

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

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,

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.

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. However, the Part D plan is not required to wait an indefinite period before issuing its decision. If the Part D plan does not receive the supporting statement within a reasonable period, 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 60 calendar days from the date of the notice of the coverage determination. The prescribing physician or other prescriber may appeal on behalf of the enrollee for a standard and expedited redetermination request. Note that under 42 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. 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 seven 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 60 calendar days from the date of the notice of the coverage determination. These requests may be written or oral, and may be requested by the enrollee, the enrollee's representative, or the prescribing physician or other prescriber acting on behalf of the enrollee. As noted 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 strongly recommends that plans notify the QIC's Plan Liaison when submitting 20 or more auto-forwarded case files for review within a 24-hour period.

4.4.4 Dismissal of a standard pre-benefit redetermination

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

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

4.5 NOTICE FOR FORMULARY CHANGES

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

The Part D plan is required to provide direct written notice to "affected" enrollees at least 60 calendar days prior to the change. An affected enrollee is a plan enrollee who is currently taking the covered Part D drug that is either being removed from the plan's formulary or is subject to a change in its preferred or tiered cost-sharing status. To the extent that the Part D plan does not give the mandatory 60-day (calendar day) advance notice, the plan will be required to provide the notice and provide a 60 day supply of the drug 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 PART D PLAN VALIDATION OF APPEALING PARTY

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

The Part D plan must carefully evaluate whether the appealing party is a proper party for purposes of appeal under Part 423. It is a straightforward validation of the appellant when the enrollee is the individual who initiates the request for a coverage determination or redetermination. It is also a relatively straightforward validation when the appellant is the prescribing physician or other prescriber appealing a coverage determination or redetermination. Except for a prescribing physician or other prescriber who may appeal in the circumstances as described, it is not as 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, phone number of enrollee
- Identifies the enrollee's Medicare number
- Identifies the name, address and telephone number of the individual being appointed
- Contains a statement that the enrollee is authorizing the representative to act on his or her behalf for the claim(s) at issue, and a statement authorizing disclosure of individually identifying information to the representative
- Contains the signature of the enrollee making the appointment, and the date signed
- 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. However, the Part D plan may choose to begin the process for review, which may include requesting medical documentation in a case that will involve medical necessity review. If the plan does not receive a properly executed appointment document within a reasonable period, the plan should dismiss the request on the basis that the appealing party is not a proper party under Part 423.

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

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

Healthcare proxy instruments typically are springing instruments. These instruments are triggered when an individual loses competence or capacity to make healthcare decisions on his or her own behalf. Again, each state's laws differ, and the Part D plan must consult the applicable state law to determine whether the appellant who presents as a healthcare proxy is a valid representative under state law for appeal purposes under Part 423. As noted above, the Part D plan should not require a representative who is a valid healthcare proxy under state law to execute an AOR form that makes the same appointment.

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

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

Part D QIC for reconsideration review.

Occasionally, these individuals fail to submit representative documentation along with their requests for reconsideration review. The Part D QIC is subject to the same representation rules as described above for Part D plans. The Part D QIC's reconsideration 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

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 appeal in process at the Part D QIC. The Part D QIC will consider any additional information that is received at a reasonable point in time prior to the expiration of the adjudicatory 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.

For auto-forwarded case files, Part D plans must attach the *Drug Case File Transmittal Form* as the cover page for each case file that is submitted, followed by the *Drug Appeal Case Narrative Form*. (Please note that the *Drug Case File Request Form* is submitted as a cover page only for case files that are provided in response to a formal case file request from the Part D QIC).

It is expected that records sent via our designated fax lines will not have redacted personally identifiable information (PII) or redacted protected health information (PHI). We accept faxes seven days a week. When faxing, please note that each case file **must** be sent in separate fax transmissions. Faxes are received and processed electronically, and multiple case files submitted in one fax transmission will process as receipt of only one case file. Therefore, multiple case files cannot be included in one fax transmission to the Part D QIC.

