1.0 Policy Statement

In accordance with applicable internal standards, external regulations and accreditation standards, Kaiser Foundation Health Plan, Inc. (KFHP) has established procedures for processing complaints from a Medicare member under the appropriate grievance and/or appeals process.

2.0 Purpose

This policy describes the minimum requirements needed to meet compliance for processing Medicare Part D grievances, coverage determinations, and Health Plan redeterminations, set forth by the Centers for Medicare and Medicaid Services (CMS), Code of Federal Regulations (CFR), and the National Committee for Quality Assurance (NCQA).

3.0 Scope/Coverage

This policy applies to all employees that process, manage, or direct Medicare member grievance and appeals in the following regions:

3.1 Southern California
3.2 Northern California
3.3 Hawaii
3.4 Georgia
3.5 Mid-Atlantic States
3.6 Northwest
3.7 Colorado
3.8 Washington

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5.0 General Provisions

5.1 Alternative Formats - Program representatives shall ensure all individuals have access to and can fully participate in the grievance system by providing assistance for those with a visual or other communicative impairment. Such assistance shall include, but is not limited to, telephone relay systems and other devices that aid disabled individuals to communicate. The Program representative shall ensure the alternative format offered to individuals results in effective communication. Alternative formats include large print, electronic documents, audio CDs, and Braille.

5.2 Arbitration – Any Medicare member’s claim that is not subject to the Medicare Appeals process or the Small Claims process, which is made against KFHP, Kaiser Foundation Hospitals, the Permanente Medical Groups, or any of their physicians, employees, or agents is subject to mandatory binding neutral arbitration. Members or their authorized representative may have the right to request arbitration, the terms of which depend on the member’s type of coverage, effective date of coverage and “opt out” actions. Members may be referred to their Evidence of Coverage for the complete arbitration provision, which includes how to initiate the arbitration, where to submit their request and any associated fees.

5.3 Case File Release – Medicare members have the right to have reasonable access to and copies of documents relevant to their case(s), free of charge, upon request.

5.4 Civil Rights Complaints (Section 1557, Patient Protection and Affordable Care Act) – Kaiser Permanente complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. The grievance procedures described in this policy provide a prompt and equitable review of complaints alleging any action prohibited by Section 1557 of the Patient Protection and Affordable Care Act. Kaiser Permanente has a designated Civil Rights Coordinator to coordinate compliance with Section 1557 of the Patient Protection and Affordable Care Act. Member Services Appeals and Grievances and the Civil Rights coordinator will jointly address any allegations of civil rights discrimination.

5.5 Confidentiality - KFHP protects the confidentiality of member information and records. KFHP uses and discloses member protected health information (PHI) according to our Notices of Privacy Practices and the Federal HIPAA (Health Information Portability and Accountability Act of 1996) Privacy and Security policies. Program representatives must obtain HIPAA authorization from an individual when his/her written permission is required to use or disclose PHI in
accordance with these policies and confidentiality regulations. Program representatives will not respond to anyone other than the member or the member’s duly authorized representative regarding matters related to a member’s health care or condition until appropriate authorization has been received. Except under limited circumstances, Program representatives may only use, disclose, and request the minimum necessary PHI to accomplish the intended purpose. Program representatives shall verify the identity of individuals prior to releasing information.

5.6 Conflicts of Interest - KFHP ensures that all grievances and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a Claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support a denial of benefits. Similarly, KFHP will not contract with a medical expert based on the expert’s reputation for outcomes in contested cases, rather than based on the expert’s professional qualifications.

5.7 Documentation – Program representatives shall ensure all encounters with Medicare members (e.g. grievances, appeals, etc.) are appropriately documented in the Member Experience Tracking and Reporting System (METRS). Documentation should include the member’s reason for filing their request, and any additional information, clinical and non-clinical, provided with the request. Specifically, for intake of an appeal, the Program representative should document the member’s reason for appealing the previous decision; confirmation that the member received a denial for the service or item; and all information presented with the member’s appeal request that might include any actions taken since the initial denial. The initial appeal denial letter must be attached in METRS.

5.8 File Retention – KFHP will retain case files on all cases filed, including relevant materials reviewed to reach a decision, for a period of ten (10) years.

5.9 Language Assistance – Program representatives shall ensure Medicare members are provided access to interpreter and translation services at no cost.

5.10 Visiting Member Program: KFHP has a visiting member program that allows members to receive care from other regions. The KFHP region that is considered the member’s “home region” will be responsible for processing grievances regarding their (visited) region. Pre-service requests, including appeals, are managed by the home region.

6.0 Provisions of Case Processing

6.1 Intake

6.1.1 Acceptance and Facilitation of a Case: Members may file an expedited or standard grievance, coverage determination, expedited coverage determination, or expedited Health Plan redeterminations either verbally,
by email, on-line through the Health Plan's web site, in person, or in writing to Kaiser Permanente. A standard Health Plan redetermination must be submitted in writing, which can include email or on-line through the Health Plan's web site (except for Georgia region).

6.1.1 Program representatives are responsible for ensuring members are afforded the right to provide additional information, which includes all written materials to support their grievance, coverage determination or Health Plan redetermination.

6.1.2 Filing Timeframes and Methods: Grievances, coverage determinations, and Health Plan redeterminations must be filed with the Health Plan within the CMS established timeframes, and must follow the required method for filing.

6.1.2.1 Grievances must be filed verbally or in writing within 60 calendar days of the event or incident.

6.1.2.2 Standard or Expedited coverage determinations may be filed verbally or in writing, at any time.

6.1.2.3 Standard Health Plan redeterminations must be filed in writing within 60 calendar days from the date of the adverse determination notice. For GA region, both verbal and written will be accepted.

6.1.2.4 Expedited Health Plan redeterminations must be filed verbally or in writing within 60 calendar days from the date of the adverse determination notice.

6.1.2.5 Good Cause: An extension may be granted if the member or authorized representative provides a good cause reason for not making the request on time, except in the case of repeat grievances.

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

6.1.2.5.1.1 The member was seriously ill, which prevented timely filing;

6.1.2.5.1.2 There was a death or serious illness in the member's immediate family;

6.1.2.5.1.3 An accident caused important records to be destroyed;

6.1.2.5.1.4 Documentation was difficult to locate within the time limits;
6.1.2.5.1.5 The member had incorrect or incomplete information concerning the grievance or appeal process;
6.1.2.5.1.6 The member lacked capacity to understand the filing time frame; or
6.1.2.5.1.7 The member did not personally receive the adverse coverage determination notice, or he/she received it late.

6.1.2.5.2 Requests for a good cause extension on grievances can be filed verbally or in writing.

6.1.2.5.3 Request for a good cause extension on Health Plan redeterminations must be filed in writing.

6.1.2.5.4 If good cause is not provided or the Health Plan denies a good cause extension, the grievance or Health Plan redetermination will be dismissed.

6.1.2.5.4.1 The Program representative shall provide written notification of the dismissal to the member or authorized representative.

6.1.2.6 Quick Reference: Filing Timeframes and Methods

<table>
<thead>
<tr>
<th>Case Type</th>
<th>Timeframe and Method</th>
<th>Good Cause Request</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grievance - Expedited &amp; Standard</td>
<td>Grievance must be filed verbally or in writing within 60 calendar days of the event or incident.</td>
<td>Can be submitted verbally or in writing.</td>
</tr>
<tr>
<td>Coverage Determination - Expedited &amp; Standard</td>
<td>Request may be filed verbally or in writing at any time.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Health Plan Redetermination - Standard</td>
<td>Request must be filed in writing within 60 calendar days from the date of the adverse determination notice. For GA region, both verbal and written will be accepted.</td>
<td>Must be submitted in writing.</td>
</tr>
<tr>
<td>Health Plan Redetermination - Expedited</td>
<td>Request must be filed verbally or in writing within 60 calendar days from the date of the adverse determination notice.</td>
<td>Must be submitted in writing.</td>
</tr>
</tbody>
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6.1.3 Authorized Representation: All KFHP members have the right to be represented by an individual to act on their behalf, upon receipt of appropriate legal authorization and/or documentation of the representative. The Centers for Medicare and Medicaid Services (CMS) Form CMS-1696, or an equivalent written notice is required for making the appointment of representation. In addition, Federal law strictly controls the release of Protected Health Information (PHI); therefore, the
Authorization for Disclosure of Personal Health Information Form (PHI Form) is required for release of PHI.

6.1.3.1 A completed PHI form is valid only for the length of the case or subsequent grievance/appeals related to the case.

6.1.3.1.1 A new PHI form is required for any new, unrelated grievance or appeal submitted by an advocate to then release the member’s PHI to the authorized representative.

