DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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MEDICARE ENROLLMENT & APPEALS GROUP

DATE: August 03, 2022

TO: All Medicare Advantage Organizations, Prescription Drug Plans, Cost Plans, Medicare-Medicaid Plans (MMPs), and PACE Organizations

FROM: Jerry Mulcahy
Director, Medicare Enrollment and Appeals Group

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

This memo announces the Centers for Medicare and Medicaid Services'(CMS) recent publishing of updates to the Parts C & D Enrollee Grievance, Organization/Coverage Determination, and Appeals Guidance. The updates incorporate the new Dismissal regulations, other revised provisions of CMS-4190, and clarifications of existing language. The updated guidance will be effective immediately**.** The guidance is included below with substantive updates in red, italicized font. The full guidance and can be found at:

https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

Questions regarding these updates or content related to the Parts C & D Enrollee Grievance, Organization/Coverage Determination, and Appeals Guidance may be submitted to https://appeals.lmi.org.

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

10.4.4 – Plan Communication to an Enrollee

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Additionally, plans should ensure enrollees with limited English proficiency are able to communicate with plans regarding initial determinations, appeals, and grievances. Enrollees with limited English proficiency should have the same level of access to plan representatives and information regarding initial determinations, appeals, and grievances as enrollees who are proficient in English. Plans may view the CMS Office of Minority Health website for strategies on how to ensure plan services to enrollees are culturally and linguistically equitable. For example, plans may incorporate the Building an Organizational Response to Health Disparities Resource Guide into plan operations. Plans may also incorporate the Office of Minority Health's Disparity Impact Statement into their operations to reduce health disparities among enrollees.

10.5.3 – When Notification is Considered Delivered by the Plan

Unless otherwise specified *(e.g., Section 40.8 of this guidance)*, written notification is considered delivered on the date (and time, if applicable) the *notice has left the possession of the* plan or delegated entity. *Generally, this occurs when the notice* has *been* deposited *into* the courier drop box or external outgoing mail receptacle (e.g., U.S. Postal Service or FedEx bin) *or for electronic delivery of required materials, the date the plan sends the materials to the enrollee (see Section 100.2.2 of the Medicare Marketing Guidelines for requirements on delivering electronic materials to enrollees). Placement into the plan or delegated entity's internal outgoing mail receptacle is not considered delivered. For* electronic payments (i.e., EFTs), *delivery occurs on* the date *(and time, if applicable)* the plan distributes the funds for payment.

Verbal notification is considered delivered on the date (and time, if applicable) a plan speaks directly to or leaves a voicemail for an enrollee or enrollee's representative. Plans may initially provide verbal notification to enrollees prior to issuing written notification.

In circumstances when verbal notification is permitted per regulatory requirements and the plan successfully provides verbal notice (e.g., spoke with the person that submitted the request or was able to leave a voicemail message)*, the required* written notification *must be sent by* the plan within 3 calendar days of the verbal notice. If the plan is not able to successfully provide verbal notice (i.e., 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 no voicemail system) answers), written notice must be sent within the applicable timeframe. Information regarding verbal notification for expedited requests can be found at §40.8 for initial determinations and §50.2.2 for level 1 appeals.

The regulations applicable to adjudication timeframes for standard Part C plan reconsiderations at 42 CFR § 422.590(a) and (c) and standard Part D redeterminations at 42 CFR § 423.590(a) do not address verbal notification. However, the plan may choose to initially provide verbal notification of the decision, but the required written notification must be issued within the

applicable adjudication timeframe. For Part C reconsiderations, the plan must issue the determination as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration.

For Part D redeterminations, the plan must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

20.2.1 – Missing or Defective Representative Form

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Dismissal of coverage and appeal requests: *The request is dismissed because the person or entity making the request is not permitted to request a coverage decision or appeal or is not a proper party. The plan must mail or otherwise transmit a written dismissal notice to the enrollee (or other proper party) and should also send the notice to the person asserting representative status. The dismissal notice must state all of the following: (1) the reason for the dismissal; (2) the right to request that the plan vacate the dismissal action; and (3) the right to request review of the dismissal. The notice should also explain how the invalid request can be cured and that the request will be processed if the enrollee or representative submits a properly executed form. See 42 CFR §§ 422.568(g) and (h), 422.582(f) and (g), 423.568(i) and (j), 423.582(e) and (f).*

See §50.9 for additional information regarding reconsideration dismissal procedures.

