

MEDICARE PART D PRESCRIPTION DRUG BENEFIT

On January 21, 2005, the Centers for Medicare & Medicaid Services (, CMS,,) issued the final regulations implementing the Medicare prescription drug benefit as well as a final guidance document addressing how the agency will review prescription drug plan formularies and procedures. The Medicare prescription drug benefit, known as the , Part D,, benefit, was established under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the , MMA,,). The final Part D regulations were published in the Federal Register on January 28, 2005.

I. Formularies – General Rules

- A. Two Drugs Per Category/Class: A plan must include at least two drugs per category and class. CMS states that this two drug requirement is a minimum standard and will not be sufficient for some categories and classes.
- B. Two Different Drugs: The minimum two drug requirement must be met with two drugs that are not therapeutically equivalent and bioequivalent and that different strengths and dosage forms must be available for each of these drugs. A plan cannot satisfy the two drug requirement by including a brand-name drug and a generic equivalent in the formulary.
- C. Exception for Offering Only One Drug in a Category/Class: Plans may include only one drug in a particular category or class if the Part D plan demonstrates and CMS approves that (1) only two drugs are available in that category or class, and (2) one drug is clinically superior to the other drug in that category or class.
- D. Changes to Categories and Classes: Plans may make changes to the categories and classes in a formulary only at the beginning of the plan year, with one exception. The statute allows mid-year changes to categories and classes to take into account new therapeutic uses of existing drugs and newly approved drugs. Plans may make changes to the drugs that populate the categories and classes, or to the preferred or tiered status of drugs, in the middle of the plan year.
- E. Notice for Formulary Changes: Plans must provide 60 days notice to affected enrollees and other specified parties when removing a drug from a formulary or changing a drug's cost-sharing. Where 60 days notice is not practical, a plan may instead provide both notice and access to a 60 day supply of the drug at current cost-sharing levels. Enrollees taking the affected drug will not be guaranteed access to the

drug for the duration of the plan year and must use the process for seeking an exception to a coverage determination to continue coverage beyond the 60 day notice period. A plan may remove a drug from a formulary without such notice where a drug is deemed unsafe by the Food and Drug Administration or removed from the market by the manufacturer.

- F. Special Populations: CMS has declined to establish open formularies or different standards for special populations (e.g., beneficiaries with conditions such as HIV/AIDS, cancer or end stage renal disease, or those dually eligible for Medicaid). CMS states that it will address the needs of these populations through the formulary review process.
- G. Transition Process: Plans must establish a , transition process,, for new enrollees prescribed Part D drugs not on their Part D plan's formulary. This process is designed to facilitate the transition of dual eligibles and other enrollees. CMS will issue additional guidance and instructions on how plans must implement this provision.

II. Formularies – CMS Review

CMS will review each Part D plan's benefit structure to ensure that the plan design does not discriminate against certain classes of enrollees. As part of this review, CMS will examine a formulary's classification system, unless the plan utilizes the United States Pharmacopeia (USP) Model Guidelines. CMS also will review how that formulary is populated (even if the plan's categories and classes are consistent with the Model Guidelines), using formularies from private plans, Medicaid, and federal employee health plans, as well as Medicare risk adjustment data and other information. Generally, CMS will look to widely-used best practices in the pharmacy benefit management industry to determine whether a plan's formulary meets the statutory and regulatory requirements. CMS's formulary review will focus on three areas: (1) P&T committees; (2) formulary review, including drug list review; and (3) benefit management tools.

The guiding principles for CMS's review of formularies are to:

- Ensure that plans provide access to medically necessary treatments
- Ensure that plans do not discriminate against any particular groups of beneficiaries
- Encourage proven approaches to drug benefit management that are in widespread use among prescription drug plans

