enrollee. As noted above, the prescribing physician or other prescriber does not need to obtain an AOR for a redetermination request. For expedited requests submitted by the enrollee, the prescribing physician or other prescriber may, but is not required to, provide oral or written support on behalf of the enrollee.

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

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

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

1. Explains that the Part D plan will automatically transfer and process the request using the 72-hour timeframe for standard determinations
2. Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the Part D plan’s decision not to expedite the determination
3. Informs the enrollee of the right to resubmit a request for an expedited determination and that if the enrollee gets his or her prescribing physician’s or other prescriber’s support indicating that applying the standard timeframe 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
4. Provides instructions about the expedited grievance process and its timeframes

If a Part D plan approves a request to expedite, it must notify the enrollee of its redetermination as expeditiously as the enrollee’s health requires, but not later than 72 hours from the date the plan receives the request for an expedited redetermination. The Part D plan may notify the enrollee of its decision orally, so long as it sends an equivalent written notice to the enrollee within three 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 CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

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

If the Part D plan fails to notify the enrollee within the timeframes 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

timeframe. The Part D plan may send these records by fax, overnight mail, through the C2C QIC D portal, or by any other means that ensures timely delivery to the Part D QIC.

Please note that it is crucial for Part D plans to send a copy of the case file, even though the case file may be incomplete, since the Part D QIC is obligated to render a determination on the request. The plan should explain why it was not able to timely complete the determination, and should identify missing information and any outstanding information requests. Please refer to §6.1 of this manual for direction on requirements for auto-forwarded case files.

The Part D QIC requires plans contact the Plan Liaison directly at MedicarePartDAppeals@C2Cinc.com to inform the QIC prior to submitting any large volume auto-forward cases. No more than 20 auto-forward cases should be submitted within a 24-hour period without QIC approval.

4.4.4 Transition from pre-benefit redetermination to retrospective redetermination

When processing a standard pre-benefit redetermination, if a Part D plan sponsor learns—by any means, including through receipt of a claim or reimbursement request—that the enrollee has obtained the drug that is the subject of the appeal, the sponsor must continue to adjudicate the appeal request and issue a substantive redetermination decision in accordance with 42 CFR Part 423, Subpart M. A Part D plan sponsor may not dismiss an otherwise valid and timely appeal request solely because the enrollee is receiving or has already received the drug at issue. Dismissals are permitted only for the reasons specified at 42 CFR § 423.582(e).

If applicable, the plan sponsor must separately process and issue a decision on any related claim or reimbursement request associated with the drug.

If the plan sponsor does not learn that the initially prospective request has become retrospective until after the case file has been forwarded to the Part D QIC, the QIC will, upon receiving information that the drug has been obtained, continue processing the appeal and issue a substantive reconsideration decision consistent with 42 CFR Part 423, Subpart M. Any related claim or reimbursement request will be addressed through a separate determination.

4.5 NOTICE FOR FORMULARY CHANGES

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

The Part D plan is required to provide direct written notice to “affected” enrollees at least 60 calendar days prior to the change. An affected enrollee is a plan enrollee who is currently taking the covered Part D drug that is either being removed from the plan’s formulary or is subject to a

change in its preferred or tiered cost-sharing status. To the extent that the Part D plan does not give the mandatory 60-day (calendar day) advance notice, the plan will be required to provide the notice and provide a 60-day supply of the drug 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 (calendar day) window either to switch to a therapeutically appropriate alternative medication, or access the Part 423 appeals process prior to the change becoming effective.

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

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

4.6 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. Under the rules, the enrollee, the enrollee's properly appointed or authorized representative, enrollee's prescribing physician, or other prescriber are permitted to make a request for a standard or expedited coverage determination, a standard or expedited redetermination, or a standard or expedited reconsideration with the Part D QIC.

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

4.6.1 Appointed Representatives

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

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

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

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

- Identifies the name, address, and phone number of the enrollee
- Identifies the enrollee's Medicare number
- Identifies the name, address and telephone number of the individual being appointed
- Contains a statement that the enrollee is authorizing the representative to act on his or her behalf for the claim(s) at issue, and a statement authorizing disclosure of individually identifying information to the representative
- Contains the signature of the enrollee making the appointment, and the date signed
- Contains the signature of the individual being appointed as representative, accompanied by a statement that the individual accepts the appointment, and the date signed

Note that all of these fields must be completed in full. When a person claiming to be a representative files a request for a coverage determination or redetermination, he or she must include a signed form or statement showing valid representation status. There is an exception for the incompetent or incapacitated enrollee 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 Part D plan must document its reasonable efforts to obtain the requisite form or statement. The plan's adjudicatory timeframe does not begin until the plan receives a properly executed appointment form or equivalent. However, the Part D plan may choose to begin the process for review, which may include requesting medical documentation in a case that will involve medical necessity review. If the plan does not receive a properly executed appointment document by the conclusion of the applicable timeframe, plus any applicable extension, the plan should dismiss the request on the basis that the appealing party is not a proper party under Part 423. The plan must mail or transmit a written dismissal notice to the enrollee and to the person asserting representative status. The dismissal should state 1) the reason for the dismissal; 2) the right to request that the plan vacate the dismissal; and 3) the right to request review of the dismissal. The notice should also explain how the invalid request can be cured and that the request will be processed if the enrollee or asserting representative submits a properly executed form.