6.1.3.1.2 If the AOR has been completed, but the PHI form has not, the member’s case may proceed. However, if the PHI form is not received by the conclusion of the case time frame, the resolution is sent to the member.

6.1.3.2 A member’s treating physician, or other prescriber, may act on behalf of a member in requesting a standard or expedited coverage determination, a standard or expedited Health Plan redetermination or a standard or expedited IRE reconsideration without submitting a representative form.

6.1.3.2.1 The physician does not have all the rights and responsibilities of a member. However, the member’s prescribing physician or other prescriber is entitled to receive verbal notification of the Health Plan’s decision, with written notification to be sent to the member.

6.1.3.2.2 A non-representative physician or other prescriber may request a standard redetermination on a member’s behalf only after he or she has provided notice to the member that he or she is making the appeal request.

6.1.3.2.2.1 If the redetermination request comes from a member’s primary care physician the member notice verification (i.e., proof that the physician notified the member of the redetermination request) is not required.

6.1.3.2.2.2 If the member’s records indicate that he or she previously visited the requesting physician or other prescriber, the plan sponsor may assume the physician or other prescriber has informed the member about the request and further verification is not needed.

6.1.3.2.2.3 If the member’s records indicate that he or she has not previously visited the requesting
physician or other prescriber, the plan sponsor should undertake reasonable efforts to confirm that the physician or other prescriber has given the enrollee appropriate notice of the appeal.

6.1.3.3 Unless otherwise noted by the member, the completed authorized representative documentation is valid for one year from the date the appointment is signed by both the member and the representative.

6.1.3.4 A valid appointment of representative form submitted with a request that specifically limits the appointment to Part C Medicare Advantage is not valid for representation of Part D prescription drug benefits. CMS Form (CMS-1696) must be executed, or equivalent, if the appointee is representing the member in both Part C and D benefits.

6.1.3.5 The Program representative must make, and document reasonable efforts, to secure a valid appointment of representation form or equivalent.

6.1.3.6 It is not required for the Health Plan to undertake a review until valid forms are obtained, but it may choose to begin the review while continuing efforts to obtain a valid appointment of representation form.

6.1.3.7 The time frame for acting on a grievance or a request for a coverage determination or redetermination does not commence until the properly executed appointment form is received.

6.1.3.7.1 A fourteen (14) day AOR wait time extension will be applied to standard grievances that are pending authorized representative documentation, prior to dismissal.

6.1.3.7.1.1 A written notification of the extension is not required in this scenario.

6.1.3.8 If the completed documentation is not received by the conclusion of the case time frame, the case will be dismissed.

6.1.3.9 Members may file a grievance with the Health Plan if they are dissatisfied with a dismissal.

6.1.4 **Contact Dates and Times:** The contact date and time for Part D cases is when the case is received anywhere within the Health Plan. All expedited requests must have a documented record of the date and time received.
Program representatives must use the following guidelines for contact dates:

6.1.4.1 The date and time of the call for telephone calls;
6.1.4.2 The earliest KFHP date stamp for written correspondence;
6.1.4.3 The earliest incoming fax transmission date and time for faxes;
6.1.4.4 The date and time of the timestamp on e-mails.

6.1.4.4.1 If authorized representation documentation is required, the time frame for acting on a case commences when valid representative documentation is received.

6.1.4.4.2 If a standard or expedited coverage determination pre-service is tolled to obtain a physician supporting statement related to an exception request, the case processing time frame begins when the physician supporting statement is received.

6.1.4.4.2.1 If a physician supporting statement was not received during the initial determination review, and was not included in the appeal submission for an exception request, the case processing time frame for a standard or expedited Health Plan redetermination pre-service, begins when this statement is received.

6.1.5 **Expedited Requests:** Program representatives shall screen all requests immediately to identify if applying the standard processing timeframes for making a coverage determination or Health Plan redetermination decision, could seriously jeopardize the enrollee’s life, health, or ability to regain maximum function.

6.1.5.1 A member or authorized representative has the right to request an expedited review of a coverage determination or Health Plan redetermination.

6.1.5.2 An expedited review must be conducted if a physician indicates on behalf of the member (either orally or in writing), that applying the standard decision timeframe could have a serious adverse effect to the member’s wellbeing.

6.1.5.3 Requests that may meet the expedited review criteria should be referred to the designated unit that handles expedited requests or the designated clinical reviewer(s) to determine if it meets expedited review criteria.
6.1.5.4 A request for payment of a service already provided is not eligible for an expedited review, unless the request includes both a payment denial and pre-service denial.

6.1.6 Denial of Request for Expedited Review

6.1.6.1 A request that does not meet criteria for expedited review, will be downgraded and processed in accordance with the procedures for standard review. The case contact date remains the same as the date of receipt by the appropriate office or department that handles expedited requests.

6.1.6.1.1 A subsequent written request is not required when a verbal request for an expedited Health Plan redetermination is downgraded to standard review.

6.1.6.2 Provide verbal notification within 24 hours of the denial for coverage determinations and Health Plan redeterminations.

6.1.6.2.1 The Program representative shall inform the member or authorized representative of their right to file an expedited grievance, if they disagree with the Health Plan’s decision not to expedite the determination.

6.1.6.2.2 The Program representative shall inform the member or authorized representative that their request will be reviewed as expedited, if the request is resubmitted with a supporting statement from their physician.

6.1.6.3 The Program representative shall provide subsequent written notification within three (3) calendar days of the verbal resolution.

6.1.7 Repeat Grievances: Members, or their authorized representative, have the right to file a repeat grievance on an issue and/or request that was previously resolved, if filed within 60 calendar days from the incident of event that caused the dissatisfaction.

6.1.7.1 Repeat grievances are processed using the same process guidelines and timeframes as grievances, with the following exceptions:

6.1.7.1.1 Repeat grievances are not eligible for good cause extensions beyond the 60-calendar day filing deadline.

6.1.7.1.2 For cases with non-appealable requests, the same decision maker from the initial grievance can render a decision.
6.1.8 **Part D Late Enrollment Penalty (LEP) Determinations:** A late enrollment penalty (LEP) is imposed if there is a continuous period of 63 days or more at any time after the end of the individual’s Part D initial enrollment period during which the individual was eligible to enroll in a Part D plan, but was not enrolled in a Part D plan and was not covered under any creditable prescription drug coverage.

6.1.8.1 An individual or their representative may ask Medicare to review their late enrollment penalty decision by mailing a completed LEP Reconsideration Request Form to the IRE. Individuals also may write a letter requesting an LEP reconsideration, provided the letter contains the elements on the LEP Reconsideration Request Form.

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

6.1.8.1.2 The IRE will inform the enrollee and the Part D plan sponsor of the final decision.

6.1.8.1.3 The final LEP reconsideration decision is not subject to appeal (that is, is not subject to further review by an Administrative Law Judge (ALJ), Medicare Appeals Council (MAC), or in a district court of the U.S.).

6.1.8.2 KFHP Member Services Appeals and Grievances staff do not process LEP reconsiderations and will only handle grievances when the issue is related to an LEP.

6.2 **Categorization (Leveling)**

6.2.1 **Levels:** Program representatives shall categorize all Medicare member encounters using the following level classifications:

6.2.1.1 **Inquiry:** Any oral or written request to a Medicare health plan, provider or facility, without an expression of dissatisfaction, e.g., a request for information or action by an enrollee. Inquiries are routine questions about benefits (i.e., inquiries are not complaints).

6.2.1.2 **Grievance:** Any complaint or dispute, other than a coverage determination, or an LEP determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part
D plan sponsor, regardless of whether remedial action is requested. Grievances may include complaints regarding the timeliness, appropriateness, access to, and/or setting of a provided item.

6.2.1.3 **Expedited Grievance:** A complaint expressing dissatisfaction that a Medicare health plan refused to expedite a coverage determination or Health Plan redetermination.

6.2.1.3.1 Expedited grievance requests should be referred to the designated unit that handles expedited reviews for processing.

6.2.1.3.2 Requests that are submitted with a supporting physician statement will be reviewed as expedited.

6.2.1.3.3 **Deny Expedited Review:** An expedited grievance filed when the Plan refuses to expedite a request, will be re-reviewed by the designated clinical reviewer(s) to determine if it meets expedited review criteria. This review will only occur when the standard case processing timeframe has not expired. If the request is approved, it will be upgraded to the expedited review process.

6.2.1.3.4 Provide verbal resolution within 24 hours for expedited grievances.

6.2.1.3.5 Provide subsequent written notification within three (3) calendar days of the verbal resolution.

6.2.1.4 **Coverage Determination:** Any determination made by or on behalf of the Health Plan regarding payment or benefits to which an enrollee believes he or she is entitled.

6.2.1.5 **Health Plan Redetermination:** The first level of the appeal process, which involves the Health Plan reevaluating an adverse coverage determination, the findings upon which it was based, and any other evidence submitted or obtained.