40.3 – Part D At-Risk Determinations

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 enrollee for prescription drug abuse;
- A limitation, or the continuation of a limitation, on access to coverage for frequently abused drugs (i.e., an enrollee 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. *Also, if on redetermination the plan sponsor affirms, in whole or in part, its decision related to an at-risk determination, the Part D plan sponsor must forward the case to the IRE contracted with CMS within 24 hours. See § 423.590(i).* For additional information and requirements on the drug management programs that a plan sponsor may utilize, see the *Improving Drug Utilization Review Controls page on the Part D website*.

40.14 – Withdrawal of an Initial Determination Request

A request for an initial determination may be withdrawn at any time before the decision is issued. This request must come from the party who requested the initial determination. If a

request to withdraw is filed with the plan, the plan will dismiss the initial determination request. The request to withdraw may be either written or verbal. See guidance related to dismissals at § 40.15.

40.15 – Dismissal of an Initial Determination Request

Plans must dismiss requests for an initial determination under any of the following circumstances:

- *The individual or entity making the request is not permitted to request an initial determination under the applicable regulation.*
- *The plan determines that the individual or entity making the request failed to make a valid request for an initial determination that substantially complies with 42 CFR §§ 422.568(a) or 423.568(a). In addition, under Part D, an enrollee may not request a tiering exception for an approved non-formulary prescription drug. See: 42 CFR § 423.578(c)(4)(iii). In this circumstance, a plan would dismiss the request and issue a dismissal notice in accordance with the notice requirements at § 40.15.1.*
- *The enrollee dies while the request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the initial determination. Financial interest means having financial liability for the item(s) or service(s) underlying the coverage request.*
- *The individual or entity who requested the review submits a timely verbal or written request for withdrawal of their request for an initial determination with the plan.*

When the plan's dismissal is due to a timely withdrawal request, the plan is required to dismiss the initial determination request and issue a dismissal notice in accordance with the notice requirements at section 40.15.1 in order to preserve the rights of other proper parties to the decision who may wish to request review of the dismissal.

The guidance in 40.15 does not alter reporting requirements. Withdrawn requests and dismissals should continue to be reported separately in their distinct categories, per existing reporting requirements.

40.15.1 – Dismissal Notice

If a plan dismisses an initial determination request, the plan must mail or otherwise transmit a written notice of the dismissal to the parties at their last known address by the conclusion of the applicable adjudication timeframe.

The dismissal notice must state all of the following:

(1) The reason for the dismissal;

(2) The right to request that the plan vacate the dismissal action; and

(3) The right to request review of the dismissal.

Consistent with the timeframe for requesting a timely appeal of an initial determination, a request for review of a dismissal must be filed within 60 calendar days from the date of the plan's dismissal notice.

Plans may use, and modify as necessary, the model Coverage Dismissal Notice when notifying an enrollee of a dismissal.

40.15.2 – Dismissal Binding Unless Modified, Reversed or Vacated

A plan's dismissal of an initial determination request is binding unless it is modified or reversed by the plan upon appeal or the dismissal is vacated for good cause. Upon receipt of a request to review a dismissal, the plan will conduct an appeal in accordance with §50 of this guidance, including the applicable adjudication timeframes for redeterminations and reconsiderations.

Requests for Review of a Dismissal of an Initial Determination Request

If a party appeals a plan's dismissal of an initial determination request and the plan determines that its dismissal was in error, the plan reverses the dismissal and processes the request for coverage in accordance with applicable adjudication timeframes and notice requirements. See: Section 40.10. The timeframe for the initial determination begins on the date/time of the plan's decision to reverse its dismissal.

If a party appeals a plan's dismissal of an initial determination request and the plan upholds its dismissal, there is no further right to appeal the dismissal to a higher-level adjudicator. However, in addition to the right to appeal a dismissal, an enrollee has the right to request that the plan vacate the dismissal action.

