Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance

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10 – Introduction

This guidance covers the appeal provisions set forth at 42 CFR Part 422 Subpart M and 42 CFR Part 423 Subparts M and U. It addresses grievances, coverage/organization determinations, and appeals for beneficiaries enrolled in a plan provided by a Medicare Advantage (MA) organization, a Medicare cost plan, health care prepayment plan (HCPP), or a stand-alone Part D plan.

Additional information related to Part C and Part D grievances, coverage/organization determinations, and appeals may be found on the following Appeals and Grievances guidance webpages:

https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/index.html

http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/

10.1 – Glossary

For purposes of this guidance, the following terminology will be used as described in the corresponding instances:

Refers to Part C Only	Refers to Part D Only	When Refers to Both Parts C & D
Medicare Advantage (MA) plan, Medicare Advantage Organization (MAO), Medicare cost plan or health care prepayment plan (HCPP)	Part D plan sponsor or plan sponsor	Plan
Request for Organization Determination	Request for Coverage Determination	Coverage Request
Organization Determination	Coverage Determination	Initial Determination
Reconsideration*	Redetermination	Level 1 Appeal

*This term is also used to refer to the IRE level of appeal (level 2 appeal) under both Part C and Part D.

> **Note:** The term "coverage decision" will be used throughout this guidance in circumstances where the term applies to both an initial determination and a level 1 appeal decision.

Unless otherwise stated in this guidance, the following definitions apply:

Appeal: As defined at 42 CFR §422.561 and §423.560, the procedures that deal with the review of adverse initial determinations made by the plan on health care services or benefits under Part

C or D the enrollee believes he or she is entitled to receive, including a delay in providing, arranging for, or approving the health care services or drug coverage (when a delay would adversely affect the health of the enrollee) or on any amounts the enrollee must pay for a service or drug as defined in 42 CFR §422.566(b) and §423.566(b). These appeal procedures include a plan reconsideration or redetermination (also referred to as a level 1 appeal), a reconsideration by an independent review entity (IRE), adjudication by an Administrative Law Judge (ALJ) or attorney adjudicator, review by the Medicare Appeals Council (Council), and judicial review.

Clean Claim (Part C Only): As defined at 42 CFR §422.500(b), a claim that has no defect, impropriety, lack of any required substantiating documentation (consistent with 42 CFR §422.310(d)), or particular circumstance requiring special treatment that prevents timely payment and that otherwise conforms to the clean claim requirements for equivalent claims under original Medicare.

Complaint: Any expression of dissatisfaction to a plan, provider, facility, or Beneficiary and Family Centered Care Quality Improvement Organization (BFCC-QIO) by an enrollee made verbally or in writing. Under Part D, a complaint may also involve a late enrollment penalty (LEP) determination.

Dismissal: A decision not to review a request for a grievance, initial determination, or appeal because it is considered invalid or does not otherwise meet Medicare Advantage or Part D requirements.

Effectuation: Authorization or provision of a benefit that a plan has approved, payment of a claim or compliance with a complete or partial reversal of a plan's original adverse determination.

Enrollee: An eligible individual who has elected a Medicare Advantage, Prescription Drug, or cost plan or health care prepayment plan (HCPP).

Grievance: Any complaint expressing dissatisfaction with any aspect of the operations, activities or behavior of a plan or its delegated entity in the provision of health care items, services, or prescription drugs, regardless of whether remedial action is requested or can be taken. A grievance does not include, and is distinct from, a dispute of the appeal of an organization determination or coverage determination.

Independent Review Entity (IRE): An independent entity contracted by CMS to review adverse level 1 appeal decisions made by the plan. Under Part C, an IRE can review plan dismissals.

Inquiry: Any verbal or written request for information to a plan or its delegated entity that does not express dissatisfaction or invoke a plan's grievance, coverage or appeals process, such as a routine question about a benefit.

Beneficiary and Family Centered Care Quality Improvement Organization (BFCC-QIO): Organizations comprised of practicing doctors and other health care experts under contract to the

federal government to monitor and improve the care given to Medicare enrollees. The BFCC-QIOs review enrollee complaints about the quality of care provided by physicians, inpatient hospitals, hospital outpatient departments, hospital emergency rooms, skilled nursing facilities (SNFs), home health agencies (HHAs), Medicare managed care plans, Medicare Part D prescription drug plans, and ambulatory surgical centers. The BFCC-QIOs also review continued stay denials in acute inpatient hospital facilities as well as coverage terminations in SNFs, HHAs, and comprehensive outpatient rehabilitation facilities (CORFs). In some cases, the BFCC-QIO can provide informal dispute resolution between the health care provider (e.g., physician, hospital, etc.) and enrollee.

Quality of Care Grievance: A complaint or grievance related to whether the quality of services provided by a plan or provider meets professionally recognized standards of health care, including whether appropriate health care services have been provided or have been provided in appropriate settings.

Reconsideration: Under Part C, the first level in the appeals process which involves a review of an adverse organization determination by a MA plan, the evidence and findings upon which it was based, and any other evidence submitted by a party to the organization determination, the MA plan or CMS. Under Part D, the second level in the appeals process which involves a review of an adverse coverage determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains. As used in this guidance, the term may refer to the first level in the Part C appeals process in which the MA plan reviews an adverse Part C organization determination or the second level of appeal in both the Part C and Part D appeals process in which an independent review entity reviews an adverse plan decision.

Redetermination: First level in the Part D appeal process in which the plan sponsor reviews an adverse Part D coverage determination, including the findings upon which the decision was based and any other evidence submitted or obtained.

Reopening: A remedial action taken to change a binding determination or decision even though the determination or decision may have been correct at the time it was made based on the evidence of record.

Representative: Under Part C, as defined in §422.561, an individual appointed by an enrollee or other party, or authorized under state or other applicable law, to act on behalf of an enrollee or other party involved in a grievance or appeal. Under Part D, as defined in §423.560 as "appointed representative", an individual either appointed by an enrollee or authorized under state or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. For both Part C & Part D, the representative will have all of the rights and responsibilities of an enrollee or other party, as applicable.

10.2 – Applicability to Employer-Sponsored Benefits

Part C Only: Managed care appeal procedures apply to all benefits offered under a MA plan, including optional supplemental benefits. However, determinations on items or services purchased by an employer, over and above the Medicare approved benefit package provided by the MA plan, such as payments of premiums or enrollee cost sharing provided by the employer, are not subject to the requirements outlined in this guidance.

Part D Only: Part D appeal procedures apply to all Part D benefits offered under an Employer/Union-Only Group Waiver Plan (EGWP). These plans are offered by Medicare Advantage Organizations, PDP Sponsors, or Cost Plan Sponsors. Part D plan sponsors of EGWPs must follow Part D determination, grievance, and appeal procedures in cases in which the provision of employer other health insurance is inextricably intertwined with drugs offered under the Part D benefit such that the two cannot be separated as a practical matter. See Chapter 12 of the Prescription Drug Benefit Manual for additional information on prescription drug benefits for EGWPs.

10.3 – Claims Processing and Appeals for Medicare Cost Plans and Health Care Prepayment Plans (HCPPs)

It is often appropriate for the Medicare Administrative Contractors (MACs) to process claims for enrollees in cost plans (except as specified otherwise, these rules affecting cost plans also apply to HCPPs) as regular Part B claims (e.g., when enrollees see an out-of-network physician without plan authorization or for certain services such as physical therapy [see Chapter 17(B), §300 of the Medicare Managed Care Manual]). It may also be appropriate for MACs to process Part B emergency or urgently needed services (See 42 CFR §417.558).

Similarly, it may be appropriate for a MAC to process claims for cost plan enrollees as regular Part A claims (e.g., when enrollees use an out-of-network facility or for certain services such as home health or hospice services [see Chapter 17(B), §300 of the Medicare Managed Care Manual]). Also, if a cost plan with a contract under section 1876 of the Social Security Act (the Act) elects "billing option 1" (i.e., chooses to have CMS pay for all hospital and skilled nursing facility (SNF) services – see 42 CFR §417.532(c)), the MAC would process any claims received (including Part B hospital outpatient claims).

However, regardless of who pays Part A or Part B claims, if an enrollee has received services through the cost plan's network, or out-of-network at the direction of the cost plan/network provider (e.g. referral), or because of an emergency inpatient admission, appeals concerning a denial of payment of such services are subject to the rules that apply to cost plan services. Pursuant to §417.600, those rights, procedures, and requirements pertaining to appeals contained in 42 CFR Part 422 Subpart M are applicable to enrollees in 1876 cost plans. (In the case of an HCPP, §417.840 requires HCPPs to apply the MA regulations at §§422.568 through 422.626 to appeals related to Part B services. Part A services are not covered under the HCPP agreement, and would always be processed under the 42 CFR Part 405 fee-for-service appeals rules.) Furthermore, the enrollee cannot be held liable for a Part A or Part B service just because a MAC

denied the claim under these circumstances. This is true even though the cost plan has no influence on the MAC decision. The 42 CFR Part 405 fee-for-service appeals rules apply to the first level appeal in a 1876 cost plan only in a case in which the enrollee self-referred out of the cost plan's provider network or hospital/SNF network without the cost plans involvement (including outpatient emergency services at an out-of-network hospital). Any disputes involving applicable cost-sharing are subject to the rules that apply to cost plan services at 42 CFR Part 422 Subpart M.

If an enrollee files an appeal with the cost plan when the appeal should have been filed with the MAC, the cost plan must inform the enrollee that the appeal should be filed with the MAC that denied the payment. The cost plan should direct the enrollee to the Medicare Summary Notice (MSN) for an explanation of the 42 CFR Part 405 fee-for-service appeals process. The cost plan must inform the enrollee in the Evidence of Coverage (EOC) that the cost plan's appeals process is only for disputes relating to organization determinations made by the plan or certain emergency admissions.

10.4 – General Responsibilities of the Plan

10.4.1 – Decision Making Timeframes

The medical exigency standard requires a plan and the independent review entity to make decisions as "expeditiously as the enrollee's health condition requires." This standard is set forth in regulations at Part 422 Subpart M and Part 423 Subpart M with respect to coverage requests and effectuation of favorable decisions.

This standard requires that the plan or the independent review entity apply, at a minimum, established accepted standards of medical practice in assessing an individual's medical condition. Evidence of the individual's condition can be obtained from the treating provider or from the individual's medical record (e.g., diagnosis, symptoms, or test results).

This standard was established by regulation to ensure that plans develop a standard for determining the urgency of coverage requests, triage incoming requests against established criteria, and prioritize each request according to these standards. Plans must treat each case in a manner that is appropriate for the facts and circumstances of the enrollee's medical condition. Plans should not routinely take the maximum time permitted for adjudicating coverage requests.

Calculation of Days for Assessing Plan Timeliness

For the purpose of assessing the timeliness of a plan's completion of a grievance, initial determination, or reconsideration, the day a plan receives the request is not counted as "day one". "Day one" is the day after receipt of the request. (Day/days are calendar days unless otherwise specified and includes weekends and holidays). Timeframes measured in hours must be met within the number of hours indicated. For example:

A MA plan receives a request for a standard organization determination on May 1. The plan

must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the plan receives the request, which would be May 15.

A Part D plan sponsor receives a request for an expedited coverage determination on May 1 at 10:30 am. Given the 24-hour timeframe, the plan must notify the enrollee of its determination no later than 10:30 am on May 2.

When a Request is Considered Received by the Plan

Plans must have processes in place to accept coverage and appeal requests 24 hours a day, 7 days a week (including holidays). Coverage requests (and for Part D, prescriber supporting statements for exception requests) are deemed "received" on the date and time:

- The plan initially stamps a document received by regular mail (i.e., U.S. Postal Service);
- A delivery service that has the ability to track when a shipment is delivered (e.g., U.S. Postal Service, UPS, FedEx, or DHL) delivers the document;
- A faxed document is successfully transmitted to the plan, as indicated on the fax transmission report;
- A verbal request is made by telephone with a customer service representative;
- A message is left on the plan's voicemail system if the plan utilizes a voicemail system to accept requests or supporting statements after normal business hours; or
- A request is received through the plan's website, provided the website and/or portal meets all applicable regulatory requirements.

Note: The processing timeframe begins when the plan, any unit in the plan, or a delegated entity (including a delegated entity that is not responsible for processing) receives a request. Plan material should clearly state where pre and post service requests should be sent, thus ensuring requests are received at the correct location and giving the plan the greatest amount of time to process the request. Plan policy and procedures should clearly indicate how to route requests that are received in an incorrect location to the correct location as expeditiously as possible.

10.4.2 – Plan Communication to an Enrollee

Plans must establish and maintain procedures for standard and expedited initial determinations, appeals and grievances. Written information about these procedures (including the quality of care grievance process available through the Beneficiary and Family Centered Care Quality Improvement Organization (BFCC-QIO)) must be provided to enrollees at initial enrollment, upon an enrollee's request and annually thereafter, as well as in any circumstance that provides

enrollee rights to initial determinations, appeals, and grievances as described throughout this guidance, including but not limited to:

- Grievance procedures available upon involuntary disenrollment initiated by the plan;

- Any changes to the plan's grievance procedures 30 days in advance of the effective date of the changes; and

- Appeals procedures upon notification of an adverse initial determination or a service or coverage termination (e.g., hospital, CORF, HHA, or SNF settings).

All written communication and notifications must be written in a manner that is understandable to the enrollee. Where applicable in standardized notices, the plan must use the approved notice language. (See §§40.12 and 50.10 for notification requirements for initial determinations and level 1 appeals, respectively.)

Plans must also provide written communications and notices described in this guidance in alternate formats and languages consistent with Section 1557 of the Affordable Care Act and Section 504 of the Rehabilitation Act of 1973. In addition, a plan's fax and e-mail or web-based portal systems must meet the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security requirements.

Unless otherwise specified, written notification is considered "delivered" on the date (and time, if applicable) the plan or delegated entity has deposited the notice in the courier drop box (e.g., U.S. Postal Service or FedEx bin).

Good Faith Effort to Provide Verbal Notification

Plans may satisfy a notification requirement by first providing verbal notice of its coverage decision to an enrollee, so long as it provides written notice thereafter, consistent with the notice requirements described below. Regardless of whether the plan can reasonably expect to notify the enrollee of a decision verbally (e.g., if the plan does not have a telephone number for the enrollee on file) it must ensure that timely written notice is provided to the enrollee.

When a plan has an enrollee's telephone number on file, but is unable to reach the enrollee at the number provided because, for example, it is either incorrect, out-of-service, or no person (or voicemail system) answers, the plan's good faith effort to provide verbal notice satisfies the notice requirement if:

- The good faith effort is documented in writing and included in the case file;

- Written notice of the decision (when written notification is required) is immediately sent to the enrollee; and

- The plan is not at fault for its inability to reach the enrollee by phone (e.g., the plan did not make a transcribing error when writing the telephone number).

If the plan successfully provides verbal notice and subsequent written notification is required, the plan must send written notice within 3 calendar days of the verbal notice. However, if a good faith effort was made but the plan is not able to provide verbal notice, written notice must be sent immediately.

10.4.3 – Role of the Medical Director

In accordance with 42 CFR §422.562(a)(4) and 423.562(a)(5), all plans must employ a medical director who is responsible for ensuring the clinical accuracy of all coverage decisions made by the plan that involve medical necessity. CMS expects plans to have processes in place for elevating issues of clinical concern to the medical director; however, it is not expected that a plan's medical director will review every medical necessity decision and CMS considers he or she to be fulfilling their responsibility through the plan's established process for when a medical director must be involved.

The medical director has overall responsibility for the plan's clinical decision-making, and as such, is expected to be involved in various aspects of related plan policies and operations including, but not limited to: medical and utilization review, benefits and claims management, formulary administration, processing coverage decisions in accordance with adjudication timeframes and notice requirements, provider/prescriber outreach, staff training, and oversight of delegated entities. The medical director must be a physician, as defined in section 1861(r) of the Act, with a current license to practice medicine in a state, territory, Commonwealth of the United States, or the District of Columbia.

10.4.4 – Delegation of Responsibilities

With the exception of the employment of the medical director, a plan may delegate any of the responsibilities discussed in this guidance to another entity or individual that provides or arranges Part C or Part D benefits. In cases of delegation, the plan remains responsible and must therefore ensure that requirements are met completely by the delegated entity and/or individual. The plan must have a comprehensive and on-going monitoring and auditing process in place to validate the performance of the delegated entities' compliance with applicable CMS requirements.

10.4.5 – Outreach for Additional Information to Support Coverage Decisions

Plans must have processes in place for making timely coverage decisions (initial requests and appeals), which includes soliciting clinical documentation, such as medical records, when necessary. If a plan does not have enough information to make a pre-service or pre-benefit coverage decision, it should make reasonable and diligent efforts to obtain all necessary information.

Plans are only required to conduct outreach to request additional information from a provider if the plan does not have all necessary information to make a coverage or appeal decision. In instances when outreach is necessary to make a coverage or appeal decision, a minimum of one attempt to obtain additional information (plans may make multiple attempts, using multiple methods for requesting information (e.g., telephone, fax, e-mail, etc.)), and involve plan physicians, is sufficient. If the plan does not receive any additional information, the plan should make the best decision it can based on the information available within the required adjudication timeframes. Plans are not required to conduct outreach prior to denying claims payments if they believe they have all the necessary information needed to make a coverage decision.

> **Part C Only:** For expedited organization determination and reconsideration requests, if medical information is needed from a non-contract provider, the MA plan must request the necessary information within 24 hours of receipt of the request.

> **Part D Only:** For expedited redetermination requests, if medical information is needed, the Part D plan sponsor must request the information within 24 hours of receipt of the request.

Plans should document all requests for information and maintain that documentation within the case file. If the plan issues an adverse decision due to the inability to obtain clinical information needed to approve coverage, the plan should clearly identify that basis and the necessary information in the written denial notice. See §§422.568(d) and (e), 422.570(d), and 422.572(d) for denials related to Part A and B services and items, and 423.568(f) and (g) for denials related to Part D benefits.

> **Note:** See §20.2.1 for information regarding missing documentation for representation (i.e., no appointment of representation form on file), and §50.1.1 for missing Waiver of Liability form (WOL) for non-contract providers.

20 – Representatives

20.1 – Representatives Filing on Behalf of Enrollees

Individuals who represent enrollees may either be appointed or authorized (for purposes of this guidance, both are referred to as "representatives") to act on behalf of the enrollee in filing a grievance, requesting an initial determination, or in dealing with any of the levels of the appeals process.

Who Can Appoint a Representative	Who Can Act or be Appointed as a Representative	Requirement for Representation
Enrollee	Any individual (e.g., relative, friend, advocate, attorney)	The enrollee must submit Form CMS-1696, Appointment of Representative (AOR), or an equivalent written notice (hereinafter, collectively referred to as a representative form).
A court acting in accordance with state or other applicable law*	An individual authorized by the court. Could include, but is not limited to: • Court appointed guardian • Individual with durable power of attorney • A health care proxy • A person designated under a health care consent statute • Executor of an estate	• A representative form is not required. • Authorized individual must produce appropriate legal papers supporting his or her status under state law.

*Plans with service areas comprising more than one state should be aware of the different state representation requirements and are responsible for determining whether a person or entity who asserts surrogate status is an appropriate surrogate under state law.

Enrollees cannot verbally appoint a representative and must submit a valid representative form. However, if a purported representative makes a verbal request and the enrollee verbally confirms they want to file the request described by the purported representative, the request must be recorded and processed as a request from the enrollee, not a representative. All communication (written and verbal) must be provided to the enrollee until a valid, written representative form is on file.

20.2 – Appointment of Representative (AOR) Form or Equivalent Written Notice

If an appointment is made using the OMB-approved Form CMS-1696, Appointment of Representative (AOR), or an equivalent written notice (see requirements below) the plan must accept it. Plans are prohibited from requiring the use of a specific form for appointments. The AOR contains the necessary elements to meet representation requirements, and is preferred. (**Note:** Section 4 of the AOR does not apply to MA plans or Part D plan sponsors.) Plans may not require information beyond what is included in the AOR or the requirements outlined below for an equivalent written notice.

Plans are required to accept an AOR with electronic signatures if the form is submitted through

the plan's secure portal, provided the portal meets all applicable regulatory and CMS website requirements.

An equivalent written notice includes the following:

- Name, address, and telephone numbers of the enrollee and the individual being appointed;
- Enrollee's HICN (Health Insurance Claim Number) or Medicare Beneficiary Identifier (MBI), or plan ID number;
- The appointed representative's professional status or relationship to the party;
- A written explanation of the purpose and scope of the representation;
- 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;
- A statement by the individual being appointed that he or she accepts the appointment; and
- Is signed and dated by the enrollee and the individual being appointed.

A representative form is valid for one year from the date it is signed by both the enrollee and the appointee, unless revoked. If the enrollee would like the same individual to continue serving as a representative after one year, the enrollee must reappoint that person by submitting a new representative form. In addition, a form is valid for the life of a grievance, coverage request, or appeal if the grievance, coverage request, or appeal was received within one year of the date a representative form is signed by both the enrollee and appointee. If the representative form is maintained and accessible by the plan, a photocopy of the signed representative form is not required to be filed with future grievances, coverage requests, or appeals made on behalf of the enrollee in order to continue representation. If the plan uses a representative form that is on file for requests, it must include a copy when sending a case file to higher level adjudicators, if applicable.