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

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

Healthcare proxy instruments typically are springing instruments. These instruments are triggered when an individual loses competence or capacity to make healthcare decisions on his or her own behalf. Again, each state's laws differ, and the Part D plan must consult the applicable state law to determine whether the appellant who presents as a healthcare proxy is a valid representative

under state law for appeal purposes under Part 423. As noted above, the Part D plan should not require a representative who is a valid healthcare proxy under state law to execute an AOR form that makes the same appointment.

Conversely, it would not be appropriate for the Part D plan to permit the same individual (designated as a healthcare proxy) to initiate an appeal without obtaining an AOR if the enrollee remains competent to make his or her own healthcare decisions. This is because the triggering event of incompetency or incapacity has not yet occurred.

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

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

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

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

4.6.2 Individuals (or entities) authorized under state law to act as surrogates on behalf of incompetent or incapacitated enrollees

An individual who becomes incompetent or incapacitated, and has not previously executed an instrument of representation (and does not have a court-appointed guardian), does not lose the right to appeal adverse determinations regarding drug benefits under Part 423 simply by virtue of these circumstances. These individuals, though unable to act on their own behalf, are legally entitled to request coverage determinations and to appeal Part D plan denials for drug benefits.

For these individuals, when a would-be representative initiates a request for a coverage determination or appeal, the Part D plan is required to ascertain whether the representative is a valid surrogate under state law, and hence a valid party for appeal purposes under Part 423 rules.

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

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

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

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

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

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

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

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

The distinction between representation and support includes any of the following elements:

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

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

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

4.7 VALIDATION OF ELIGIBILITY OF APPEAL

The Part D plan must determine whether a complaint or dispute is a request for a coverage determination or constitutes a grievance. Actions that constitute coverage determinations are defined in a previous section. 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 CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, for a detailed discussion on distinguishing between complaints that are coverage determinations and complaints that are grievances. On reconsideration review, the Part D QIC will examine the complaint to ensure that it constitutes an appealable issue. If the complaint does not present an appealable issue, the Part D QIC will dismiss the appeal request and remand the case to the Part D plan for processing under the plan's grievance procedures. If a reconsideration request contains both an appealable issue and a grievance, the Part D QIC will issue a decision on the appealable issue and dismiss the grievance and remand to the plan for processing.

4.8 IDENTIFICATION OF APPEAL CLASSES AND TYPES

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

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

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

4.9 RESPONSIBILITY TO CONDUCT A FULL AND MEANINGFUL DETERMINATION

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

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

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

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

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

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

5.1 CASES THAT MUST BE SUBMITTED TO THE PART D QIC

An enrollee who has received an adverse redetermination for a medication has the right to request that it be reconsidered by the Part D QIC. Requests for reconsideration review may be standard (either prospective or retrospective), or expedited (prospective only). The enrollee or the enrollee's representative, or an enrollee's prescribing physician or other prescriber may submit a request for reconsideration by filing a signed written request with the Part D QIC within 65 calendar days from the date of the notice of the redetermination. The 65-day timeframe for filing may be extended if the Part D QIC finds that the appealing party has demonstrated good

cause for the late filing. The CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, sets forth examples of circumstances that constitute good cause. The decision of the Part D QIC whether or not to grant an extension for good cause is final and not subject to appeal.

The Part D QIC, upon receipt of a request for reconsideration review, will fax a *Part D QIC Case File Request Form (Drug 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. The form contains various identifiers, which will permit the plan to accurately identify the associated case file. In the event the Part D plan cannot identify the appeal and associated case file, the Part D plan must immediately contact the Part D QIC 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 seven-day per week basis. The Medicare law and rules mandate that drug appeal reconsideration reviews generally be completed no later than 72 hours for expedited requests and seven calendar days for standard requests. Given the very short decision-making timeframes and that substantive review cannot be undertaken without the case file, the Part D QIC will request a case file as soon as possible after it receives a request for reconsideration review.

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

The Part D plan also must submit drug appeal cases in which it has not made a decision within the applicable decision timeframe. These cases are auto-forwarded by the plan and are not requested by the Part D QIC. The Part D plan must submit any information submitted with the request, along with other information that is relevant from processing the coverage determination or redetermination to the Part D QIC at the time of auto-forwarding. 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 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 timeframe 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.

Beginning January 1, 2021, the Part D plans will be required to auto-escalate any case files to the QIC for reconsideration review that involve an adverse DMP At-Risk Determination made under the rules in 42 CFR §423.153(f). The Part D plan is required to submit general information regarding its DMP, as well as specific information relative to case management of the at-risk beneficiary. This information includes, but is not limited to, information from previous plans regarding the enrollee, steps taken to determine level of risk, prescriber communications, notifications sent to the enrollee and prescriber, and specific limitations (prescriber and/or pharmacy) and point of sale edits implemented for safety.