Requests to Vacate Dismissal of an Initial Determination Request

A plan may vacate its own dismissal if good cause is established within 6 months of the date of the notice of the dismissal. A plan may find good cause to vacate a dismissal if, for example, the plan determines the dismissal was issued in error because the documentation in the administrative case file shows the reason for dismissing the request was incorrect. For examples of where good cause may exist, please see § 50.3. If a party submits a request to vacate a dismissal of an initial determination request and the request contains sufficient evidence or other documentation that supports a finding of good cause for vacating, the plan makes a favorable good cause determination. Once the plan makes a favorable good cause determination, it vacates its prior dismissal action and performs an initial determination consistent with the timeframes at § 40.10. Where a finding for good cause is made, the plan should document the reason for that finding in the case file.

If the plan does not find good cause to vacate the dismissal, the dismissal remains in effect. The plan issues a letter (not a dismissal notice) explaining that good cause has not been established and the dismissal cannot be vacated. The plan should explain in clear language why the information submitted with the request to vacate the dismissal does not establish good cause to vacate the dismissal action.

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 and non-contract provider* 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.

A non-contracted provider who has furnished a service to an enrollee can be a party to an organization determination, in accordance with 42 C.F.R. § 422.574(b). Thus, pursuant to 42 C.F.R. § 422.578, a non-contracted provider may request that an organization determination be reconsidered by the plan. Even reconsideration requests submitted by non-contracted providers that relate to the type or level of service furnished to the enrollee must be reviewed in accordance with the administrative appeal processes outlined in 42 C.F.R. Part 422, Subpart M.

In the following examples a non-contracted provider who is the enrollee's assignee must be afforded full administrative appeals rights in accordance with 42 C.F.R. Part 422 Subpart M:

• Diagnosis code/DRG payment denials. A non-contracted provider submits a claim to a plan. The plan initially approves the claim, which is considered a favorable organization determination (see 42 C.F.R. 422.566(b)). The plan later reopens and revises the favorable organization determination and denies the DRG code on the basis that a different DRG code should have been submitted and recoups funds.

• Downcoding. A plan approves coverage for inpatient services from a non-contracted provider, which is considered a favorable organization determination (see 42 C.F.R. 422.566(b)). The plan later reopens and revises the favorable organization determination (e.g., retrospective review) and determines the enrollee should have received outpatient services.

• Bundling issues and disputed rate of payment. Pre- and post-pay bundling and global payment determinations. For example, denial of procedure codes -- as mutually exclusive to another paid procedure code, or due to inclusion in a previously paid global surgical package.

• Level of care or rate of payment denials. Payment of a reduced fee schedule amount for a

course of treatment. For example, a provider bills a procedure code for a visit but the plan reimburses based on a lower level of care.

Further, even if the plan partially pays for coverage (i.e., denies coverage as requested but approves or pays for part of the service), a non-contracted provider who according to 42 C.F.R. §422.574(b) is a party to the organization determination may request reconsideration under the Medicare administrative appeals process; a non-contracted provider does not need to receive zero payment to request a reconsideration or to otherwise access the Subpart M appeals process.

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.

50.2.2 – How to Process Requests for Expedited Level 1 Appeals

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Parts C & D

Change of Review Priority

After a request is initiated as a standard or expedited review, a provider may contact the plan to change the review priority (standard or expedited).

If the provider indicates that the enrollee's health requires an expedited decision, the plan must begin the applicable expedited review period at the time they receive the physician's request to expedite the decision.

***Note:** A change of priority does not allow for extra review time. If the remaining standard review period is less than the applicable expedited review period, the original standard deadline still applies.*

50.3 – Good Cause Exception for Late Filing

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If the plan denies a party's request for a good cause extension for late filing, the request for reconsideration is dismissed. See § 50.9 for information on dismissal procedures.