> **Note:** A representative form submitted with a request that specifically limits the appointment to MA or Part D benefits is not valid for requests that involve Part D or MA benefits, respectively. In these instances, the enrollee must properly execute separate representative forms.

20.2.1 – Missing or Defective Representative Form

When a grievance or a request for an initial determination or level 1 appeal is filed by a person claiming to be a representative, but the party does not provide the valid representative documentation to show that the individual is authorized to act on the enrollee's behalf, the plan

should:

- For expedited requests, develop procedures to ensure that expedited requests are not inappropriately delayed.

- Inform the enrollee and purported representative, in writing, that the grievance, coverage request, or appeal is not valid until documentation is provided.

- Make and document its reasonable efforts to secure the necessary representative documentation.

The plan must not issue a decision until or unless such documentation is obtained. The plan is not required to undertake a review until or unless such documentation is obtained, but may choose to begin the review while continuing efforts to obtain the representative documentation. The timeframe for acting on a grievance, coverage request, or appeal begins when the documentation is received.

If the plan does not receive representative documentation within a reasonable time for grievances and coverage requests or by the conclusion of the determination timeframe for the type of case, plus any applicable extension, the following apply:

- **Grievances and coverage requests:** May be dismissed on the grounds that a valid request was not received. The plan should notify the enrollee and the person asserting representative status of the dismissal in writing. The dismissal notice should explain the reason(s) for the dismissal, how the invalid request can be cured, and that the request will be processed if the enrollee or representative resubmits a properly executed form.

- **Appeal requests:** May be dismissed. The plan should notify the enrollee and the person asserting representative status of the dismissal in writing, explaining that if the representative documentation is submitted after the 60-day filing deadline for requesting an appeal has expired, a good cause statement explaining why the form was not filed timely should be included with the requested documentation.

Part C Only: If a MA plan dismisses an appeal, the MA plan must send a written dismissal notice that states the reason for dismissal and explains the right to request IRE review of the dismissal within 60 calendar days after receipt of the written notice of the MA plan's dismissal. See §50.9 for additional information regarding reconsideration dismissal procedures.

Note: A prescribing physician or other prescriber (a health care professional other than a physician that is authorized under state law or other applicable law to write prescriptions), provider, or supplier may not charge an enrollee for representation in filing a grievance, coverage request, or appeal. Administrative costs incurred by a representative during the appeals process are not reasonable costs for Medicare reimbursement purposes.

20.3 – Authority of a Representative

The representative has all of the rights and responsibilities of an enrollee in filing a grievance, obtaining a coverage request, or in dealing with any levels of the appeals process.

If an enrollee has identified a representative, all notices or other correspondence that must be sent to the enrollee per the regulations at 42 CFR Part 422 or 423 Subpart M must be sent to the enrollee's representative instead of to the enrollee.

30 – Grievances

A grievance is a complaint expressing dissatisfaction with any aspect of the operations, activities, or behavior of a plan or its delegated entity in the provision of health care or prescription drug services or benefits, regardless of whether remedial action is requested. The regulations at 42 CFR §422.564(a) and 423.564(a) require each plan to have meaningful procedures for the timely resolution of grievances between enrollees and the plan or any of its delegated entities. This process applies when the plan directly receives the grievance. Plans must provide all enrollees with written grievance procedures upon initial enrollment, involuntary disenrollment, annually, and upon request. The plan must also notify enrollees about any changes to its grievance procedures 30 days in advance of the effective date of the change.

Decisions made under the grievance process are not subject to appeal.

30.1 – Classification between Grievances, Inquiries, Coverage Requests, and Appeals

An enrollee or a provider may contact a plan to file, make, or request a grievance, inquiry, coverage request, or appeal. Grievance procedures are separate and distinct from initial determination and appeal procedures. Any communication from an enrollee or a provider must be reviewed on a case-by-case basis to determine how it should be categorized. The enrollee or provider is not required to use any specific language to indicate what they are requesting. Plans must determine whether the matter or the issue is a grievance, coverage request, appeal, or combination of more than one category. In these instances, plans must notify the enrollee (verbally or in writing) if the issue is a grievance or an appeal. If an enrollee raises two or more issues in one complaint, then each issue should be processed separately and simultaneously (to the extent possible) under the appropriate procedure. Plans should ensure that customer service representatives are trained to distinguish between coverage requests and grievances.

> **Note**: If the plan misclassifies a grievance as an appeal and the case goes to the IRE, the IRE will dismiss the appeal and return the case to the plan for proper processing. The plan must notify the enrollee in writing that the case was misclassified and will be handled through the plan's grievance process. For initial determination requests misclassified as grievances, see §40.13. For appeals that are misclassified as grievances see §50.11.

Examples of Inquiries, Grievances, Coverage Requests, and Appeals

Inquiries may include the following:

- An enrollee calls the plan to determine if a drug or service is covered, the plan tells the enrollee that it is not covered, the enrollee does not complain about the exclusion or non-coverage, does not make a request for the drug or service, nor does the enrollee argue that it should be covered under certain circumstances.

Grievances may include complaints concerning the following:

- An enrollee's involuntary disenrollment initiated by the plan;
- A change in premiums or cost sharing arrangements from one contract year to the next;
- Lack of quality of the care received;
- Plan benefit design;
- Difficulty contacting the plan via phone;
- Interpersonal aspects of care;
- The appeals process;
- The plan's decision not to expedite a coverage or appeal request;
- General dissatisfaction about a co-payment amount, but not a dispute about the amount the enrollee paid;
- General complaint about a drug not being on the formulary or listed as an excluded drug; or
- Calculation of True Out-of-Pocket (TrOOP) costs.

Coverage Requests may include when an enrollee:

- Calls requesting or indicating they want a drug, service, or item;
- Wants to continue care with a provider who is no longer contracted with the plan (out of network coverage);
- Wants to continue receiving services already received in accordance with the original organization determination (this is a request for a new set of services);
- States that their drug was rejected at the pharmacy but they need it; or
- States that a drug is not excluded from Part D coverage for the indication for which it is being prescribed.

***Coverage Requests for Part D Only may include when an enrollee argues that*:**

- A drug is a covered Part D drug under §1860D-2(e)(1) of the Act or is covered under §1860D-2(e)(1) for a specific indication;

- A drug is not excluded under §1860D-2(e)(2) of the Act or is not excluded under §1860D-2(e)(2) for a specific indication;

- A drug is not excluded under §1860D-43 of the Act; or

- A drug is covered by the plan as a supplemental benefit.

Conversely, if an enrollee is not disputing that a drug is not a covered Part D drug or is excluded from coverage, but has a question or general complaint about the drug not being covered, the transaction should be processed as an inquiry or a grievance, respectively.

Appeals may include the following:

- An enrollee calls after receiving a bill stating they believe that the plan has required them to pay a co-pay amount that should be the plan's responsibility or they dispute the calculation of the co-pay amount.

- An enrollee calls his or her plan and states, "I would like to file a complaint. You denied my request for drug X or service Y and I need it." When an adverse initial determination has been made, the enrollee's dispute should be treated as an appeal of the denial. Therefore, either an appeal should be started or, if the plan does not accept verbal standard appeal requests, they must inform the enrollee of how to submit a written appeal request.

Examples of Both a Grievance and a Coverage Request:

- A complaint concerning untimely receipt of a service or Part D drug that has already been covered may be treated as a grievance. If the enrollee also states that he or she was unable to obtain the covered service or Part D drug and that the delay will adversely affect his or her health, it should be processed as a coverage request, as well as a quality of care grievance.

- An enrollee complains that they had to wait so long for a service or Part D drug that they went out-of-network. This should be treated as a coverage request for the out-of-network service or Part D drug, as well as a grievance about the timeliness of the service/benefit.

- An enrollee has a benefit that covers one pair of eyeglasses every 24 months with a maximum contribution of $70.00. The enrollee asserts that the prescription was wrong, and requests that the plan cover another pair of glasses. The enrollee indicates that the previously rendered services are inadequate, or substandard in quality. Therefore, this would be classified as a grievance (quality of care grievance) and the request for a new pair of glasses is a new coverage request.

30.1.1 – Inquiries Related to Non-Part D and Excluded Drugs

When a Part D plan sponsor receives an inquiry (that is, a question that is not a request for a coverage determination) about a drug that is never covered by Part D or is an excluded drug, it should explain the following to the requestor:

- Certain drugs (or the requested drug) are not covered Part D drugs under 1860D-2(e)(1) of the Act, or are excluded from coverage under 1860D-2(e)(2) or 1860D-43 of the Act and the plan sponsor cannot or does not offer the drug as a supplemental benefit;

- Because the drug is not a covered Part D drug under 1860D-2(e)(1) of the Act, or is excluded from coverage under 1860D-2(e)(2) or 1860D-43 and is not offered as a supplemental benefit, the enrollee may not obtain it through the coverage determination, exceptions, or appeals processes;

- The enrollee should work with his or her physician or other prescriber to determine whether a drug on the plan's formulary is medically appropriate for treating the enrollee's condition; and

- The enrollee, physician, or other prescriber has the right to contact the plan sponsor and request a coverage determination if he or she believes that the requested drug is:

    - A covered Part D drug under section 1860D-2(e)(1) of the Act or covered under 1860D-2(e)(1) for the indication it is being prescribed for;

    - Not excluded under section 1860D-2(e)(2) of the Act or not excluded under 1860D-2(e)(2) for the purpose for which it was prescribed;

    - Not excluded under section 1860D-43 of the Act; or

    - Covered by the plan as a supplemental benefit.

A plan sponsor should provide this information either verbally or in writing. If a plan sponsor chooses to provide this information in writing, it may use the model Notice of Inquiry. If a plan sponsor provides this information verbally, this should be documented by the plan sponsor.

30.2 – Procedures for Handling a Grievance

Procedures for processing a grievance are as follows:

Filing Method	Filing Deadline	Processing Requirements
In writing	No later than 60 days after the incident that precipitates the grievance*	Plans must: • Complete the investigation as expeditiously as the case requires, based on the enrollee's heath status, but no later than 30 days of receipt of the request, or within 24 hours for expedited grievances.

Filing Method	Filing Deadline	Processing Requirements
		• Accept any information or evidence concerning the grievance. • Take prompt, appropriate action, including a full investigation if necessary. • Provide a response to all grievances raised in the complaint. • Have procedures for tracking and maintaining records about the receipt and disposition of grievances. • Be able to log or capture enrollees' grievances in a centralized location that is readily accessible. The record should include documentation of all telephone calls, correspondence, and case notes related to the grievance. • Expedite the grievance if: o It is related to a decision not to grant an enrollee's request to expedite an initial determination or appeal, and (for **Part D Only**) the enrollee has not yet obtained the drug; or o **Part C Only:** it involves a MA plan's decision to extend a timeframe related to an organization determination or appeal.
Verbal	Same as in writing.	Same as in writing; however, if a verbal grievance can be resolved during the same call by the customer service representative, the plan must document details of the resolution and proceed to log and report the call as a grievance.

*A plan may, but is not required to, accept and process a grievance that is filed after the 60-day deadline. If the plan chooses not to accept untimely filing, they may dismiss the grievance.

**Plus a 14-day extension if the enrollee requests the extension or if the plan justifies a need for additional information and documents how the delay is in the best interest of the enrollee. Plan must promptly notify the enrollee in writing if the extension is going to be taken and explain the reason for the delay. See: 42 CFR §§422.564(e)(2) or 423.564(e)(2).

Notification requirements for grievances are as follows:

Filing Method	Notification Requirements
In writing	• For standard grievances, notification must be made no later than 30 days from receipt**. • For expedited grievances, notification must be made no later than 24 hours from receipt. • Response must: o Be in writing; o Address all issues raised in the grievance; and o Be written in a manner that is understandable to the enrollee. **Note:** If the enrollee's representative submits a request, the representative must be notified in lieu of the enrollee.
Verbal	• Same timeframes as above. • Response may be verbal or in writing, unless specifically requested in writing or the grievance raises a quality of care issue (see §30.3). **Note:** If the enrollee's representative submits a request, the representative must be notified in lieu of the enrollee.

30.3 – Quality of Care Grievances

A quality of care grievance is a type of grievance that is related to whether the services provided by a plan or provider meets professionally recognized standards of health care. Examples of a quality of care grievance include any instances where an enrollee infers or states they believe:

- They were misdiagnosed;
- Treatment was not appropriate; and/or
- They received, or did not receive, care that adversely impacted or had the potential to adversely impact their health.

Quality of care grievances may be received and acted upon by the plan, the Beneficiary and Family Centered Care Quality Improvement Organization (BFCC-QIO), or both. For any grievance submitted to the BFCC-QIO, plans must cooperate with the BFCC-QIO in resolving the grievance, including directing providers to respond to BFCC-QIO requests for information, within 14 days. Plans should provide any records and requested information as quickly as possible and within 14 days.

30.3.1 – Procedures for Handling a Quality of Care Grievance

Method for Filing	Filing Deadline	Processing Requirements
Verbally or in writing with the plan	No later than 60 days after the incident that precipitates the grievance*	Plans must: • Respond in writing within 30** days of receipt, and as expeditiously as the enrollee's health condition requires. • Written notice must: o Include a description of the enrollee's right to file a grievance with the BFCC-QIO and contact information for the BFCC-QIO; and o Be written in a manner that is understandable to the enrollee. **Note:** If the enrollee's representative submits a request, the representative must be notified in lieu of the enrollee. • If applicable: o Cooperate with the BFCC-QIO in resolving the grievance. o Comply with requirements at 42 CFR Part 476 regarding timely submission of requested information to the BFCC-QIO if an enrollee files a grievance with the BFCC-QIO and the plan.

*A plan may, but is not required to, accept and process a grievance that is filed after the 60-day deadline. If the plan chooses not to accept untimely filing, they may dismiss the grievance.

**Plus a 14-day extension (if applicable). Plan must notify the enrollee in writing if the extension is going to be taken and explain the reason for the delay. See: 42 CFR §§422.564(e)(2) or 423.564(e)(2).

30.4 – Procedure for Handling Withdrawn Grievances

If an enrollee submits a written grievance and then contacts the plan at a later date to request a withdrawal of the grievance, the plan may choose to permit an enrollee or their representative to withdraw the grievance verbally. The plan must clearly document that the enrollee does not want to proceed with the grievance procedures. The plan should send a written confirmation of that withdrawal to the enrollee.

40 – Coverage Determinations, Organization Determinations (Initial Determinations) and At-Risk Determinations

A coverage determination/organization determination (hereafter referred to as an initial determination) is a decision made by the plan, or its delegated entity, on a request for coverage (payment or provision) of an item, service, or drug.

40.1 – Part C Organization Determinations

The Part C regulations define an "organization determination" by reference to five specific categories of decisions; this guidance provides additional guidance on what MA plan determinations are within that definition.

An organization determination is any determination (i.e., an approval or denial) made by a MA plan, or its delegated entity with respect to the following:

- Payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services;

- Payment for any other health services furnished by a provider (other than the MA plan), that the enrollee believes are covered under Medicare, or if not covered under Medicare, should have been furnished, arranged for, or reimbursed by the MA plan.

- Refusal to authorize, provide, or pay for services, in whole or in part, including the type or level of services, which the enrollee believes should be furnished or arranged by the MA plan;

- Reduction, or premature discontinuation, of a previously authorized ongoing course of treatment; or

- Failure of the MA plan to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.

Whenever an enrollee contacts a MA plan to request a service, the request itself indicates that the enrollee believes the MA plan should provide or pay for the service. However, when a provider declines to furnish a service requested by an enrollee, this is not an organization determination (the provider is making a treatment decision). In this situation, the enrollee must contact the MA plan to make a coverage request for the service in question, or the provider may make the coverage request on the enrollee's behalf. The MA plan must educate enrollees and providers that when there is a disagreement with a provider's decision to decline to furnish a service or a course of treatment, in whole or in part, the enrollee has a right to request and receive an organization determination from the MA plan.

40.2 – Part D Coverage Determinations

A coverage determination is any determination made by the Part D plan sponsor, or its delegated entity, with respect to the following:

- A decision about whether to provide or pay for a drug that an enrollee believes may be covered by the plan sponsor, including a decision related to a Part D drug that is:
    - not on the plan's formulary;
    - determined not to be medically necessary;
    - furnished by an out-of-network pharmacy; or
    - otherwise excluded under §1862(a) of the Act if applied to Medicare Part D.
- A decision on the amount of cost sharing for a drug;
- Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;
- Whether an enrollee has, or has not, satisfied a prior authorization or other utilization management requirement;
- A decision about a tiering exception request under 42 CFR §423.578(a); or
- A decision about a formulary exception request under 42 CFR §423.578(b).

Note: A plan sponsor is not required to treat the presentation of a prescription at the pharmacy as a request for a coverage determination. Accordingly, the plan sponsor is not required to provide the enrollee with a written denial notice at the pharmacy as a result of the transaction. However, as required under 42 CFR §423.562(a)(3), plan sponsors must arrange with their network pharmacies to distribute the standardized pharmacy notice developed by CMS to notify enrollees of their right to request a coverage determination. See §40.12.3 for information about required notification at the point of sale.

40.3 – Part D At-Risk Determinations

[This guidance was developed as a result of recent changes to federal regulation to support the implementation of the Comprehensive Addiction and Recovery Act (CARA) and will be effective January 1, 2019.]

An at-risk determination is a decision made under a plan sponsor's drug management program under the rules at 42 CFR §423.153(f) that involves:

- Identification of an individual as an at-risk beneficiary for prescription drug abuse;

- A limitation, or the continuation of a limitation, on access to coverage for frequently abused drugs (i.e., a beneficiary specific point-of-sale (POS) edit or the selection of a prescriber and/or pharmacy for purposes of lock-in); or

- Information sharing for subsequent Part D plan enrollments.

An at-risk determination is subject to the existing Part D benefit appeals process and timeframes as described in this section of the manual. If an enrollee disagrees with an at-risk determination made under a plan sponsor's drug management program, the enrollee has the right to request a redetermination and potentially higher levels of appeal. For additional information and requirements on the drug management programs that a plan sponsor may utilize, see Chapter 6 of the Prescription Drug Benefit Manual.

40.4 – Prior Authorization and Other Utilization Management Requirements

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 plan's determination on whether to grant approval of a service or a drug for an enrollee constitutes an initial determination and is subject to appeal. In addition, if a plan denies coverage of a service or 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[1] Thus, the adjudication timeframe, notice, and other requirements applicable to coverage determinations or organization determinations under parts 422 & 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 plan must accept and process the request as a coverage determination or organization determination and should contact the physician or prescriber for information needed to satisfy the PA, in accordance with the outreach guidance at §10.4.5.

The remainder of this section applies to Part D only

The decision to place a medication on a PA list or subject it to a UM requirement is not a coverage determination and is not subject to appeal. However, an enrollee may request that the Part D plan sponsor waive the PA or UM requirement, which would be treated as an exception request.

Plan sponsors must determine whether a request that involves PA or other UM requirement is either a coverage determination request where an enrollee is attempting to satisfy a PA

[1] For Part D, this denial would occur after an enrollee has formally requested a coverage determination with a Part D plan sponsor because, as indicated in §40.2 above, the presentation of a prescription at the pharmacy counter is not considered a request for a coverage determination unless a plan sponsor chooses to treat it as such.

requirement, or an exception request where the enrollee is asking the plan sponsor to waive a PA requirement. If the plan sponsor does appropriate outreach and is still unable to determine if the enrollee/prescriber is asking for an exception to the PA criteria (meaning the person was unresponsive to the request), the case should be treated as an attempt to satisfy the PA criteria.

Attempting to Satisfy a PA or other UM Requirement

A case where an enrollee/physician/other prescriber is attempting to satisfy a PA requirement (i.e., the enrollee/physician/other prescriber is aware that a PA requirement for the prescription drug exists and, for example, submits a PA form to the plan sponsor in an attempt to satisfy the PA requirement) should be processed as a coverage determination. The plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 24 hours after receiving the request for expedited cases, or no later than 72 hours after receiving the request for standard cases. Where an enrollee/physician/other prescriber is attempting to satisfy a PA requirement and the plan sponsor has a PA form available for seeking prior authorization for the requested drug, the plan sponsor should promptly provide the physician or other prescriber with the PA form. An enrollee, physician, or other prescriber may use the model Medicare Part D Coverage Determination Request Form to request an override to a PA or other UM requirement.

Asking a Plan Sponsor to Waive a PA or other UM Requirement

Where an enrollee or an enrollee's prescribing physician or other prescriber is asking a plan sponsor to waive a PA or other UM requirement (e.g., a physician or other prescriber indicates that an enrollee would suffer adverse effects if he or she were required to satisfy the PA requirement), he or she is asking for an exception and the prescribing physician or other prescriber must submit a statement to support the request consistent with the requirements set forth in 42 CFR §423.578(b)(5). A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form to request an exception and/or submit a supporting statement. If the request or supporting statement is made in writing, plan sponsors are prohibited from requiring a physician or other prescriber to submit the request or supporting statement on a specific form. If the exception request involves benefits not yet received, the plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 24 hours after receiving the physician's or other prescriber's supporting statement for expedited cases, or no later than 72 hours after receiving the physician's or other prescriber's supporting statement for standard cases. If the exception request involves reimbursement for benefits already received, the plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision (and make payment when appropriate) no later than 14 calendar days after receiving the request.