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

The Part D QIC must receive case files for expedited drug appeal reconsideration requests within 24 hours from the time that the Part D plan receives a request to produce and forward a specific case file. The Part D QIC must receive case files for standard drug appeal reconsideration requests within 48 hours from the time that the Part D plan receives a request to produce and forward a specific case file. As noted above, the Part D plan receives a request for a case file when it receives a successfully transmitted fax at its office, or a telephone call or email. The Part D plan may forward the case file by fax, overnight mail, the C2C appeals portal 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 timeframe, the Part D plan must auto-forward both the request and the case file within 24 hours of the expiration of the plan's adjudicatory timeframes. The Part D plan may forward the case file by fax (C2C has a dedicated auto-forwarded fax line), overnight mail, the C2C appeals portal or any other means so long as the plan is able to track the shipment. For adverse DMP at-risk determinations, the Part D plan must also auto-forward the appeal request and case file to the Part D QIC.

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 timeframe begins when it receives a valid request for reconsideration. The Medicare law does not permit the Part D QIC to extend its decision-making timeframes for case files that are not submitted timely.

When the case file is not submitted timely, the Part D QIC must make its decision based on the information on hand. For drug appeals, this may include the reconsideration request, any additional information submitted by the appealing party or prescribing physician or other prescriber, statements the Part D QIC has solicited from the prescribing physician or other prescriber, and information in the Health Plan Management System (HPMS).

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

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

5.3.1 Content and Organization of the Case File

5.3.2 Additional Guidance on Selection and Inclusion of Records

5.3.1 Content and Organization of the Case File

Case files can be submitted to the Part D QIC by mail, fax or through the C2C web portal.

C2C has four dedicated fax lines for drug benefit appeals:

- Standard appeals (case files and appeal related documents) - (904) 539-4097
- Expedited appeals (case files and appeal related documents) - (904) 539-4093
- Auto-forwarded appeals (case files for untimely plan coverage determinations/redeterminations and DMP at-risk determinations) - (904) 539-4099
- Effectuations - (904) 539-4101

When submitting case files in response to a request for the case file from the Part D QIC, the Part D plan must include the *Drug Case File Request Form* as the cover page, followed immediately by the *Drug Case File Transmittal Form* and the *Drug Appeal Case Narrative Form*. Including these forms in the order requested greatly facilitates efficient intake and processing by the Part D QIC.

The *Drug Case File Transmittal Form* and the *Drug Appeal Case Narrative Form* are available for downloading from the C2C website. These forms are the Part D plan's main working tools for submitting case files to the Part D QIC.

The *Drug Case File Transmittal Form* is self-explanatory and must be completed in full by the Part D plan. Included in this form are crucial identifiers for reconsideration processing, such as the plan contract number, plan ID number or formulary ID number, and the plan type. The Part D QIC needs this information to access the Part D plan's formulary in the HPMS, as applicable. Additionally, the form requires the Part D plan to provide various data elements and information about the appeal at the plan level of review. This information is needed to facilitate accurate entry of required data into the CMS Medicare Appeals System (MAS).

For auto-forwarded case files where the Part D plan has failed to timely decide within its adjudicatory timeframe, or for appeals involving DMP At-Risk Determinations, Part D plans are strongly encouraged to use C2C's dedicated fax line for auto-forwarded appeals: 904-539-4099. Using this designated fax line versus submitting by mail or through the C2C portal will greatly assist C2C in the processing of these appeals.

PART D QIC DRUG APPEAL RECONSIDERATION PROCESS

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

- 6.1 The Part D QIC Case Processing Time Standards
- 6.2 Administrative Case Intake
- 6.3 Policies on Communication with Part D plans and Appellants during Case Processing
- 6.4 Adjudicator Case Review
- 6.5 Physician Review
- 6.6 Requests to Part D Plan for Additional Information
- 6.7 The Part D QIC Reconsideration Notices
- 6.8 Enrollee Requests for Case Files
- 6.9 Part D Plan Dismissal Processing and 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.

Appeal Priority	Maximum Adjudication Timeframe
Expedited	72 hours
Standard Coverage (pre-service)	7 calendar days
Standard Payment (retrospective)	14 calendar days

The Part D QIC's adjudicatory timeframe 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 by mail, fax or through the C2C portal. Email requests will not be accepted. Faxes and portal submissions are received when successfully transmitted. Mailed submissions are received when the mail is delivered to and received by the Part D QIC's Operations Department.

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

1. Enrollee's name
2. Enrollee's Medicare number
3. Identification of the item for which Reconsideration is requested, e.g., the prescription drug, including dose and quantity

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

6.6.2 Request for Information process

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

- The Adjudicator identifies a deficiency and checks the case file to verify that the information is, in fact, absent
- The Adjudicator requests the information by faxing a Request for Information Form (RI) to the fax number provided for the Case Contact on the *Drug Case File Transmittal Form* or by calling the Case Contact
- The Part D plan Case Contact calls the Part D QIC if there are any questions about the RI
- The Part D plan Case Contact develops the RI response and submits the response to the Part D QIC within the timeframe specified on the RI form
- The Adjudicator reviews the RI response and incorporates the information into the reconsideration case file
- If the RI response is insufficient, the Adjudicator contacts the Plan Contact if time permits

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

The Part D plan may transmit personally identifiable health information to the Part D QIC if the plan transmits the information to one of our dedicated and secure fax lines or through the web portal. Alternatively, the Part D plan may send documents containing such information by overnight mail. The Part D plan should not send confidential information by email. Please note that due to the abbreviated timeframes for reconsideration review, fax transmission (or use of the portal during QIC business hours) is the preferred approach.

