

PRESCRIPTION DRUG APPEAL AND GRIEVANCE DEFINITIONS

Appeal: Any procedure that deals with the review of adverse coverage determinations made by the plan sponsor on the benefits under the prescription plan portion that the enrollee believes they are allowed to receive, including a holdup in providing or approving the drug coverage (when a delay would negatively affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage. These procedures include redeterminations by the plan sponsor, reconsiderations by the independent review entity (IRE), Administrative Law Judge (ALJ) hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Appointed Representative: A person appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in obtaining a grievance, coverage determination, or in dealing with any of the levels of the appeals process under Medicare guidelines.

Complaint: A complaint may involve a grievance, coverage determination, or both. A complaint also may involve a low-income subsidy (LIS) or late enrollment penalty (LEP) determination. Every complaint must be handled under the appropriate process.

Coverage Determination: Any decision made by or on behalf of a plan sponsor regarding payment or benefits to which an enrollee believes he or she is entitled.

Effectuation: Compliance with a full or partial reversal of a plan sponsor's original adverse coverage determination. Compliance may involve payment of a claim, or authorization for or provision of a benefit.

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

Grievance: Any complaint or dispute, other than one that involves a coverage determination or an LIS or 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. A grievance may also include a complaint that a plan sponsor refused to expedite a coverage determination or redetermination. Grievances may include complaints regarding the timeliness, appropriateness, access to, and/or setting of a provided item.

Independent Review Entity (IRE): An independent entity contracted by CMS to review Part D plan sponsor denials of coverage determinations.

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 coverage determination/exception request.

Quality Improvement Organization (QIO): Organizations including practicing doctors and other health care experts under contract to the Federal government to watch and improve the care given to Medicare enrollees. They review complaints raised by enrollees about the quality of care provided by physicians, inpatient hospitals, hospital outpatient departments, hospital emergency rooms, skilled nursing facilities, home health agencies, Medicare managed care plans, Medicare Part D prescription drug plans, and ambulatory surgical centers. The QIOs also review continued stay denials in acute

inpatient hospital facilities as well as coverage terminations in skilled nursing facilities (SNFs), home health agencies (HHAs) and comprehensive outpatient rehabilitation facilities (CORFs).

Quality of Care Issue: A quality of care issue may be filed through the plan sponsor's grievance process and/or a QIO. A QIO must determine whether the quality of services (including both inpatient and outpatient services) provided by a plan sponsor meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings.

Redetermination: The first level of the appeal process, which involves a Part D plan sponsor reevaluating an adverse coverage determination, the findings upon which it was based, and any other evidence submitted or obtained.