6.2.1.5.1 For an appeal filed within the appropriate timeframe on an adverse coverage determination, where member is found to no longer have Health Plan benefits, the Plan must initiate and process the appeal based on Health Plan coverage at time of the initial determination.

6.2.1.6 **IRE Reconsideration:** A review by the independent review entity contracted by CMS to re-evaluate an adverse organization
determination by the Medicare health plan. The IRE is also referred to as the Part D Qualified Independent Contractor (QIC).

6.2.1.7 **ALJ Hearing**: A level of appeal available to Medicare members where an Administrative Law Judge (ALJ) re-evaluates the IRE reconsideration decision.

6.2.1.7.1 Requests received by the Health Plan for an ALJ hearing from a member must be forwarded immediately to the appropriate ALJ hearing office.

6.2.1.8 **Medicare Appeals Council**: A level of appeal available to Medicare members that are dissatisfied with the ALJ hearing decision may request that the MAC review the ALJ’s decision or dismissal. The MAC may initiate a review on its own motion or at the request of CMS or the IRE after an ALJ’s written hearing decision or dismissal is issued. The MAC conducts a de novo review and may either issue a final decision or dismissal, or remand the case to the ALJ with instructions on how to proceed with the case.

6.2.1.8.1 If the MAC grants a request for an expedited review (a decision which the MAC must make within 5 calendar days of the receipt of the request for expedited review), the MAC must generally issue a decision, dismissal order, or remand, as appropriate, as expeditiously as the enrollee’s health condition requires, but no later than 10 calendar days from the date the MAC receives the request for an expedited MAC review.

6.2.1.9 **Federal District Court**: A member may request judicial review of an ALJ’s decision if the MAC denied the member’s request for review or reversed the ALJ decision.

6.2.1.9.1 In certain situations, a member may request expedited access to judicial review (EAJR) in place of an ALJ hearing or MAC review. The member may make a request for EAJR only once with respect to a question of law or regulation for a specific matter in dispute in an appeal.

6.2.2 **Cases with Multiple Issues and Requests**: Cases with multiple issues or requests will have each issue or request processed independently and simultaneously in accordance with the procedural requirements applicable
to the specific issue or request, which may require creating multiple levels in METRS.

6.2.2.1 Appropriate case leveling of issues or requests will be determined by a combination of the membership type, primary date of occurrence, and/or the substance of the case.

6.2.2.2 Complaints may include both grievances and appeals (coverage determinations and Health Plan redeterminations). The grievance process and the appeals process are separate and distinct. A member complaint may contain a grievable issue and an appealable issue as well. KFHP determines whether the issues meet the definition of grievances, coverage determination or Health Plan redetermination, and resolve them within the appropriate process. If a member has two or more issues in one complaint, then each issue should be processed separately and simultaneously (to the extent possible) under the proper process.

6.2.3 **Dual Eligibility:** Members with dual coverage have additional rights that must be provided under a separate process based on that coverage (e.g., Medicaid, FEHBP). A separate case may be required when a member with dual membership files a complaint.

6.2.4 **Misclassified Cases**

6.2.4.1 Should a case be misclassified and the Health Plan later determines that the incorrect letter(s) were issued; the Program representative is responsible for notifying the member in writing that the issue was misclassified and will be handled through the appropriate process (e.g. level).

6.2.4.2 A resolution letter will be sent to the member under the correct case process.

6.2.4.3 The timeframe for processing the case through the correct process begins on the original date the case was received by the Health Plan, as opposed to the date the Health Plan discovers its error.

### 6.3 Acknowledgement

6.3.1 **Acknowledgement Timeframes:** All grievances and appeals will be acknowledged by the Program representative either verbally or in writing.

6.3.2 If all verbal acknowledgement requirements are not fulfilled during initial case intake, additional contact with the member must occur to properly acknowledge the request.

6.3.3 The Program representative should make, and document reasonable attempts, to provide verbal acknowledgement.
6.3.4 Verbal acknowledgement and documentation must include (at minimum):

6.3.4.1 Notification to the member that his/her request has been received;

6.3.4.2 Date request was received;

6.3.4.3 Whether the request is a grievance or appeal;

6.3.4.4 Clarification of the request;

6.3.4.5 A description of the process, including relevant timeframes, and;

6.3.4.6 Contact information the member can use for case status and questions.

6.3.5 Written acknowledgement will be provided by using the approved acknowledgement letter template.

6.3.6 Acknowledgement Timeframes:

6.3.6.1 Grievances will be acknowledged within five (5) calendar days, from date of contact.

6.3.6.2 Expedited grievances will be acknowledged within 24 hours, from date & time of contact.

6.3.6.3 Pre-service coverage determinations will be acknowledged within 24 hours, from the date & time of contact.

6.3.6.4 Post-service coverage determinations will be acknowledged within five (5) calendar days, from date of contact.

6.3.6.5 Health Plan redeterminations will be acknowledged within three (3) calendar days, from receipt of written appeal.

6.3.6.6 Expedited coverage determinations and Expedited Health Plan redeterminations will be verbally acknowledged within 24 hours, from the date & time the request is received by the appropriate office or department designated to review expedited requests.

6.3.7 Quick Reference: Acknowledgement Timeframes and Methods

<table>
<thead>
<tr>
<th>Level Type</th>
<th>Timeframes</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grievance - Standard</td>
<td>Within five (5) calendar days from the date of receipt by the Health Plan.</td>
<td>Verbal or Written</td>
</tr>
<tr>
<td>Expedited Grievance</td>
<td>Within 24 hours, from the time of receipt by the Health Plan.</td>
<td>Verbal</td>
</tr>
<tr>
<td>Coverage Determination</td>
<td>Within 24 hours, from the time of receipt by the Health Plan.</td>
<td>Verbal</td>
</tr>
<tr>
<td>Pre-Service</td>
<td></td>
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6.4 Coding

6.4.1 Capturing all Issues and Requests: The Program representative shall ensure all issues and requests raised by the member or authorized representative are properly coded in the system of record. Each issue and request will be accounted for under the appropriate level.

6.5 Investigation

6.5.1 Reviewing all Issues and Requests: The Program representative shall complete a thorough review of the case synopsis, including any additional information provided by the member or authorized representative, throughout the case, to ensure adequate investigation of all issues and requests. All investigatory actions shall be documented in METRS.

6.5.2 Potential Quality of Care Issues: Grievances that contain one or more potential quality of care issue will be referred to the Quality Department for investigation and review.

6.5.2.1 The Quality Department’s oversight process assures that there are effective quality assurance systems in place for the potential quality of care referral activities. These activities will be handled in a manner consistent with Federal and State laws and Organizational privacy and security policies and procedures governing the confidentiality of such information.

6.5.3 Outreach Requirements for Supporting Clinical Documentation:
Reasonable and diligent efforts should be made as to obtain relevant medical records from Plan or non-Plan providers, that will assist with the investigation and/or decision-making process, as early in the case review process as possible.

6.5.3.1 A minimum of 2 outreach attempts should be made and must be documented and should include:

6.5.3.1.1 A specific description of the required information;

6.5.3.1.2 The name, phone number, fax number, e-mail, and/or mailing address, as applicable, for the point of contact, and;
6.5.3.1.3 Call records should include specific information about who was contacted, what was discussed/requested, and what information was obtained.

6.5.3.2 If medical information is needed from non-contract providers to make a decision, the Program representative must request the necessary information from the non-contract provider within 24 hours of the initial request.

6.5.4 Medical Necessity Denials or Partial Denials: At least one physician, practicing in the same or similar specialty must review cases involving medical necessity.

6.5.4.1 The physician must not have been, or currently involved in member’s care and treatment.

6.5.5 Administrative Reviews: Non-clinical issues should be forwarded to the designated administrative staff for review, and input as needed.

6.5.6 The reviewer must not have been involved in the issue under review, or be a subordinate of the person who is the subject matter of the issue.

6.5.7 Investigation documentation should include, but is not limited to the following:

6.5.7.1 The name, title, and department of person(s) providing the information. Including specialty, if applicable;

6.5.7.2 The name of the KP system used to obtain information (e.g., KP Health Connect, Foundation System); and,

6.5.7.3 Clear and concise explanation of the substance of the question(s), issue(s), and/or request(s);

6.5.7.4 The date(s) of any/all actions taken;

6.5.7.5 All actions taken, including those affecting any aspect of clinical care involved (e.g., counseling, re-training, etc.) as appropriate;

6.5.7.6 Any/all required follow up instructions.

6.6 Decision/Committee Review

6.6.1 Case Review Preparation: Program representatives have overall responsibility for preparation and presentation of the request, to the applicable reviewers/decision-makers for a decision.