Whether submitted by fax, portal or overnight mail, the Part D plan should place the *Request for Information Form* on top of the plan's RI response. If the Part D plan places more than one RI response in a mailed package, it should separate each response with the appropriate RI Form.

6.7 THE PART D QIC RECONSIDERATION NOTICES

6.7.1 The Part D QIC Reconsideration determination definitions

Upon completion of its Reconsideration, the Part D QIC issues a "reconsideration determination"

notice to the enrollee or his or her appointed representative, or to the enrollee and the treating prescriber for appeals filed by a prescriber on behalf of the enrollee. The general categories of the Part D QIC Reconsideration determination notices include:

"Unfavorable"

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

"Favorable"

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

"Partially Favorable"

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

"Dismissal: Enrollee Requests Withdrawal"

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

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

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

"Dismissal: Grievance"

The Part D QIC has determined that one or more of the issues in dispute are grievances with the Part D plan or other entity, as defined by CMS in Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance, which the QIC does not have jurisdiction to make a decision upon. Grievances are remanded back to the plan for handling through their internal grievance process.

"Dismissal: Dismiss Request to Reopen"

The Part D QIC has determined that there was no new information provided or other good cause for the QIC to reopen and issue a revised reconsideration.

6.7.2 General characteristics of the Part D QIC reconsideration notices

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

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

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

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

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

6.8 ENROLLEE REQUESTS FOR CASE FILES

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

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

6.9 PART D PLAN DISMISSAL PROCESSING AND APPEALS

Effective January 1, 2022, Part D Plans are required—when dismissing an appellant's redetermination request—to inform the appellant about the right to request reconsideration review of the dismissal to the Part D QIC and to provide the applicable reconsideration request form for filing for review at the reconsideration level. Note: There is only one level of appeal/review of plan dismissals. If a plan dismisses an initial determination (i.e., coverage determination level) and the enrollee requests an appeal that the plan reviews and upholds, the enrollee cannot then request that the IRE also review the plan's dismissal of the initial determination request. In addition to the right to one level of appeal for plan dismissals, an enrollee also has the right to ask the plan to vacate its dismissal action.

The enrollee or other party may request review of the Part D plan's dismissal by filing a written request for review with the Part D QIC within 65 days of receiving the Part D Plan's notice of dismissal. The enrollee or other party requesting review of the dismissal must provide evidence sufficient to refute the basis for the dismissal.

In the event a request for reconsideration of a plan dismissal is not received timely (i.e., more than 65 days after the appellant's receipt of the plan's notice of dismissal), the QIC will dismiss the request in the absence of good cause.

6.9.1 Part D Plan dismissal case file requests

The process and timeframe for case file requests and transfer of case files is the same as drug benefit appeals. See sections [5.2](#) and [5.3](#). Additionally, the plan should include any documentation of attempts made by the plan to have the appealing party correct any appeal request deficiencies.

6.9.2 Content of plan case file to be submitted to the Part D QIC

The Part D Plan must follow the same directions for dismissals as for any other prescription drug benefit appeal, as set forth in [section 5.3](#). When a case file is requested pursuant to an appeal for dismissal review, the Part D plan must complete and return the *Reconsideration Case File Request Form*, the *Part D Prescription Drug Case Transmittal Form* and the *Part D Prescription Drug Case Narrative Form* for each case file requested and in the order as set forth in [section 5.3](#) (i.e., *Reconsideration Case File Request Form* on top). For auto-forwarded cases, the Part D plan must complete and forward the *Part D Prescription Drug Case Transmittal Form* and the *Part D Prescription Drug Case Narrative Form* for each case submitted. In addition, the Part D plan must include a copy of the *Notice of Dismissal of Appeal Request* that was sent to the appellant, which identifies the drug requested and the reason for the dismissal. The plan should also include any supplemental information relative to the request that was submitted by the appellant.

There are five plan dismissal reasons, as set forth in the regulations, and it is expected that the plan's Notice of Dismissal will identify one of these reasons:

1. Not a Proper Party — The individual making the request is not permitted to request a redetermination
2. Not a Valid Request — The individual making the request failed to make out a valid request for a redetermination
3. Untimely Filing — When the party fails to file the redetermination request within the proper filing time frame
4. Enrollee dies while the appeal request is pending, and there is no financial interest on the part of the surviving spouse or estate and the representative does not wish to pursue the appeal
5. Request Withdrawn — The party filing the request submits a timely request for withdrawal of the request for a redetermination

6.9.3 Part D QIC review of plan dismissal appeal requests

Once the Part D QIC has received the case file from the Part D Plan, the QIC will review the contents of the file and the *Notice of Dismissal of Appeal Request*, along with any supplemental information submitted by the appellant. After this review, the Part D QIC will determine if the Plan's dismissal was correct.