40.5 – Part D Exceptions

Coverage determinations include a plan sponsor's decision on an enrollee's exception request, which can be a request for an exception to the plan sponsor's tiered cost-sharing structure, or formulary or utilization management requirement. An exception request may include a request

for benefits, a request for payment, or both.

40.5.1 – Tiering Exceptions

[This guidance was developed as a result of changes to federal regulation for tiering exceptions and will be effective January 1, 2019.]

If a plan sponsor uses a tiered cost-sharing structure to manage its drug benefits, it must establish and maintain reasonable and complete exceptions procedures that permit enrollees to obtain a non-preferred drug in a higher cost-sharing tier at the more favorable cost-sharing terms applicable to alternative drugs in a lower cost-sharing tier.

Plans are permitted to limit the availability of tiering exceptions to applicable cost-sharing tiers containing the same type of alternative drug(s) for treating the enrollee's condition. Specifically, the following limitations may be applied by the plan:

- Brand name drugs are eligible for tiering exceptions to the lowest applicable cost-sharing associated with brand name alternatives.
- Biological products are eligible for tiering exceptions to the lowest applicable cost-sharing associated with biological alternatives.
- Non-preferred generic drugs are eligible for tiering exceptions to the lowest applicable cost sharing associated with alternatives that are either brand or generic drugs.

Plans are not required to offer tiering exceptions for brand name drugs or biological products at the cost-sharing level of alternative drugs, where the alternatives include only generic or authorized generic drugs.

A plan sponsor that maintains a specialty tier in which it places very high cost drugs and biological products may design its exception process so that Part D drugs placed on the specialty tier are not eligible for a tiering exception. However, the specialty tier may be considered a preferred tier for purposes of tiering exceptions. If the specialty tier has a more preferable cost-sharing than a drug placed on a non-preferred tier and there is an applicable alternative drug on the specialty tier, the plan may approve the tiering exception down to the cost-sharing of the specialty tier.

40.5.2 – Formulary Exceptions

Formulary exceptions include requests for non-formulary drugs, as well as requests to have a PA or other UM requirement waived for that enrollee. This language ensures that drugs that otherwise would not be covered (for example, because they are obtained out of network or excluded under §1862(a) of the Act), are not covered through the exceptions process, though these coverage determinations can be appealed through the appeals process.

Unlike under the tiering exceptions process, the regulations do not specify what level of cost sharing applies when an exception is approved under the formulary exceptions process. Instead, a plan sponsor has the flexibility to determine what level of cost sharing will apply for non-formulary drugs approved under the exceptions process. However, a plan sponsor is limited to choosing a single cost-sharing level that applies to one of its existing formulary tiers. For example, a plan sponsor may apply the non-preferred level of cost sharing for all non-formulary drugs approved under the exception process. Plans may also elect to apply a second less expensive level of cost sharing for approved formulary exceptions for generic drugs, so long as the second level of cost sharing is associated with an existing formulary tier and is uniformly applied to all approved formulary exceptions for generic drugs.

> **Note:** Under 42 CFR §423.578(c)(4)(iii), an enrollee is prohibited from requesting a tiering exception for a non-formulary drug approved under the formulary exception process. However, a drug that is subject to a UM requirement is a formulary drug (i.e., a UM requirement placed on a formulary drug does not make that drug a non-formulary drug). Therefore, an enrollee who requests a UM exception and receives an approval, may also request a tiering exception for the same formulary drug.

40.5.3 – Supporting Statements for Exception Requests

The physician's or other prescriber's supporting statement is any statement, verbal or written, that indicates the drug is medically necessary. The statement does not have to be complete with all required information for it to be considered received and for the timeframe to start. The adjudication timeframes for processing exception requests are the same timeframes for other coverage determinations under Part D (see §40.10). However, when a benefit request must be resolved under the exceptions process, the adjudication timeframe is tolled pending receipt of the prescriber's supporting statement. CMS has developed a model Request for Additional Information form that plan sponsors may use to request a supporting statement and/or additional information.

If upon receiving the supporting statement the plan sponsor still needs additional information, the plan sponsor must obtain the additional information, make its decision, and notify the enrollee and/or physician or other prescriber, as appropriate, within the following timeframes after receiving the initial written supporting statement (i.e., the timeframe is not tolled if the plan sponsor asks for additional information after it has received a written supporting statement):

- 24 hours for expedited requests for benefits;
- 72 hours for standard requests for benefits; or
- 14 calendar days for reimbursement requests.

If the physician or other prescriber provides a verbal supporting statement, and the plan sponsor determines that the verbal statement does not sufficiently demonstrate the medical necessity of the requested drug, the plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement. If the plan sponsor requires a written statement, it must immediately contact the enrollee's prescribing physician or other prescriber

(or the enrollee and the enrollee's prescribing physician or other prescriber) and request the supporting statement. The request must explicitly state that the physician or other prescriber is required to indicate factors (1) and/or (2) for tiering exceptions, or (1), (2), and/or (3) for formulary exceptions discussed below, as applicable, in the written supporting statement. The plan sponsor may also request additional supporting medical documentation as part of the written supporting statement. If the plan sponsor requires additional medical documentation, it must clearly identify the type of information that must be submitted.

Criteria for Tiering Exceptions

The prescriber's supporting statement must indicate that the drug(s) in the applicable lower cost-sharing tier(s) for the treatment of the enrollee's condition would:

(1) Not be as effective as the requested drug; and/or

(2) Have adverse effects.

Written Supporting Statements: If the physician provides a written statement indicating factors (1) and/or (2), but the plan sponsor believes it needs additional information to support one of those factors, the plan sponsor must obtain the additional information.

Criteria for Formulary Exceptions

The prescriber's supporting statement must indicate that the requested drug is medically necessary for one of the following reasons:

(1) All covered Part D drugs on any tier of the plan's formulary would not be as effective for the enrollee as the requested non-formulary drug, and/or would have adverse effects;

(2) The number of doses available under a dose restriction for the requested drug:

   a. Has been ineffective in the treatment of the enrollee's disease or medical condition; or
   b. Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

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

evidence, is likely to cause an adverse reaction or other harm to the enrollee.

Written Supporting Statements: If the physician provides a written statement indicating factors (1), (2), and/or (3), but the plan sponsor believes it needs additional information to support one of those factors, the plan sponsor must obtain the additional information.

40.5.4 – Adjudication Timeframes for Coverage Determinations Involving an Exception

The adjudication timeframes for exception requests are the same as the timeframes for other coverage determination requests. However, if the exception request involves benefits not yet received, the start of the timeframe is tolled (i.e., it does not begin) until the plan sponsor receives the prescriber's supporting statement. If the exception request is received without a supporting statement and the plan sponsor does not have sufficient information to approve, for example, through claims history or information contained in a previously adjudicated exception, the plan sponsor may conduct outreach to obtain it. See §10.4.5 for additional information regarding outreach guidelines.

Tolling the start of the adjudication timeframe is only permissible when ALL of the following are true:

- The request is at the coverage determination level; and
- The request involves an exception; and
- The prescriber has not provided a supporting statement; and
- It involves a request for benefits (rather than reimbursement).

Although the adjudication timeframe for these requests does not begin until the plan sponsor receives the supporting statement, the plan sponsor must not keep the request open indefinitely. If the plan sponsor does not receive the physician's or other prescriber's supporting statement indicating the required factors within a reasonable period of time, the plan sponsor should make its determination based on whatever evidence exists, if any. What determines a reasonable amount of time will depend on the facts and circumstance of each case; however, CMS does not believe it should exceed 14 calendar days, provided that the plan sponsor has contacted the enrollee and/or physician or other prescriber and clearly identified the information needed to process the request.

40.5.5 – Approval of an Exception Request

Type of Approval	Plan Requirement
Granting an Exception	• A plan sponsor must grant an exception when it determines that the applicable criteria have been met.

Type of Approval	Plan Requirement
	• Once an exception is granted, the plan sponsor is prohibited from requiring the enrollee to request approval for a refill or new prescription to continue using the Part D prescription drug approved under the exceptions process for the remainder of the plan year, so long as: ▪ the enrollee remains enrolled in the plan; ▪ the physician or other prescriber continues to prescribe the drug; and ▪ the drug continues to be safe for treating the enrollee's condition.
Continuation of Coverage Under an Approved Exception	• A plan sponsor may choose not to require an enrollee to resubmit an exception request at the beginning of a new plan year. • Whether or not a plan sponsor decides to allow coverage under an approved exception to continue into the subsequent plan year for a renewing enrollee the plan sponsor must send a written notice to the enrollee at least 60 days prior to the end of the plan year, unless: ▪ The plan sponsor sent an approval letter to the enrollee when it granted the exception at the coverage determination or redetermination level which clearly identified the date that coverage will end in the approval letter; or ▪ The plan sponsor sent written notice to the enrollee when it effectuated a reversal of its adverse coverage determination or redetermination decision by the IRE or other appeal entity, and clearly identified the date that coverage will end in the notice. Such notice is not the decision letter overturning the initial adverse determination, but is a notice explaining the terms of the approval as ordered by the IRE or other appeal adjudicator.

Note: The regulations at 42 CFR §423.578(f) affirmatively state that nothing in §423.578 should be construed to mean that the prescriber's supporting statement will result in an automatic favorable determination.

If a plan sponsor is required to send a written notice to the enrollee at least 60 days prior to the end of the plan year or the date coverage ends, the notice must:

- Explain that the exception will not be extended,
- Provide the date that coverage will end (e.g., on December 31, 2018),
- Explain the right to request a new exception once the current exception expires, and

- Provide instructions for making a new exceptions request.

Plan sponsors are prohibited from assigning drugs approved under the exceptions process to a designated tier, co-payment, or other cost-sharing requirement that does not otherwise exist on the plan sponsor's approved formulary. Additionally, drugs approved under the exceptions process must be authorized or effectuated without the plan sponsor placing additional edits on the request (e.g., the plan sponsor cannot place an unapproved quantity limit or duration limit on the approved drug).

> **Note**: For more information regarding formulary changes, such as removal of a drug from the formulary or changing its cost-sharing status, see Chapter 6 of the Prescription Drug Benefit Manual. Plan sponsors may use the model Notice of Formulary or Cost-sharing Change to notify enrollees whenever it changes its formulary or the cost-sharing status of a drug during the plan year.

40.5.6 – Approval of a Tiering Exception Request

[This guidance was developed as a result of recent changes to federal regulation for tiering exceptions and will be effective January 1, 2019.]

A plan must grant a tiering exception when it determines that factors (1) and/or (2) discussed in 40.5.3 have been met. The regulations at 42 CFR § 423.578(f) state that nothing in the regulations should be construed to mean that the physician's or other prescriber's supporting statement will result in an automatic favorable determination. When a tiering exception is approved, the plan sponsor must provide coverage for the drug in the higher cost-sharing tier at the cost-sharing level that applies to the drug in the lowest applicable tier when preferred alternatives sit on multiple lower tiers. The cost-sharing must be at the most favorable cost-sharing tier that contains applicable alternative drugs, unless such alternative drugs are not applicable pursuant to the limitations set forth at § 423.578(a)(6).

40.6 – Who May Request an Initial Determination

Enrollees or their representatives may make a request for all types of coverage under both Part C and Part D. Other parties that may request an initial determination include:

Type of Request	Who May Request
Part C, Standard Pre-Service Request	• Contract or non-contract provider/physician that furnishes, or intends to furnish, services to the enrollee. • Staff of said provider's/physician's office acting on said physician's behalf (e.g., request is on said physician's letterhead).

Type of Request	Who May Request
Part C, Expedited Request	• A physician or staff of said physician's office acting on said physician's behalf (e.g., request is on said physician's letterhead).
Part C, Payment Request	• Contract or non-contract providers.
Part D, Standard or Expedited Request	• An enrollee's prescribing physician or other prescriber. • Staff of said prescriber's office acting on said prescriber's behalf (e.g., request is on said prescriber's letterhead or comes from the prescriber office fax machine).
Part D, Payment Request	Only an enrollee or an enrollee's representative may request reimbursement under Part D (direct member reimbursement).

40.7 – Guidelines for Accepting Initial Determination Requests

Plans must have processes in place for receipt and documentation of initial determination requests, as described below.

Filing Method	Plan Requirement
Verbal	• Establish and maintain a process for categorizing and documenting verbal requests. • Retain documentation of a verbal request in the case file. • If the plan does not accept verbal requests for payment, the plan must explain the procedures the enrollee must follow for filing a written request.
Written	• Must accept any written request. • The plan is prohibited from requiring requests to be on a specific form. • Retain documentation in the case file. • The plan or other entity may develop a pre-service, benefit, and/or payment request form (for optional use). **Part D Only:** • Requests may be made on CMS' Model of Coverage Determination Request Form.

Filing Method	Plan Requirement
	• Part D plan sponsors may encourage enrollees to include copies of their prescriptions with their reimbursement requests, but cannot require it. • Plan sponsors must provide immediate access to the coverage determination process via their internet website. The mechanism used to accept coverage determination requests via a website is subject to the same privacy and security safeguards as the rest of the plan sponsor's operations in accordance with 42 CFR §423.136.

If, upon receipt of a coverage request, a plan does not have enough information to make a coverage decision, it must make reasonable and diligent efforts to obtain the necessary information. For additional information see §10.4.5.

40.8 – How to Process Requests for Expedited Initial Determinations

Who May Request an Expedited Determination	Plan Requirements
• An enrollee • An enrollee's representative • **Part C**: Any physician • **Part D**: Prescribing physician or other prescriber	• Establish an efficient and convenient means for individuals to submit verbal or written requests; • Establish procedures for accepting and processing verbal and written requests for an expedited decision; • Develop a process for receiving the request, including designating an office and/or department to receive both verbal or written requests and a telephone and fax number to facilitate receipt of the requests; • Document all verbal requests and maintain in the case file; • Promptly decide whether to expedite the request: ▪ If a request is made or supported by a physician, prescribing physician, or other prescriber who indicates applying the standard timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function (the physician does not have to use these exact words), the plan must process as expedited. ▪ Plans may, but are not required to, expedite payment requests. ▪ If a request involves both a payment request and pre-service or pre-benefit request, the enrollee has a right to ask for an expedited initial determination for the pre-service or pre-benefit request.

Note: A plan must not take or threaten any punitive action against a physician who acts on behalf or in support of a request for expedited determination.

Action Following Denial of a Request for an Expedited Initial Determination

Following denial of a request for an expedited initial determination, plans must:

- Transfer the request to the standard initial determination process;
- Give the enrollee prompt verbal notice of the denial to expedite the request; and
- Deliver a written notice within 3 calendar days of the verbal notice of the denial to expedite the request. See §40.12 for notification requirements.

Action Following Acceptance of a Request for Expedited Initial Determinations

If a plan grants a request for expedited determination, the initial determination must be made in accordance with the following:

Part C Only

Decision	Processing Requirements for Expedited Determinations
Favorable	• Provide notice* of favorable decision to the enrollee (and the physician involved, as appropriate) as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request. • The MA plan may notify the enrollee verbally or in writing and notification must be received by the enrollee within 72 hours (i.e., mailing the determination within 72 hours in and of itself is insufficient).
Partially Favorable or Adverse	Provide written notification* to the enrollee of the decision (and the physician involved, as appropriate) as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

*See §40.12.1 for notification requirements.

Extension of Timeframe

The MA plan may only extend the 72-hour timeframe by up to 14 days if:

- The enrollee requests the extension; or
- The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a non-contract provider in order to make a decision favorable to the enrollee (the MA plan should not extend the timeframe to get evidence to deny the

coverage request that may change a MA plan's decision to deny; or

- The extension is justified due to extraordinary, exigent or other non-routine circumstances and is in the enrollee's interest.

When the MA plan extends the timeframe, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if they disagree with the MA plan's decision to grant an extension.

Note: MA plans are expected to have sufficient and appropriate contract terms to get information and records from contract providers as necessary for expedited (and standard) organization determinations. MA plans should not generally or regularly extend the timeframe for an expedited organization determination to seek information or records from a contract provider but may do so if it is justified in the enrollee's interest and due to extraordinary, exigent, or other non-routine circumstances.

If the MA plan needs information from a non-contract provider, the MA plan must request the necessary information from the non-contract provider within 24 hours of the initial request for an expedited organization determination (See 42 CFR §422.572 and §10.4.5 regarding Outreach for Additional Information). Regardless of whether the MA plan needs information from non-contract providers, the MA plan is responsible for meeting the timeframe and notice requirements for expedited determinations.

Part D Only

Decision	Processing Requirements for Expedited Determinations
Favorable or Adverse (including requests that involve an exception)	• The Part D plan sponsor must make the decision and provide the enrollee (and the prescribing physician or other prescriber involved, as appropriate) written notice* of its decision as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request or, for exceptions, receipt of the physician's or other prescriber's supporting statement. • If the plan sponsor initially provides verbal notification of its decision, it must mail, fax, or e-mail written confirmation of its decision within 3 calendar days of the verbal notification. • A plan sponsor may not extend the timeframe by dispensing a temporary supply of the requested medication. For example, if a plan sponsor receives a request outside of its normal business hours, it cannot approve a 72-hour supply of the requested medication and defer issuing a decision for 72 hours.

*See §40.12.3 for notification requirements.

40.9 – Who Must Review an Initial Determination

If a plan initially reviews a request and expects to issue a partially or fully adverse decision based on medical necessity, the review must be completed by a physician, as defined in section 1861(r) of the Act, or other appropriate healthcare professional who has:

- Sufficient medical and other expertise;
- Knowledge of the Medicare coverage criteria; and
- A current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

Part C Only: The reviewer must apply the prudent layperson standard (as described in 42 CFR §422.113(b)(1)) when making determinations regarding emergency services.

Part D Only: A pharmacist would generally be considered an appropriate health care professional for purposes of meeting this requirement.

In general, the application of a clear statutory or contract exclusion set forth in the plan sponsor's Evidence of Coverage, does not constitute a decision based on the lack of medical necessity. Conversely, an adverse decision based on a determination that the clinical documentation supporting the coverage request is unavailable or insufficient (i.e., there is unmet criteria) is generally considered a denial based on the lack of medical necessity.

40.10 – Processing Timeframes

Plans must have processes in place to accept coverage requests 24 hours a day, 7 days a week (including holidays) and to notify enrollees of coverage decisions within the applicable timeframe. For information regarding when a request is considered received, please see §10.4.1.

Part C

Type	Processing Timeframe	With Extension
Pre-Service	14 calendar days*	28 days*
Payment	30 days**	N/A
Expedited	72 hours	17 days

*14-day extension if the enrollee requests the extension or if the MA plan justifies a need for additional information and documents how the delay is in the best interest of the enrollee. MA plan must notify enrollee in writing if extension is going to be taken and explain the reason for the delay. See: 42 CFR §422.568(b)(1) and (2).

**Non-contract providers: The MA plan must pay 95 percent of clean claims within 30 calendar days of the request. All other claims submitted by non-contract providers or enrollees must be paid or denied within 60 calendar days from the date of the request. For additional guidance, see 42 CFR §422.520.

Contract providers: The timeframe for processing payment requests is based on the contract terms between the MA plan and the provider. For additional guidance, see 42 CFR §422.520.

Part D

Type	Processing Timeframe
Standard	72 hours*
Expedited	24 hours*
Payment**	14 calendar days

*Or no later than 24/72 hours after receiving the physician's or other prescriber's supporting statement if the request involves an exception (see §40.5.4 of this guidance for timeframes and additional information regarding exception requests).

**Includes claims submitted by physicians, prescribers, and enrollees.

A Part D plan sponsor may not extend the applicable adjudication timeframe by dispensing a temporary supply of the requested medication. For example, if a plan sponsor receives a request outside of its normal business hours, it cannot approve a 72-hour supply of the requested medication and defer issuing a decision for 72 hours; the plan sponsor must make its determination within the applicable timeframe.

40.11 – Effect of Failure to Meet the Timeframe for an Initial Determination

If a plan fails to provide the enrollee with a timely notice of its decision, this failure constitutes an adverse decision.

Part C Only: The MA plan must explain in its annual Evidence of Coverage (EOC) that enrollees have the right to appeal if the MA plan fails to provide timely notice of a decision.

Part D Only: If the Part D plan sponsor does not provide notice of its coverage determination within the required timeframe, it must forward the complete case file to the IRE within 24 hours of the expiration of the adjudication timeframe. The case file must contain the enrollee's request and any verbal and/or written evidence obtained by the plan sponsor. Refer to §50.12.3 to determine how to prepare the case file for the IRE and what documents/items to send with the case file.

Although the plan sponsor failure to provide notice of a decision within the required timeframe constitutes an adverse decision, the plan sponsor is not required to send the adverse decision notice, but instead, the plan sponsor should notify the enrollee that his or her decision was not made timely and is being forwarded to the IRE for review. The plan sponsor should send the notification to the enrollee within 24 hours of the expiration of the adjudication timeframe. Please see §40.12.2 for enrollee notification requirements.

Note: Because the adjudication timeframe for an exception request involving a request for

benefits does not begin until the plan sponsor receives the physician's or other prescriber's supporting statement as indicated in §40.5.4, plan sponsors must not automatically forward case files to the IRE if a supporting statement is not received.

When a plan sponsor makes a fully favorable decision on a coverage determination in less than 24 hours after the end of the adjudication timeframe, the plan sponsor should consider effectuating and notifying the enrollee of the favorable decision (within the 24 hour period the case must be forwarded to the IRE) in lieu of forwarding the case to the IRE.