50.4 – Withdrawal of a Level 1 Appeal Request

A pending level 1 appeal may be withdrawn at any time before the decision is issued by filing a request with the plan. The request to withdraw must be filed by the [arty who requested the level 1 appeal. If a request to withdraw is filed with the plan, the plan will dismiss the level 1 appeal request. The request to withdraw may be written or verbal. 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 appeal. A notice of dismissal must be issued to all parties to the appeal and include:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

Part C Only: If the withdrawal request from the party that requested a reconsideration is received after the plan has forwarded the case file to the IRE, the plan must forward the withdrawal request to the IRE for processing.

See the content related to dismissal of a level 1 appeal at section 50.9.

50.8 – Service or Benefit Received Prior to Notice of Decision

Part C Only

If an enrollee requests a pre-service reconsideration but the MA plan becomes aware that the enrollee has *received* the *requested item/*service/*Part B drug* before the MA plan completes its reconsideration, the MA *plan must process the request as a request for payment or dismiss the request if it is unable to obtain the information necessary to process a payment request. The plan must process the reconsideration as a request for payment if the plan is able to obtain the necessary information (e.g., receipt from enrollee; provider claim). If the MA plan denies payment, it must send the case to the IRE for reconsideration. If the plan can't process the reconsideration as a payment request, the request should be dismissed with an explanation of what is needed by the plan to process a request for payment.*

If the case is sent to the IRE and the IRE becomes aware that the enrollee has received the requested item/service/Part B drug, the IRE must process the reconsideration as a request for payment if it is able to obtain the necessary information (e.g., receipt; claim); otherwise, the IRE should dismiss the request with an explanation of what is needed to process a request for payment.

Part D Only

If an enrollee requests a pre-benefit redetermination and the Part D plan sponsor becomes aware that the enrollee has received the prescription drug before it completes its redetermination, the plan sponsor must *process the request as a request for payment or dismiss the request if it is unable to obtain the information necessary to process a payment request. The plan sponsor must process the redetermination as a request for payment if the plan sponsor is able to obtain the necessary information (e.g., receipt from enrollee). If the plan sponsor can't process the redetermination as a payment request, the request should be dismissed with an explanation of what is needed by the plan sponsor to process a request for direct member reimbursement.*

If the plan sponsor upholds its denial and the enrollee appeals to the IRE and, during the processing of the appeal, the IRE becomes aware that the enrollee has received the requested drug, the IRE must process the reconsideration as a request for payment if it is able to obtain the necessary information (e.g., receipt from enrollee); otherwise, the IRE should dismiss the request with an explanation of what is needed to process a request for payment.

50.9 – Dismissal of a Level 1 Appeal Request

Plans must dismiss appeal requests under any of the following circumstances:

- *The individual or entity making the request is not a proper party to the appeal under the applicable regulation. This includes the following situations: If 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), the MA plan is obligated to make attempts to secure the missing documentation (see §20.2.1).*
- *If a non-contracted provider requests a reconsideration of a denied claim (i.e., post-service appeal) but fails to provide a waiver of liability statement indicating that it will not bill the enrollee regardless of the outcome of the appeal, the MA plan should make attempts to secure the missing documentation prior to dismissing the request. Please note: a pre-service reconsideration request by a physician who is providing treatment to an enrollee, upon providing notice to the enrollee, is considered a valid request.*

- *When the plan determines the party failed to make a valid request for an appeal that substantially complies with the applicable regulation for making a valid request for a level 1 appeal.*
  - *For example, when the party fails to file the level 1 appeal within the proper filing timeframe in accordance with the applicable regulation.*
- *When the enrollee dies while the appeal is pending and the enrollee's spouse or estate has no*

remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the level 1 appeal. Financial interest means having financial liability for the item(s) or service(s) underlying the coverage request.

- *When the individual or entity that requested the reconsideration submits a timely written request to withdraw their request for a level 1 appeal.*

When the dismissal is the result of a timely withdrawal request, the plan is required to mail or otherwise transmit a dismissal notice in accordance with the notice requirements in section 50.9.1 in order to preserve the rights of other proper parties to the decision who may wish to request review of the dismissal. The dismissal notice will explain that the withdrawal request is the reason for dismissal. For reporting purposes, this scenario is categorized as a withdrawal in reporting to CMS.