The Part D QIC will issue an unfavorable decision if the QIC agrees with the plan's reason for dismissal. The QIC may also issue an unfavorable decision if the QIC determines the appeal request was not filed in a timely manner or there is no jurisdiction to review the appeal (i.e., there has already been one level of review, and the plan issued a redetermination upholding the dismissal issued at the coverage determination level). The QIC may also issue an unfavorable decision if the QIC discovers the plan has approved the requested service or has vacated the dismissal and is in the process of issuing a substantive decision.

If the Part D QIC disagrees with the plan's reason for dismissal, the QIC will remand the case to plan. The QIC may also remand to the plan if the QIC determines there is insufficient information from the plan to review the dismissal, the request was miscategorized and is a grievance versus an appeal or the prior level of appeal has not been exhausted.

The Part D QIC's decision regarding a plan's dismissal is binding and not subject to further review. Accordingly, the Part D QIC letter will not provide appeal rights to the OMHA level of appeal.

6.9.4 Timeframe for Review of Part D Plan dismissal appeal requests

All dismissal review requests will be reviewed by the Part D QIC in accordance with the timeframes applicable to the priority of the appeal. See [section 6.1](#).

7. CREDITABLE COVERAGE/LATE ENROLLMENT PENALTY RECONSIDERATIONS

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

An enrollee who has received notice of the imposition of an LEP or an increase in the LEP, where the increase is due to reporting additional uncovered months (except in a case where the number of uncovered months increases as a result of a Part D QIC reconsideration decision), has the right to request that the Part D QIC reconsider the LEP. There is no expedited review process for LEPs. The enrollee or the enrollee's representative may submit a request for LEP reconsideration by filing a signed written request with the Part D QIC within 60 calendar days from the date of the notice of the LEP. The 60-day timeframe for filing may be extended if the Part D QIC finds that the

appealing party has demonstrated good cause for the late filing. CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance Manual, sets forth examples of circumstances that constitute good cause. The decision of the Part D QIC whether or not to grant an extension for good cause is final and not subject to appeal.

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

7.1.1 Timeframe for Case File Submission

Upon request for a case file from the Part D QIC, the Part D plan shall forward an enrollee's LEP case file containing all creditable coverage and LEP-related correspondence and information in possession by the Part D plan. The case file forwarded by the Part D plan must include the Notice of Late Enrollment Penalty Letter sent to the enrollee that advises of the penalty—as well as any other relevant Late Enrollment Penalty notices sent to the enrollee—and any documents or additional information the Part D plan has solicited from relevant sources regarding the enrollee's creditable prescription drug coverage. The Part D plan shall deliver (by mail, fax or web portal) a copy of the requested information within 14 calendar days after receiving the request for a case file.

In the event a Part D plan has no information to forward to the Part D QIC, the Part D plan shall return the Case File Request Form to the Part D QIC. The Part D plan shall check the applicable box(es) under the "Comments" section and provide explanatory text in the "Additional Comments" section, which acknowledges the requested information is unavailable and explains the reason for same. The Part D plan shall deliver this response to the Part D QIC by mail, fax or web portal no later than 14 calendar days after receiving the request for a case file.

7.1.2 Content and Organization of the Case File

When submitting a case file(s) in response to a request from the Part D QIC, the Part D plan must include the *LEP Case File Request Form* as the cover page, followed immediately by the *LEP Case File Transmittal Form* and the *LEP Appeal Case Narrative Form*. Including these forms in the order requested greatly facilitates efficient intake and processing by the Part D QIC. Moreover, completing these forms in their entirety with accurate and responsive information is essential to meaningful reconsideration review.

The *LEP Case File Transmittal Form* and the *LEP Appeal Case Narrative Form* are available for downloading from the C2C website. These forms are the Part D plan's main working tools for submitting case files to the Part D QIC.

The *LEP Case File Transmittal Form* is self-explanatory and must be completed in full by the Part D plan. Information to be provided in the form includes the enrollee's name, address, phone number and Medicare HIC Number, and the Part D plan contract number and plan ID number.

These identifiers are required for reconsideration processing. The Part D plan also is required to provide Plan Level LEP Information, which includes dates of uncovered months and evidence reviewed to determine lack of creditable coverage for the uncovered months and imposition of an LEP. This information is needed to facilitate accurate and meaningful adjudication by the Part D QIC.

Notice of Late Enrollment Penalty Letter: The case file forwarded by the Part D plan must include the Notice of Late Enrollment Penalty Letter sent to the enrollee and advising of the penalty, as well as any other relevant Late Enrollment Penalty notices sent to the enrollee. With respect to an LEP(s) imposed by a previous plan that is no longer operational, if the previous plan was part of the same parent organization as the current plan, the current plan must obtain and forward the Notice of Late Enrollment Penalty Letter sent to the enrollee by the previous plan. The Part D plan shall also forward any accompanying documents and information the Part D plan has solicited or received from relevant sources regarding the enrollee's creditable prescription drug coverage that may be meaningful to reconsideration review.

If the Part D plan has rescinded an LEP, the Part D plan shall indicate on the returned *Part D QIC Case File Request Form* and the *LEP Case File Transmittal Form* the date the LEP was rescinded and the date the enrollee was notified of the rescission. If the rescission letter has been sent, the Part D plan must include this letter.