If CMS determines that the Part D Plan has a pattern of not issuing timely decisions or not forwarding the enrollee's request to the IRE for review within the required timeframe, the plan sponsor may be considered to be out of compliance with the terms of its Part D contract and/or subject to intermediate sanctions in accordance with subpart O of 42 CFR Part 423.

Part D Transition Period Note: Part D plan sponsors must ensure new enrollees receive a meaningful transition process when they have been, prior to enrollment, stabilized on a medication that is either not on the plan formulary or is subject to utilization management requirements. Two of the steps involve plan sponsors providing a temporary supply of the requested medication and sending the enrollee a written notice explaining when the supply will end and the procedures for requesting an exception. A transition process is not meaningful if an enrollee who is in the transition period files an exception request and the plan sponsor does not make a decision timely or does not forward the enrollee's request/case file to the IRE within the appropriate timeframe. Therefore, when an enrollee who is in the transition period files an exception request and the plan sponsor does not make its decision timely and/or fails to forward a request/case file to the IRE as required, the plan sponsor must provide the enrollee with a temporary supply of the requested prescription drug (when not medically contraindicated) until the case is resolved by the plan sponsor or the IRE issues a reconsideration decision.

For more information about the Part D transition policy, see Chapter 6, §30.4 of the Prescription Drug Benefit Manual.

40.12 – Notification Requirements for Initial Determinations

Plans must provide notices for initial determinations using the most efficient manner of delivery to ensure the enrollee receives the notice in time to act. If the request was filed by the enrollee's representative, the representative must be notified in lieu of the enrollee.

40.12.1 – Part C Notification Requirements

Pre-Service Approvals

For favorable decisions on a pre-service request, notice may be provided verbally or in writing to the requesting party. Verbal or written notice of a favorable decision must explain any conditions of the approval, such as the duration of the approval. As a best practice, MA plans

are encouraged to provide written notice of favorable decisions (again, including any applicable conditions/parameters of the approval). If a provider submits the request on behalf of the enrollee, the MA plan must notify the enrollee as well as the provider of its determination. If the enrollee's representative submits a request, the representative must be notified in lieu of the enrollee.
If the enrollee agrees, the MA plan may send the notice by fax or e-mail.

Pre-Service Denial and Discontinuation/Reduction of Previously Authorized Ongoing Course of Treatment

A written denial notice is required to be sent to the enrollee (and physician involved, as appropriate) whenever a MA plan's determination is partially or fully adverse to the enrollee. For Part C organization determination denials, MA plans must use approved notice language when issuing written denial notices to enrollees.

The standardized denial notice is the Notice of Denial of Medical Coverage or Payment (Form CMS-10003-NDMCP), also known as the Integrated Denial Notice (IDN). MA plans may use a separate written notice of denial document, such as a plan-generated claims statement to the enrollee or provider, but must use the approved standard language. An example of a plan-generated statement is an EOB, detailing what the MA plan has paid on the enrollee's behalf, and/or the enrollee's liability for payment.

If a MA plan uses its existing system-generated notification (i.e., EOB) regarding payment denials as its written notice of determination, the MA plan must ensure that the EOB contains the OMB-approved language of the IDN verbatim in its entirety and meets the content requirements as described in the IDN form instructions and listed below. When issuing an EOB in place of the IDN, the MA plan must notify the enrollee via the EOB within the required timeframe. When providing the decision, the MA plan must also take into account the enrollee's presenting medical condition, disabilities, and special language requirements, if any.

When using the standardized IDN, the MA plan must provide:

- A specific and detailed explanation of why the medical services/items were denied, including a description of the applicable coverage rule or applicable plan policy (e.g., Evidence of Coverage provision) upon which the action was based, and a specific explanation about what information is needed to approve coverage must be included, if applicable;

- Information regarding the enrollee's right to appeal and the right to appoint a representative to file an appeal on the enrollee's behalf;

- For service denials, a description of both the standard and expedited appeal processes, including the specific department or address for reconsideration requests and a description of conditions for obtaining an expedited reconsideration, the timeframes for each, and the other elements of the appeals process;

- For payment denials, a description of the standard reconsideration process and timeframes, and the rest of the appeals process; and

- The enrollee's right to submit additional evidence in writing or in person.

MA plans must also provide a written denial when an enrollee requests an organization determination following a provider's refusal to furnish an item or service.

MA plans are not required to issue an IDN if there is no enrollee liability beyond the applicable cost sharing. An EOB would be issued and indicate any applicable cost sharing.

For provider notice requirements in hospital, SNF, HHA, and CORF settings, please see §100.

Enrollee and Non-contract Provider Payment Requests

Requestor	Payment Approval	Payment Denial
Enrollee or Representative	Receives payment and EOB.	• The enrollee or representative receives an IDN or an EOB.* • Document must include notice of appeal rights.
Non-contract provider	• Provider receives payment and remittance notice (see "Non-Contract Provider Payment Request section below). • Enrollee receives EOB.	• Provider receives remittance notice (see "Non-Contract Provider Payment Request section below). • Enrollee receives EOB* with appeal rights.

*When issuing an EOB in place of the IDN, the MA plan must notify the enrollee via the EOB within the required timeframe. An IDN is not required if there is no enrollee liability beyond the applicable cost sharing, however, an EOB would be issued and include any applicable cost sharing.

Note: For approved and denied payment requests from a contracted provider, the enrollee receives an EOB. Terms of remittance for contract providers are determined by the contract between the MA plan and the provider.

Non-Contract Provider Payment Requests

If the MA plan approves a request for payment from a non-contract provider, the provider receives payment and a remittance advice/notice.
If the MA plan denies a request for payment from a non-contract provider, the MA plan must notify the non-contract provider of the specific reason for the denial and provide a description of the appeals process. MA plans must deliver either a remittance advice/notice or other similar notification that states the non-contract provider:

- Has the right to request a reconsideration of the MA plan's denial of payment,

- Must submit a Waiver of Liability form holding the enrollee harmless regardless of the outcome of the appeal. (MA plans must include the form as an enclosure or attachment and/or provide a direct link to the form);

- Has 60 calendar days from the remittance notification date to request a reconsideration;

- Should include documentation, such as a copy of the original claim or remittance notification showing the denial, and must include any clinical records and other documentation that supports the provider's argument for reimbursement; and

- Return the request for reconsideration to the MA plan following the instructions provided by the plan on where to send the request.

MA plans may not use the CMS standardized form, IDN, to notify non-contract providers of a claim denial. However, MA plans may use the IDN as a model template to develop a non-contract provider denial notice with appeal rights in accordance with the above requirements.

Denial of a Request for an Expedited Organization Determination

Notice of the denial of a request for an expedited organization determination must:

- Explain that the MA plan will automatically transfer and process the request using the required timeframe for standard requests;

- Inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA plan's decision not to expedite the determination;

- Provide instructions about the expedited grievance process and its timeframes; and

- Inform the enrollee of the right to resubmit a request for an expedited determination with a physician, prescribing physician, or other prescriber's support, including that if the enrollee gets the support indicating that applying the standard timeframe for making determinations could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function, the request will be expedited automatically.

MA plans may use a Part C model notice, Notice of Right to an Expedited Grievance to notify enrollees about their expedited grievance rights.

40.12.2 – Part D Notification Requirements

Approvals

For favorable decisions, Part D plan sponsors must adhere to the following notification requirements:

- Enrollee notification must be in writing. If the enrollee's representative submits a request, the representative must be notified in lieu of the enrollee.

- Written notices must explain the conditions of the approval (the plan sponsor may develop its own written approval notice). The conditions of approval may include (but are not limited to):

- The duration of an approval;

- Limitations associated with an approval; and/or

- Any coverage rules applicable to subsequent refills.

Verbal notice may initially be provided to the enrollee as long as written notice is mailed within 3 calendar days of verbal notification.

If requested by an enrollee's prescribing physician or other prescriber on behalf of the enrollee, the plan sponsor must provide notice to the prescriber and written notice to the enrollee.

If a plan sponsor successfully notifies the physician or prescriber verbally, the plan sponsor does not need to send a written follow-up.

Denials

If the request is denied in whole or in part, plan sponsors must adhere to the following notification requirements:

- Enrollee notification must be in writing. If the enrollee's representative submits a request, the representative must be notified in lieu of the enrollee.

- If notice is provided within required timeframe, enrollee receives Notice of Denial of Medicare Prescription Drug Coverage, Form CMS-10146 (see §40.12.3 for specific CMS-10146 requirements).

- If requested by prescribing physician, notify both the prescriber and the enrollee.

If a plan sponsor successfully notifies the physician or prescriber verbally, the plan sponsor does not need to send a written follow-up.

Action Following Denial for Expediting Review

If the plan sponsor denies a request to expedite a coverage determination, it must transfer the request to the standard coverage determination process (as described in section 40.8), provide prompt oral notice of the denial, and subsequently deliver (i.e. mail) written notice within 3 calendar days after providing oral notice.

- If an enrollee has identified a representative, the plan sponsor must provide notice to the enrollee's representative instead of the enrollee.

- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision.

The oral notice and written follow-up notice must:

1. Explain that the plan will automatically transfer and process the request using the 72 hour time frame for standard determinations;

2. Inform the enrollee of the right to file an expedited grievance if he or she disagrees with the plan's decision not to expedite the determination;

3. Inform the enrollee of the right to resubmit a request for an expedited determination and that, if the enrollee gets his or her prescribing physician's or other prescriber's support indicating that applying the standard time frame for making determinations could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function, the request will be expedited automatically; and

4. Provide instructions about the expedited grievance process and its time frames.

CMS has developed a model notice, Notice of Right to an Expedited Grievance, that Part D plan sponsors can use whenever a request to expedite is denied.

Untimely Decisions

If the plan sponsor fails to provide notice of a decision within the required timeframe, the plan sponsor is not required to send the adverse decision notice, but instead, the plan sponsor should notify the enrollee that his or her decision was not made timely and is being forwarded to the IRE for review. The notice must:

- Advise the enrollee of his/her right to submit additional evidence that may be pertinent to the enrollee's case, if the enrollee chooses;

- Direct the enrollee to submit such evidence to the independent review entity; and

- Include information on how to contact the independent review entity.

CMS has developed a model Notice of Case Status that plan sponsors can use in lieu of the adverse decision notice to notify enrollees whenever cases are forwarded to the IRE.

40.12.3 – Part D Coverage Determination Notices

Notification by Network Pharmacies: Medicare Prescription Drug Coverage and Your Rights

When a pharmacist explains to an enrollee that a drug is not on a Part D plan's formulary, or is subject to prior authorization, step therapy, or other limitation, the transaction does not constitute a coverage determination, unless the plan sponsor treats the presentation of the prescription as a request for a coverage determination.

Plan sponsors must arrange with network or preferred pharmacies to provide enrollees with a written copy of the standardized pharmacy notice (Medicare Prescription Drug Coverage and Your Rights, Form CMS-10147) when the enrollees' prescription cannot be filled under the Part D benefit and the issue cannot be resolved at the point of sale. Permissible exceptions to this requirement are detailed below. CMS expects plan sponsors to have internal controls in place to reasonably ensure that network pharmacies are complying with this requirement and must arrange with their network pharmacies (including mail-order and specialty pharmacies) to distribute the notice to enrollees. The pharmacy notice must be provided to the enrollee if the pharmacy receives a transaction response indicating the claim is not covered by Part D and the designated NCPDP response code is returned.

The designated NCPDP response code is NOT returned in the following scenarios:

- The claim rejects only because it does not contain all necessary data elements for adjudication;
- The drug in question is an over the counter (OTC) drug that is not covered by the enrollee's plan;
- The prescription is written by a sanctioned provider who has been excluded from participation in the Medicare program;
- The drug is not listed on the participating CMS Manufacturer Labeler Code List;
- The drug is not listed on the FDA Electronic List—NDC Structured Product Labeling Data Elements File (NSDE);
- The Part D plan sponsor rejects the claim for the drug in question only because of a "refill too soon/early refill" edit;
- The drug in question is not covered by the Part D plan benefit, but is covered by a co-administered insured benefit managed by a single processor. In this scenario, the

pharmacy submits a single claim transaction for the drug and the drug is covered by the co-administered insured benefit after being rejected by Part D and processed in accordance with the benefits offered by the supplemental payer.

Note: If the drug is not covered by the Part D plan, but the enrollee pays for the cost of the drug pursuant to plan-sponsored negotiated pricing or a discount card program (which may provide a lower price but leaves the enrollee responsible for 100 percent of the drug cost), a designated NCPDP response code will be returned notifying the pharmacy to provide the enrollee with a copy of the pharmacy notice.

For Mail Order Pharmacies:

The notice should be provided to the enrollee via the enrollee's preferred method of communication (fax, electronic, or first class mail) as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the pharmacy's receipt of the original transaction response indicating the claim is not covered by Part D.

For Home Infusion Pharmacies:

Enrollees brought on service by the home infusion pharmacy, the pharmacy can also choose to deliver the notice in person with delivery of home infusion drugs or through an infusion nurse, as long as the next scheduled visit is within 72 hours of the receipt of the transaction code indicating the claim cannot be covered by Part D.

For Pharmacies Serving Long-Term Care Facilities:

Given the uniqueness of the long-term care (LTC) setting, there is typically no point-of-sale encounter between the pharmacy and the enrollee (LTC resident) and, therefore, no practical means for the pharmacy to provide the notice directly to the enrollee. In most instances where there is an issue with the prescription, CMS expects that the pharmacist will contact the prescriber or an appropriate staff person at the LTC facility to resolve the matter and ensure the resident receives the needed medication or an appropriate substitute, obviating the need to deliver the notice. If the matter cannot be resolved, the pharmacy must fax or otherwise deliver the notice to the enrollee, the enrollee's representative, prescriber, or an appropriate staff person at the LTC facility as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the pharmacy's receipt of the original transaction response indicating the claim is not covered by Part D.

Note: If the enrollee is a self-pay resident and the pharmacy cannot fill the prescription under the Part D benefit, the pharmacy must, upon receipt of the transaction response, fax or otherwise deliver the notice to the enrollee, the enrollee's representative, prescriber, or an appropriate staff person at the LTC facility. After distribution of the notice, the LTC pharmacy should continue to work with the prescriber or facility to resolve the matter and ensure the resident receives the needed medication or an appropriate substitute.

For Indian Health Service, Tribe and Tribal Organization, and Urban Indian Organization

(I/T/U) Pharmacies:

Because IHS enrollees' prescription drugs, when dispensed through I/T/U pharmacies, are filled and dispensed at no cost to the enrollee regardless of whether the drug is rejected at POS by the Part D plan, I/T/U pharmacies are exempt from the requirement to distribute the pharmacy notice.

> **Note:** This exemption applies only to I/T/U pharmacies that dispense prescriptions at no cost to the enrollee. Any network commercial pharmacy providing services to IHS-eligible Part D enrollees must distribute the notice in accordance with the requirements in this section.

Standardized Denial Notice: Notice of Denial of Medicare Prescription Drug Coverage

The Part D plan sponsor must use the approved standardized denial notice (Notice of Denial of Medicare Prescription Drug Coverage, Form CMS-10146). The standardized denial notice has been written in a manner that is understandable to the enrollee. The denial rationale must be specific to each individual case and written in a manner calculated for an enrollee to understand. See the Notice of Denial of Medicare Prescription Drug Coverage, along with the instructions and examples of the denial rationale for additional guidance.

Plan sponsors must complete the applicable sections of the model Notice of Redetermination form and send it to the enrollee (and physician or other prescriber when appropriate) with each adverse coverage determination notice.

> **Note:** Plan sponsors that do not provide notice within the required timeframe should not use the Notice of Denial of Medicare Prescription Drug Coverage form, but should provide notice that the case has been forwarded to the IRE (plan sponsors may use the model Notice of Case Status).

40.13 – Procedures for Handling Misclassified Initial Determinations

If the plan misclassifies a coverage request as a grievance and later discovers the error, the plan must notify the enrollee in writing that the issue was misclassified and will be handled as a coverage request. The timeframe for processing the request begins on the date the request is received by the plan, not the date the plan discovers its error. Plans are expected to audit their own coverage and grievance processes for the presence of errors and institute appropriate quality improvement projects as needed.

40.14 – Withdrawal of a Request for an Initial Determination

The party that submits a request for an initial determination may withdraw the request in writing at any time before the decision is issued. A plan may also choose to accept verbal withdrawal requests. For verbal withdrawal requests, the plan should clearly document in their system the date and the reason why the party chose not to proceed with the initial determination procedures. The plan should send a written confirmation of that withdrawal to the party within 3 calendar

days, clearly indicating which request is being withdrawn (i.e. name of drug or type of service or item requested).

50 – Reconsiderations and Redeterminations (Level 1 Appeals)

A party (as described below) to an adverse initial determination has a right to a reconsideration (Part C) or redetermination (Part D) by the plan. A reconsideration or redetermination (hereinafter referred to as a level 1 appeal) consists of a review of an adverse initial determination, the evidence and finding upon which it was based, and any other evidence that the parties submit or that is obtained by the plan.

Part C Only: The parties to an organization determination for purposes of an appeal include:

- The enrollee (including his or her representative);
- An assignee of the enrollee (i.e., a physician or other provider who has furnished a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service);
- The legal representative of a deceased enrollee's estate; or
- Any other provider or entity (other than the MA plan) determined to have an appealable interest in the proceeding.

Part D Only: The parties to a coverage determination include the enrollee and the enrollee's representative, if applicable. In some cases, as described in this section, the enrollee's prescribing physician or other prescriber is also a party. However, an enrollee's prescribing physician or other prescriber does not have all of the rights and responsibilities of the enrollee with respect to party status, unless the physician or other prescriber is the enrollee's representative.

50.1 – Who May Request a Level 1 Appeal

Part C

Type of Request	Who May Request An Appeal
Standard Pre-Service Reconsideration	• An enrollee; • An enrollee's representative; • The enrollee's treating physician acting on behalf of the enrollee* or staff of physician's office acting on said physician's behalf (e.g., request is on said physician's letterhead).; or • Any other provider or entity (other than the MA plan) determined to have an appealable interest in the proceeding.
Standard Payment Reconsideration	• An enrollee; • An enrollee's representative; • Non-contract provider (see §50.1.1 for non-contract provider payment appeals); or • The legal representative of a deceased enrollee's estate.
Expedited Reconsideration (Cannot expedite payment reconsiderations)	• An enrollee; • An enrollee's representative; • Any physician or staff of physician's office acting on said physician's behalf (e.g., request is on said physician's letterhead) acting on behalf of the enrollee.

*If the enrollee's records indicate that he or she has not previously visited the requesting physician, the MA plan should undertake reasonable efforts to confirm that the enrollee has received appropriate notification of the appeal.

Note: Contract providers (including subcontracted entities) do not have appeal rights under the provisions discussed in this guidance. Contract provider disputes involving plan payment denials are governed by the appeals/dispute resolution provisions in the contract between the provider and the plan.

Part D

Type of Request	Who May Request An Appeal
Standard or Expedited Redetermination	• An enrollee; • An enrollee's representative; • An enrollee's prescribing physician or other prescriber acting on behalf of the enrollee*; or • Staff of a physician's office acting on a physician's behalf (e.g., request is on the office's letterhead)

*If the enrollee's records indicate that he or she has not previously visited the requesting physician or prescriber, the plan sponsor should undertake reasonable efforts to confirm that the enrollee has received appropriate notification of the appeal.

50.1.1 – Requirements for Provider Claim Appeals (Part C Only)

The appeal provisions set forth at 42 CFR Part 422 Subpart M and described in this guidance are designed to protect enrollee rights related to grievances, organization determinations, and appeals.

A non-contract provider, on his or her own behalf, may request a reconsideration for a denied claim only if the non-contract provider completes a Waiver of Liability (WOL) statement, which provides that the non-contract provider will not bill the enrollee regardless of the outcome of the appeal).

If an appeal is submitted, the WOL must be filed with the appeal. The appeal should include other supporting documentation (e.g., copy of remittance advice/notice and clinical records claim). Non-contract providers who have executed a WOL are not required to complete the representative form because the provider is not representing the enrollee, and thus does not need a written representative form. Furthermore, because the enrollee no longer has an appealable interest under 42 CFR Part 422 Subpart M, plan notices/correspondence regarding the non-contract provider's appeal would be delivered to the non-contract provider and not the enrollee. If the WOL isn't filed with the appeal, the plan should make and document reasonable efforts to obtain the WOL. The plan is not required to undertake a review of the appeal until or unless the form is obtained, but it may choose to begin the review while continuing efforts to obtain a WOL. The adjudication timeframe begins when the WOL is received by the plan. If the plan does not receive the WOL by the end of the adjudication timeframe the plan issues a dismissal notice per the dismissal procedures set forth in this guidance. See §50.9.

> **Note**: Providers can use electronic signatures on WOL documentation when it is submitted through the plan's secure portal, provided the portal meets all applicable regulatory and CMS website requirements.

50.2 – Level 1 Appeal Requests

A party may request a level 1 appeal by filing a written request with the plan. Plans must accept verbal requests for expedited appeals and may accept verbal requests for standard appeals.