50.9.1 – Dismissal Notice

If a plan dismisses a level 1 appeal request, the plan must mail or otherwise transmit a written notice of the dismissal to the parties at their last known address by the conclusion of the applicable adjudication timeframe.

The dismissal notice must state all of the following:

(1) The reason for the dismissal;

(2) The right to request that the plan vacate the dismissal action; and

(3) The right to request IRE review of the dismissal.

Consistent with the timeframe for requesting a timely appeal, a request for review of a dismissal must be filed with the IRE within 60 calendar days from the date of the plan's dismissal notice.

Plans may use, and modify as necessary, the model Notice of Dismissal of Appeal Request when notifying an enrollee of a dismissal.

Part C only

The rule requiring that a Part C case be automatically sent to the IRE if the plan upholds a denial on the merits of the request does not apply in the case of a dismissal of a request for a level 1 appeal (reconsideration) because the MA organization is not making a substantive decision on the merits of the request. If the plan dismisses a level 1 appeal request, the enrollee or other party has the right to request IRE review of the plan's dismissal; Part C plans must forward the case file for a dismissal to the IRE when a proper party to the appeal requests IRE review of the dismissal under § 422.590(i). The enrollee also has the right to request that the plan vacate the dismissal.

50.9.2 – Dismissal Binding Unless Modified, Reversed or Vacated

The plan's decision regarding its dismissal of a level 1 appeal request is binding unless the enrollee or other party requests review by the Independent Review Entity or the dismissal action

is vacated by the plan. A plan may vacate its own dismissal within 6 months of the date of the dismissal if good cause is established.

Upon receipt of a request to review a plan's dismissal of a level 1 appeal request, the IRE will contact the appropriate plan to obtain the case file. Plans must assemble and forward the case file to the IRE (place in the mail or otherwise transmit the case file). The case file should be forwarded within 24 hours of receiving the IRE's case file request. The plan should refer to the IRE website or the IRE Reconsideration Process Manual for information on case file content, organization, and the most appropriate method of transmitting the case file.

If the IRE determines that the plan's dismissal of the level 1 appeal request was in error, the IRE vacates the dismissal and remands the case to the plan for reconsideration or redetermination (level 1 appeal). The level 1 appeal must be conducted by the plan consistent with applicable adjudication timeframes in § 50.7.1. The adjudication timeframe begins when the plan receives the IRE's remand order vacating the plan's dismissal. The IRE's decision regarding a plan's dismissal of a level 1 appeal request is binding and not subject to further review.

Requests to Vacate Dismissal of a Level 1 Appeal Request

A plan may vacate its own dismissal if good cause is established within 6 months of the date of the notice of the dismissal. A plan may find good cause to vacate a dismissal if, for example, the plan determines the dismissal was issued in error because there was good cause for late filing of an appeal request. If a party submits a request to vacate a dismissal of a level 1 appeal request and the request contains sufficient evidence or other documentation that supports a finding of good cause for vacating, the plan makes a favorable good cause determination. Once the plan makes a favorable good cause determination, it vacates its prior dismissal action, and performs a redetermination or reconsideration consistent with section 50.7, including applicable adjudication timeframes. For example, if a Part C plan dismisses a standard pre-service reconsideration request for an item or service and the plan later finds good cause to vacate the dismissal action, the plan must notify the enrollee (or other party) of the level 1 appeal decision within 30 calendar days (assuming no extension is taken) of vacating the dismissal. Where a finding for good cause is made, the plan should document the reason for that finding in the case file.

If the plan does not find good cause to vacate the dismissal (and the dismissal has not been appealed or overturned on appeal), the dismissal remains in effect. The plan issues a letter (not a dismissal notice) explaining that good cause has not been established and the dismissal cannot be vacated. The plan should explain in clear language why the information submitted with the request to vacate the dismissal does not establish good cause to vacate the dismissal action.