Part D plans can submit case files by mail or electronically via C2C's dedicated LEP fax line or through the C2C portal. It is permissible to send evidentiary documentation to C2C's designated fax line without redacting personally identifiable information. C2C accepts faxes and portal submissions seven days a week. When submitting case files electronically, the plan must submit each case file separately with the *LEP Case File Request Form* as the cover page for each case followed by the *LEP Case File Transmittal Form* and the *LEP Appeal Case Narrative Form*. It is imperative for plans to follow these directions and avoid comingling cases into a single image. This is needed to facilitate proper handling of the plan's transmission.

Part D plans can also submit case files by mail. For mailed submissions, the Part D plan similarly must use the *LEP Case File Request Form* as the cover page, followed by the *LEP Case File Transmittal Form* and the *LEP Appeal Case Narrative Form* for the case file. The Part D plan should place the associated documents and records in an envelope or container for proper mailing.

Mailed case files and appeal related correspondence mail should be addressed to:

C2C Innovative Solutions, Inc.
Part D LEP Reconsiderations
P.O. Box 44165
Jacksonville, FL 32231-4165

For Mail sent by couriers such as FedEx and UPS:

C2C Innovative Solutions, Inc.
Part D QIC
301 W. Bay St., Suite 1100
Jacksonville, FL 32202

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

- Include a cover letter that identifies the contents of the package
- Separate each case file that is submitted
- For each case file submitted, place the *LEP Case File Request Form* on top of each case file submitted; this form serves as the cover page for the case file
- For each case file submitted, place the *LEP Case File Transmittal Form* and the *LEP Appeal Case Narrative Form* immediately after the *LEP Case File Request Form* cover page
- 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 the specific new case

The LEP case file submitted to the Part D QIC should be organized to include the following documents, as applicable and available:

A. LEP Case File Transmittal Form

- As noted, this form is self-explanatory and must be fully and accurately completed by the Part D plan when submitting a case file to the QIC.
- The information requested in this form is required for the Part D QIC to adjudicate the LEP.

B. LEP Case Narrative Form

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

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

- The Declaration or Prior Prescription Drug Coverage (Attestation Form) asks the enrollee to attest whether s/he had creditable prescription drug coverage and to identify the source(s) and date(s) of his/her previous coverage. If the Part D plan

was able to obtain a written or telephonic Declaration of Prior Prescription Drug Coverage (Attestation Form) from the appealing party, the Part D plan shall include a copy of the Declaration of Prior Prescription Drug Coverage (Attestation Form) as a part of the case file.

D. Beneficiary Notice of Late Enrollment Penalty

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

E. Other Important Documents

- The Part D plan should include any other documents or information that it believes is relevant to the enrollee's case file.

Representation Documents

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

F. Part D Plan Enrollment Application

- The Part D plan shall include a copy of the enrollee's Part D plan enrollment application.

- The Part D plan enrollment application should indicate the enrollee's name, the particular Part D plan elected, the date with which the application was signed, and whether the enrollee elected direct bill or withdrawal of premiums from his or her Social Security payments.

G. Notice Informing Beneficiary of Part D Enrollment Effective Date

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

H. BEQ/MARx Screens

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

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

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

J. Evidence of Special Circumstances

- The Part D plan should include any evidence of special circumstances that may impact adjudication of the LEP. This may include proof an enrollee lived abroad or was incarcerated, and, therefore, did not reside in a Part D service area during his/her Part D IEP.

K. Notice of Creditable or Non-Creditable Prescription Drug Coverage

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

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

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

7.2 LEP RECONSIDERATION PROCESS

The purpose of this section is to provide the Part D plan with an overview of the process that the

Part D QIC follows in rendering the QIC level Reconsideration for Part D QIC LEP reconsiderations. The enrollee will send his or her signed completed LEP Reconsideration Request Form to C2C, the current Part D QIC, in accordance with the instructions provided on the form. Enrollees also may send a letter to request a reconsideration of an LEP, provided the letter contains the elements on the LEP Reconsideration Request Form.

The Part D QIC shall request a copy of the enrollee's case file from the Part D plan, and draft a reconsideration decision based on the case file, the information supplied by the enrollee, and any other information that the Part D QIC obtains from its own investigation. The Part D QIC will inform the enrollee and the Part D plan of the final decision, generally within 90 calendar days of receipt of the enrollee's reconsideration request, subject to a possible 14-calendar day extension of this timeframe, as described under §2.30 of this manual. The reconsideration decision issued by the Part D QIC is not subject to further appeal.

7.2.1 Elements of an LEP Reconsideration Request

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

- A completed, signed LEP Reconsideration Request Form or a signed, written request for reconsideration containing the elements on the LEP Reconsideration Request Form. If an enrollee submits a reconsideration request that is not signed, the Part D QIC will attempt to cure this deficiency by contacting the enrollee, by phone or writing, to obtain confirmation of the enrollee's intent to proceed with the reconsideration. If the Part D QIC is unable to cure this deficiency within a reasonable timeframe, the QIC will proceed with adjudicating the reconsideration.
- If the enrollee has named a representative, proof of valid representation must be submitted to show the individual is legally authorized to represent the enrollee.