50.2.1 – Guidelines for Accepting Level 1 Appeal Requests

Method for Filing Request	Standard	Expedited
Written	Must Accept	Must Accept
Verbal	May accept **Note:** In the event that a plan does not accept a verbal request, the plan must explain to the party how to file a written request.	Must accept **Note**: If a verbal request to expedite a level 1 appeal is denied by the plan, the plan cannot require the party to re-file the request in writing. Instead, the plan must automatically transfer the request to the standard process.

Note: If a plan does accept verbal requests, the plan's policy should include repeating the summarized request back to the caller. Failure to take steps to ensure that verbal requests are properly and accurately handled may result in CMS determining that the MA plan has inadequate policies and procedures under §§422.562, 422.582, 423.562, and 423.582. For Part C plans, an acknowledgement letter should be sent to enrollee (in lieu of or in addition to repeating the request verbally) to confirm the facts and basis of the appeal and that the reconsideration request is properly and accurately noted and addressed by the MA plan. Notice should advise the enrollee to immediately contact the plan if the acknowledgement letter does not correctly capture the enrollee's request.

Part D Only: Part D plan sponsors must accept web/internet based requests and protect individual health information received via the web/internet. See requirements at §423.128(b)(7)(ii), and §423.136.

Part C Only: MA plans may, but are not required, to accept web/internet requests.

For both standard and expedited level 1 appeal requests, the following guidelines apply:

- Must be filed within 60 calendar days from the date of the notice of the initial determination. For requests received after the 60-day filing timeframe, please see §50.3 regarding good cause exceptions for late filing.

- Request should include: Name of the enrollee, information identifying which denial is being appealed, and contact information for the appellant. Unless the request is from a representative, for which proof of appointment is required (see §20.2), plans cannot require additional information in a request (e.g., appellant signature).

- The appellant is not required to use any specific language to indicate they are requesting an appeal (e.g., "I am requesting an appeal"). The appellant may say, for example, "I do not agree with your decision" or "Please review this decision". Requests for appeals should not be classified as requests for a reopening (see §80 for guidance regarding reopenings).

- For verbal requests, plans should repeat the summarized verbal request back to the caller and/or send an acknowledgement letter to enrollee to confirm the facts and basis of the appeal to ensure the request is properly and accurately noted and addressed by the plan. Notice should advise the enrollee to immediately contact the plan if the acknowledgement letter does not correctly capture the enrollee's request.

- The processing timeframe begins when the plan, any unit in the plan, or a delegated entity (including a delegated entity is not responsible for processing the request) receives a request. If an appeal request is received in the incorrect department, the plan must have polices for prompt transfer of the call or document(s) to the appropriate department that handles appeals.

50.2.2 – How to Process Requests for Expedited Level 1 Appeals

Who May Request an Expedited Level 1 Appeal	Plan Requirements
• An enrollee • An enrollee's representative • **Part C** - A physician (regardless of whether affiliated with the plan) • **Part D** – Prescribing physician or other prescriber acting on behalf of the enrollee	• Establish an efficient and convenient means for individuals to submit verbal or written requests; • Establish procedures for accepting and processing verbal and written requests for an expedited decision; • Develop a process for receiving the request, including designating an office and/or department to receive both verbal or written requests and a telephone and fax number to facilitate receipt of the requests; • Document all verbal requests in writing and maintain in the case file; • Promptly decide whether to expedite the request: o If a physician (Part C)/prescribing physician or other prescriber (Part D) makes a request or

	supports an enrollee's request for an expedited appeal and indicates that applying the standard timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function (the physician does not have to use these exact words), the plan must process as expedited. o Plans may, but are not required to, expedite appeals for payment requests for drugs or services already furnished.

Requests for an expedited level 1 appeal must be received within 60 days unless there is good cause (see §50.3).

Note: A plan must not take or threaten any punitive action against a physician who acts on behalf or in support of a request for expedited determination.

Part C Only: If an enrollee misses the deadline to file for immediate BFCC-QIO review of an inpatient hospital discharge or SNF, HHA, or CORF termination decision, then the enrollee may request an expedited reconsideration with the MA plan. MA plans should have a process in place to distinguish between misdirected requests that should go to the BFCC-QIO (see §§422.622(b) and 422.626(a)(1)) and valid requests to the MA plan (i.e., requests made because the window for filing with the BFCC-QIO has expired).

MA plans are encouraged to automatically expedite all valid requests for reconsideration of inpatient hospital discharges and SNF, HHA, or CORF termination decision. If the MA plan expedites the request, it must be processed under rules at §422.590(d) and guidance described in this section.

If a request for review of an inpatient hospital discharge or SNF, HHA, or CORF termination decision received by the MA plan is within the BFCC-QIO filing timeframe, MA plans should inform the enrollee they must contact the BFCC-QIO to request the reconsideration. MA plans should ensure that network hospitals, SNFs, HHAs, and CORFs are aware of and fulfill their own responsibilities in connection with reviews of a hospital discharge or SNF, HHA, or CORF termination. MA plans are also encouraged to contact the BFCC-QIO to inform them the enrollee wants to file an immediate BFCC-QIO review of a hospital discharge or SNF, HHA, or CORF termination and forward a detailed notice and case file to the BFCC-QIO.

See §100 of for additional information related to hospital discharge and SNF, HHA, or CORF termination decisions.

Part D Only: Plans may choose to expedite a redetermination request from an enrollee without requiring the enrollee's prescribing physician or other prescriber to submit a new statement indicating that applying the standard timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. However, if a plan sponsor chooses to do so, it should, at a minimum, ensure the enrollee has not obtained

the drug in dispute.

Action Following Acceptance of a Request for Expedited Level 1 Appeal

The plan must adhere to the following:

Part C

Reconsideration Decision	Processing Requirements for Reconsiderations
Favorable	• Ensure the person or persons conducting the reconsideration were not involved in the organization determination.* • As expeditiously as the enrollee's health condition requires, but no later than 72 hours (or up to 14 days with an extension) after the request, the MA plan must: o Make the decision; and o Give notice to the enrollee (and the physician involved, as appropriate); and o Authorize or provide the service. • Notification must be provided within the 72-hour timeframe (i.e., mailing the determination within 72 hours in and of itself is insufficient). • The MA plan may notify the enrollee verbally or in writing**. If the MA plan initially provides verbal notification of its decision, it must mail, fax, or e-mail written confirmation of its decision within 3 calendar days. • Verbal or written notification of the decision must explain conditions of the approval including (but not limited to): o The duration of the approval; and o Limitations associated with the approval. • If the enrollee agrees, the MA plan may send the notice by fax or e-mail.
Partially Favorable or Adverse	• Ensure the person or persons conducting the reconsideration were not involved in the organization determination.* • As expeditiously as the enrollee's health condition requires, but no later than 72 hours (or up to 14 days with an extension) after the request, the MA plan must: o Make the decision; and o Forward the case file to the IRE within 24 hours of its

Reconsideration Decision	Processing Requirements for Reconsiderations
	affirmation (see §50.12 for guidance on forwarding case files to the IRE); and o Notification must be provided within the 72-hour timeframe (i.e., mailing the determination within 72 hours in and of itself is insufficient). • The MA plan may notify the enrollee verbally or in writing. If the MA plan initially provides verbal notification of its decision, it must mail, fax, or e-mail written confirmation of its decision within 3 calendar days.

*When the issue is the denial of coverage based on a lack of medical necessity, the reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician need not be of the same specialty or subspecialty as the treating physician.
** notice requirements can be found in §50.10.1.

Extension of Timeframe

The MA plan may only extend the 72-hour timeframe up to 14 days if:

- The enrollee requests the extension; or
- The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a non-contract provider that may change a MA plan's decision to deny an item or service; or
- The extension is justified due to extraordinary, exigent or other non-routine circumstances and is in the enrollee's interest.

If the MA plan extends the timeframe, the MA plan must notify the enrollee in writing the reasons for the extension and inform the enrollee of the right to file an expedited grievance if the enrollee disagrees with the decision to extend the timeframe.

If the MA plan needs information from a non-contract provider, the MA plan must request the necessary information from the non-contract provider within 24 hours of the initial request for an expedited reconsideration. Regardless of whether the MA plan needs information from non-contract providers, the MA plan is responsible for meeting the timeframe and notice requirements for expedited reconsiderations. (See §10.4.5 for additional guidance regarding outreach for additional information.)

MA plans are expected to have sufficient and appropriate contract terms to get information and records from contract providers as necessary for expedited (and standard) reconsiderations. MA plans should not generally or regularly extend the timeframe for an expedited reconsideration to seek information or records from a contract provider but may do so if it is justified in the enrollee's interest and due to extraordinary, exigent, or other non-routine circumstances.

Part D

Level 1 Appeal Decision	Processing Requirements for Expedited Determinations
All Decisions (Favorable or Adverse, including requests that involve an exception)	• Ensure the person or persons conducting the reconsideration were not involved in the coverage determination.* • Part D plan sponsors must make the decision and provide written notice** to the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request or receipt of the physician's or other prescriber's supporting statement for exceptions (plan sponsors may not extend the timeframe by dispensing a temporary supply of the medication). • If the plan sponsor initially provides verbal notification of its decision, it must mail, fax, or e-mail written confirmation of its decision within 3 calendar days of the verbal notification. • If the plan sponsor fails to provide the enrollee or prescribing physician or other prescriber, as appropriate, with the decision for the expedited redetermination within the timeframes described above, they must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe (see §50.12 for information regarding forwarding cases to the IRE).

*When the issue is a denial of coverage based on a lack of medical necessity, the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician need not be of the same specialty or subspecialty as the treating physician.

**Notice requirements can be found in §50.10.2.

If the plan needs medical information, the plan must request the necessary information within 24 hours of the initial request for an expedited level 1 appeal. Regardless of whether the plan needs information, the plan is responsible for meeting the timeframe and notice requirements for expedited level 1 appeals (for exceptions requests, see §40.5.3 for tolling requirements).

Action Following Denial of a Request for an Expedited Level 1 Appeal

Following denial of a request for an expedited initial determination, plans must:

- Transfer the request to the standard coverage or organization determination process;
- Give the enrollee prompt verbal notice of the denial including the enrollee's rights; and
- Deliver a written notice of the enrollee's rights within 3 calendar days of the verbal notice of the denial to expedite the request.

Notice of the denial of a request for an expedited initial determination must:

- Explain that the plan will automatically transfer and process the request using the required timeframe for standard requests;

- Inform the enrollee of the right to file an expedited grievance if he or she disagrees with the plan's decision not to expedite the determination;

- Inform the enrollee of the right to resubmit a request for an expedited determination with a physician, prescribing physician, or other prescriber's support, including that if the enrollee gets the physician/prescriber support indicating that applying the standard timeframe for making determinations could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function, the request will be expedited automatically; and

- Provide instructions about the expedited grievance process and its timeframes.

Plans may use a model notice (Notice of Right to an Expedited Grievance and Notice of Right to an Expedited Grievance for Part D) to notify enrollees about their expedited grievance rights.

50.3 – Good Cause Exception for Late Filing

Plans may accept a request for a standard or expedited level 1 appeal after the 60-day timeframe if a filing party shows good cause. A request to file a level 1 appeal after the timeframe must be in writing and state why the request for a level 1 appeal was not filed on time.

If an untimely appeal request does not include an explanation as to why the request wasn't filed timely, the plan may make an attempt to obtain information supporting good cause for the late filing. The plan should consider the circumstance that kept the party from making the request on time and whether any organizational actions might have mislead the party. Plan policies governing good cause justification when the request for a level 1 appeal is outside the 60-day timeframe should not be discriminatory and should provide for equal and fair treatment of enrollees.

Examples of circumstances where good cause may exist include (but are not limited to) the following situations:

- The party did not receive the notice for the adverse initial determination, or they received it late;

- The party was seriously ill, which prevented a timely appeal;

- There was a death or serious illness in the party's immediate family;

- An accident (e.g., a natural or man-made disaster) caused important records to be destroyed;

- Documentation was difficult to locate within the time limits;

- The party had incorrect or incomplete information concerning the level 1 appeal process;

- The party lacked capacity to understand the timeframe for filing a level 1 appeal; or

- The party sent the request to an incorrect address, in good faith, within the time limit and the request did not reach the plan until after the time period had expired.

- The delay is a result of late (or delayed) provision of enrollee documents that needed to be converted to an alternate format (e.g., large print, Braille, etc.). This includes a delay in delivery to the enrollee of the converted documents, as well as allowing additional time for the enrollee to respond.

If the plan obtains information establishing good cause, the adjudication timeframe (i.e., the timeframe in which the plan must make its decision on the level 1 appeal) begins on the date the plan receives that information.

If the plan denies a party's request for a good cause extension, the party may file a grievance with the plan.

Part C Only: If the MA plan denies a party's request for a good cause extension, the MA plan must dismiss the request (See §50.9 for more information on dismissal procedures).

Part D Only: If the plan sponsor denies a party's request for a good cause extension, the party does not have the right to appeal the plan sponsor denial of the good-cause extension.

50.4 – Withdrawal of Request for a Level 1 Appeal

The party who files a request for a level 1 appeal may withdraw the request in writing at any time before an appeal decision is mailed by the plan. A plan may also accept withdrawal requests verbally, provided that the plan mails a written confirmation of the withdrawal to the party within 3 calendar days from the date of the verbal request. The written confirmation should clearly indicate which request is being withdrawn (i.e. name of drug or type of service or item requested).

If the withdrawal request is received after the plan has forwarded the case file to the IRE, then the plan must forward the withdrawal request to the IRE for processing.

50.5 – Actions the Appealing Party Can Take During a Level 1 Appeal

50.5.1 – Opportunity to Submit Evidence

The plan must provide the parties to the appeal a reasonable opportunity to present evidence related to the appeal, in person or in writing (e.g. by telephone, fax, or hand-delivered to a plan's physical location). A party is not required to submit additional evidence, but each party may exercise this right if they choose. The plan must take all of the evidence into account when making the decision.

50.5.2 –Enrollee Request for Case File Content

Enrollees may request a copy of the contents of the case file at any point during the appeals process. Upon an enrollee's request, the plan must:

- Provide the enrollee with a copy of the contents of the case file, including, but not limited to, a copy of supporting medical records and other pertinent information used to support the decision.

- Make every reasonable effort to accommodate an enrollee's request for case file material (e.g., allowing the enrollee or authorized representative to obtain the material at a plan location or mailing the material to any address specified by the enrollee or authorized representative).

- Abide by all applicable federal and state laws regarding confidentiality and disclosure for mental health records, medical records, or other health information. (See 45 CFR Subpart E regarding the privacy of individually identifiable health information.)

The plan may charge the enrollee a reasonable amount for copying and mailing the case file. When the case file is requested, the plan must inform the enrollee of the per-page copying cost and provide an estimate of the total copying and mailing cost. The plan may not charge the enrollee an additional cost for courier delivery of the material to a plan location that would be over and above the cost of mailing the material to the enrollee.

In the case of an expedited level 1 appeal, the opportunity to present evidence is limited by the short timeframe for making a decision, therefore, the plan must inform the parties of the conditions for submitting the evidence, including the party's right to request a 14-day extension if the party feels they will need additional time.

50.6 – Who Must Conduct a Level 1 Appeal

The plan must designate someone other than the person involved in making the initial determination to perform the level 1 appeal. If the initial denial was based on a lack of medical

necessity, then the level 1 appeal must be performed by a physician with expertise in the field of medicine that is appropriate for the item, service, or drug in question.

If the physician is not of the same specialty or subspecialty as the treating physician, the physician must have the appropriate level of training and expertise to evaluate the necessity of the requested drug, item, or service. This does not require the physician to always have the same specialty training as the treating physician. For example, where there are few practitioners in a highly specialized field of medicine, a plan may not be able to hire a physician of the same specialty or sub-specialty to review adverse initial determinations.

Part C Only: The physician performing the reconsideration must apply the prudent layperson standard (as described in 42 CFR §422.113(b)(1)(i)) in cases involving emergency and urgently needed services.

50.7 – Conducting a Level 1 Appeal

50.7.1 – Processing Timeframes

Parts C & D Level 1 Appeal Adjudication Timeframes

Type	Part C Processing	Part C Processing with Extension	Part D Processing
Standard Pre-Service or Benefit	30 days	44 days	7 days*
Expedited Pre-Service or Benefit	72 hours	17 days	72 hours
Payment**	60 days	N/A	14 days [change based on federal regulation. Effective January 1, 2019]

* Part D redetermination exception requests cannot be tolled for receipt of the prescribing physician's supporting statement.
** Payment requests cannot be expedited.

Plans must authorize or provide the service or benefit as expeditiously as the enrollee's health condition requires, but no later than the timeframes listed above (based on when the request was received).

Part D Only: The Part D plan sponsor must authorize payment for the benefit within 14 calendar days from the date it receives the request and make payment (i.e., mail the payment) no later than 30 calendar days after the date the plan sponsor receives the request.

Occasionally, the plan may not have complete documentation, such as medical records or other pertinent information, to make a decision on a request for a level 1 appeal. In such cases, the plan may seek additional information for a decision as outlined in §10.4.5 regarding outreach for additional information. If the plan cannot obtain all relevant documentation, it must issue the decision no later than the applicable timeframes outlined above.

Extension of Timeframe

Part C Only: For standard pre-service and expedited reconsiderations the MA plan may extend the timeframe by up to 14 calendar days only if:

- The extension is requested by the enrollee;
- The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a non-contract provider that may change a MA plan's decision to deny an item or service; or
- Is in the enrollee's best interest due to extraordinary, exigent, or other non-routine circumstances, such as a natural disaster.

When the MA plan extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA plan's decision to grant an extension. When extensions are used, the MA plan must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon the expiration date of the extension.

Part D Only: Extensions of the adjudication timeframes are not permitted in Part D. A Part D plan sponsor may not extend the adjudication timeframe by dispensing a temporary supply of the requested medication. For example, if a plan sponsor receives a request outside of its normal business hours, it cannot approve a 72-hour supply of the requested medication in dispute and defer issuing a decision for 72-hours; the plan sponsor must make its determination within the appropriate adjudication timeframe.

50.7.2 – Effect of Failure to Meet the Timeframe for Level 1 Appeals

If a plan fails to provide the enrollee with a level 1 appeal decision within the timeframes specified for both standard and expedited appeals, this failure constitutes an adverse decision. In this case, the plan must forward the complete case file to the IRE (see §50.12.1 regarding forwarding adverse level 1 appeals to the IRE). The plan's failure to provide notice of the level 1 appeal decision within the required timeframe constitutes an adverse decision, but the plan is not required to send the adverse decision notice to the enrollee.

Part C Only: MA plans are not required to notify beneficiaries upon forwarding cases to the Part C IRE. MA plans opting to inform parties when a case has been forwarded to the IRE

may use the *Notice of Appeal Status*.

Part D Only: Plan sponsors should notify the enrollee that the appeal decision was not made timely and is being forwarded to the IRE for review. CMS has developed a model Notice of Case Status that plan sponsors can use in lieu of the adverse decision notice to notify enrollees whenever cases are forwarded to the IRE. The plan sponsor must send the notification to the enrollee within 24 hours of the expiration of the adjudication timeframe.

Note: When a plan makes a fully favorable determination on a level 1 appeal less than 24 hours after the end of the adjudication timeframe, the plan should consider effectuating and notifying the enrollee of the favorable appeal decision (within the 24 hour period the appeal must be forwarded to the IRE) in lieu of forwarding the appeal to the IRE.

If CMS determines that the plan has a pattern of not processing level 1 appeals within the required timeframes, the plan may be considered to be out of compliance with the terms of its Medicare contract and/or subject to intermediate sanctions in accordance with 42 CFR Part 422 or Part 423, subpart O.

Part D Only: The "Transition Period Note" in §40.10 also applies to this section.

50.8 – Service or Benefit Received Prior to Notice of Decision

Part C Only: If an enrollee has requested a standard pre-service reconsideration but the MA plan becomes aware that the enrollee has obtained the service before the MA plan completes its reconsideration, processing stops and the MA plan must dismiss the request. When the claim is subsequently submitted for payment, the MA plan should make its determination on whether to pay for the service. If the MA plan denies payment, it will then issue either an Integrated Denial Notice (IDN) or a system generated explanation of the enrollee's benefit and applicable appeal rights. The denial at that stage will be an organization determination.

In such cases, if the MA plan does not become aware that the enrollee has already received the service, but forwards the adverse pre-service reconsideration case to the IRE, the IRE will dismiss the pre-service reconsideration request when the IRE receives information indicating that the service has already been obtained.

Part D Only: If an enrollee has requested a standard pre-benefit redetermination and the Part D plan sponsor becomes aware that the enrollee has obtained the prescription drug before it completes its redetermination, the plan sponsor must stop processing the claim as a pre-benefit redetermination, and process the claim as a request for payment instead (i.e., process the claim as a redetermination request for payment).

If, after the enrollee submitted the pre-benefit appeal, the plan sponsor is not aware that the enrollee has already received the requested drug and the plan sponsor continues to deny the pre-benefit redetermination and sends the case to the IRE on appeal, the IRE must stop processing the claim as a pre-benefit reconsideration, and process the claim as a request for payment if it

receives information indicating that the drug has been obtained.

50.9 – Dismissals (Part C Only)

MA plans should dismiss reconsideration requests under any of the following circumstances:

- An individual requests a reconsideration on behalf of an enrollee, but a properly executed appointment of representative form has not been filed and there is no other documentation to show that the individual is legally authorized to act on the enrollee's behalf. This does not relieve the MA plan of its obligation to make attempts to secure the missing documentation (see §20.2.1).