Submissions may also be made through the C2C QIC Part D portal (<https://www.c2cinc.com//Appellant-Signup>). For assistance on how to use the C2C portal or issues encountered, the Part D plan should contact the Part D QIC Liaison.

Plans are required to submit formularies, formulary policies and Evidences of Coverage (EOCs) or other subscriber materials for each appeal, as appropriate, to ensure a complete administrative record for appeal adjudication at the QIC level and levels of appeal beyond the QIC level. Plans may submit this information by mailing a CD-ROM to C2C, or alternatively, may fax the information or submit as a PDF attachments via the C2C portal.

When sending cases files by overnight mail, the Part D plan should attach as a cover letter the *Drug Case File Request Form* or the *Drug Case File Transmittal Form* depending on whether the

plan is submitting case files in response to the Part D QIC's request or submitting auto-forwarded case files, respectively. The Part D plan should place the associated documents and records in an envelope or container for shipping. C2C's office is open to accept case files sent by overnight mail or tracked mail on Monday through Friday, excluding most Federal holidays. Unless indicated otherwise, packages for drug appeals should be addressed to:

Part D Prescription Drug Benefit Appeals

C2C Innovative Solutions, Inc.
Part D Drug Reconsiderations
P.O. Box 44166
Jacksonville, FL 32231-4166

For Mail sent by couriers such as FedEx and UPS:

C2C Innovative Solutions, Inc.
Part D QIC
301 W. Bay St., Suite 600
Jacksonville, FL 32202

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

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

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

Procedural Documents for Drug Appeal Case Files

A. Reconsideration Drug Case Narrative Form

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

B. Request for Coverage Determination and Coverage Determination Notice

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

C. Request for Redetermination and Redetermination Notice

- The request for a redetermination may include any submitted written requests from an appropriate party or oral requests that are documented and transcribed by the Part D plan.
- The Redetermination Notice is the CMS mandated notice (see 42 CFR §423.590(g)) that is sent to the appealing party when the Part D plan makes an adverse redetermination.
- The Part D plan should also indicate if the appellant requested an expedited redetermination, and whether the plan in fact expedited the request. If the plan declined to expedite the request, the plan should include information explaining its decision to handle in accordance with standard decision-making timeframes.
- Prescriber Statement
- For appeals involving an exceptions request, the Part D plan must submit oral and written statements provided by the prescribing physician or other prescriber and/or solicited by the plan during the appeal. The Part D QIC will accept oral statements that have been transcribed by the Part D plan as well as phone logs documenting telephone conversations.
- If the Part D plan has not been able to obtain a statement from the prescribing physician or other prescriber, the plan must document its attempts in the record.
- The Part D plan must include the prescribing physician's or other prescriber's office address, telephone and fax numbers, and email address, if available. If the case file provided by the Part D plan is insufficient, the Part D QIC is required to solicit the comments of the prescribing physician or other prescriber, and will need contact numbers for the prescriber.

D. Representation Documents

- For appeals initiated by representatives at the plan level, the Part D plan must include documentation showing that the representative is a valid party for purposes of Part 423 appeals.
- Documents or instruments showing valid representation may include the following:
 - AOR document (CMS-1696 form or other similar writing in compliance with 42 CFR §405.910
 - Instrument executed by an enrollee that confers representative authority in accordance with state law, e.g., POA or DPOA, health care proxy appointment, or a will or other estate documentation naming an executor to handle a deceased enrollee’s estate
 - Representative authority conferred by state law that authorizes a designated individual to act on behalf of an incapacitated or incompetent enrollee, e.g., surrogacystatute
 - Representative appointment made for an incapacitated or incompetent enrollee pursuant to a court of law, e.g., guardianship appointment
 - Representative appointment made by a court of law on behalf of a deceased enrollee that has not named an executor to handle his or her estate
- If the Part D plan has not been able to validate a party who appeals as a representative, the plan should include this information in the record and document its attempts to remedy the defect.
- For representative authority conferred pursuant to state law, the Part D plan should complete the attestation on the *Drug Case File Transmittal Form* indicating that it has determined that the appellant is a proper representative under state law.

