COVERAGE DETERMINATION AND APPEALS PROCESSES

Part D plans are required to have a coverage determination process, which includes an exceptions process, and appeals processes that provide enrollees with the opportunity to challenge the exclusion of a particular drug from a plan's formulary or the placement of a drug on a higher cost-sharing tier. CMS will provide substantial enrollee protections with these processes, which build on Medicare Advantage protections and reflect additional considerations for prescription drugs. CMS will review each plan's coverage determination and appeals processes to ensure that enrollees have access to medically necessary drugs.

CMS asked for comments on the coverage determination and appeals processes in the proposed rule and in response, has made significant changes to better serve enrollees by shortening timeframes and simplifying processes for plan decisions on coverage determination and appeals. CMS also requires earlier notice to enrollees about formulary or tiered cost sharing structure changes and their right to appeal. Below is a description of the key elements of these important beneficiary protections, including more detail regarding the changes from the proposed rule to the final rule.

Coverage Determinations

As an initial step, enrollees file a request for a coverage determination with their plans in certain circumstances, such as when a plan does not pay for a Part D drug. Each plan must have a procedure for making timely coverage determinations on standard and expedited requests made by enrollees. Physicians and appointed representatives (such as a family member) may assist enrollees in requesting a coverage determination.

CMS shortened the timeframes for plans to make coverage determinations, including exceptions, so that enrollees will quickly receive decisions about their needed medications. Plans must make their determinations as expeditiously as an enrollee's health condition requires, but no later than 24 hours for expedited decisions involving enrollees who suffer from serious health conditions (reduced from 72 hours in the proposed rule), and 72 hours for standard decisions (reduced from 14 days in the proposed rule). Another change from the proposed rule is, if a plan does not make a coverage determination or redetermination within the appropriate timeframes, the decision is automatically forwarded to the independent review entity for review.

Also, in response to comments received, plans must notify enrollees of any changes to their formularies or cost sharing levels at least 60 days in advance of such change taking effect. If the plan does not provide the enrollee with such notice, it must provide the enrollee with a 60-day supply of the drug and the notice of change when the enrollee requests a refill of the drug affected by the change. This 60-day notice requirement provides adequate time for enrollees to request an exception and file an appeal, if needed. This requirement is consistent with the notice provision contained in the National Association of Insurance Commissioners' model guidelines, which were created to assist States with developing the policies they use to regulate health insurance plans offering prescription drug benefits.

Plans must also arrange with network pharmacies to provide notice to enrollees explaining how they can obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist.

Exceptions Process

The exception process, which ensures that beneficiaries have access to prescription drugs they need, is unique to the drug benefit. It provides a straightforward process for an enrollee to obtain a covered Part D drug at a more favorable cost-sharing level or obtain a Part D drug that is not on the plan's formulary. Enrollees may request an exception under the following circumstances:

- The enrollee is using a drug covered on a plan's formulary that has been removed during the plan year for reasons other than safety;
- The enrollee's physician prescribed a non-formulary drug for the enrollee that the physician believes is medically necessary;
- The enrollee is using a drug that has been moved during the plan year from the preferred to the non-preferred cost sharing tier; or
- The enrollee's physician prescribed a drug for the enrollee that is included in a plan's more expensive cost sharing tier because the prescribing physician believes the drug included in the less expensive cost sharing tier is medically inappropriate for the enrollee.

Generally, plans must grant exceptions when they determine that it is medically appropriate to do so. If the exceptions request involves a plan's tiered cost sharing issue, the Part D drug being prescribed may be covered if the prescribing physician determines that the preferred drug for treatment of the same condition would not be as effective as the preferred drug or would have an adverse effect for the enrollee, or both. If the enrollee is requesting coverage of a non-formulary drug, the drug may be covered if the prescribing physician determines that all of the drugs on the formulary would not be as effective as the non-formulary drug or would have adverse effects for the enrollee, or both. In both cases, the plan would have to agree with the physician's determination.

Appeals Process

Once a plan makes an unfavorable coverage determination such as denying an exception request, the enrollee, or his or her appointed representative, may appeal the plan's decision. The Part D appeals process is modeled after the Medicare Advantage appeals process that is currently being used successfully.

There are five levels of the appeals process that an enrollee may appeal to:

Level		Standard Appeal	Expedited Appeal*
1	Redetermination by Part D Plan	If the Part D plan's initial coverage determination is unfavorable, an enrollee may request a ***redetermination*** and the plan has up to 7 days, reduced from the proposed 30 days, to make its decision.	Same as standard except the timeframe is up to 72 hours for the plan to make its decision.
2	Reconsideration by Independent Review Entity (IRE)	If the Part D plan's redetermination is unfavorable, an enrollee may request a ***reconsideration*** by an IRE, which is a CMS contractor that reviews determinations made by a plan. The IRE has up to 7 days, reduced from the proposed 30 days, to make its decision.	Same as standard except the timeframe is up to 72 hours for the IRE to make its decision.
3	Administrative Law Judge (ALJ)	If the IRE's reconsideration is unfavorable, an enrollee may request a hearing with an ALJ if the amount in controversy requirement is satisfied.	Not applicable.
4	Medicare Appeals Council (MAC)	If the ALJ's finding is unfavorable, the enrollee may appeal to the MAC, an entity within the Department of Health and Human Services that reviews ALJ's decisions.	Not applicable.
5	Federal District Court	If the MAC's decision is unfavorable, the enrollee may appeal to a Federal district court, if the amount in controversy requirement is satisfied.	Not applicable.

*An expedited decision is requested based on the urgency of an enrollee's health condition.

Medicare Oversight

CMS and Part D plans will be providing a considerable amount of information to beneficiaries, caregivers, patient advocacy groups, providers, and the general public about coverage determination and appeals processes so that all Medicare beneficiaries receive medically necessary drugs and their continuity of care is preserved. CMS will be monitoring plans and reviewing beneficiary's complaints to ensure that plans do not engage in discriminatory practices. Enforcement actions will be taken against plans that violate Medicare's requirements.