A. Pharmacy & Therapeutics (“P&T”) Committees

1. Membership:

- (a) a majority of members must be practicing physicians, pharmacists, or both;
 - (b) at least one physician and one pharmacist must be experts in the care of the elderly or disabled; and
 - (c) the committee must represent various specialties that adequately represent the needs of plan beneficiaries, including representation of , high volume specialists.,,
2. Conflicts of Interest: At least one member pharmacist and one member physician must be independent and free of conflict with respect to the Part D plan *and with respect to pharmaceutical manufacturers*. P&T committee members that have certain non-employee relationships with manufacturers (for example, consulting, advisory, or research relationships) may be considered independent if those relationships do not comprise a significant source of income for that member and that member does not otherwise have any conflicts of interest. CMS does not provide guidance on what constitutes a significant source of income. All members should sign a conflict of interest statement revealing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions.
 3. P&T Committee Decisions as Binding: CMS makes a distinction between decisions that are solely clinical and decisions that involve both clinical and non-clinical factors. In the Final Rule, CMS clarifies that P&T committee decisions regarding which drugs are placed on a plan's formulary are binding on a plan, whereas P&T committee recommendations on issues such as utilization review, cost-sharing, generic substitution, quantity limits, therapeutic interchange, and evaluating treatment protocols should be considered advisory and not binding.
 4. Meeting frequency: Committees should meet on a regular basis, and not less than quarterly.
 5. New Drugs/New Indications: P&T Committees must only make a , reasonable effort,, to review a new chemical entity or new indication (approved by the Food and Drug Administration) within 90 days. The P&T Committee must make a decision on each new chemical entity or indication, within 180 days of the release onto the market of the new chemical entity or indication. If a P&T Committee fails to meet this timeframe for a decision,

it must provide a clinical justification. Plans must make new drugs available to enrollees more expeditiously when medically appropriate through the exceptions process.

B. Formulary Review

1. USP Safe Harbor: Plans utilizing a formulary classification system that is consistent with the model guidelines issued by the USP will satisfy a safe harbor and have their formulary classification system approved. In such cases the formulary must still undergo a drug list review and a benefit management tools review before the formulary will be approved.
2. Two Drugs Per Category/Class: The two drugs per category and class is a minimum standard, and regardless of the classification system a plan uses, the agency may require more than two drugs per category or class.
3. Outliers: CMS will look at formulary outliers to determine whether a formulary is discriminatory. Examples of outliers include lack of sufficient drugs in a class or inappropriate tier placement.
4. Drug List Review:
 - a. CMS will review formularies for at least one drug in each of the , Formulary Key Drug Types,, identified by USP. Plans may present a reasonable clinical justification for formularies that do not contain at least drug in each of these categories.
 - b. When developing a tier structure for its formulary, plans should utilize standard industry practices. Tier 1 should be the lowest cost-sharing tier, and any other tiers within the structure should be higher cost-sharing tiers in ascending order. CMS expects that drugs will be placed in a less preferable position only when drugs that are therapeutically similar (i.e., provide similar treatment outcomes) are in more preferable positions on the formulary.
 - c. CMS's review will focus on identifying drug categories that may discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions.
 - d. CMS will use national treatment guidelines as benchmarks in determining whether plan formularies

provide appropriate access to drugs. CMS provides a list of conditions (not all-inclusive) for which the agency will specifically use best practice guidelines to analyze whether the formulary provides appropriate access to drugs. CMS states that it expects that the drugs or drug classes included within these widely accepted guidelines will not place an undue burden on Part D plans since these drugs are usually placed in favorable positions on commonly used, best practice formularies.

- e. CMS expects that formularies will contain a majority of drugs within the following classes: antidepressants, antipsychotics, anticonvulsants, antiretrovirals, immunosuppressants, and antineoplastics. CMS will check to see that enrollees using drugs in one of these classes have ,uninterrupted access to all drugs in that class,, although this could include access through an exceptions process.
 - f. CMS will use Medicare risk adjustment data to assess whether proposed formularies are not including commonly used drugs or are placing such drugs in an unfavorable tier position. A similar assessment will be made for certain drug classes identified in Appendix A to the final formulary guidance. This list is derived from the Medicare Current Beneficiary Survey.
5. Long-Term Care (,LTC,,): Part D plans must provide medically necessary drugs to enrollees that are residents in LTC facilities.

C. Benefit Management Tools

1. Best Practices: CMS will look to best industry practices to evaluate plan use of utilization tools such as prior authorization, step therapy, quantity limitations, and generic substitution. CMS will seek justification when plans fall outside of best practices.
2. Drug Utilization Review (,DUR,,): CMS will review plan DUR practices to confirm that they meet best industry practices. Neither the final rule nor the final formulary guidance sets forth specific requirements for DUR.

Plans must submit formulary changes (additions, deletions, tier changes) to CMS as they occur. CMS will review these changes to ensure that formularies remain nondiscriminatory and meet other minimum standards.

III. Exceptions and Appeals Processes

A. **Exceptions:** Enrollees may seek exceptions to a drug's cost-sharing status or for drugs that are not on the plan's formulary. This process allows enrollees to seek non-preferred formulary drugs at the same cost-sharing level as a preferred formulary drug. Enrollees also may use the formulary process to request that a non-formulary drug be covered as a preferred formulary drug.