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

7.2.2 Reasons for Requesting LEP Reconsideration

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

1. The individual had prior creditable prescription drug coverage that the enrollee believes may have not been considered
2. The individual had prior prescription drug coverage but didn't get a notice that clearly explained if the drug coverage was creditable. In this case, the enrollee should submit any evidence, such as a copy of an organization's notice regarding prescription drug

coverage, or other material, such as, a Summary of Benefits that the enrollee found unclear or misleading

3. The individual believes the LEP is wrong because he or she was not eligible to enroll in a Medicare drug plan during the period stated by the plan
4. The individual believes the LEP is wrong because he or she was unable to enroll in a Medicare drug plan due to a serious medical emergency during the period the individual was eligible to enroll in a drug plan
5. The individual has/had extra help from Medicare to pay for prescription drug coverage; that is, the low-income subsidy for Medicare prescription drug coverage

Refer to CMS IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 4, for additional guidance on the opportunity for certain individuals to enroll in Medicare Part D without a LEP.

If additional information or evidence can help explain why an enrollee's LEP is incorrect, he or she should submit such proof with the LEP Reconsideration Request Form. Enrollees are asked to send to the Part D QIC any proof that helps support the request. Part D plans shall instruct enrollees to send this material to the Part D QIC to the address or fax number shown on the LEP Reconsideration Request Form. Enrollees should also be advised to include their "Medicare number", and for any documents they wish to submit, to send photocopies of the original documents.

7.2.3 LEP Reconsideration Process Timeline

The Part D QIC will notify the enrollee of the final LEP reconsideration decision generally within 90 calendar days of receiving an enrollee's request for reconsideration, subject to a possible 14 calendar day extension as described in §2.30 of this manual. In cases where an individual other than the enrollee requests a reconsideration, the Part D QIC will not begin the reconsideration review until it receives documentation verifying that the individual is the enrollee's representative or is authorized under state law to act on behalf of an enrollee. The Part D QIC will attempt to obtain representative documentation by requesting information from the individual who filed the reconsideration request. If the Part D QIC cannot obtain verification of an individual's status as the representative within a reasonable period, the Part D QIC will dismiss the reconsideration request.

7.2.4 Requests for Information

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

7.3 LEP RECONSIDERATION DECISIONS

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

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

7.3.1 Favorable Decision

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

7.3.2 Partially Favorable Decision

If the Part D QIC determines that a late enrollment penalty should be partially reversed, the Part D QIC will issue a "Partially Favorable" decision reversing the Part D plan's creditable coverage determination based on the Part D QIC's review of the reconsideration request. The Part D QIC will uphold the Part D plan's decision for any remaining uncovered months based on the Part D QIC's review of the reconsideration request. In this circumstance, the enrollee may owe an LEP, but if so, it will be less than the LEP assessed by the Part D plan.

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

Note: Favorable and Partially Favorable Reconsideration Decision Letters

If the Part D QIC issues a final decision letter that reverses or partially reverses the Part D plan's creditable coverage determination, the final decision letter shall contain an explanation of how the enrollee can obtain reimbursement of the disputed LEP, if applicable.

7.3.3 Unfavorable Decision

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

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

7.3.4 Dismissal of an LEP Reconsideration Request

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

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

7.3.5 Vacating a Dismissal

A dismissal issued by the Part D QIC is binding, unless vacated. If a Part D enrollee requests the

dismissal be vacated and shows good cause that the reconsideration request should not be dismissed, the dismissal of the reconsideration request may be vacated. The enrollee may request to vacate a dismissal within 60 calendar days after the date of the dismissal notice. The Part D QIC will notify the enrollee and the Part D plan in writing if the dismissal is vacated.

7.3.6 Withdrawal of an LEP Reconsideration Request

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

7.4 LEP EXCLUSIONS

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

7.4.1 Low Income Subsidy Eligible Enrollees

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

If an enrollee was paying an LEP before qualifying for an LIS, the enrollee is not exempt from those payments. If an enrollee who is currently paying an LEP becomes LIS eligible, he/she is still responsible for any unpaid LEP amount owed prior to the LIS eligibility effective date. The Part D QIC will issue a “Partially Favorable” decision requiring the enrollee to pay any LEP amounts that he or she may have owed up until the LIS eligibility date. The enrollee is not responsible for any LEP amounts assessed after he or she became LIS eligible, and any amounts paid by the enrollee following his or her LIS eligibility date must be reimbursed by the Part D plan.

Note: For LIS-eligible beneficiaries, MARx automatically resets any LEP. The Part D plan only needs to contact the MAPD Help Desk if MARx fails to reset the LEP.

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

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

7.4.3 Serious Medical Emergency

If the enrollee indicates on the LEP Reconsideration Request Form, that s/he incurred a lapse in creditable prescription drug coverage of 63 calendar days or more due to a serious medical

emergency (i.e., unexpected hospitalization), the enrollee must submit proof of the medical emergency to the Part D QIC. The documentation submitted must support that the medical emergency affected the enrollee's ability to timely enroll with a Part D plan.

7.4.4 Subsequent Initial Enrollment Periods

If an individual is eligible for Medicare prior to turning age 65 (for example, based on disability), the individual will be assigned a new Medicare IEP upon turning age 65. Therefore, if an enrollee is issued an "Unfavorable" Reconsideration decision by the Part D QIC, the enrollee will continue to pay this LEP while enrolled in a Part D plan. However, this LEP ends on the day before the new Medicare IEP begins.