- The enrollee or other party fails to file the reconsideration within the established timeframes and good cause for late filing has not been established.

- A non-contract provider requests a reconsideration of a denied claim but fails to provide a waiver of liability statement indicating that the non-contract provider will not bill the enrollee regardless of the outcome of the appeal. Prior to dismissal, the MA plan should make attempts to secure the missing documentation.

- The MA plan becomes aware that the enrollee has obtained the service before the plan completes its pre-service reconsideration (see §50.8).

- Any other circumstance where the MA plan lacks jurisdiction to review the case.

Notice for Dismissal of a Reconsideration

If a MA plan dismisses a reconsideration request, the MA plan must send a written notice of the dismissal to the parties at their last known address at the conclusion of the applicable adjudication timeframe. The dismissal is not considered an adverse determination, however, the dismissal notice must state the reason for the dismissal and explain the right to request IRE review of the dismissal within 60 calendar days after receipt of the written notice of the MA plan's dismissal. MA plans may use the model Notice of Dismissal of Appeal Request when notifying an enrollee of a dismissal.

> **Note:** If the conclusion of the adjudication timeframe falls on the weekend or a holiday, the dismissal notice may be sent the next business day.

The MA plan's dismissal is binding unless the enrollee or other party requests IRE review.

Upon receipt of a dismissal review request, the IRE will contact the appropriate MA plan to obtain the case file. MA plans must assemble and forward the case file to the IRE within 24 hours of receiving the IRE's case file request (i.e. place in the mail). The IRE does not have to receive the case file within 24 hours of the request.

If the IRE determines that the MA plan's dismissal was in error, the IRE vacates the dismissal and remands the case to the MA plan for reconsideration. The IRE's decision regarding a MA plan's dismissal is binding and not subject to further review.

50.10 – Notification Requirements for Level 1 Appeal Decisions

50.10.1 - Part C Notification Requirements

Favorable Decisions

For favorable decisions, the MA plan must:

- Notify the requesting party and the enrollee in writing of its favorable determination.
- If the enrollee's representative filed the appeal, the representative must be notified in lieu of the enrollee.
- Ensure written notification for appeals for service requests explain the conditions of the approval which include (but are not limited to):
    - The duration of the approval; and
    - Limitations associated with the approval.

Partially Favorable, Adverse, or Untimely Decisions

For partially favorable, adverse, or untimely decisions, the MA plan must send a copy of the complete case file with a written explanation of the MA plan's decision to the IRE within the applicable timeframe (see §50.12 for timeframes and case file requirements). MA plans are not required to notify beneficiaries upon forwarding cases to the Part C IRE. MA plans opting to inform parties when a case has been forwarded to the IRE may use the *Notice of Appeal Status*.

> **Note:** See §50.7.2 if the MA plan makes a favorable determination for a reconsideration request in less than 24 hours after the adjudication timeframe.

For notice requirements following denial of a request for an expedited reconsideration, see §50.2.2.

50.10.2 - Part D Notification Requirements

Favorable Decisions

For favorable decisions, the Part D plan sponsor must:

- Notify the enrollee in writing in a readable and understandable form, in accordance with the regulatory requirements at §423.590(h). If the enrollee's representative filed the appeal, the representative must be notified in lieu of the enrollee.

- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must provide notice to the prescriber and written notice to the enrollee.

- If a plan sponsor provides verbal notification to a physician or other prescriber, the plan sponsor does not need to send a written follow-up.

- Written notices must explain the conditions of the approval. The conditions of approval may include (but are not limited to):

    - The duration of the approval;

    - Limitations associated with the approval; and/or

    - Any coverage rules applicable to subsequent refills.

Adverse Decisions

If the request is denied, in whole or in part, the Part D plan sponsor must:

- Notify the enrollee in writing. The plan sponsor may use the model Notice of Redetermination language, or it may develop its own notice. If the enrollee's representative filed the appeal, the representative must be notified in lieu of the enrollee.

- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must provide notice to the prescriber and written notice to the enrollee.

- If a plan sponsor provides verbal notification to a physician or other prescriber, the plan sponsor does not need to send a written follow-up.

- In accordance with the regulatory requirements at §423.590(g), the notice must use approved notice language in a readable and understandable form, and must:

    - State the specific reason for denial that takes into account the enrollee's presenting medical condition, disabilities, and special language requirements, if any;

    - Contain the enrollee's HICN or MBI, plan sponsor name, plan identification number, contract identification number, and formulary identification number;

    - Provide a description of any applicable Medicare coverage rule or any other

applicable plan policy upon which the denial was based, including any specific formulary criteria that must be satisfied for approval. If the drug could be approved under the exception rules, the notice must explicitly state the need for a supporting statement and clearly identify the type of information that should be submitted when seeking a formulary or tiering exception; and

- Inform the enrollee of his or her right to a reconsideration (level 2 appeal).

  Note: For adverse drug coverage redeterminations, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process.

  For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process.

For notice requirements following denial of a request for an expedited redetermination, see §50.2.2.

Untimely Decisions

If the plan sponsor fails to provide notice of a decision within the required timeframe, the plan sponsor is not required to send the adverse decision notice, but instead, the plan sponsor should notify the enrollee that his or her decision was not made timely and is being forwarded to the IRE for review. The notice must:

- Advise the enrollee of his/her right to submit additional evidence that may be pertinent to the enrollee's case, if the enrollee chooses;
- Direct the enrollee to submit such evidence to the independent review entity; and
- Include information on how to contact the independent review entity.

CMS has developed a model Notice of Case Status that plan sponsors can use in lieu of the adverse decision notice to notify enrollees whenever cases are forwarded to the IRE.

Note: See §50.7.2 if the plan sponsor makes a favorable decision for a redetermination request in less than 24 hours after the adjudication timeframe.

50.11 – Procedure for Handling Misclassified Appeals

If the plan misclassifies an appeal as a grievance and later discovers the error, the plan must immediately forward the request to the appropriate division for processing and notify the enrollee in writing that the request was misclassified and will be handled through the appeals process. The timeframe for processing the appeal begins on the date the appeal is received by

the plan, as opposed to the date the plan discovers its error. Plans are expected to audit their own appeals and grievance for the presence of errors and institute appropriate quality improvement projects as needed.

50.12 – Timeframes and Responsibilities for Forwarding Case Files to the Independent Review Entity

50.12.1 – Forwarding Case Files – Plan Responsibilities

If a MA plan appeal decision affirms the adverse initial determination (in whole or in part) or a Part D plan sponsor does not provide notice of its standard or expedited redetermination within the required timeframe or an enrollee has filed a reconsideration request and the IRE has requested the enrollee's file from the plan, the plan must:

- Make reasonable and diligent efforts to gather and forward all pertinent documentation, including medical records.

- Submit a written explanation with the complete case file (the case file must satisfy the requirements in §50.12.3) to the IRE contracted by CMS within the forwarding timeframes, as set forth in §50.12.2.

- Submit the case file by mail or overnight delivery service, fax, or the IRE web portal. Plans may access the web portal and the user's guide on the IRE's website.

The plan should contact the IRE for additional information on electronic submission of case files.

> **Note:** If a plan makes a fully favorable determination in less than 24 hours after the end of the applicable adjudication timeframe, the plan should consider promptly notifying the enrollee of the favorable decision (within the 24 hour period the case must be forwarded to the IRE) in lieu of forwarding the case to the IRE. See §50.7.2 for additional information regarding untimely decisions made in less than 24 hours after the adjudication timeframe.

For cases forwarded to the IRE, the plan must make reasonable and diligent efforts to gather and forward all pertinent information to the IRE. If CMS determines that the plan has a pattern of not making appropriate efforts to forward information to the IRE, the plan will be considered to be out of compliance with the terms of its Medicare contract and/or subject to intermediate sanctions in accordance with subpart O of 42 CFR Part 422 or Part 423.

For additional instructions, plans may refer to the IRE's Reconsideration Process Manual for Part C and the IRE's Reconsideration Process Manual for Part D.

50.12.2 – Forwarding Case Files - Timeframes

Part C Timeframes

Case Type for Adverse and Untimely Decisions	Forward no later than
Expedited	24 hours of the decision (or no later than expiration of extension)
Standard Pre-Service	30 calendar days of receipt of request (or no later than expiration of extension)
Standard Payment	60 calendar days of receipt of request

Note: For purposes of calculating timely receipt of the appeal case file by the independent review entity, the MA plan should refer to the IRE's Reconsideration Process Manual, Section 5.2.

Part D Timeframes

Case Type for Decisions	Forward no later than
Expedited	24 hours of receipt of IRE's request for case files
Standard	48 hours of receipt of IRE's request for case files
Untimely	24 hours of the expiration of the adjudication timeframe

50.12.3 – Preparing the Case File for the Independent Review Entity

The following should be included in the case file forwarded to the IRE:

What To Include In A Case File When Forwarding to the IRE	Part C	Part D
Appeal Case File Transmittal Form/Cover Sheet	✓	✓
Reconsideration Background Data Form	✓	N/A
Case Narrative	✓	✓
Copy of the Initial Determination Request and Notice	✓	✓
Copy of the Level 1 Appeal Request and Notice	✓	✓

What To Include In A Case File When Forwarding to the IRE	Part C	Part D
Copy of information used to make the plan internal Level 1 decision, including supporting documentation such as medical records, or evidence submitted by the enrollee, provider, and/or prescriber.	✓	✓
Expedited information regarding the Coverage Determination and Redetermination	N/A	✓
Representation documentation for representative appeals	✓	✓
A complete copy of the relevant Evidence of Coverage on a CD (compact disc)	✓	✓
The name and specialty of the prescribing physician or other prescriber and contact numbers for street address, telephone, fax, and e-mail.	N/A	✓
Copy of the relevant plan formulary on a CD, including descriptions of any utilization management requirements	N/A	✓
Exceptions process/criteria for determining medical necessity	N/A	✓
Any internal plan medical reviews that were obtained during redetermination review	N/A	✓
Description of medical documentation missing from the case file based on the failure of the prescribing physician or other prescriber to submit additional medical documentation requested by the plan.	N/A	✓

Plans should refer to the most current version of the Part C Reconsideration Manual or the Part D Reconsideration Manual for information concerning all required forms. Plans are expected to fully complete all appropriate sections of the required forms in support of CMS' appeals data collection activities.

50.12.4 – Including Evidence of Coverage and Formulary in Case Files

CMS strongly recommends that the plan include complete copies of the relevant Evidence of Coverage (EOC) and their CMS approved formulary (Part D plans, if applicable) with any case files sent to the IRE for review. ALJs at the Office of Medicare Hearings & Appeals (OMHA) and the Medicare Appeals Council (Council) have indicated that these documents are needed in their entirety in order to properly adjudicate appeals. It is in a plan's best interest to ensure that each case file sent to the IRE includes a compact disc (CD) with complete versions of the EOC and/or formulary relevant to an enrollee's specific case. Failure to include this information could result in an unfavorable appeals decision and/or, in the case of Part D, CMS declining to refer an

ALJ or attorney adjudicator decision to the Council for review. Plans may not mail or fax paper copies of the complete EOC and/or formulary to the IRE.

Include the CD with the case file in the following manner:

- The CD must be properly labeled with the plan name and contract number, formulary ID (Part D), enrollee name/HICN/MBI, and appeal number;
- The CD must be securely affixed to the paper case file;
- All documents on the CD must be in PDF or Word format and should not be encrypted; and
- The CD should only include the EOC and/or formulary applicable to the specific case being adjudicated (a plan must not place copies of all of its EOCs and formularies on the CD).

60 – Reconsiderations by the Independent Review Entity (Level 2 Appeal)

60.1 – Who May Request a Level 2 Appeal

Part C Only: All partially favorable or adverse reconsideration decisions are forwarded to the IRE. A party does not have to make a request for a level 2 appeal.

Part D Only:

- An enrollee,
- An enrollee's representative, or
- An enrollee's prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee in accordance with §423.600(a).

60.2 – How to Request a Level 2 Appeal (Part D Only)

Method of Filing	Type of Request	Timeframe for Filing
Written*	Standard or Expedited	Within 60 calendar days from the date of the notice of the redetermination, unless the IRE extends the timeframe for good cause.

*May be made on the model Request for Reconsideration, or on any other written document and sent to the enrollee. If the model notice is used, plan sponsors should complete the applicable sections with each adverse redetermination notice.

60.3 – Processing Timeframes

The IRE must conduct the reconsideration as expeditiously as the enrollee's health condition requires, but not exceed the required timeframes outlined below.

Processing Timeframes

Type of Request	Part C	Part D*
Standard	Pre-service: 30 days Payment: 60 days	Benefit: 7 days Payment: 14 days
Expedited (Payment requests cannot be expedited)	72 hours	72 hours

*For exception requests, the Part D timeframe may be tolled until the supporting statement is received. See §40.5.4 for additional information regarding tolling.

60.4 – Good Cause Extension (Part D Only)

If a party misses the 60-day timeframe for requesting an IRE reconsideration, he or she may request a good-cause extension. The extension request must be filed with the IRE, in writing, and include the reason why he or she did not request a reconsideration timely. If the party shows good cause, the IRE may extend the timeframe for filing a request for reconsideration. The IRE should consider the circumstance that kept the party from making the request on time and whether any actions by the Part D plan sponsor may have misled the party. Examples of circumstances where good cause may exist include (but are not limited to) the situations described in §50.3. The decision by the IRE on whether to grant an extension for good cause is final and not subject to appeal.

60.5 – IRE Notification and Retention Requirements

When the IRE completes its reconsideration, it is responsible for notifying the parties of its decision and providing a copy of the decision to the plan. Under Part C, the IRE is also responsible for sending a copy of the decision to the CMS Regional Office that oversees the MA plan.

The reconsideration notice must:

- Be written in a manner that is understandable to the enrollee that takes into account the enrollee's presenting medical condition(s), disabilities, or special language requirements, if any, and:

- Include specific reasons for the decision.

If the decision is adverse (i.e., does not completely reverse the plan's adverse determination) the notice must also:

- Inform the parties of the right to an ALJ hearing if the amount in controversy meets the appropriate threshold requirement (see §70.2 for threshold requirements; plans may not appeal to the ALJ or attorney adjudicator); and

- Describe procedures that the parties must follow to obtain an ALJ hearing, including the filing location.

The IRE is responsible for storing reconsideration case files in accordance with CMS' Records Management Program. For additional retention requirements, see the Part C Reconsideration Manual or the Part D Reconsideration Manual.

60.6 – Withdrawal of Request for a Level 2 Appeal

The party who files a request for reconsideration may withdraw the request at any time by writing to the IRE and requesting the withdrawal before the IRE mails its decision.

60.7 – Effect of a Reconsideration Determination

An IRE reconsideration determination is final and binding on the enrollee and the plan, unless a party files a request for a hearing before an ALJ or attorney adjudicator (level 3 appeal).

Part C Only: Pursuant to 42 CFR §422.600, any party to the Part C reconsideration determination, except the MA plan, has a right to request a level 3 review if the amount in controversy thresholds are met (see §70.2 for threshold requirements).

Part D Only: Pursuant to 42 CFR §423.2000, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to request a level 3 review if the amount in controversy thresholds are met (see §70.2 for threshold requirements).

Note: The Remainder of §60 Applies to Part D Only

60.8 – Reconsideration of Late Enrollment Penalty Determinations

Under §1860D-13(b) of the Act and 42 CFR §§423.46 and 423.56(g), the Secretary or his or her designee imposes a late enrollment penalty (LEP) 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.

"Creditable prescription drug coverage" is coverage that meets Medicare's minimum standards since it is expected to pay, on average, at least as much as Medicare's standard prescription drug coverage. This may include but is not limited to:

- Employer-based prescription drug coverage, including the Federal Employees Health Benefits Program (FEHBP);
- State Pharmaceutical Assistance Programs (SPAPs);
- Military-related coverage (for example, VA, TRICARE coverage); and
- Certain Medicare supplemental (Medigap) policies.

See 42 CFR §423.56(b) for a complete list of types of prescription drug coverage that may be determined to be creditable.

As outlined at 42 CFR §423.56(c) and (d), with the exception of Prescription Drug Plan Sponsors, Medicare Advantage Organizations, Section 1876 Cost-Based Contractors, and PACE organizations offering prescription drug plans, entities that offer prescription drug coverage must make an annual determination of creditable coverage status and provide a disclosure notice to Medicare eligible individuals (see the appropriate plan enrollment guidance for information related to Part D enrollment eligibility). See Chapter 4 of the Prescription Drug Benefit Manual for additional guidance regarding creditable coverage period determinations and the calculation and assessment of the LEP.)

> **Note**: Prescription drug discount cards, free clinics, or drug discount websites do not constitute creditable prescription drug coverage. Also, the "certificate of creditable coverage" an enrollee may receive when his or her health coverage ends does not mean the prescription drug coverage met Medicare's minimum standards – unless the notice specifically mentioned the enrollee had "creditable" prescription drug coverage that expected to pay as much as Medicare's standard prescription drug plan pays. Furthermore, workers compensation set-aside arrangements do not constitute creditable prescription drug coverage, since this prescription coverage is only for medication related to a work injury. For additional guidance concerning creditable coverage-related requirements, see the material posted on the Creditable Coverage page on the CMS website.

An enrollee, or his or her representative may request a review, or reconsideration, of a decision to impose an LEP. An enrollee may only obtain review under the circumstances listed on the LEP Reconsideration Request Form. Unless otherwise stated in §20.1 of this guidance, the enrollee's representative has all of the rights and responsibilities of an enrollee under Part D LEP reconsideration procedures.

The LEP reconsideration is conducted by the IRE under contract with Medicare.

60.8.1 – Summary of the LEP Reconsideration Process

The LEP Reconsideration Process is described below:

- When a Part D plan sponsor sends a letter notifying an enrollee of the imposition of or increase in the LEP ("LEP letter"), and the increase is due to reporting additional uncovered months, except in a case where the number of uncovered months increases as a result of an IRE decision, the plan sponsor shall include the Part D LEP Reconsideration Notice: "Your Right to Ask Medicare to Review Your Medicare Part D Late Enrollment Penalty" and the LEP Reconsideration Request Form.

- The information provided by the plan advises the enrollee that he or she has 60 calendar days from the date on the LEP letter to request reconsideration of the LEP, or the request may not be considered. If the 60-day timeframe for filing has expired, the enrollee may request a good-cause extension, subject to the requirements described in §60.4 of this guidance. The enrollee must explain his or her reason for filing late on a separate sheet and send this explanation along with the LEP Reconsideration Request Form.

- The enrollee sends his or her signed, completed LEP Reconsideration Request Form to the IRE, in accordance with the filing instructions provided on the form. Enrollees also may write a letter requesting an LEP appeal, provided the letter contains the elements on the LEP Reconsideration Request Form.

- The IRE shall request a copy of the case file from the plan sponsor and make a decision based on the case file, the information supplied by the enrollee, and any other information the IRE deems relevant.

- The IRE will inform the enrollee and the plan sponsor of the final decision.

- The plan sponsor, if applicable, shall report a revised creditable coverage determination to CMS and notify the enrollee in writing of the new LEP amount and any refund due. (Refer to Chapter 4 of the Prescription Drug Benefit Manual for more information.)

- The final LEP reconsideration decision is not subject to appeal (that is, is not subject to further review by an Administrative Law Judge (ALJ) or attorney adjudicator, Council, or in a district court of the U.S.), although CMS can review and revise a decision upon request.

60.8.2 – Part D Plan Responsibilities under the LEP Reconsideration Process

The Part D plan sponsor shall become familiar with LEP procedures so it is able to assist enrollees throughout the LEP reconsideration process. For example, the plan sponsor shall:

- Attempt to obtain a completed Declaration of Prior Prescription Drug Coverage form,

(Exhibit 1D in Chapter 4 of the Prescription Drug Benefit Manual) from the enrollee at the beginning of the creditable coverage determination process, where the enrollee appears to have a qualifying break in creditable prescription drug coverage. Obtaining the Declaration may avoid the assessment of a LEP and the need for reconsideration.

- Send the enrollee the Part D LEP Reconsideration Notice, "Your Right to Ask Medicare to Review Your Part D Late Enrollment Penalty", and the LEP Reconsideration Request Form at the same time the plan sponsor sends an enrollee his or her LEP letter.

- Assist the enrollee in completing the LEP Reconsideration Request Form upon request. For example, the plan sponsor shall help an enrollee determine which checkbox to mark as his or her reason for seeking reconsideration.

- The plan sponsor shall inform the enrollee that his or her request must include the following:

    - A completed, signed LEP Reconsideration Request Form or a signed, written request for reconsideration containing the elements on the LEP reconsideration request form; and

    - If the enrollee has named a representative, proof that the individual has authority to represent the enrollee.

      Note: In addition to the items above, the plan sponsor shall inform the enrollee that his or her request should include any additional information that may help the enrollee's case, including evidence that the IRE should consider (e.g., notice from an employer sponsored health plan indicating that prior drug coverage was creditable). See §60.8.4.

- The plan sponsor shall instruct enrollees to send this material to the IRE at the address or fax number shown on page 2 of the LEP Reconsideration Request Form, to include their HICN or MBI on any separate materials, and to only send photocopies of their original documents.