6.6.2 Reviews Involving Medical Necessity: Decision making for medical necessity request(s), require physician review for final determination. Review and response by a physician, or other appropriate health care
professional, with the same or similar specialty, should be included for this review.

6.6.2.1 Requests that involve benefit determinations, may be reviewed by non-physicians, designated by the Health Plan.

6.6.3 **Appeal Decision Makers:** Any person involved in the previous determination is not eligible to participate in the Health Plan redetermination (appeal) level of that request.

6.6.3.1 A person involved in a subsequent level of review will not be a subordinate of any person involved in the initial determination.

6.6.4 **Documentation of Decision/Committee Review:** Decision documentation must be completed within METRS.

6.6.4.1 Decision making documentation should include, but is not limited to the following:

- 6.6.4.1.1 The date, and time of decision for expedited requests;
- 6.6.4.1.2 Decision and rationale;
- 6.6.4.1.3 Names and titles of decision makers;
- 6.6.4.1.4 Physician titles, including specialty/qualifications.

### 6.7 Extensions

6.7.1 Extensions are allowed if the member or authorized representative requests it, or the Health Plan justifies the need for information, and documents how the delay is in the best interest of the member.

6.7.2 When the Health Plan extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.

6.7.3 A fourteen (14) day extension is allowed on the following level type:

6.7.3.1 Grievance – Standard

6.7.4 **Pending Authorized Representative Documentation:** A fourteen (14) day AOR wait time extension will be applied to standard grievances that are pending authorized representative documentation, prior to dismissal of the case.

6.7.5 No extension or additional time is allowed on the following level types:

- 6.7.5.1 Expedited Grievances,
- 6.7.5.2 Coverage Determinations (standard or expedited),
- 6.7.5.3 Health Plan Redeterminations (standard or expedited).

### 6.8 Exception Requests
6.8.1 Member’s may request an exception request for the following type of exceptions:

6.8.1.1 Tiering exception to obtain a non-preferred drug at the lowest cost-share applicable to drugs in a preferred tier.

6.8.1.2 Non-Formulary exception to obtain a drug that is not included on the plan’s formulary.

6.8.1.3 Formulary UM exception to obtain a formulary drug that is subject to the following restriction that the requestor believes should not apply:

- 6.8.1.3.1 Prior Authorization;
- 6.8.1.3.2 Quantity Limit;
- 6.8.1.3.3 Step Therapy.

6.8.1.4 Hospice exception to obtain prescription drugs under Part D coverage when the enrollee has elected hospice. The drug must be for treatment of a condition that is unrelated to the terminal prognosis of the individual.

6.8.2 Exception requests are processed as standard or expedited coverage determinations and Health Plan redeterminations.

6.8.3 Once an exception is granted, the Health Plan is prohibited from requiring the member to request approval for a refill or new prescription to continue using the Part D prescription under the exception process for the remainder of the plan year, so long as the member remains enrolled in the Health Plan, the physician or other prescriber continue to prescribe the medication, and it continues to be safe for treating the member’s condition.

6.8.4 Physician Supporting Statement for Exceptions: The timeframes for the exception process (standard and expedited) begin when the member’s prescribing physician or other prescriber provides a supporting statement to demonstrate medical necessity of the drug.

6.8.4.1 For tiering exceptions, the physician's or other prescriber's supporting statement must indicate that the drug in the lowest cost-sharing tier for the treatment of the member’s condition is medically necessary due to the following two factors:

- 6.8.4.1.1 Would not be as effective as the requested drug in the higher cost-sharing tier; and/or
- 6.8.4.1.2 Would have adverse effects.
6.8.4.2 For formulary exceptions, the physician's or other prescriber's supporting statement must indicate that the drug for the treatment of the member's condition is medically necessary due to the following three factors:

6.8.4.2.1 All covered Part D drugs on any tier of a plan's formulary would not be as effective for the member as the non-formulary drug, and/or would have adverse effects;

6.8.4.2.2 The number of doses available under a dose restriction for the prescription drug:

6.8.4.2.2.1 Has been ineffective in the treatment of the member’s disease or medical condition or,

6.8.4.2.2.2 Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the member, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug’s effectiveness or patient compliance; or

6.8.4.2.3 The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:

6.8.4.2.3.1 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

6.8.4.2.3.2 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 member.

6.8.5 The Health Plan must allow a reasonable opportunity for the prescribing physician to respond, and will toll the time frame on the following levels:

6.8.5.1 Expedited coverage determination – 5 calendar days,
6.8.5.2 Coverage determination pre-service – 10 calendar days
6.8.6 Tolling will also apply at the Health Plan redetermination level for pre-service standard and expedited levels, if no physician supporting statement was received during the initial determination review and was not included in the submission of the appeal.

6.8.6.1 Expedited Health Plan redetermination – 5 calendar days,
6.8.6.2 Health Plan redetermination pre-service – 10 calendar days

6.8.7 Tolling the timeframe is not allowed for coverage determination and Health Plan redetermination post-service reimbursement requests, under the exceptions process. The timeframe for these levels begin when the request is received and is not tolled pending receipt of a prescriber’s supporting statement.

6.8.8 The time frame is not tolled if the plan asks for additional information after it has received a written supporting statement.

6.8.9 If the Health Plan does not receive the supporting statement, which should include multiple outreach attempts, the Plan should make its determination based on the clinical information available, at that time.

6.9 Resolution

6.9.1 Resolution Letter Requirements: A resolution letter will be sent on all cases that require written resolution notification and must comply with CMS notice requirements. The resolution letter will be sent as expeditiously as the member’s health requires, but no later than the designated case timeframe. The resolution letter will:

6.9.1.1 Provide the outcome for all issues and requests in a clear and concise manner, including any follow up information to assist the member with next steps (e.g., medication status and location for pick up, upcoming appointments, confirmation of discussion with physician, etc.);

6.9.1.2 Include Quality Improvement Organization (QIO) language, if any potential quality of care issue was alleged;

6.9.1.3 Include HIPAA (Health Insurance Portability and Accountability Act) language, if a complaint has been raised with allegations of breach of personal health information (PHI).

6.9.1.4 Provide resolution notification to the member’s prescribing physician or other prescriber involved, for pre-service coverage determinations, as appropriate.

6.9.1.5 Provide a decision rationale for all denials;
6.9.1.5.1 Include the clinical reasons for a medical necessity denial based on physician review, and any criteria, guidelines or protocols used;

6.9.1.5.2 Identify any criterion, guideline or protocol used as the basis for the decision, in sufficient detail including a clear and concise clinical explanation as to why the member does not meet the criterion, guideline, or protocol.

6.9.1.5.3 If appropriate, the letter should tell the member any actions that the member needs to take to meet the criteria, guideline, or protocol;

6.9.1.5.4 Include specific provisions in the contract or evidence of coverage for benefit denials.

6.9.1.6 Include any further available process rights, and other information on how to dispute the determination (e.g., how to initiate arbitration, Quality Improvement Organization review, IRE Reconsideration review, etc.)

6.9.1.7 Inform the member or authorized representative of their right to submit a written request to initiate an IRE reconsideration.

6.9.1.8 Resolution of grievances related to late enrollment penalties (LEP) inform the member of their right to submit a LEP reconsideration request through the IRE.

6.9.1.9 Approval letters must include an explanation of how the request has been, or will be, effectuated. If applicable, an explanation of next steps must be included.

6.9.1.9.1 Additionally, the following conditions for approval must be provided:

   6.9.1.9.1.1 The duration of an approval;

   6.9.1.9.1.2 Limitations associated with an approval; and/or;

   6.9.1.9.1.3 Any coverage rules applicable to subsequent refills.

6.9.1.10 Send a separate letter to members that have dual coverage and have additional rights that their Medicare letter does not inform them about (e.g., Medicaid, CalPERS, FEHBP), under the applicable level.
6.9.2 **Verbal Resolution:** A verbal notice will provide the member or authorized representative with a clear and concise explanation of the case outcome. Certain level types require a resolution letter to follow the verbal resolution. The following types of cases can be verbally resolved:

6.9.2.1 All expedited levels and standard pre-service coverage determinations require a verbal resolution, followed by a written resolution.

6.9.2.2 Standard grievances are eligible for verbal resolution, with no written notice to the member, under the following circumstances.

6.9.2.2.1 Member initiated the case verbally;
6.9.2.2.2 Member does not request the response in writing;
6.9.2.2.3 Case does not contain a potential quality of care issue, actual, or perceived;
6.9.2.2.4 Case does not contain a HIPAA complaint;
6.9.2.2.5 Case does not contain a complaint which occurred within a Kaiser Permanente hospital licensed space;
6.9.2.2.6 Case does not contain a complaint that requires written based on a regulatory state requirement; and
6.9.2.2.7 We are able to speak directly with the member or authorized representative to provide verbal resolution.