E. Other Procedural Documents

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

Evidentiary Documents for Drug Appeals Case Files

A. Applicable Formulary Rules/Exceptions Criteria

- For determinations involving a tiering exception request or a formulary exception request, the Part D plan must provide the applicable exceptions procedures/criteria for determining whether the exceptions request should be granted. The plan must explain its basis for not granting an exceptions request, and should include a copy of any internal medical review that it obtained relative to its determination.
- For formulary exception requests involving an off-formulary drug, the Part D plan

should provide a listing of all applicable drugs on the plan's formulary that the enrollee needs to have tried and failed for consideration of the off-formulary drug. Medical records from the prescriber showing drugs prescribed, trialed and failed should be included with the case file.

- The Part D plan must also provide a description of any cost-utilization tools applicable to the drug in dispute, e.g., dose restrictions, step therapy requirements, and therapeutic substitution. For example, for a drug subject to Step Therapy requirements, the plan must include a complete description of the steps required for approval.
- Part D plans must provide complete copies of the relevant formulary pertinent to adjudicating the drug benefit in dispute. The formulary must be submitted along with the case file. The formulary may be copied onto a CD and mailed to C2C using tracked mail. Alternatively, the formulary may be submitted through the C2C Portal as a PDF attachment to a case file, or submitted through one of the applicable C2C fax lines along with the case file. Formularies on CDs that are mailed separately from the case file must be identified by a cover sheet identifying the QIC case number, plan name, plan contract and plan ID, and formulary ID.

B. Evidence of Coverage or Other Subscriber Materials

- The Part D plan should include a complete copy of the relevant Evidence of Coverage (EOC) along with any other subscriber documents, as applicable. Plans may mail the EOC to C2C on a CD-ROM, or submit electronically through one of C2C's dedicated fax lines along with the case file or through the C2C portal as a PDF attachment along with the case file. CDs mailed to C2C should be sent via tracked mail.

C. Cost-Sharing/TrOOP Calculations

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

D. Medical Records

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

E. Medicare Rules

- The Part D plan case file should reference Medicare law, regulations or other CMS

special guidance material, as relevant to the disputed drug benefit.

F. Redetermination Evidence

- The Part D plan should include any additional evidence and/or facts presented by the enrollee and/or the prescribing physician or other prescriber at the plan redetermination level.
- This evidence includes screen shots from the ABII system for applicable cases. These screen shots are required to be sent to C2C upon request.

G. Other Evidentiary Information/Documents

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

Evidentiary and Procedural Documents for DMP At-Risk Determinations

Part D plans are required to submit the following documentation and information, as applicable:

A. Plan DMP policies/procedures

B. Enrollee case management documentation, including but not limited to:

- OMS/MARx notifications/reports
- Prior plan documentation and information regarding PARB/ARB status including limitations and edits
- Information and records on the enrollee's medical condition, history of utilization of FADs, and treatment plan(s)
- Consideration of exemptions
- Prescriber notices
- Prescriber responses to inquiries
- Prescriber verification of PARB/ARB status

C. Enrollee notices (Initial and Second Notices)

- Initial Notice
- Second Notice

D. Documentation on selecting prescriber/pharmacy limitations

- Beneficiary access considerations
- Beneficiary preferences
- Prescriber/Pharmacy notifications
- Prescriber/Pharmacy Acceptance Confirmation

E. Any other relevant documentation/information.

Part D plans should note that the above sections, as labeled, correspond with the Exhibits box of the *Drug Case File Transmittal Form*. Part D plans are required to provide only those lettered Exhibits that are pertinent to a given case file that is being submitted. If a lettered Exhibit does

not apply to a particular case file, the plan should omit the Exhibit, but should not re-letter the other Exhibits to achieve chronological order.