- Retain a copy of the LEP letter sent to an enrollee. If the plan sponsor retains a copy of the LEP letter in the enrollee's file, that information will be readily and easily available if the enrollee requests review of the LEP and the IRE requests this information.

- Send the IRE a copy of the enrollee's case file, which includes copies of any information the plan sponsor used in making its creditable coverage determination for the enrollee, including, but not limited to:

    - the enrollee's Part D initial enrollment period (IEP) or subsequent IEP end date (and how it was derived); and

    - the enrollee's creditable coverage attestation materials ("Declaration of Prior

Prescription Drug Coverage" form, Exhibit 1D in Chapter 4 of the Prescription Drug Benefit Manual), and any documentation from CMS of the enrollee's enrollment in a plan or in a plan whose sponsor received the retiree drug subsidy.

If the IRE partially or fully reverses a plan sponsor's creditable coverage determination, the plan sponsor shall comply with the requirements described under Chapter 4 of the Prescription Drug Benefit Manual concerning adjustment or removal of an LEP.

60.8.3 – Requests for Information

Upon request, the plan sponsor shall forward to the IRE any information necessary to make a reconsideration decision, including all creditable coverage and LEP-related information received in accordance with Chapter 4 of the Prescription Drug Benefit Manual, such as information from a current or previous enrollee.

Information Availability	Timeframe*	Requirement
The requested information is available	Within 14 calendar days	Deliver (by mail or fax) a hard copy of the requested information.
The requested information is not available	Within 14 calendar days	Deliver (by mail or fax) a brief letter to the IRE acknowledging that the requested information is unavailable and explain the reason.

*after receiving the request for information

60.8.4 – Reasons for Requesting LEP Reconsideration and Presentation of Evidence

An enrollee may request review of their LEP decision if he or she:

- Had prior creditable prescription drug coverage that the enrollee believes may have not been considered.

- Had prior prescription drug coverage but didn't get a notice that clearly explained whether the drug coverage was creditable. In this case, the enrollee should submit any evidence, such as a copy of a plan sponsor's letter or other material, for example, a Summary of Benefits that the enrollee found unclear or misleading.

- 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 Medicare drug plan.

- 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.

- 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 Chapter 4 of the Prescription Drug Benefit Manual for additional guidance on the opportunity for certain individuals to enroll in Medicare Part D without an LEP.

60.8.5 – IRE LEP Processing Timeframes

IRE Timeframes for Processing

Scenario	Timeframe	IRE Action/Notification
No extension was requested and good cause for extension was not found by the IRE.	90 calendar days	• Notify the enrollee of the final decision (including a decision to dismiss the request). • If an enrollee has identified a representative, the IRE will send any notice or other correspondence to the enrollee's representative instead of to the enrollee.
Enrollee requests an extension or the IRE finds good cause to extend.	90 calendar days with a 14-day extension	Good cause would include, for example, when the IRE finds a need for additional information and considers the delay to be in the interest of the enrollee, such as receipt of additional information that may reduce the number of uncovered months upon which the LEP was based.
An individual other than the enrollee files for reconsideration.	The timeframe will not begin until the IRE 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 IRE will attempt to cure any defect in an Appointment of Representative form (CMS-1696) or other equivalent written notice by requesting information from the individual who filed the request. If the IRE cannot verify an individual's status as the representative within a reasonable time period, not to exceed 30 calendar days after the date of the request, the IRE will determine that the reconsideration request be dismissed.

Note: In all cases, the IRE strives to notify an enrollee of its final decision as quickly as possible. However, the IRE may take longer than the 90-day timeframe to process an LEP reconsideration decision in certain cases depending, among other issues, on the amount of research the IRE has to perform to verify whether an enrollee's prior prescription drug coverage was creditable.

60.8.6 – Withdrawal of an LEP Reconsideration Request

An enrollee may withdraw his or her LEP reconsideration request in writing at any time before the IRE mails the final decision. For purposes of a withdrawal, "enrollee" also includes a former enrollee or his or her representative.

60.8.7 – Dismissal of an LEP Reconsideration Request

Instances in which the IRE 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. The word "spouse", as used in 42 CFR §423.2052(a)(5), includes same-sex spouses as well as opposite-sex spouses. Because civil unions and domestic partnerships are not marriages, civil union and domestic partners are not regarded as spouses by CMS;

- 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; or

- An enrollee requests a reconsideration of an issue that is ineligible for LEP reconsideration or is otherwise ineligible for review. For example, the IRE will not make actuarial determinations concerning whether an enrollee's prescription drug coverage was creditable; that 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.

Dismissals are not appealable.

Vacating a Dismissal

The dismissal is binding, unless the dismissal is vacated. If a Part D enrollee requests the

dismissal be vacated and he or she shows good cause that the reconsideration request should not be dismissed, the dismissal of the reconsideration request may be vacated. The enrollee must request that the dismissal be vacated within 60 days after the date of the dismissal notice. The IRE will notify the enrollee and the Part D plan sponsor in writing if the dismissal is vacated.

70 – Key Aspects of Administrative Law Judge (ALJ)/Attorney Adjudicator, Council, and Judicial Review

70.1 – Parties to a Hearing

Who May Request Review

Level of Review	Part C	Part D*
Third Level: ALJ/attorney adjudicator	Any party to the reconsideration, except the MA plan, has a right to a hearing. The parties to a hearing are the parties to the reconsideration, the MA plan, and other person/entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ or attorney adjudicator.	Enrollee
Fourth Level: Council	Any party to the ALJ or attorney adjudicator's decision or dismissal, including the MA plan.	Enrollee
Fifth Level: Federal Court	Any party, including MA plan (must notify all other parties).	Enrollee

*An enrollee's prescribing physician or other prescriber may request an initial determination, redetermination or level 2 appeal, but cannot request a higher level of appeal without being the enrollee's representative. See, for example, 42 CFR §§423.1970 and 423.2002 for information on the right to an ALJ hearing.

70.2 – Amount in Controversy

In general, the amount in controversy (AIC) is computed as the actual amount charged (or amount enrollee would have been charged) minus applicable deductible or coinsurance. For Part D, if the basis for the appeal is the refusal by the plan to provide drug benefits, AIC is determined by using the projected value of those benefits. Projected value includes any costs the enrollee could incur based on the number of refills prescribed for the disputed drugs during the plan year. For Part C, if the basis for the appeal is the MA plan's refusal to provide services, the AIC is computed using the projected value of those services. For Parts C and D, appeals may be aggregated to meet the AIC. See §423.1970(c); [§405.1006(e) and (f)].

Level of Review	Amount in Controversy Requirement
Third Level: ALJ/attorney adjudicator	• Part C ALJ hearing/attorney adjudicator review: https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/ALJ.html • Part D ALJ hearing/attorney adjudicator review: https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/ALJHearing.html If the request for ALJ hearing shows that the required AIC is not satisfied, the appeal is dismissed at the OMHA level.
Fourth Level: Council	No amount in controversy requirement. If a case is reviewed by the Council, whether it is a review of a dismissal or a decision at the OMHA level, there is no additional AIC to be met with the expectation that the claim has already met the AIC for the third level of appeal. No additional AIC is required for the fourth level of review.
Fifth Level: Federal Court	If a case is appealed to the fifth level, the claim must then meet the AIC established by the Secretary for Federal Court review. • Part C federal court: https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Fed.html • Part D federal court: https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/FederalCourtReview.html

70.3 – Filing Requests for Review

At the third, fourth, and fifth levels of review, the request must be filed within 60 calendar days of receipt of a decision or dismissal from the IRE, ALJ/attorney adjudicator, or the Council, respectively. (Unless there is evidence to the contrary, the date of receipt of a decision or dismissal is presumed to be 5 calendar days after the date of decision or dismissal). Extension of filing deadline may be granted for good cause. The request for good cause extension must be in writing (except for requests for Part D expedited hearings, for which the extension may be made verbally or in writing) and state the reason the request was late.

Level of Review	How to file a request	If the applicable request form is not used, written requests should include the following:
Third Level: ALJ/attorney adjudicator	• With the entity/office specified in the IRE decision or dismissal; or • In writing* – OMHA-100 may be used	• Appellant's name, address, telephone number and Medicare number; • The representative's name, address, and telephone number, if applicable. • Case number or appeal number, if any, assigned by the IRE; • Reasons the appellant disagrees with the IRE decision or dismissal; • Statement of additional evidence to be submitted and the date it will be submitted; and • Additional request content for Part C only: Dates of service of claim(s) being appealed, if applicable. • Additional request content for Part D only: • Name of prescription drug in dispute and plan name. • A statement that the enrollee is requesting an expedited hearing, if applicable. If appellant is requesting an expedited hearing, the request should explain why the standard timeframe may seriously jeopardize the enrollee's life, health, or ability to regain maximum function.
Fourth Level: Council	With the Council (Address noted in ALJ/attorney adjudicator's decision); In writing* – DAB-101 may be used **Part C Only:** If the MA plan requests review, the MA plan must concurrently notify the enrollee by sending a copy of the request and accompanying documents submitted to the Council.	**Part C Requests** (if form DAB-101 is not used): • Name • Medicare number • Service(s)/item(s) for which review is requested • Date(s) of service • Date of ALJ or attorney adjudicator decision or dismissal • Name and signature of party or party's representative • Request must identify parts of the ALJ or attorney adjudicator decision with which the

Level of Review	How to file a request	If the applicable request form is not used, written requests should include the following:
		party disagrees and explain reason for disagreement. **Part D Only:** Same as above requirements for written requests filed at the third level of review. Also must include: • Case number or appeal number, if any, assigned by OMHA; • Reasons the appellant disagrees with the ALJ or attorney adjudicator decision. dismissal or other determination being appealed; • Signature of enrollee or representative, if any; and • A copy of the ALJ's or attorney adjudicator's decision should be included with the request. The DAB-101 form requests that the decision or dismissal order being appealed be attached to the request form.
Fifth Level: Federal Court	Civil action must be filed in a district court of the U.S. where the enrollee resides or, if none, in the U.S. district court for the District of Columbia. **Part C Only:** Action may be filed in the district court where the party (e.g. MA plan) has its principal place of business. See: §§422.612, 405.1130 – 1140 (Part C) and §§423.2130 – 423.2140 (Part D) for procedures related to requesting judicial review.	Not governed by Medicare regulations but an amount in controversy threshold applies (see §70.2 for threshold requirements).

*Under Part D, expedited requests may be submitted verbally or in writing.

Part D Only: The Council may initiate a review on its own motion or at the request of CMS or the IRE within 60 calendar days after the date of ALJ/attorney adjudicator's written decision or dismissal. The Council will mail notice of the results of its own motion review to the enrollee and to CMS or the IRE as appropriate.

70.4 – Review Procedures

70.4.1 – Decision-Making Timeframes

There are no statutory or regulatory decision-making timeframes for Part C appeals at the third level of review and beyond. All timeframes begin on the date the request is received, unless the timeframe has been extended as provided in the regulations. See also 42 CFR §422.562(d). For further information on hearings and decisions by an ALJ or attorney adjudicator, see 42 CFR §§422.600-602 (Part C) and 42 CFR §§423.2000-2063 (Part D).

The following timeframes are only applicable under Part D.

Part D Timeframes

Level of Review	Expedited	Standard
Third Level: ALJ/attorney adjudicator	Generally within 10 calendar days*	Generally within 90 calendar days
Fourth Level: Council	Generally within 10 calendar days*	Generally within 90 calendar days
Fifth Level: Federal Court	N/A	N/A

* The medical exigency standard applies.

70.4.2 – Part D Plan Sponsor, CMS, or IRE Requesting ALJ Hearing Participation (Part D Only)

Participating in a hearing allows the Part D plan sponsor, CMS, or the IRE to file position papers and/or provide testimony to clarify factual or policy issues, but does not include calling or cross-examining witnesses. If a plan sponsor, CMS, or the IRE requests participation in an ALJ hearing, how and when the request to participate is made is as follows:

Request to Participate Filing Timeframes

Standard	Expedited
• If no hearing is scheduled, the request must be sent within 30 calendar days after notification that a standard request for hearing was filed. • If a hearing has been scheduled, the request must be sent within 5 calendar days after receiving the notice of hearing.	• If no hearing is scheduled, the request must be sent within 2 calendar days after notification that a request for expedited hearing was filed. • If a hearing has been scheduled, the request must be sent within 1 calendar day after receiving the notice of hearing.

Where to Send Request

Standard	Expedited
• If the Part D plan sponsor, CMS, or the IRE requests participation after receiving the notice of hearing, written notice of a request to participate must be sent to the ALJ and the enrollee. • If the plan sponsor, CMS, or the IRE requests participation before the notice of a hearing is received or if no notice is required, written notice of a request to participate must be sent to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ (if the request is not yet assigned) and the enrollee.	• If the plan sponsor, CMS, or the IRE requests participation, the request may be made verbally for an expedited hearing and OMHA will notify the enrollee of the request to participate.

Note: The assigned ALJ or attorney adjudicator has discretion not to allow CMS, the IRE, and/or plan sponsor to participate.

70.4.3 – Submitting Evidence at the Third Level of Review

An enrollee or other party must submit written or other evidence that he or she wishes to have considered at the hearing as follows:

Part C Only: Parties must submit all written or other evidence with the hearing request, or by the date specified in the hearing request, or, if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing. This requirement does not apply to an unrepresented enrollee.

Part D Only: Submit all written or other evidence with the hearing request, or by the date specified in the hearing request, or, if a hearing is scheduled, within:

- 10 calendar days of receiving the notice of hearing for standard hearings (these submission requirements do not apply to unrepresented enrollees in standard Part D appeals (see §423.2018(b)(3))).
- 2 calendar days of receiving the notice for expedited hearings.

If an enrollee wishes evidence on a change in medical condition (after the coverage determination was made) to be considered, the ALJ/attorney adjudicator will remand the case to the Part D IRE.

80 – Reopening and Revising Determinations and Decisions

A reopening is a remedial action taken to change a binding determination or decision even though the binding determination or decision (i.e., initial determination or level 1 appeal) may have been correct at the time it was made based on the evidence of record.

Given the remedial nature of a reopening, CMS expects the reopening process to be used sparingly by plans. If a plan routinely or excessively uses the reopening process, this may indicate that the plan does not have sufficient procedures in place for properly processing initial determinations and level 1 appeals. For example, frequent use of the reopening process may indicate that the plan is not thoroughly reviewing requests or is not conducting reasonable outreach for missing information (see §10.4.5 for outreach requirements). Plans and other adjudicators shall not use the reopening process in a manner that interferes with enrollee access to the appeals process. Plans may be subject to compliance action if found to be routinely using the reopening process in a manner that interferes with enrollee access to the appeals process.

When adjudicators reopen initial determinations or appeals, they must comply with the reopening regulations listed below:

- 42 CFR §422.616; and
- 42 CFR §§423.1978 – 423.1986.

Pursuant to 42 CFR §422.616(a), the reopening regulations in Part 405 (i.e., §§405.980 – 405.986) are applicable to Part C, unless otherwise specified.

80.1 – Guidelines for Reopening

A decision to reopen is at the discretion of the adjudicator who has authority to conduct a reopening. Adjudicators with authority to conduct a reopening include:

- A plan to revise the initial determination or level 1 appeal decision;
- An IRE to revise its reconsideration determination;
- An ALJ or attorney adjudicator to revise his or her decision; or
- The Council to revise the ALJ or attorney adjudicator decision or its review decision.

The filing of a request for a reopening with the IRE, ALJ, or the Council does not relieve the plan of its obligation to make payment for, authorize, or provide benefits or services as specified in 42 CFR §§422.618, 423.1978(b), and 423.1980(a)(3), consistent with 42 CFR §422.616(c) and guidance in this guidance.

> **Part C Only:** 42 CFR §422.618(c)(2) does not apply to an ALJ decision following Federal District Court remand. Pursuant to 42 CFR §405.1140(a), a decision by the Office of Medicare Hearings & Appeals is the final decision of the Secretary, unless the Council assumes jurisdiction. Part 405 provisions (i.e., §§405.980 – 405.986) apply to Medicare Advantage Organizations, unless the subpart provides otherwise per 42 CFR §422.562(d).

A reopening request:

- May be initiated by a plan, the IRE, ALJ or attorney adjudicator, the Council, or requested by an enrollee or any other party to the determination or decision;
- May be made verbally or in writing;
- Should include the specific reason for requesting the reopening (a statement of dissatisfaction is not grounds for a reopening); and
- Must be made within the timeframes permitted for reopening (as set forth in §80.3).

If the request for reopening is denied, the enrollee or other party must be notified that the determination or decision will not be reopened. If the request was received in writing, the adjudicator must notify the requestor in writing of the decision not to reopen. The decision on whether to reopen is binding and not subject to appeal.

When a determination or decision is reopened and revised (including revision of the rationale for a decision that is not revised), the plan, IRE, ALJ or attorney adjudicator, or the Council that reopened the decision must provide written notification to the parties to that determination or decision, as described in §80.6.

After reopening, a revised determination or decision is binding unless it is appealed or otherwise subsequently reopened. Only the portion of the determination or decision revised by the reopening may be appealed. The timeframe to request an appeal of the revised determination or decision begins on the date of the revised determination or decision.

80.2 – Reopenings Separate and Distinct from Appeals

The reopening process is separate and distinct from the appeals process. When a party has filed a valid request for a level 1 appeal, level 2 appeal, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen a case that is under appeal until all appeal rights for that case are exhausted or a subsequent request by the appellant to withdraw the appeal has been granted. For example, if a party requests a level 2 appeal and a reopening of an initial determination simultaneously, the level 2 appeal would be the only action processed. As a result, a party cannot have an appeal and a reopening occurring simultaneously with respect to the same case.

Part C Only: A MA plan cannot reopen and modify its pre-service reconsideration decision after the case file for the adverse decision has been forwarded to the IRE, as CMS considers this an issue still under appeal.

Part D Only: A Part D plan sponsor cannot reopen and modify its decision if additional information is received after an appellant files a request for an IRE reconsideration or the plan sponsor is required to forward the case to the IRE, unless a subsequent request by the appellant to withdraw the IRE reconsideration request has been granted.

Comparison of Reopenings and Appeals

Characteristic	Reopening	Appeal
Request by Adjudicator	✓	N/A
Subject to Appeal Rights*	N/A*	✓
Binding on all Parties	✓	✓
Clerical Errors **(Part C Only)**	✓	N/A

*****Although the decision whether or not to reopen a determination or decision is not appealable, an adverse revised determination or decision is subject to appeal. An adverse revised determination or decision as a result of a reopening must state the rationale and basis for the reopening and revision and any right to appeal the adverse determination or decision.

80.3 – Timeframes for Reopening

80.3.1 – Timeframes for Initiating a Reopening

The timeframes for initiating a reopening are as follows:

Reopening Entity	180 Calendar Days*	Within 1 Year*	Within 4 years*	Any time
Plan	N/A	For any reason (if the case is not under appeal, see §80.2)	For good cause as defined in §80.5	• If reliable evidence exists (i.e., relevant, credible, and material) that the initial determination or level 1 appeal was procured by fraud or similar fault. **Part C Only:** • If the determination is unfavorable, in whole or in part, but only for the purpose of correcting a clerical error on which that determination was based. • To effectuate a decision issued under the coverage (National Coverage Determination (NCD)) appeals process** **Part D Only:** Part D plan sponsors may, but are not required to, classify and process clerical errors as reopenings.
IRE, ALJ or attorney adjudicator, Council	For good cause as defined in §80.5	N/A	N/A	If the reconsideration or decision was procured by fraud or similar fault.

*From the date of the decision.
**When reopening is initiated by the plan.

Plans must afford enrollees appropriate access to the appeals process by not repeatedly reopening initial determinations and level 1 appeals after denial notices have been sent.
If the enrollee, provider or prescriber has submitted evidence after the initial determination or level 1 appeal request has been denied, the plan must ascertain whether the enrollee, provider or prescriber is seeking an appeal or a reopening (generally, these should be treated as appeals).

Part C Only: For denied claims, if the enrollee or provider submits additional information after the initial denial or an upheld decision on reconsideration but before the case is sent to the IRE MA plans should process as a reopening.
For pre-service denials, if the MA plan has issued a denial letter with appeal rights and subsequently receives additional information, the MA plan should process as an appeal. A MA plan cannot reopen and modify its pre-service reconsideration decision after the case file for the adverse decision has been forwarded to the IRE, as CMS considers this an issue still under appeal.

80.3.2 – Timeframes for Processing a Reopening

A party to an initial determination has a reasonable expectation to the administrative finality of a determination issued by the plan. For reopenings requested by a party that the plan agrees to reopen, the reopening action should be completed within 60 days from the date of receipt of the party's reopening request.

For reopenings requested by a party at the IRE level, within 30 calendar days of receipt of the request for reopening, the IRE will notify the party in writing as to whether or not it shall reopen the case. If the IRE agrees to reopen the request, it will issue a revised determination within 120 days of receipt of the request.

80.4 – Reopening Based on Clerical Error

For purposes of this section, clerical error includes human and mechanical errors on the part of the MA plan such as:

- Mathematical or computational mistakes;
- Inaccurate data entry or coding;
- Computer errors; or
- Denials of claims as duplicates.