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

Note: MARx automatically resets LEP and creditable coverage periods when a new IEP begins. The plan only needs to contact the MAPD Help Desk if the system fails to reset these values.

7.5 CMS REVIEW

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

8.0 POST-RECONSIDERATION DETERMINATION PROCESSING FOR DRUG APPEALS

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

- 8.1 The Part D QIC Monitoring of Part D Plan Compliance with Determinations that have been Reversed on Appeal (Favorable and Partially Favorable)

- 8.2 The Part D QIC Reopening Process for Drug and LEP Appeals
- 8.3 Administrative Law Judge Process
- 8.4 Medicare Appeals Council Process

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

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 section 90 of the CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. Part D Plan effectuation timeframes.

8.1.1 Part D Plan effectuation timeframes

The following table summarizes CMS requirements for timeliness of Part D plan effectuation for plan determinations that are reversed in whole or in part by the Part D QIC, ALJ or Council:

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

If a Part D plan has questions on how to effectuate a Part D QIC determination, the plan should contact the Part D QIC Plan Liaison at MedicarePartDAppeals@C2Cinc.com.

A Part D plan may request for a reopening (see §8.2 of this manual), however the filing of a request to reopen does not relieve the plan of its obligation to make payment for, authorize, or provide benefits or services as specified in 42 CFR §§422.618, 423.1978(b), and 423.1980(a)(3), consistent with 42 CFR §422.616(c) and information provided in CMS Parts C & D Enrollee

Grievances, Organization/Coverage Determinations, and Appeals Guidance Manual unless the Favorable decision is missing vital information needed to effectuate the decision or if the drug was previously approved and the Favorable decision should have been dismissed.

8.1.2 The Part D QIC Reconsideration Compliance Monitoring

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

1. The Part D QIC provides the Part D plan with a copy of the fully or partially favorable decision and other information necessary to effectuate the decision. Included with the copy of the decision is a *Notice of Requirement to Comply*. This notice details the Part D plan's responsibilities, including the timeframe 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, OMHA, Council or 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 CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. However, the Part D plan may submit its own statement of compliance form, provided it contains all of the information set forth in the model notice and the notice is approved through the appropriate CMS marketing procedures.
3. If the Part D QIC does not receive the compliance notice within 14 calendar days, it will mail the Part D plan a reminder notice.
4. If the Part D QIC does not receive the compliance notice within 30 calendar days of the reminder notice, the Part D QIC will report the plan's failure to comply with CMS. The Part D plan is not copied on this report to CMS.

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 can be faxed to the Part D QIC's dedicated fax line for effectuations or submitted through the C2C portal. The dedicated effectuation fax line is (904) 539-4101. Notices of compliance must be submitted separately from other Part D plan documents and/or correspondence.

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

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

8.2.1 Overview

A reopening is a remedial action taken to change a final determination or decision even though the determination or decision may have been correct based on the evidence of record at the time. 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 OMHA Judge or Attorney Adjudicator may reopen to revise an OMHA decision, and the Council may reopen to revise a Council decision.

The Part D QIC may reopen a reconsideration decision on its own motion or at the request of a Part D plan or enrollee within 180 calendar days from the date of the reconsideration decision for good cause. Good cause for reopening may be established when:

1. There is new and material evidence that was not available or known at the time of the determination or decision, and the evidence may result in a different conclusion
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

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

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

The request for a reopening:

1. Must be made in writing
2. Should be clearly stated
3. Should include the specific reasons for requesting the reopening (a statement of dissatisfaction is not grounds for a reopening)
4. Must be made within the CMS timeframes 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 notify the enrollee in writing of its decision not to reopen. If the Part D QIC does find good cause for reopening, the Part D QIC will process the request as described below and in accordance with CMS rules.

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

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

Part D plans should note the Part D QIC is not permitted to reopen and modify a reconsideration decision in circumstances where an enrollee (or an enrollee's representative) has filed a valid request for an appeal of the reconsideration decision. The Part D QIC has no jurisdiction once an appeal request is filed with OMHA 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 timeframe at the coverage determination or redetermination levels has expired and the Part D plan is required to auto-forward the case file to the Part D QIC, unless a subsequent request to withdraw has been

decision to the enrollee at his or her last known address, to CMS, to the IRE and to the Part D plan sponsor.

8.3.3 Medicare Appeals Council Decisions

Council Effectuation:

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

1. Within 2 business days of receipt of Council decisions that overturn, in whole or in part, the OMHA decision, the Part D QIC provides the plan with 1) an effectuation notice and 2) a copy of the Council decision by fax.
2. The Part D plan is required to submit to the Part D QIC a statement attesting to compliance (effectuation) with the decision by Council. The documentation must state when and how compliance occurred (e.g., benefit authorization, payment made, etc.).
3. If the Part D QIC does not receive the compliance notice within 14 calendar days, it will mail the Part D plan a reminder notice.
4. If the Part D QIC does not receive the compliance notice within 30 calendar days of the reminder notice, the Part D QIC will report the plan's failure to comply with CMS. The Part D plan is not copied on this report to CMS.