5.3.2 Additional Guidance on Selection and Inclusion of Records

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

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

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

- Drug Case File Transmittal Form and Drug Appeal Case Narrative Form
- Request for a Coverage Determination and the Coverage Determination Notice
- Request for a Redetermination and the Redetermination Notice
- Redetermination evidence presented by the enrollee and/or the prescribing physician
- Representation documentation for representative appeals
- Expedited information regarding the Coverage Determination and Redetermination
- The relevant Evidence of Coverage and/or other subscriber materials

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

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

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

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

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

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

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

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

6. PART D QIC DRUG APPEAL RECONSIDERATION PROCESS

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

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

6.1 THE PART D QIC CASE PROCESSING TIME STANDARDS

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

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

4. Name of the authorized representative, if applicable, and documentation of valid appointment
5. Name of the Part D plan that made the determination

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

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

For appeals involving auto-forwarded case files that have not been completed timely by the Part D plan, or auto-forwarded case files for DMP At-Risk Determinations, the Part D QIC's adjudicatory timeframe begins when the Part D QIC receives the case file from the Part D plan. Case files that are faxed through one of the dedicated fax lines or submitted through the C2C portal are received when successfully transmitted.

The case file sent by the Part D plan must contain the following information:

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

5. Name and contact information of the prescriber
6. Name of the Part D plan that made the determination

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

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

Case Intake Process

Step 1

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

Step 2

Verification and validation of the appealing party. The adjudicatory timeframe will begin when the Part D QIC verifies that the requesting party is the enrollee or a valid representative for the enrollee. The Part D QIC will take reasonable steps to validate the appealing party. If the Part D QIC is not able to validate the appealing party, the Part D QIC will wait at least 24 hours after the expiration of the applicable timeframe before dismissing the case (but may wait for a longer period-of-time if it is reasonable under the circumstances of the case). As appropriate, and pursuant to CMS direction, in lieu of dismissing the request for lack of proof of valid representation, the Part D QIC may proceed with adjudicating the appeal and send the reconsideration decision to the enrollee instead.

Step 3

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

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

For standard reconsiderations, the Part D QIC will notify the enrollee and the enrollee's representative of the Reconsideration decision via a hard copy mailing or fax. For these reconsiderations, the Part D QIC is required to notify the enrollee and the enrollee's representative in writing within seven calendar days after receiving a valid and complete request for reconsideration review.

6.2 ADMINISTRATIVE CASE INTAKE

The tasks involved in administrative case intake are as follows:

- 1 Opens and sorts new case files and appeal requests sent via mail, fax or the portal
- 2 Creates a case file in the MAS
- 3 Sends the Part D plan a request for the case file
 - The Part D QIC will request the case file from the Part D plan as soon as possible from the moment of receipt of the request for reconsideration.
 - The Part D QIC will initiate this process by faxing to the Part D plan the *Reconsideration Case File Request Form*.
 - The Part D plan is required to deliver the case file to the Part D QIC within 24 hours (of receipt of the fax) for expedited requests and within 48 hours (of receipt

of the fax) for standard requests.

- **Note:** Due to the short timeframes for reconsideration review, the Part D QIC expects to send requests for case files, and receive case files forwarded by Part D plans, on a daily basis, including holidays and weekends. Part D plans are expected to be able to receive and process case file requests seven days a week in accordance with the noted timeframes for submission of expedited and standard cases.

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

6.3.1 *All evidence should be in writing*

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

6.3.2 *Communications regarding the potential Part D QIC determination are not permitted*

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

6.4 ADJUDICATOR CASE REVIEW

An "Adjudicator" is a professional trained by the Part D QIC to: 1) Manage the Part D QIC case reconsideration; 2) Prepare cases for adjudication; 3) Draft reconsideration decision recommendations, as appropriate; and 4) Issue or finalize reconsideration decisions. C2C Adjudicators include Physician Reviewers, Appeals Professionals (typically nurses) and Reconsideration Analysts. Reconsiderations involving medical necessity review are processed by Appeals Professionals and adjudicated by Physician Reviewers. Reconsiderations not involving medical necessity review are processed and adjudicated by Appeals Professionals or Reconsideration Analysts.