Part C Only: A MA plan must remedy a clerical error (which include minor errors and omissions) using the reopening process instead of the appeal process. If the MA plan receives a request for reopening and does not agree that the issue is a clerical error, the MA plan must dismiss the reopening request. Although a party cannot appeal a MA plan's decision not to reopen, the MA plan must notify the party of their rights to appeal the initial adverse decision, provided timeframes to appeal the denial has not expired (see §80.6 for notice requirements).

Part D Only: Part D plan sponsors may, but are not required to, classify and process clerical errors as reopenings.

80.5 – Good Cause for Reopening

Constitutes Good Cause for Reopening	Does Not Constitute Good Cause for Reopening
• There is new and material evidence that was not available or known at the time of the determination or decision and may result in a different conclusion. • The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision. In other words, the decision was clearly incorrect based on all the evidence presented in the appeal file.	• A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise. **Part C Only:** This provision does not preclude MA plans from conducting reopenings to effectuate coverage decisions issued under the authority granted by section 1869(f) of the Act. See §405.986(b). **Part D Only:** Adjudicators may reopen to apply the current law or CMS or Part D plan sponsor policy rather than the law or CMS or plan sponsor policy at the time the coverage determination is made in situations where the enrollee has not yet received the drug and the current law or CMS or plan sponsor policy may affect whether the drug should be received. • A request to reopen a claim based upon a third party payer's error in making a primary payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form.

80.5.1 – New and Material Evidence

In order for evidence to be considered new and material for a plan or IRE reopening, it must meet the following requirements:

- Was not readily available or known to the person or entity requesting/initiating the reopening at the time of the initial determination or redetermination;
- Does not include evidence that was or reasonably could have been, available to the decision-maker at the time the decision was made; and
- May result in a conclusion different from that reached in the initial determination or

redetermination.

In determining whether the evidence is new and material, adjudicators must consider whether evidence is new and material from the perspective of the person or entity requesting or initiating the reopening.

80.6 – Notification Requirements for Reopenings

When any determination or decision is reopened and revised, (including revision of the rationale for a decision), the plan, IRE, ALJ, or the Appeals Council must provide written notification to the parties to that determination or decision, including to the plan, at their last known address.

Written notification must:

- State the rationale and basis for the reopening and revision;
- State the specific reason for the revision or change in rationale, written in a manner that is understandable to the enrollee; and
- Provide information on any appeal rights.

If a reopening results in issuance of payment to a provider, a revised remittance advice notice must be issued.

90 – Effectuation

When a plan's decision is reversed in whole or in part by any other appeal entity, the plan must authorize or provide the service or benefits as expeditiously as the enrollee's health condition requires, however, no later than the timeframes listed below (based on when notice was received).

Part C

Type of Request	IRE Reconsiderations	Other Entity Reconsiderations
Standard Pre-Service	Provide within 14 calendar days*	No later than 60 calendar days
Expedited Pre-Service	No later than 72 hours	No later than 60 calendar days
Payment	No later than 30 calendar days	No later than 60 calendar days**

* The MA plan must authorize the service within 72 hours or as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days.

** Special rule for when the MA plan seeks review from the Council. If the MA plan requests review of the ALJ's decision by the Council during the appeal (i.e. not on remand), the MA plan may await the outcome of the review before it pays for, authorizes, or provides the service under dispute. A MA plan that files an appeal with the Council

must concurrently send a copy of its appeal request and any accompanying documents to the enrollee and must notify the independent outside entity that it has requested an appeal. This delay is not available when the request for review by the Council follows a remand to the ALJ by the Council or a federal court.

Part D

Type of Request	Other Entity Reconsiderations
Standard Benefit	No later than 72 hours
Expedited Benefit	No later than 24 hours
Payment*	Authorize payment with 72 hours, make payment (i.e. mail the payment) no later than 30 calendar days.

* In addition to reimbursing the enrollee, when the Part D plan sponsor makes a favorable decision on a reimbursement exception request, the plan sponsor must also authorize the benefit going forward. Likewise, if a reimbursement request is approved for an enrollee who satisfied a UM requirement, the plan sponsor should reimburse the enrollee for the amount owed, and effectuate the drug going forward in accordance with their CMS formulary.

In general, a favorable coverage determination or appeal decision is retroactive to the date of the earliest request or prescription purchase approved in a coverage determination or appeal decision.

Since approved exceptions are valid for the remainder of the plan year, all prescriptions purchased between the date of the earliest prescription approved under a coverage determination or appeal decision (that involves an exception) and the end of the plan year are reimbursable.

Note: A Part D plan sponsor may choose not to require enrollees to submit subsequent requests once a coverage determine involving a UM is approved.

90.1 – Independent Review Entity Monitoring of Effectuation Requirements

CMS requires the IRE to monitor a plan's compliance with effectuating decisions that fully or partially reverse an original plan determination (denial). The process is as follows:

- The IRE issues a copy of the reconsidered determination to the plan. Included with this copy is a Notice of Requirement to Comply;

- Pursuant to the compliance notice and §§422.618, 422.619, 423.636(b), and 423.638(b), the plan is required to mail to the IRE a statement attesting to compliance with the IRE's decision. This documentation is to confirm when and how compliance occurred (e.g., service authorization, payment made, etc.). Notification to the IRE that the plan "intends to pay for" or "intends to provide" the service are not sufficient. The plan must provide the IRE with affirmative notice that the IRE's decision has been effectuated by payment or provision of the service. The plan's notice of compliance should be forwarded to the IRE concurrent with the plan's effectuation;

- If the IRE does not obtain the compliance notice within 2 weeks, it will mail the plan a reminder notice; and if the IRE does not receive the plan's compliance report within 30 days of the reminder notice, the IRE reports the plan's failure to comply with CMS. The plan is not copied on the notice to CMS.

90.2 – Effectuation Requirements for Former Plans

A plan is legally responsible under its contract and the regulations to authorize, provide, or pay for all Medicare covered services or prescription drugs that are denied and upon appeal are found to be services the plan should have authorized, provided, or paid for its enrollees. CMS policy is that an enrollee is entitled to receive a service and/or payment of a service or prescription drug from a plan from which the enrollee either voluntarily or involuntarily disenrolled prior to a final decision on appeal. The plan must follow the requirements found at 42 CFR §§422.100, 423.104 422.504, and 423.505 as they relate to individual disenrollment or contract termination/service area reduction.

100 – Provider Notices in Hospital, SNF, HHA, and CORF Settings (Part C Only)

100.1 – Hospital Settings – Important Message from Medicare and Detailed Notice

An enrollee has the right to request an immediate review by the Beneficiary and Family Centered Care Quality Improvement Organization (BFCC-QIO) of a decision that inpatient hospital care is no longer necessary. For all MA enrollees, hospitals must deliver valid, written notice of an enrollee's rights as a hospital inpatient, including discharge appeal rights, using the standardized form, CMS Form R-193, Important Message from Medicare (IM).

To request a BFCC-QIO review (immediate review), the enrollee must follow the steps listed on the IM. If the enrollee does not make a timely request to the BFCC-QIO, the enrollee may contact his or her MA plan to request an expedited reconsideration (see §50.2.2 for processing requests for expedited reconsiderations), as indicated on the IM.

Delivery and form instructions for the standardized notice (Important Message from Medicare) can be found in §200 of Chapter 30 of the Medicare Claims Processing Manual. For additional guidance, including a copy of the IM, see the Hospital Discharge Appeal Notices webpage.

100.1.1 MA Plan Responsibilities Following BFCC-QIO Notification of Appeal

When a BFCC-QIO notifies the MA plan that an enrollee has requested an immediate review, the plan must:

- Properly execute and deliver (directly or by delegation) a Detailed Notice of Discharge (DND), Form CMS-10066, to the enrollee as soon as possible, but no later than noon of the day after the BFCC-QIO's notification. (Instructions for the DND can be found in §200.4.2 of Chapter 30 of the Medicare Claims Processing Manual.)

- Ensure delivery of the DND, regardless of whether it has delegated that responsibility to its providers.

- At an enrollee's request, the MA plan must provide to the enrollee a copy of any documentation that it sends to the BFCC-QIO, including written records of any information provided by telephone. This documentation must be provided to the enrollee no later than close of business of the first day after the material is requested.

- Provide, directly or by delegation, all information that the BFCC-QIO needs to make its determination, including copies of the IM and the DND (if applicable). This information must be provided as soon as possible, but no later than noon of the day after the BFCC-QIO notifies the MA plan of the enrollee's request.

Note: The delegation of notice delivery or other functions is determined by the contract between the MA plan and its providers. The BFCC-QIO determines whether the MA plan and the hospital should make the information available by telephone or in writing.

The MA plan is financially responsible for continued coverage of services during the BFCC-QIO review, regardless of whether it has delegated responsibility for authorizing coverage or discharge determinations to its providers.

For information regarding responsibilities of the BFCC-QIO, please see §422.622(d).

100.2 – Skilled Nursing Facility (SNF), Home Health (HH), and Comprehensive Outpatient Rehabilitation Services (CORF) Settings

An enrollee has the right to request an immediate review by the Beneficiary and Family Centered Care Quality Improvement Organization (BFCC-QIO) when a SNF, HHA, or CORF decides to terminate previously approved coverage (which includes a MA plan or contract provider directing an enrollee to seek care from a non-contract provider/facility). All enrollees receiving covered services in these settings must receive a Notice of Medicare Non-Coverage (NOMNC), delivered by the facility or provider, before their services end. Instructions for the NOMNC can be found in §260 of Chapter 30 of the Medicare Claims Processing Manual. For additional

guidance, including a copy of the NOMNC, see the MA Expedited Determination Notices webpage.

Note: Unlike 1876 Cost Plans, HCPPs are not regulated by the rules contained in this section and 42 CFR §422.624-626. HCPP enrollees follow the original Medicare immediate review process (42 CFR 405 Subpart J and Chapter 30 of the Medicare Claims Processing Manual).

100.2.1 – MA Plan Responsibilities Following BFCC-QIO Notification of Appeal

When the BFCC-QIO notifies the MA plan that an enrollee has requested an appeal, the MA plan must:

- Properly execute and deliver (directly or by delegation) a Detailed Explanation of Non-coverage (DENC)*, to the enrollee as soon as possible, but no later than close of business of the day of the BFCC-QIO's notification. (Instructions for the DENC can be found in §260.4.5 of Chapter 30 of the Medicare Claims Processing Manual. For additional guidance, including a copy of the DENC, see the MA Expedited Determination Notices webpage.)

- Ensure delivery of the DENC, regardless of whether it has delegated that responsibility to its providers.

- At an enrollee's request, the MA plan must provide to the enrollee a copy of any documentation that it sends to the BFCC-QIO, including written records of any information provided by telephone. This documentation must be provided to the enrollee no later than close of business of the first day after the documentation is requested.

- Provide, directly or by delegation, all information that the BFCC-QIO needs to make its determination, including copies of the notices sent to the enrollee. This information must be provided, as soon as possible, but no later than close of business of the day the BFCC-QIO notifies the MA plan of the enrollee's request.

Note: The delegation of notice delivery or other functions is determined by the contract between the MA plan and its providers. The BFCC-QIO determines whether the MA plan and the hospital should make the information available by telephone or in writing.

The MA plan is financially responsible for continued coverage of services during the BFCC-QIO review, regardless of whether it has delegated responsibility for authorizing coverage or discharge determinations to its providers.

Contracted Hospitals and CAHs must follow the guidance for Original Medicare (fee-for-service) hospitals and CAHs found in §260 of Chapter 30 of the Medicare Claims Processing Manual.

100.3 – Part A Medicare Outpatient Observation Notice (MOON)

Hospitals and Critical Access Hospitals (CAHs) are required to provide written and verbal explanation to Original Medicare and Medicare Advantage enrollees who receive observation services as outpatients for more than 24 hours.

The process for delivery of this standardized notice (Form CMS-10611), the Medicare Outpatient Observation Notice (MOON), can be found in §400 of Chapter 30 of the Medicare Claims Processing Manual. For additional guidance, including a copy of the MOON, see the "Downloads" section on the Beneficiary Notices Initiative webpage.

110 – Part C Data

Note: The data disclosure requirements described in this section do not apply to HCPPs.

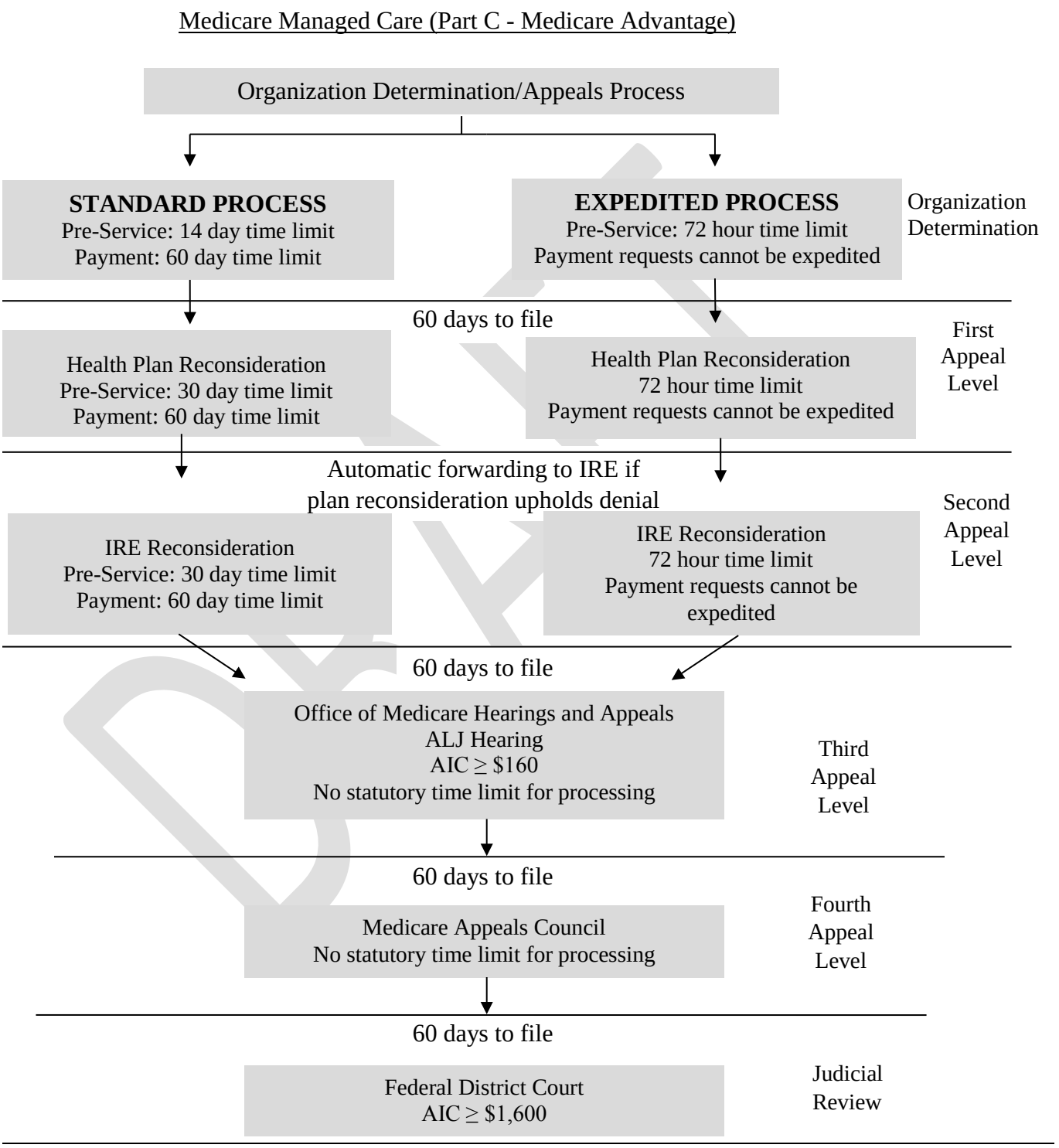
Upon request, MA plans are required to disclose grievance and appeals data to MA enrollees in accordance with the regulatory requirements at 42 CFR §422.111(c)(3).

For purposes of this section, appeals data means all appeals filed with the MA plan that are accepted for review or withdrawn upon the enrollee's request, excluding dismissed appeals. Grievances are limited to quality of care grievances under this effort.

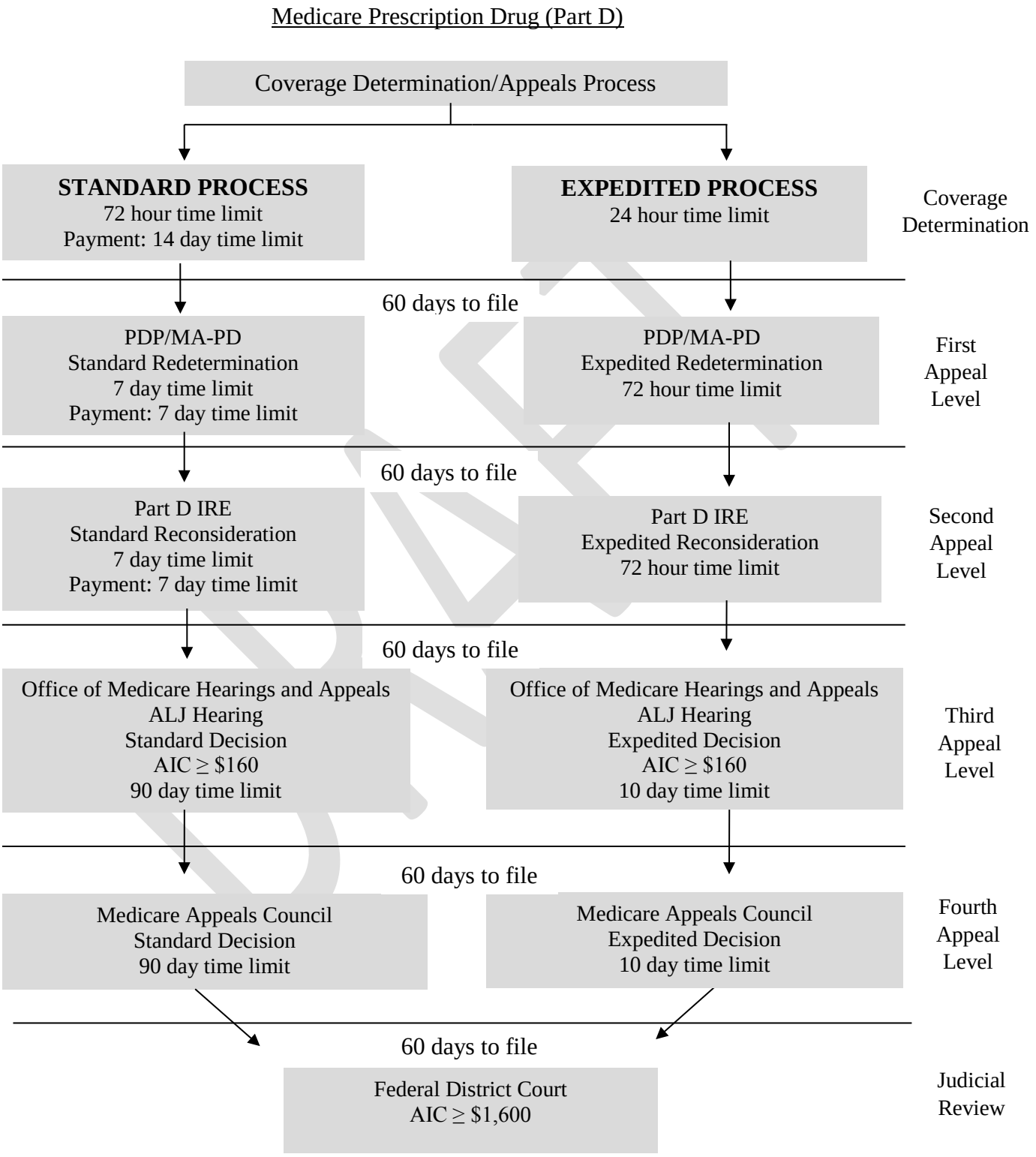
The MA plan should not send out a subset or partial list of the data, even if only a subset of the data is requested. For example, if an enrollee requests data on the number of appeals received by the MA plan, then the MA plan must send the enrollee a complete report of both its appeal and grievance data for the reporting period.
The OMB-approved form and instructions used to report this information to the enrollee is the Appeal and Grievance Data Form, Form CMS-R-0282.

Appendices

Appendix 1 – Medicare Managed Care (Part C) Appeals Process Overview



Appendix 2 – Medicare Prescription Drug (Part D) Appeals Process Overview



Appendix 3 – Resources

Part C Regulations at 42 CFR Part 422 Subpart M:

https://www.ecfr.gov/cgi-bin/text-idx?SID=1f450ef3db8f90e7c0f2c0fba827e8f3&node=sp42.3.422.m&rgn=div6

Part D Regulations at 42 CFR Part 423 Subparts M and U:

https://www.ecfr.gov/cgi-bin/text-idx?SID=1de979b56f209e3d7eb12fabeae2b1aa&mc=true&node=pt42.3.423&rgn=div5#sp42.3.423.m

Medicare Managed Care Appeals and Grievances Notices and Forms:

https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Notices-and-Forms.html

Medicare Prescription Drug Appeals and Grievances Notices and Forms:

https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/PlanNoticesAndDocuments.html

https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.html

Part C Appeals Mailbox: Part_C_Appeals@cms.hhs.gov

Part D Appeals Mailbox: PartD_Appeals@cms.hhs.gov