

The Basics

Prescription Drug Formularies

A formulary is a list of prescription drugs that has been approved by a state, health plan, or hospital and can be dispensed without prior authorization. Formularies have long been used to control the cost and utilization of prescription drugs. Some formularies are more restrictive than others: "Open" formularies provide coverage for both listed and nonlisted drugs (although physicians are encouraged to prescribe those drugs that are included on the list). "Closed" formularies generally provide coverage only for drugs that are included on the list. Many other formulary approaches fall somewhere in between, encouraging the use of listed drugs by charging higher copayments for those not listed. Under a tiered cost-sharing approach, for example, generic and "preferred" drugs require lower copayments than brand name and nonpreferred drugs. Formulary processes typically include procedures that enable access to nonformulary drugs when they are medically necessary and allow patients to appeal coverage decisions.

HOW DO MEDICAID PROGRAMS USE FORMULARIES?

Federal Medicaid law permits states to use formularies but places some requirements on their establishment. These requirements, found in Section 1927(d)(4) of the Social Security Act (SSA), include the following:

- The formulary must be developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the state's governor or by the state's drug use review board.
- The formulary must include all covered outpatient drugs of any manufacturer that has entered into a rebate agreement with the federal government.
- A covered drug may be excluded from the formulary if it "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome...over other drugs included in the formulary." In such cases, a publicly available written explanation must be provided.
- A state must have in place a prior authorization program (that meets the requirements set forth in federal Medicaid law) that permits coverage of an otherwise excluded drug.
- The formulary must meet other requirements imposed in order "to achieve program savings consistent with protecting the health of program beneficiaries."

HOW WILL NEW LAW USE FORMULARIES?

The recently enacted Medicare Prescription Drug, Improvement, and Modernization Act of 2003 permits sponsors of prescription drug plans and Medicare Advantage prescription drug plans to develop and use drug formularies, including the use of tiered cost-sharing. Among the key provisions are the following:

Formulary Development and Management

- A formulary must be established by a pharmacy and therapeutic (P&T) committee which includes a majority of practicing physicians and/or pharmacists. At least one physician and one pharmacist on the committee must be independent of the sponsoring plan and have expertise in the care of the elderly or the disabled.
- In developing and reviewing the formulary, the committee must make clinical decisions based on “the strength of scientific evidence and standards of practice” and, when determining which drugs should be included in the formulary, the committee must consider whether certain covered drugs provide “therapeutic advantages in terms of safety and efficacy.”
- Drugs in each therapeutic category and class of covered drugs must be included in the formulary; changes to formulary categories and classes may only be made at the beginning of each plan year.
- Plan sponsors may utilize other entities to develop and manage their formulary.

Provider and Patient Education

- Plan sponsors must educate providers and patients about the formulary and “appropriate” notice must be given before a drug may be removed from the formulary or before a drug’s preferred status is changed.
- Plan sponsors must disclose to beneficiaries, at the time of enrollment and at least annually, information about how the plan’s formulary works, including tiered cost sharing and its application to specific drugs. Plan sponsors must also make available to beneficiaries, through an Internet Web site, information related to changes in the formulary, including changes to the tiered status of a drug.

Exceptions/Appeals

- Beneficiaries may request that a nonpreferred drug be treated as a preferred drug in cases where different cost sharing applies if the prescribing physician determines that the preferred drug(s) (*a*) would not be as effective as the nonpreferred drug or (*b*) would have adverse effects for the beneficiary—or both. A plan sponsor must have an exceptions process for these situations, and denials of exceptions must be subject to an appeals process.

Calculation of Out-of-Pocket Costs

- The cost of prescription drugs not included in a plan’s formulary does not count for purposes of calculating a beneficiary’s out-of-pocket expenditures.

For more information:

- Section 1860D-4 of the SSA, as enacted by section 101 of P.L. 108-173.
- Section 1927(d)(4) of the SSA.