The tasks that the Appeals Professional or Reconsideration Analyst may complete in reconsideration review include:

1. Determining if the contested issue is subject to appeal, and dismissing if not appealable

2. Determining if the appealing party is a valid party for purposes of appeal, and taking steps to remedy defects
3. Requesting additional information from the Part D plan, treating prescriber, enrollee and/or representative, as needed, for adjudication
4. Assessing or verifying appeal priority of the reconsideration
5. Determining if the case may be decided based upon coverage only (e.g., cost-sharing dispute), or if a medical necessity determination is required
6. Preparing and processing the case file for review by a Physician Reviewer if a medical necessity determination is required
7. Conducting research and identifying the applicable CMS and plan rules and/or policies pertinent for adjudication
8. Downloading formularies, formulary policies, EOCs and other subscriber materials from HPMS, as needed
9. Determining if the case should be referred to the Part D QIC's legal counsel or other designated staff for policy or coverage clarification. and Issuing a final reconsideration determination

6.5 INDEPENDENT PHYSICIAN REVIEW

The Medicare rules for Part D state that a physician must make determinations of medical necessity. The Part D QIC adjudication staff includes physicians responsible for adjudicating reconsiderations that require physician review. The QIC also has access to a panel of board certified physicians that represent nearly 80 different American Board of Medical Specialties and sub-specialties.

When additional information is required of the treating prescriber, the QIC Physician Reviewer may fax a request for the information to the prescriber or call the prescriber to obtain the information needed.

6.6 REQUESTS TO THE PART D PLAN FOR ADDITIONAL INFORMATION

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

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

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

The Part D QIC is under no obligation to seek additional information from the Part D plan, and may decide a case at any time based upon the information available. The Part D QIC will rarely be able to use this process for appeals involving expedited reconsiderations due to the abbreviated appeal 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. For mailings, if the Part D plan places more than one RI response in a package, it should separate each response with the appropriate RI Form.

6.7 THE PART D QIC RECONSIDERATION NOTICES

6.7.1 *The Part D QIC Reconsideration determination definitions*

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

7. CREDITABLE COVERAGE/LATE ENROLLMENT PENALTY RECONSIDERATIONS

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

An enrollee who has received notice of the imposition of an LEP or an increase in the LEP, where the increase is due to reporting additional uncovered months (except in a case where the number of uncovered months increases as a result of a Part D QIC reconsideration decision), has the right to request that the Part D QIC reconsider the LEP. There is no expedited review process for LEPs. The enrollee or the enrollee's representative may submit a request for LEP reconsideration by filing a signed written request with the Part D QIC within 60 calendar days from the date of the notice of the LEP. The 60-day 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, sets forth examples of circumstances that constitute good cause. The decision of the Part D QIC whether or not to grant an extension for good cause is final and not subject to appeal.

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

7.1.1 *Timeframe for Case File Submission*

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

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

7.1.2 *Content and Organization of the Case File*

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 *LEP Case File Request Form* as the cover page, followed immediately by the *LEP Case File Transmittal Form* (which is required) and the *LEP Appeal Case Narrative Form*

(which is strongly recommended). Including these forms in the order requested greatly facilitates efficient intake and processing by the Part D QIC.

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.

If the Part D plan has rescinded an LEP, the Part D plan shall indicate on the *LEP Case File Transmittal Form* the date the LEP was rescinded and the date the enrollee was notified of the rescission.

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 this 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

Mail sent by courier, such as FedEx and UPS, should be sent to:

C2C Innovative Solutions, Inc.
Part D QIC
301 W. Bay St., Suite 600
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 casefile.

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 and 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. The Part D QIC will allow for a reasonable timeframe, not exceeding 14 calendar days, for the enrollee to return a valid reconsideration request after a written request for signature. If the Part D QIC is unable to cure this deficiency within this timeframe, the QIC will proceed in 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 a Late Enrollment Penalty (LEP) reconsideration requires the Part D QIC to determine if an enrollee had a qualifying break in creditable prescription drug coverage prior to enrolling with the Part D plan. The Part D QIC will make this determination based on information contained in the enrollee's LEP Reconsideration Request, the Part D plan's LEP case file, and an independent investigation of the enrollee's prior prescription drug coverage conducted by the Part D QIC.