6.9.2.3 Verbal resolution and documentation must include:

6.9.2.3.1 The outcome of all issues raised;
6.9.2.3.2 The decision(s);
6.9.2.3.3 The rationale for a denial, in whole or in part;
6.9.2.3.4 Appeal rights for the denial decision;
6.9.2.3.5 Provider rationale for denial along with any internal protocols or guidelines used in making the decision;
6.9.2.3.6 Provide any internal or external next steps available for further review/appeal of the decision;
6.9.2.3.7 Explain how the request will be effectuated if approved, in whole or in part, including:

6.9.2.3.7.1 The duration of an approval;
6.9.2.3.7.2 Limitations associated with an approval; and/or;

6.9.2.3.7.3 Any coverage rules applicable to subsequent refills.

6.9.2.4 Verbal resolution is provided as expeditiously as the member’s medical condition requires and no later than the required timeframe.

6.9.2.5 When contacting a member for verbal resolution, the Program representative must make, and document at least 2 attempts to provide verbal resolution.

6.9.2.5.1 If the member cannot be reached, leave a message stating that the case has been resolved, and request a call back. Do not provide any PHI.

6.9.2.5.2 Grievances eligible for verbal resolution, require a written resolution, if after 2 attempts we are unable to speak directly with the member or authorized representative.

6.9.2.6 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. However, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.

6.9.3 Verbal Resolution with Subsequent Written Resolution: Except for level types that only require written resolution, or meet verbal resolution criteria, a verbal resolution explaining the decision to the member must be followed by a written resolution.

6.9.4 Quick Reference: Resolution Timeframes & Methods:

<table>
<thead>
<tr>
<th>Quick Chart Review for Resolution Timeframes &amp; Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level Type</td>
</tr>
<tr>
<td>------------</td>
</tr>
<tr>
<td>Grievance - Standard</td>
</tr>
<tr>
<td>Expedited Grievance</td>
</tr>
</tbody>
</table>
6.9.5 **Untimely Resolution**

6.9.5.1 If the Health Plan fails to resolve an expedited or standard, coverage determination or Health Plan redetermination within the required timeframe, the case must be forwarded to the IRE for reconsideration, within 24 hours of the expiration timeframe.

6.9.5.1.1 When a verbal resolution is untimely for cases that require a verbal resolution followed by a written resolution, the case must be forwarded to the IRE for reconsideration, within 24 hours of the expiration timeframe.

6.9.5.1.2 The Health Plan must notify the member that it has forwarded his or her request to the IRE for review within 24 hours of the expiration of the adjudication timeframe.
6.9.5.2 For untimely expedited or standard Coverage Determinations and Redeterminations, the Plan does not need to forward the case file to the IRE if the Health Plan makes a completely favorable decision within 24 hours of the adjudication timeframe expiration and notifies the enrollee of the decision.

6.9.6 Withdrawals

6.9.6.1 A member or authorized representative may elect to withdraw a grievance or coverage determination at any time prior to notification to the member or authorized representative of the case outcome.

6.9.6.2 A member or authorized representative may withdraw a Health Plan redetermination at any time before the decision is mailed, by submitting a written request to withdraw to the Health Plan. The Health Plan may withdraw the appeal upon receipt of the written request.

6.9.6.2.1 A verbal Health Plan redetermination withdrawal request may also be accepted, provided written confirmation of the withdrawal is sent within three (3) calendar days from the date of the verbal request.

6.9.6.2.2 If the written withdrawal request is received after the untimely Health Plan redetermination case has been forwarded to the IRE for reconsideration, the Health Plan must forward the withdrawal request to the IRE for processing.

6.9.6.3 If there is a potential quality of care issue (PQI), the issue is forwarded to the Quality Department, even if the concerns have been withdrawn.

6.9.6.4 All withdrawal requests are documented and a closure letter confirming the withdrawal is sent to the member or authorized representative.

6.9.7 Dismissals

6.9.7.1 The Health Plan may dismiss a case for the following reasons:

6.9.7.1.1 If the authorized representative documentation has not been received.

6.9.7.1.1.1 The dismissal must be in writing.

6.9.7.1.2 If good cause is not provided for untimely filing or the Health Plan denies a good cause extension.
6.9.7.1.3 If the request was authorized, rendered, or paid prior to Member Services Grievance & Appeals receiving the request.

6.9.7.1.3.1 If the request was satisfied by a party outside of, and after receipt by Member Services Grievance & Appeals, the date and time that the request was authorized, rendered, or paid should be captured within METRS as both our approval decision and effectuation date and time.

6.9.7.1.4 If the request is related to a pre-service Health Plan redetermination and the Program representative becomes aware that the member has obtained the prescription drug before completing the redetermination, the request must be dismissed and processed as a post-service Health Plan redetermination request for payment instead.

6.9.7.1.5 If the member passed away.

6.9.7.2 Members may also file a grievance with the Health Plan if they are dissatisfied with a dismissal.

6.10 Effectuation

6.10.1 Effectuation Timeframes: CMS mandates that most Part D level types be effectuated within the case resolution timeframe.

6.10.1.1 Pre-service requests must be authorized by the required process level timeframe or provided as expeditiously as the member’s health condition requires.

6.10.1.2 Payment for post-service Health Plan redeterminations must be authorized within 7 calendar days from the date it receives the request for redetermination, and payment must be mailed no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

6.10.2 Proof of Effectuation Documentation: Appropriate proof of effectuation documentation must be attached in METRS. Include clear and complete documentation demonstrating the following:

6.10.2.1 Proof that the drug was authorized or provided on a specific date and time (e.g. system screen shot), including any applicable authorization number. A screenshot from the Pharmacy Benefits
Management (PBM) system illustrating the override code is required for pre-service approvals.

6.10.2.2 Proof that payment was made on a specific date (e.g. system screen shot), including check/reference number, amount paid and recipient. A screen shot from RxClaim system is required for Part D claim refunds.

6.10.3 Independent Review Entity Effectuation Requirements: Upon completion of its reconsideration, the IRE issues a "reconsideration determination" notice to the appealing party, with a copy to the Plan and the CMS Regional Office.

6.10.3.1 For any overturn determination, the IRE notice will contain an explanation of how the member can obtain the disputed payment or covered service, and will be directed to the Plan to obtain the service or payment.

6.10.3.2 The Plan is required to submit to the IRE a Notice of Effectuation (NOE) attesting to effectuation of the decision.

6.10.3.2.1 The documentation must state when and how effectuation occurred (e.g. benefit authorization, payment made, etc.).

6.10.3.3 Proof of effectuation (e.g. screen shot or copy of check or authorization) must also be submitted to the IRE to demonstrate compliance.

6.10.3.3.1 Notification to the IRE that the Plan intends to pay for or provide the benefit, or unidentified internal computer screen prints as the statement of compliance, do not meet the notice of effectuation requirement.

6.10.3.4 The IRE Approval Confirmation Letter must be issued to the member or authorized representative upon completion of the effectuation for a fully or partially favorable decision.

6.10.4 Administrative Law Judge Effectuations: Once a decision is made, the ALJ will issue his/her decision to the appealing party, with a copy to the Plan and the CMS Regional Office.

6.10.4.1 If the ALJ Hearing decision is to overturn the health plan’s denial, the health plan must pay for, authorize, or provide the service under dispute.

6.10.4.2 However, if the health plan requests a Medicare Appeals Council review of the ALJ decision, the health plan may await the
outcome of the review before paying for, authorizing, or providing the service under dispute.

6.10.4.2.1 Written confirmation of the effectuation must be sent to the IRE using the appropriate form.

6.10.4.2.2 Written confirmation of the effectuation must be sent to the member using the approved letter.

6.10.4.2.3 The letter will include how the case has been effectuated along with the name, title and telephone number of the Program representative who implemented the IRE’s decision.

6.10.5 Medicare Appeals Council Effectuations: A copy of the MAC’s decision will be mailed to the parties if the organization determination is reversed in whole or in part.

6.10.5.1 The Health Plan must pay for, authorize, or provide the service under dispute.

6.10.5.2 Written confirmation of the effectuation must be sent to the IRE using the appropriate form.

6.10.6 Federal District Court Judicial Review: A copy of the Federal Court’s decision will be mailed to the parties if the organization determination is reversed in whole or in part.