1. Exceptions for Non-Preferred Drugs: Plans must establish a process that includes the following: (1) the criteria that will be used to evaluate a physician's supporting statement of medical necessity; (2) a consideration of whether the requested drug has a therapeutic equivalent on the plan formulary; and (3) consideration of the number of formulary drugs in the same category and class as the requested drug. Plans must grant an exception when the plan determines that the requested drug is medically necessary for treatment of the enrollee's condition, consistent with the physician's supporting statement. If a plan grants the exception, the drug must be available at the cost-sharing level for preferred drugs.
2. Exceptions for Non-Formulary Drugs: Plans must establish an exceptions process that includes the following: (1) the criteria that will be used to evaluate a physician's supporting statement of medical necessity; (2) a process for addressing specific circumstances, such as formulary changes and cost utilization tools that result in non-coverage of a drug; (3) a process for gathering and comparing scientific and medical evidence to evaluate the safety and effectiveness of the requested drug and a preferred drug; and (4) a description of the cost-sharing that will apply if the exceptions request is granted. An enrollee may not seek an exception to the formulary tier for a non-formulary drug.
3. Timeframes: Plans must respond to exceptions requests within 72 hours (within 24 hours for expedited determinations, which are available in circumstances in which the standard timeframe may seriously jeopardize the health or life of the enrollee or the enrollee's ability to regain maximum function). A plan must complete a redetermination, where requested, within 7 days (72 hours for an expedited redetermination).
4. Emergency Supply of Medication: There is no requirement that a plan provide enrollees with an emergency supply of medication during the exceptions and appeals process.
5. Physician Supporting Statement: The statute requires a physician's supporting statement for tiering and non-formulary exceptions. This requires plans to obtain a supporting

statement from the prescribing physician that the preferred drug for the treatment of the same condition either would not be as effective for the enrollee, would have adverse effects for the enrollee, or both. This statement does not need to be in writing. A plan may require the prescribing physician to provide additional supporting medical documentation as part of a written follow-up. The physician's supporting statement, while required for an exceptions request, does not obligate a plan to automatically approve the exceptions request. CMS states that a physician's supporting statement should be given considerable weight.

6. High-Cost or Unique Products: The final regulations permit a plan to create a special tier for high cost and unique products, such as biologics, and exempt this special tier from the exceptions process.

B. Appeals: The exceptions process is just one type of coverage determination, that a plan may make and an enrollee may appeal. Other coverage determinations include: (1) failure to provide or pay for a covered Part D drug that the enrollee believes may be furnished by the plan (including failure to pay because the drug is not on formulary, the drug is determined not to be medically necessary, the drug is furnished by an out-of-network pharmacy); (2) failure to provide a coverage determination in a timely manner when such a delay would adversely affect the health of the enrollee; a decision on the amount of cost-sharing for a drug.

1. Prior Authorization: An enrollee may not appeal a plan's decision to place a drug on prior authorization. An enrollee may appeal a plan's determination of whether to cover the drug for the particular enrollee, however.
2. Who May Appeal: The following parties have the right to seek or appeal a coverage determination: (1) the enrollee; (2) the enrollee's appointed representative; (3) the prescribing physician, on behalf of the enrollee.
3. Written Notice: A plan sponsor must provide written notice of a denial. The notice must use appropriate notice language that is readable and understandable, state the specific reasons for the denial, and inform the enrollee of the right to seek a redetermination. For a coverage denial, the plan must explain the standard and expedited redetermination process and the rest of the appeals process. For payment denials, the plan must describe the standard redetermination process and the rest of

the appeals process. (An expedited determination is not available for payment for drugs already furnished).

IV. Low-Income Beneficiaries and States

A. Dual Eligibles: Individuals dually eligible for Medicare and Medicaid will no longer receive prescription drugs through the Medicaid program effective January 1, 2006. CMS will auto-enroll full benefit dual eligibles into Part D plans before January 1, 2006. CMS also will facilitate the enrollment of other beneficiaries eligible for low-income assistance. This may include prospective enrollment where beneficiary silence on CMS's suggested enrollment will be considered consent. CMS will issue further operational guidance on the enrollment assistance and procedures for these other low-income beneficiaries. Full benefit dual eligibles may enroll in or disenroll from a plan at any time.

B. State Contributions to Part D Costs for Dual Eligibles: When dual eligibles begin receiving prescription drug benefits through Part D, States will be required to make monthly payments to the federal government to defray a portion of the Medicare drug expenditures for these individuals. This is referred to as the ,clawback,, provision. State contributions will be phased-down over a 10-year period. For 2006, states will contribute 90% of an amount based on state Medicaid drug expenditures. This amount is calculated using a State's specified expenditures for 2003 and applying a growth factor. The payment formula includes adjustments to account both for rebates received by a State under the Medicaid program and for federal matching funds. The payment formula is based on a weighted average of the following:

1. Gross base 2003 Medicaid per capita expenditures, including dispensing fees, made by the State and reported in MSIS for covered outpatient drugs. This amount excludes drugs not covered by Part D. This amount is based on MSIS drug claims paid during 2003 and is before rebates and FMAP have been taken into account; and
2. Estimated actuarial value of prescription drug benefits provided under comprehensive capitated Medicaid managed care plans.