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

7.3.1 *Favorable Decision*

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

7.3.2 *Partially Favorable Decision*

If the Part D QIC determines that a 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. The enrollee is further directed to contact the appropriate CMS Regional

Office should there be any additional questions and/or concerns.

7.3.3 Unfavorable Decision

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

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

7.3.4 Dismissal of an LEP Reconsideration Request

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

- An enrollee failed to request a timely LEP reconsideration and did not have good cause for missing the filing deadline
- An enrollee dies while the reconsideration is pending and the enrollee's surviving spouse or estate has no remaining financial interest in the reconsideration
- An individual requesting the reconsideration is not the enrollee, and the authority of the individual seeking a reconsideration cannot be verified within a reasonable time period, not to exceed 30 calendar days after the date of the reconsideration request
- An enrollee requests a reconsideration of an issue that is ineligible for LEP reconsideration. For example, the Part D QIC will not make actuarial determinations concerning whether an enrollee's prescription drug coverage was creditable. 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 QIC will dismiss a reconsideration request when it determines that that an LEP was not imposed by the Part D plan. The Part D QIC will issue a "Dismissal" notice to the appealing party and the appropriate Part D plan(s) advising of the dismissal for no pending LEP
- The Part D QIC will dismiss a reconsideration request when it determines that an LEP was rescinded by the Part D plan. The Part D QIC will issue a "Dismissal" notice to the appealing party and Part D plan(s) advising of the dismissal for the rescinded LEP

- The Part D QIC will dismiss the reconsideration request if appropriate representation documentation from the party requesting reconsideration on behalf of an enrollee was not provided by the requesting party and could not be obtained by the Part D QIC

7.3.5 Vacating a Dismissal

A dismissal 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. The Part D plan must report a revised creditable coverage period determination indicating 0 (zero) uncovered months to CMS effective with the LIS eligibility date.

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 qualifies for Medicare Savings Program or Medicaid) is not subject to the LEP, as long as he or she remains enrolled in Part D.

The Part D QIC will issue a “Favorable” decision for this enrollee if at the time of the uncovered months, he or she was a dual eligible member.

7.4.3 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. The day before the enrollee’s new IEP begins, the Part D plan must report a revised creditable coverage period determination indicating 0 (zero) uncovered months to CMS, in accordance with Medicare guidelines.

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

7.5 CMS REVIEW

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

8.0 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
- 8.2 The Part D QIC Reopening Process
- 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 DETERMINATIONS)

Compliance ("effectuation") is defined as the Part D plan's payment of a claim, or authorization and arrangement for a drug benefit, as instructed in the Part D QIC Reconsideration determination notice. For a complete discussion regarding effectuating redeterminations or decisions, the Part D plan should refer to 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 regarding a Part D QIC determination, the plan should contact its Part D QIC Plan Liaison. Please note the Part D QIC is not authorized to waive compliance timeframes with any final determination.

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

8.1.2 The Part D QIC Reconsideration Compliance Monitoring

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

1. The Part D QIC provides the Part D plan with a copy of the fully or partially favorable decision and other information necessary to effectuate the decision. Included with the copy of the decision is a *Notice of Requirement to Comply*. This notice details the Part D plan's responsibilities, including the 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 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 MAC may reopen to revise a MAC 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. May be made verbally or in writing
2. Should be clearly stated
3. Should include the specific reasons for requesting the reopening (a statement of dissatisfaction is not grounds for a reopening)
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 or verbal statement to the Part D QIC that sets forth this information. If a Part D plan alleges error as a basis for reopening, the plan should clearly describe its rationale for concluding that the reconsideration decision is erroneous on the face of the evidence. If a Part D plan alleges new and material information as a basis for reopening, the plan should clearly identify the new information it has received, explain why the information was not previously available, and explain how the new information may modify the reconsideration decision. The Part D QIC will evaluate the written or verbal statement submitted by the Part D plan and determine if there is good cause for reopening review. If the Part D QIC does not find good cause for reopening, the Part D QIC will notify the Part D plan about its decision not to reopen. If the Part D QIC does find good cause for reopening, the Part D QIC will reopen on its own motion and process the request as described below and in accordance with CMS rules.