6.10.6.1 The health plan must pay for, authorize, or provide the service under dispute.

6.10.6.2 Written confirmation of the effectuation must be sent to the IRE using the appropriate form.

6.10.7 Quick Reference: Effectuation Timeframes Table

<table>
<thead>
<tr>
<th>Quick Reference: Effectuation Timeframes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level Type</strong></td>
<td><strong>Timeframe</strong></td>
</tr>
<tr>
<td>Grievance Standard</td>
<td>As quickly as the member's health requires, but no later than 45 calendar days from date of receipt by the Health Plan.</td>
</tr>
<tr>
<td>Coverage Determination - Standard - Pre-Service</td>
<td>Authorize or provide within 72 hours from the date/time of receipt by the Health Plan, or earlier if enrollee health dictates.</td>
</tr>
<tr>
<td>Coverage Determination - Standard - Post-Service</td>
<td>Mail payment within 14 days from the date of receipt by the Health Plan.</td>
</tr>
<tr>
<td>Coverage Determination - Expedited - Pre-Service</td>
<td>Authorize or provide within 24 hours from the date/time of receipt by the Health Plan, or earlier if enrollee health dictates.</td>
</tr>
<tr>
<td>Health Plan Redetermination - Standard - Pre-Service</td>
<td>Authorize or provide within 7 days from the date of receipt by the Health Plan, or earlier if enrollee health dictates.</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Health Plan Redetermination - Standard - Post-Service | Authorize payment within 7 days from the date of receipt by the Health Plan, or earlier if enrollee health dictates.  
Check/Payment must be mailed within 30 days from date of contact. |
| Health Plan Redetermination - Expedited - Pre-Service | Authorize or provide within 72 from the date/time of receipt by the Health Plan, or earlier if enrollee health dictates. |
| IRE Reconsideration - Standard - Pre-Service | Authorize or provide benefit within 72 hours, from receipt of notice.  
Fax written confirmation to the IRE within 14 calendar days from the date of effectuation using the appropriate form.  
Plan is not required to notify member. |
| IRE Reconsideration - Standard - Post-Service | Authorize payment for the benefit within 72 hours and pay within 30 calendar days, from receipt of the notice.  
Fax written confirmation to the IRE within 14 calendar days from the date of effectuation.  
Plan is not required to notify member. |
| IRE Reconsideration - Expedited - Pre-Service | Authorize or provide benefit within 24 hours, from receipt of notice.  
Fax written confirmation to the IRE within 14 calendar days from the date of effectuation.  
Plan is not required to notify member. |
| ALJ Hearing | Pay for, authorize, or provide the service under dispute as expeditiously as the member's health condition requires, but no later than the following:  
Expedited Requests: Authorize or provide within 24 hours from receipt of notice.  
Standard Pre-Service Requests: Authorize or provide within 72 hours from receipt of notice.  
Standard Post-Service Requests: Authorize within 72 hours and pay within 30 days from receipt of notice.  
However, if the Health Plan requests a Medicare Appeals Council review of an ALJ decision, the health plan may await the outcome of the review before paying for, authorizing, or providing the service under dispute.  
Send written confirmation to the IRE within 14 calendar days from the date of the effectuation.  
Plan is not required to notify member. |
**6.11 Reopening**

**6.11.1 Reopening and Revising Determination and Decisions:** A reopening is a remedial action taken to change a final determination or decision even though the determination or decision was correct based on the evidence of record. That action may be taken by:

- **6.11.1.1** The Health Plan to revise the coverage determination or redetermination;
- **6.11.1.2** An IRE to revise a reconsideration;
- **6.11.1.3** An ALJ to revise a hearing decision; or
- **6.11.1.4** The MAC to revise an ALJ hearing or review decision

**6.11.2 Clerical Errors:** The Health Plan must process clerical errors (which include minor errors and omissions) as a reopening, instead of a redetermination.

- **6.11.2.1** If the Health Plan receives a request for reopening and disagrees that the issue is a clerical error, the Health Plan must dismiss the reopening request and advise the party of any appeal rights,
provided the timeframe to request an appeal on the original denial has not expired.

6.11.2.2 The Health Plan has the discretion to determine what meets the definition of a clerical error. Clerical error includes human and mechanical errors on the part of the party or the Health Plan such as:

6.11.2.2.1 Mathematical or computational mistakes;
6.11.2.2.2 Inaccurate data entry; or
6.11.2.2.3 Denial of claims as duplicates

6.11.3 The Health Plan cannot reopen and modify its decision if additional information is received after a member has filed a request for an IRE reconsideration or the adjudication timeframe at the coverage determination or redetermination level has expired and the Health Plan is required to forward the member’s request to the IRE, unless a subsequent request to withdraw has been granted.

6.11.4 If the member has not requested a review by the IRE, or the applicable adjudication time frame has not expired, and the Health Plan receives additional information that would change the Health Plan’s decision, the Health Plan may reopen and modify its decision.

6.11.5 The filing of a request for a reopening with the IRE, ALJ, or MAC does not relieve the Health Plan of its obligation to make payment for, authorize, or provide service(s).

6.11.6 A decision by the Health Plan, IRE, ALJ, or MAC on whether to reopen is final and not subject to appeal.

6.11.7 Guidelines for Reopening:

6.11.7.1 Request must be made in writing;
6.11.7.2 Request for reopening must be clearly stated;
6.11.7.3 The request must include the specific reason for requesting the reopening (a statement of dissatisfaction is not grounds for a reopening, and should not be submitted); and
6.11.7.4 Request should be made within the timeframes permitted for reopening.

6.11.8 Timeframes and Requirements for Reopening:

6.11.8.1 Reopening of coverage determinations and redeterminations initiated by the Health Plan:
6.11.8.1.1 Within one year from the date of the coverage determination or redetermination for any reason.

6.11.8.1.2 Within four years from the date of the coverage determination or redetermination for good cause.

6.11.8.1.3 At any time if there exists reliable evidence (i.e., relevant, credible, and material) that the coverage determination was procured by fraud or similar fault.

6.11.8.1.4 At any time if the coverage determination or redetermination is unfavorable, in whole or in part, to the party, but only for the purpose of correcting a clerical error on which that determination was based.

6.11.8.2 Reopening of coverage determinations and Health Plan redeterminations by a party:

6.11.8.2.1 Within 1 year from the date of the coverage determination or Health Plan redetermination for any reason.

6.11.8.2.2 Within 4 years from the date of the coverage determination or Health Plan redetermination for good cause.

6.11.8.2.3 At any time if the coverage determination is unfavorable, in whole or in part, to the member but only for the purpose of correcting a clerical error on which that determination was based.

6.11.8.3 Reopening of IRE reconsiderations, hearing decisions by an ALJ, and MAC reviews:

6.11.8.3.1 The applicable review body may reopen its decision on its own motion or at a member’s request within 180 days from the date of the applicable IRE reconsideration, ALJ hearing decision or MAC review, for good cause.

6.11.8.3.2 If the IRE reconsideration, ALJ hearing decision, or MAC review was procured by fraud or similar fault, then the IRE, the ALJ or the MAC, as applicable, may reopen at any time.

6.11.8.4 Reopening IRE reconsiderations, ALJ hearing decisions, and MAC reviews requested by a Party:
6.11.8.4.1 Within 180 days from the date of the IRE reconsideration, ALJ hearing decision or MAC review decisions for good cause.

6.11.9 **Good Cause Reopening:** Good cause may be established when:

6.11.9.1 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; or

6.11.9.2 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.

6.11.9.3 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, is not a basis for reopening a determination or hearing decision under this section. This provision does not preclude the Health Plan from conducting reopening’s to effectuate national coverage decisions.

6.11.10 **Notice of a Revised Determination or Decision:**

6.11.10.1 Reopening initiated by the Health Plan, IRE, ALJ or the MAC:

6.11.10.1.1 When any determination or decision is reopened and revised, the Health Plan, IRE, ALJ or the MAC must mail its revised determination or decision to the parties involved at their last known address.

6.11.10.1.2 An adverse determination or decision must state the rationale and basis for the reopening and revision and any right to appeal and must also be provided to the member at their current location.

6.11.10.2 Reopening initiated at the request of a party:

6.11.10.2.1 The Health Plan, IRE, ALJ or MAC must mail its revised determination or decision to the parties to that determination or decision at their last known address.

6.11.10.2.2 An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

6.12 **Independent Review Entity (IRE)**
6.12.1 Member initiated IRE Review: If the Health Plan confirms, in whole or in part, its adverse coverage determination, the member, authorized representative, prescribing physician or other prescriber, who is dissatisfied with the Health Plan redetermination, has a right to file a reconsideration with the Part D Qualified Independent Contractor (QIC), also known as the IRE.

6.12.1.1 The member, not the Health Plan, must file a signed, written request for reconsideration with the IRE within 60 days of the date of the adverse determination, unless the member can show good cause for an extension.

6.12.1.2 IF the IRE accepts the member’s request for reconsideration, the IRE will request the member’s file from the Health Plan.

6.12.1.3 Program representatives will process member file requests from the IRE within the required time frame of 48 hours for standard reconsiderations and 24 hours for expedited reconsiderations.