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	✓	✓

What To Include In A Case File When Forwarding to the IRE	Part C	Part D
Reconsideration Background Data Form (not required if submitting via IRE web portal)	✓	N/A
Case Narrative	✓	✓
Copy of the Initial Determination Request and Notice	✓	✓
Copy of the Level 1 Appeal Request and Notice	✓	✓
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	✓	✓
If file is not submitted via IRE web portal *for Part C or for Part D,* a complete copy of the relevant Evidence of Coverage on a *universal digital storage device (e.g. USB flash drive)*	✓	✓
The name and credentials 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 *universal digital storage device* if not submitted via IRE web portal), 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	✓
Dismissal Case File Data Form	✓	N/A

Plans may submit case files using the IRE web portal *for Part C or for Part D*. Plans should refer to the most current version of the Part C Reconsideration *Process* Manual or the Part D Reconsideration *Procedures* 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 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 submit case files with the EOC and and/or formulary using the IRE web portal *for Part C or for Part D*. Plans may not mail or fax paper copies of the complete EOC and/or formulary to the IRE.

If plans do not submit via the web portal, they should send information on a *universal digital storage device (e.g. USB flash drive)*. Include the *device* with the case file in the following manner:

- The *universal digital storage device* must be properly labeled with the plan name and contract number, formulary ID (Part D), enrollee name/HICN/MBI, and appeal number;
- The *universal digital storage device* must be securely affixed to the paper case file;
- All documents on the *universal digital storage device* must be in PDF or Word format and should not be encrypted; and
- The *universal digital storage device* 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 *universal digital storage device*).

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).
- *All partially favorable or adverse at-risk redetermination decisions are automatically forwarded by the plan to the IRE within 24 hours. A party does not have to make a request for a level 2 appeal related to an at-risk determination.*

60.6 – Dismissal of a Level 2 Appeal

The IRE must dismiss a level 2 appeal under any of the following circumstances:

- *The individual or entity making the request is not a proper party to the appeal under the applicable regulation*
- *When the IRE determines the party failed to make a valid request for an appeal that substantially complies with the applicable regulation for making a valid request.*
- ***Part D only**: When the party fails to file the appeal within the proper filing timeframe in accordance with the applicable regulation and there is no good cause for the late filing.*
- *When the enrollee dies while the appeal is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the reconsideration or redetermination. Financial interest means having financial liability for the item(s) or service(s) underlying the coverage request.*
- *When the party that requested the appeal submits a timely request for withdrawal of the request for reconsideration.*

60.6.1 – Dismissal Notice

If the IRE dismisses a level 2 appeal, the IRE must mail or otherwise transmit a written notice of the dismissal to the parties at their last known address by the conclusion of the applicable adjudication timeframe.

The dismissal notice must state all of the following:

(1) The reason for the dismissal;

(2) The right to request that the IRE vacate the dismissal action; and

(3) The right to request ALJ review of the IRE's dismissal.

Consistent with the timeframe for requesting a timely appeal, a request for review of a dismissal by the IRE must be filed with the ALJ within 60 calendar days from the date of the IRE's dismissal notice.

When a dismissal is prompted by a timely withdrawal request, the IRE is required to mail or otherwise transmit a dismissal notice in accordance with the notice requirements in order to preserve the rights of other proper parties to the decision who may wish to request ALJ review of the dismissal

60.6.2 – Dismissal Binding Unless Modified, Reversed or Vacated

The IRE's decision regarding its dismissal of a level 2 appeal is binding unless the enrollee or other party requests review by the ALJ or the decision is vacated by the IRE. In addition to the right to request ALJ review of an IRE dismissal, an enrollee (or other party) has the right to

request that the IRE vacate the dismissal action. The IRE may vacate its own dismissal within 6 months of the date of the dismissal if good cause is established.