Part D plans should note the Part D QIC is not permitted to reopen and modify a reconsideration decision in circumstances where an enrollee (or an enrollee's representative) has filed a valid request for an appeal of the reconsideration decision. The Part D QIC has no jurisdiction once an appeal request is filed with 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 granted.

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

8.2.2 Process for conducting reopening review

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

1. The Part D QIC receives and logs the reopening request
2. The Reopening Adjudicator reviews the reopening request and determines whether to grant reopening
3. The Part D QIC notifies the reopening requestor of its decision whether or not to grant reopening within 30 calendar days of the receipt of the reopening request
4. If reopening is granted, the reopening review is completed by issuing a revised reconsideration decision in accordance with the process and procedures described in Section 6 of this manual for reconsideration review. Reopening reconsiderations for both drug and LEP appeals must be completed, and notice provided, as expeditiously as the enrollee's health requires, but no later than 120 calendar days from the date the Part D QIC receives the request to reopen
5. If the Reopening reconsideration reverses an unfavorable reconsideration (that is, the Reopening reconsideration finds in favor of the enrollee in whole or in part), a *Notice of Requirement to Comply* is also issued to the Part D plan. The Part D plan is then responsible for "effectuation" as per §8.1 of this manual

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

The Part D QIC may also receive OMHA remands as per §8.3, where the QIC may be ordered by an ALJ to reopen the reconsideration decision. If reopened, the QIC issues a revised reconsideration or dismissal, as appropriate, and as expeditiously as the enrollee health requires, but no later than 60 calendar days after receipt of the OMHA Order of Remand and case file.

8.3 ADMINISTRATIVE LAW JUDGE PROCESS

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

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

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

If an appellant mistakenly sends a request for an ALJ hearing or Attorney Adjudicator on-the-record review to the Part D QIC, the Part D QIC will forward the request to OMHA. If an appellant mistakenly sends a request for an ALJ hearing or Attorney Adjudicator on-the-record to the Part D plan, the plan similarly should forward the request to OMHA.

Once a hearing request is appropriately filed, OMHA contacts the Part D QIC to request the case file. The Part D QIC maintains an electronic copy of all case files. If required by OMHA, the Part D QIC will print a paper copy of the case file and forward to the ALJ or Attorney Adjudicator within five calendar days of receipt of the request for a standard ALJ review or Attorney Adjudicator on-the-record review. If an ALJ or Attorney Adjudicator has granted expedited review, the Part D QIC has 24 hours to forward the case file to the ALJ or Attorney Adjudicator.

8.3.2 *Tracking and conduct of ALJ hearing*

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

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

8.3.3 Notices of Hearing (NOH)

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

8.3.4 OMHA Decisions

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

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

8.4 MEDICARE APPEALS COUNCIL PROCESS

8.4.1 Enrollee Requests for Council Review

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

Attorney Adjudicator's decision or dismissal. The regulations under part 423, subpart U regarding Council review apply to Part D appeals to the extent applicable.

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

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

8.4.2 Referral to the Council for Own Motion Review

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

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

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

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

The Part D QIC's legal counsel (or other designated staff) reviews all favorable ALJ and Attorney Adjudicator decisions within two business days to determine if there is a perceived error of law material to the outcome of the case or a procedural issue that may affect the general public interest. The Part D QIC works closely with CMS in determining which cases are appropriate for

Council referral. The Council generally chooses not to undertake Own Motion Review for those cases where the record does not contain a complete Evidence of Coverage and Formulary. Accordingly, the Part D QIC makes every effort to help ensure that these documents are provided to the ALJ or Attorney Adjudicator at the time of the ALJ hearing or Attorney Adjudicator review, and Part D plans should insure these documents are included with their Reconsideration case file submissions to the Part D QIC.