C. Long-Term Care ("LTC") Population:

1. LTC pharmacies: Plans must develop standard contracting terms and conditions, including performance and service criteria, to offer to all LTC pharmacies in the plan's service area. Plans must demonstrate to CMS that they have contracts with a sufficient number of LTC pharmacies to ensure convenient access to drugs for institutionalized beneficiaries within the

- service area. CMS will provide additional guidance that includes discussion of performance and service criteria, convenient access, and other issues relating to LTC pharmacies.
2. Special Enrollment Period (,SEP,,): There is a SEP for PDP enrollment and disenrollment for beneficiaries entering, living in or leaving an institution; for MA-PD enrollees, there is an unlimited open enrollment period for institutionalized individuals (,OEPI,,), although MA plans may choose not to participate.
 3. Dispensing Fees: The definition of dispensing fee applies to LTC pharmacies as well. Part D plans may pay these pharmacies under MTMPs for some of the special services provided by these pharmacies but not reimbursed through dispensing fees.

D. Medicare Advantage Special Needs Plans:

1. The MMA provided for the creation of several new types of managed care plans, including specialized MA plans for special needs individuals (,Special Needs Plans,, or ,SNPs,,). SNPs are MA plans that either exclusively enroll special needs individuals, or enroll a greater proportion of special needs individuals than occur nationally in the Medicare population. In order to be eligible to enroll in a SNP as a ,special needs individual,, a beneficiary must be otherwise eligible to enroll in an MA plan, and be (1) ,institutionalized,, (2) entitled to medical assistance under a State Medicaid plan, or (3) have a ,severe or disabling chronic condition,,. Under the Final Rule, SNPs are required to offer Part D coverage to all enrollees.
2. For purposes of eligibility to enroll in a SNP, ,institutionalized,, is defined as an individual who continuously resides or is expected to continuously reside for 90 days or longer in a skilled nursing facility (,SNF,,), nursing facility (,NF,,), SNF/NF, intermediate care facility for the mentally retarded (,ICF/MR,,), or an inpatient psychiatric unit. Under the Final Rule, individuals who reside in the community but require a level of care equivalent to those in one of the institutions listed above also can be considered ,institutionalized,,. CMS intentionally did not set forth a detailed definition of ,severe and disabling chronic condition,, because they wanted to maintain flexibility. In the Final Rule CMS indicates that the criteria the agency will consider in reviewing an application for a SNP include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against ,sicker,, members of

the target population. Payment for SNPs is determined under the same risk adjustment and other methodologies CMS uses for other types of Medicare Advantage plans.

E. State Pharmaceutical Assistance Programs (“SPAPs”):

1. Non-discrimination: SPAPs that assist Part D eligible individuals with prescription drug costs provide such assistance to enrollees in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls. This precludes an SPAP from designating a preferred Part D plan for its enrollees. SPAPs may provide their enrollees with educational information comparing all of the available Part D plans, including information on the following: which plans have lower premiums after application of any SPAP premium subsidy; which plan formularies cover the drugs utilized by the SPAP enrollee; which plans offer these drugs at the most favorable combination of deductibles, coinsurance, and negotiated prices; and which plans use the same pharmacy network as the SPAP.
2. Auto-enrollment: To the extent that an SPAP enrolls beneficiaries into Part D plans, it should do so in accordance with the process set forth in the Final Rule for random auto-enrollment. CMS may facilitate the enrollment of SPAP enrollees who do not select a Part D plan.
3. Coordination of Benefits: The statute authorizes CMS to establish procedures and requirements to promote coordination of benefits between Part D plans and SPAPs. CMS will issue these requirements by July 1, 2005.
4. Application: These rules apply to qualified SPAPs only. SPAPs that are not qualified are not subject to these restrictions; cost-sharing contributions from non-qualified SPAPs will not count towards TrOOP.

F. PACE: PACE (Program of All Inclusive Care for the Elderly) will be treated similar to local MA plans in that PACE enrollees will receive Part D benefits through the PACE plan if the plan offers such coverage. Although CMS did not extend auto-enrollment to PACE, individuals who are in PACE plans as of December 31, 2005, will be deemed enrolled with that organization for their Part D benefit as of January 1, 2006.