6.12.2 IRE Case Packet: The IRE has developed standardized forms for case file submission that must be used by the Program representative when submitting a case file packet for review:

6.12.2.1 Part D Case Transmittal Form
6.12.2.2 Part D Drug Case Narrative Form

6.12.3 Auto-Forwarding Untimely Cases to the IRE: If the decision is not made within the applicable time frame, the case must be auto-forwarded by the plan as they are not requested by the IRE. The Program representative will follow the same case packet submission steps as case files requested by the IRE.

6.12.4 IRE Decisions: Upon completion of its reconsideration, the IRE issues a "reconsideration determination" notice to the appealing party, with a copy to the Health Plan and the CMS Regional Office. The IRE will fax their decision notification to the Health Plan.

6.12.4.1 The IRE must conduct the reconsideration as expeditiously as the enrollee’s health condition requires, but no later than Health Plan’s time frames for processing redeterminations.

6.12.4.2 Overturn: If the IRE agrees with the member and approves the original request(s), in full or partial, the notice will provide the appealing party with information about the “favorable” decision.

6.12.4.2.1 The overturn notice will contain an explanation of how the member can obtain the disputed payment
or covered service, and he or she will be directed to the Health Plan to obtain the service or payment.

6.12.4.2.2 A notice to comply with the IRE reconsideration determination is also included. This notice details the Plan's responsibilities, including the time frame by which a compliance notice must be received by the IRE.

6.12.4.2.3 All overturn decisions should be reviewed with a manager/supervisor to determine if a request for a reopening review to contest the decision can be submitted.

6.12.4.2.4 If a decision notice is not received within the applicable IRE review timeframe, the Program representative should search for the appeal status on the IRE website using the IRE Appeal Number.

6.12.4.2.5 The IRE Appeal Number must be entered in to the designated field in METRS.

6.12.4.2.6 Approval of a Former Member: If a member’s coverage terminates after the Health Plan reconsideration is processed, the Health Plan is legally responsible to authorize, provide or pay for all Medicare covered services. Program representatives will process with effectuation.

6.12.4.3 Uphold: If the IRE agrees with the Health Plan and denies the member’s request(s), the notice will provide the appealing party with information about the “unfavorable” decision. There is no further correspondence required from the Plan.

6.12.4.4 Partial Approvals: If the IRE disagrees with a portion of the request, the IRE will issue a “partially favorable” decision notice. The Health Plan will proceed with effectuation of the approved portion of the request.

6.13 **Administrative Law Judge (ALJ) Hearings**

6.13.1 **Threshold Amount for Filing:** If the amount remaining in controversy meets the appropriate statutory threshold requirement, any party to the reconsideration, except the health plan, who is dissatisfied with the reconsidered determination, has a right to a hearing before an ALJ.

6.13.1.1 A request for an ALJ hearing must be in writing and must be filed with the entity specified in the IRE's reconsideration notice.
6.13.1.2 The IRE will compile the reconsideration file and forward it to the appropriate ALJ hearing office.

6.13.2 **Filing Timeframe:** Except when an ALJ extends the timeframe, a party must file a request for an ALJ hearing, within sixty (60) days of the date of the notice of a reconsidered determination. Any request for a “good cause” extension must be in writing and state the reasons why the request was late. If the party shows good cause for missing the deadline, the ALJ may grant an extension.

6.13.3 **ALJ Hearing Participation by the Health Plan:** Member Services Appeals and Grievances staff will attend the hearing and present all evidence related to the case.

6.13.4 Following the hearing, the judge will take all matters into consideration and issue a written decision which will be sent to all parties in the reconsideration process (member/representative/health plan).

6.13.5 If the ALJ upholds KFHP’s decision, the member will be informed by the ALJ regarding other available appeal avenues including the Medicare Appeals Council (MAC) and Federal District Court (FDC), if the amount in controversy is met.

**6.14 Medicare Appeals Council (MAC) Review**

6.14.1 The MAC may grant or deny the request for review of the ALJ’s decision or dismissal. If it grants the request, it may either issue a final decision or dismissal, or send the case back to the ALJ with instructions on how to proceed with the case.

6.14.2 A request for a MAC review must be filed in writing to the MAC within sixty (60) days of the date of the receipt of the ALJ hearing decision or dismissal.

6.14.3 If the health plan requests a MAC review, it must concurrently notify the member by sending a copy of the request, as well as accompanying documents that it submits to the MAC. The health plan must also notify the IRE that it has requested a MAC review.

6.14.4 A copy of the MAC’s decision will be mailed to the parties.

**6.15 Federal District Court Judicial Review**

6.15.1 A judicial review of an ALJ’s decision may be requested if:

6.15.1.1 The MAC denied the parties’ request for review, and

6.15.1.2 The amount in controversy (AIC) is met.
6.15.2 Any party, including the health plan (upon notifying all other parties), may request judicial review of a MAC decision if:

6.15.2.1 The MAC denied the parties’ request for review; or
6.15.2.2 It is the final decision of CMS; and
6.15.2.3 The amount in controversy is met.

6.15.3 To request a judicial review, a party must file a civil action in a district court.

6.15.4 Expedited Access to Judicial Review (EAJR): A member can make a request for expedited judicial review if:

6.15.4.1 The IRE has made a determination and the member has filed a request for an ALJ hearing, or;
6.15.4.2 An ALJ has made a decision and the member has filed a request for MAC review, and
6.15.4.3 The requestor is a member,
6.15.4.4 The amount in controversy meets the threshold requirements,
6.15.4.5 If there is more than one member to the hearing or MAC review, each member concurs, in writing, with the request of the EAJR, and
6.15.4.6 There are no material issues of fact in the dispute.

7.0 Definitions

7.0.1 Acknowledgement: The act of contacting the member and informing them that we received their case and setting expectations.

7.0.2 Appeal: Any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing, or approving drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in section 4223.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity (IRE), Administrative Law Judge (ALJ) hearings, review by the Medicare Appeals Council (MAC), and judicial reviews.

7.0.3 Arbitration: A contractual dispute resolution process in which a neutral arbitrator determines the final settlement of a Claim.

7.0.4 Case: A system record that captures all activities surrounding a member encounter and its associated events.

7.0.5 Centers for Medicare & Medicaid Services (CMS): Federal agency that administers the Medicare and Medicaid Programs.
7.0.6 **Claim**: Any request for reimbursement of Part D drugs which the Medicare member has already received from a non KP provider. The request for payment is submitted to the Claims Administration Department. A Claim is not a “pre-service” request.

7.0.7 **Clerical Error**: A clerical error includes such human and mechanical errors such as mathematical or computational mistakes, inaccurate coding and compute errors.

7.0.8 **Closed Case**: A Medicare Part D grievance, coverage determination or redetermination which has been resolved by the Health Plan.

7.0.9 **Coding**: The act of assigning a category associated with the process level to ensure compliant case work and regulatory reporting.

7.0.10 **Complaint**: A Part D complaint may involve a grievance, coverage determination or both. If an enrollee addresses two or more issues in one complaint, each issue should be processed separately and simultaneously (to the extent possible) under the proper procedure. A Part D complaint also may involve a low-income subsidy (LIS) or late enrollment penalty (LEEP) determination. Every complaint must be handled under the appropriate process i.e., grievance or appeal.

7.0.11 **Decision**: A determination of how the member’s request is resolved.

7.0.13 **Effectuation**: The demonstration that the member has been provided payment of a claim, authorization for a service, or a provision of services.

7.0.12 **Enrollee**: A Part D eligible individual who has elected a Part D plan offered by KFHP as a Part D plan sponsor.

7.0.13 **Expedited Review**: A review process overseen by physicians used to render a decision involving an imminent or serious threat to the health of the member, including, but not limited to, severe pain, potential loss of life, limb or major bodily function. Expedited requests not meeting criteria are processed as a standard review process.

7.0.14 **Extension**: Additional time allowed by Medicare regulations to reach a decision for certain level types if the member requests the extension or if the Health Plan justifies a need for additional information and documents how the delay is in the interest of the member (for example, the receipt of authorized representative documentation or non-Plan medical records).

7.0.15 **External Review**: For purposes of this policy and procedure, the external review process refers to the case review and decision process conducted by an external review entity (e.g. IRE, ALJ, MAC, Federal District Court) related to a grievance or appeal that has previously undergone a review by the Health Plan.

7.0.16 **Grievance Form**: A form provided to members who wish to register a written Medicare grievance, initial request for coverage determination or redetermination.