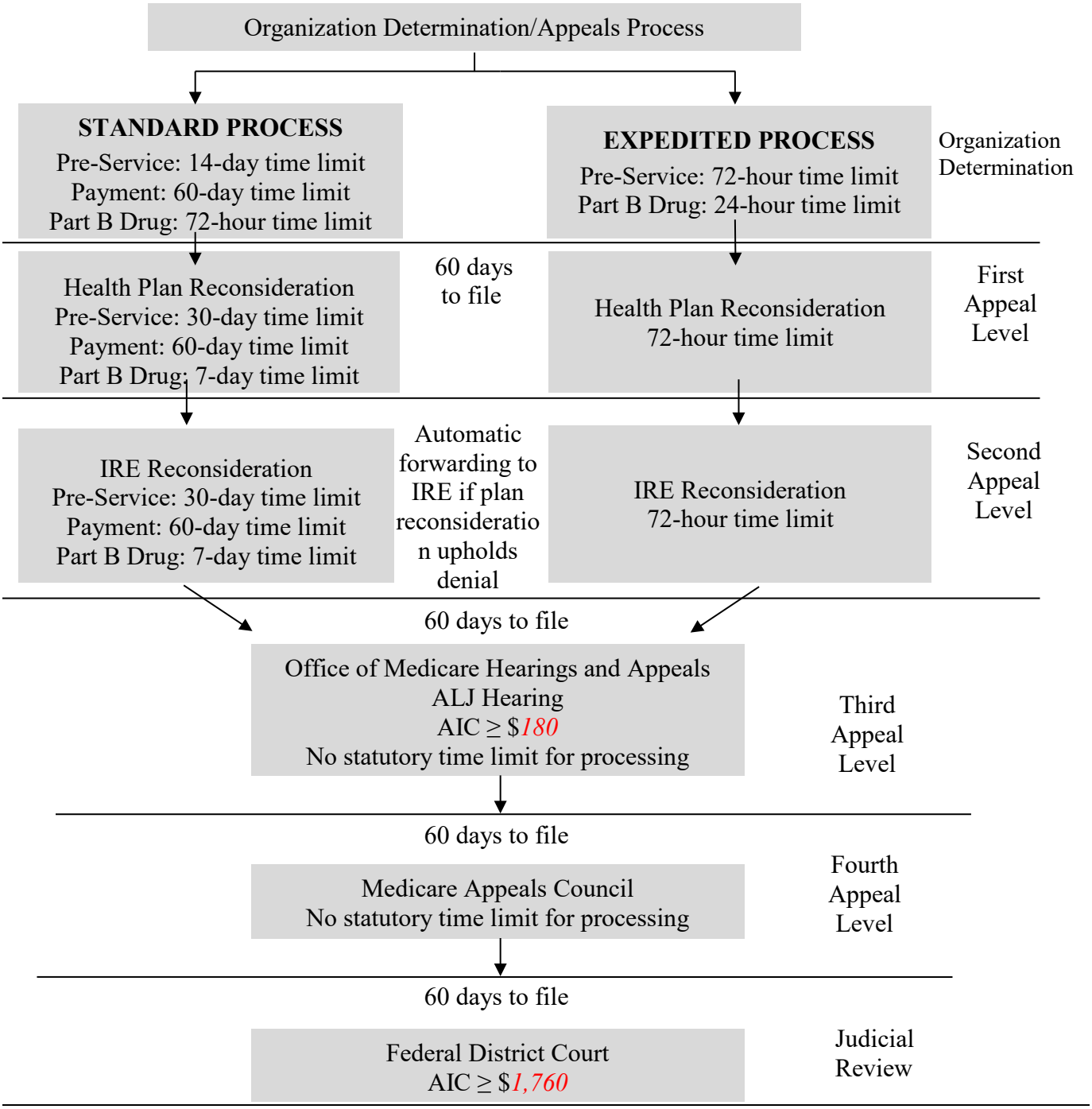
70.2 – Amount in Controversy

In general, the amount in controversy (AIC) is computed as the actual amount charged (or amount enrollee would have been charged) minus applicable deductible, coinsurance or copayments. 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, reduced by any cost sharing amounts including deductible, coinsurance or copayments that may be collected from the enrollee. 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. Per § 422.600(b), in applying the provisions at § 405.1006(d) to the calculation of the AIC in Part C cases, the reference to coinsurance should be read to include coinsurance and copayment amounts. For Parts C and D, appeals may be aggregated to meet the AIC. See §423.1970(c); [§405.1006(e) and (f)].

Appendices

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

Medicare Managed Care (Part C - Medicare Advantage)



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

Medicare Prescription Drug (Part D)