7.0.17 **Inquiry**: Any oral or written request to a Part D plan sponsor or one of its contractors that does not involve a request for a Part D coverage determination/formulary exception request. Inquiries are requests for information, clarification or assistance that is not an expression of dissatisfaction or a request for services or payment of services.
7.0.18 **Initial Request**: A Medicare member’s first contact with a Program representative in which they make a request for a benefit or service. The outcome would be a Part C organization determination or Part D coverage determination.

7.0.19 **Intake**: The process of gathering information relevant to set up the case for a member’s grievance or appeal.

7.0.20 **Investigation**: The process whereby all relevant facts are compiled, documented, and reviewed in order to determine the appropriate resolution.

7.0.21 **Level Type**: Within KFHP Part D complaints are categorized as a grievance, coverage determination or redetermination.

7.0.22 **Life Threatening**: Diseases or conditions where the likelihood of death is high unless the course of the disease or condition is interrupted.

7.0.23 **LIS**: The Low-Income Subsidy program established by CMS provides extra help (a subsidy) with prescription drug costs for eligible individuals whose income and resources are limited. This help takes the form of subsidies paid by the Federal government to the drug plan in which the Medicare beneficiary enrolls. The subsidy provides assistance with the premium, deductible and co-payments of the program. Beneficiaries may apply for the Low-Income Subsidy (LIS) with the Social Security Administration (SSA) or with their State Medicaid agency.

7.0.24 **Medical Necessity**: A service or supply that is appropriate and required to prevent, diagnose or treat a condition or clinical symptoms in accord with generally accepted professional standards of practice that are consistent with the standard of care in the medical community.

7.0.25 **Medicare Advantage (MA) Program**: Replaces the Medicare + Choice (M+C) program under Part C established through Medicare enacted in Title II of The Medicare Prescription Drug, improvement, and Modernization Act of 2003 (MMA). Changes include, but are not limited to, the following: expanded options for special needs patients, amended coverage election periods, modification of calculation of the annual capitation rate, and coverage for certain screening exams. KPSA is an MA program.

7.0.26 **Medicare Modernization Act of 2003 (MMA)**: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 includes (i) Title I (Part D) establishes the outpatient prescription drug program and (ii) Title II (Part C) establishes and regulates the Medicare Advantage (MA) program which replaces Medicare + Choice.

7.0.27 **Medicare Cost Member**: A KFHP member who has assigned Medicare Part B benefits to KFHP.

7.0.28 **Part D**: Medicare’s Outpatient prescription drug program established through MMA of 2003.

7.0.29 **Part D Drug**: Prescription drugs, biological products, insulin, vaccines, and certain medical supplies associated with the injection of insulin. The following drugs are excluded from Part D:

7.0.29.1 Drugs used for anorexia, weight loss, or weight gain (except to treat AIDS related cachexia);

7.0.29.2 Fertility drugs;

7.0.29.3 Drugs for cosmetic purposes or hair growth;
7.0.29.4 For relief of coughs or colds;
7.0.29.5 Prescription vitamins and minerals, except prenatal vitamins, fluoride treatments and therapeutic niacin for lowering cholesterol;
7.0.29.6 Nonprescription drugs;
7.0.29.7 Outpatient drugs for which the manufacturer requires monitoring or associated tests be purchased exclusively from the manufacturer as a condition of sale;
7.0.29.8 Barbiturates and benzodiazepines;

7.0.30 **Potential Quality of Care Issue (PQI):** Member expressed concern relating to the quality of care, which is not yet substantiated.

7.0.31 **Prescription Exception Process:** The exceptions process is the method by which the Health Plan handles requests to prescribe non-formulary Part D drugs. The Health Plan must allow members to request:
7.0.31.1 Coverage of Part D drugs not on the Health Plan’s Part D formulary;
7.0.31.2 Continued coverage of a drug the plan has removed from its Part D formulary;
7.0.31.3 An exception to the plan’s policy regarding coverage for a step therapy;
7.0.31.4 An exception to a plan’s dosing limitations;
7.0.31.5 A tiering exception requested by an Individual KPSA member.

7.0.32 **Post-service Request:** A request for payment or reimbursement of drugs, care or services the member has already received.

7.0.33 **Pre-service Request:** A request for the provision of drugs, care or services the member has not yet received. See “Service”.

7.0.34 **Program Representative:** A KFHP Member Services Appeals and Grievances employee responsible for processing and responding to Medicare members’ Part D grievances, initial requests for Part D coverage determinations and redeterminations as outlined in this Policy and Procedure.

7.0.35 **Quality Improvement Organization (QIO):** Organization comprised of practicing doctors and other health care experts under contract with the Federal government to monitor and improve the care given to Medicare members. The QIO reviews complaints raised by members about the quality of care provided by physicians, inpatient hospitals, hospital outpatient departments, hospital emergency rooms, skilled nursing facilities and home health. They also review continued stay denials in acute inpatient hospital facilities as well as coverage terminations in Skilled Nursing Facilities, Home Health and Comprehensive Outpatient Rehabilitation Facilities.

7.0.36 **Quality of Care Issue:** Grievance issues based off of the member’s perspective pertaining to the clinical care, treatment plan or coordination of care. A quality of care issue may be filed through the Health Plan’s grievance process and/or the Quality Improvement Organization (QIO). The QIO must determine whether the quality of services (including both inpatient and outpatient services) provided by the Health Plan meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings.
7.0.37 **Reopening**: A remedial action taken to change a final determination or decision even though the determination or decision was correct based on the evidence of record.

7.0.38 **Representative (Appointed/Authorized)**: An individual appointed by a Medicare member, or authorized under State or other applicable law, to act on behalf of a Medicare in obtaining a grievance, coverage determination, or in dealing with any of the levels of the appeals process. Except as provided under Medicare regulations, the Representative will have all of the rights and responsibilities of a member in obtaining a coverage determination or in dealing with any of the levels of the appeals process, subject to the applicable rules described under Subpart M of the Medicare Part C regulations.

7.0.39 **Resolution Letter**: A written notice of the outcome of the Medicare Part D grievance, initial request for Part D coverage determination or redetermination sent to the member or representative with a clear and concise explanation of how the Health Plan resolved the Medicare Part D grievance, Part D coverage determination, or redetermination. This notice will include information regarding the member’s rights for further review, including how to obtain those rights.

7.0.40 **Seriously Debilitating**: Diseases or conditions that cause major, irreversible loss of function of the body or body part(s).

7.0.41 **Standard Review**: A review process used to render a decision involving requests that are not an imminent or serious threat to the health of the member.

7.0.42 **Verbal Resolution**: Verbal notice of the outcome of the case. Verbal notice will provide the member or representative with a clear and concise explanation of how the health plan resolved the case.

### 8.0 References / Appendices

8.0.1 **Quick Reference: Case Processing Timeframes**

<table>
<thead>
<tr>
<th>Level Type</th>
<th>Intake</th>
<th>Contact Date and Time</th>
<th>Ack</th>
<th>Resolution</th>
<th>Effectuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grievance - Standard</td>
<td>60 days to file</td>
<td>When the case is received by the Health Plan.</td>
<td>5 days (written or verbal)</td>
<td>30 days (written or verbal) One-time 14-day Extension:</td>
<td>As quickly as the member's health requires, but no later than 45 calendar days from the date of contact.</td>
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<td>plans applied, in the best interest of the member</td>
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<tr>
<td>Expedited Grievance</td>
<td>60 days to file</td>
<td>When the case is received by the Health Plan.</td>
<td>24 hours (verbal)</td>
<td>24 hours verbal, written resolution within 3 days of verbal.</td>
<td>N/A</td>
</tr>
<tr>
<td>Coverage Determination - Standard</td>
<td>At any time</td>
<td>When the case is received by the Health Plan.</td>
<td>Pre-Service: 24 hours (verbal)</td>
<td>Pre-Service timeframe: 72 hours verbal, written resolution within 3 days of verbal.</td>
<td>By level resolution due date.</td>
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<tr>
<td>Coverage Determination - Expedited</td>
<td>At any time</td>
<td>When the case is received by the Health Plan.</td>
<td>24 hours (verbal)</td>
<td>24 hours verbal, written resolution within 3 days of verbal.</td>
<td>By level resolution due date.</td>
</tr>
<tr>
<td>Health Plan Redetermination - Standard</td>
<td>60 days to file (written request)</td>
<td>When the case is received by the Health Plan.</td>
<td>3 days (verbal)</td>
<td>7 days (written)</td>
<td>Pre-Service: By level resolution due date.</td>
</tr>
<tr>
<td>Health Plan Redetermination - Expedited</td>
<td>60 days to file</td>
<td>When the case is received by the Health Plan.</td>
<td>24 hours (verbal)</td>
<td>72 hours verbal, written resolution within 3 days of verbal.</td>
<td>By level resolution due date.</td>
</tr>
</tbody>
</table>

**Policy Revision History**

**Revision Dates:**

**August 23, 2018**