
MID-YEAR FORMULARY CHANGES

Although access to comprehensive, accurate formularies is particularly important when consumers are shopping for coverage, formulary transparency remains important throughout the year since consumer health needs change over time. Despite the need for ongoing transparency and formulary stability, many plans change their formularies during the course of a plan year. Changes may be made as new drugs are added to the market or as utilization, pricing, and medical knowledge evolves over time.

Mid-year formulary changes can have significant consequences for consumers. This is particularly true when plans remove a drug from a formulary altogether, move a drug to a higher level tier, otherwise increase cost-sharing for a drug, or impose more restrictive UM than what was originally in place when a consumer selected a plan. Because a change in drug coverage does not result in eligibility for a special enrollment period, many consumers who lose access to a drug through a mid-year formulary change will remain locked in a plan that does not meet their health needs. Some enrollees may receive continued access to their medication through the plan's exceptions process, but many enrollees are not aware of this option and not all exception requests are granted.

Mid-year formulary changes are occurring in marketplace plans. According to an Avalere study of formularies in all 50 states and DC, nearly half of analyzed plans revised their formularies between October 2013 and September 2014.²¹⁹ Although the study did not find widespread negative mid-year changes in 2014, some plans dramatically reduced drug coverage for at least four classes of medication used to treat cancer, diabetes, multiple sclerosis, and asthma. Of the 41 plans that changed their formularies, 33 reduced drug coverage for at least one of these four classes of medication.²²⁰ Six of these plans—18 percent—made significant drug coverage reductions, removing between 15 and 57 products during the plan year, and five of these plans saw drug coverage fall in at least one class by more than 15 percent.²²¹ Given these findings—and continued incentives for plans to limit adverse selection—regulators should remain vigilant in monitoring mid-year formulary changes.

Plans should have flexibility to make some mid-year formulary changes, such as adding newly approved drugs or biologics, removing drugs from a formulary after the FDA deems a drug unsafe, or eliminating UM requirements. These formulary changes have the potential to enhance consumer coverage, rather than detract from it, and should be allowed at any time.

However, plans should not be able to reduce the generosity of coverage after a consumer has enrolled. In particular, plans should be prohibited from making mid-year formulary changes—changes made between the date on which open enrollment begins and the end of the plan year—that negatively affect enrollee access to drugs. Such negative changes include:

- Removing a covered drug from a formulary except when the FDA deems a drug unsafe or a manufacturer removes a drug from the market;
- Moving a drug to a higher formulary tier or otherwise imposing higher cost-sharing;
or
- Imposing more restrictive UM.

Although we strongly recommend that regulators prohibit mid-year formulary changes that reduce drug coverage, states that continue to allow this practice should adopt additional consumer protections. First, if a plan is removing a drug from its formulary, the plan should be required to continue covering that drug for all affected enrollees at the same cost-sharing level for the remainder of the year, a requirement adopted in Medicare Part D (Figure 22). Alternatively, states should allow a special enrollment period for enrollees who lose access to a needed drug due to a mid-year formulary change. Second, state insurance regulators should review and approve any mid-year formulary change that negatively affects enrollee access prior to the change being implemented to ensure that it does not discriminate against enrollees with significant health conditions or on other bases that are prohibited under the Affordable Care Act. In addition, insurers and their designees should be required to provide at least 60 days advance notice to enrollees, prescribers, and in-network pharmacies when making a mid-year formulary change. In particular, notices should include easy-to-understand information about the plan's drug exceptions processes and how a consumer can begin the process of securing an exception.

FIGURE 22:
Mid-Year Formulary Changes in Medicare Part D

Medicare has recognized the importance of formulary stability and imposes a number of limitations on mid-year formulary changes for drugs covered under Medicare Part D. Key components of the policy include the following:

- Part D sponsors can expand coverage at any time by adding drugs, reducing cost-sharing, or deleting UM.
- Part D sponsors must seek CMS approval for negative formulary changes, including removal of a drug from a formulary, higher cost-sharing, or new or more restrictive UM. Even if approved, affected enrollees are exempt from the change for the remainder of the plan year.
- Part D sponsors must provide 60 days advance written notice of an approved negative change to affected enrollees, pharmacies, and other stakeholders.

Source(s): Centers for Medicare and Medicaid Services, Chapter 6: Part D Drugs and Formulary Requirements, Medicare Prescription Drug Benefit Manual (Rev. 18, Jan. 2016).

State Action.

A number of states have prohibited or limited mid-year formulary changes or required insurers that do make such changes to notify consumers. Texas, for instance, enacted legislation to prohibit most mid-year formulary changes except at the time of coverage renewal (Figure 23). Even then, insurers must comply with additional requirements, such as notifying each affected enrollee and group sponsor and ensuring that the change is made uniformly across all identical or similar plans.

Nevada similarly prohibits most mid-year formulary changes but did so through the regulatory process. In 2015, the Nevada Division of Insurance promulgated regulations to prohibit insurers in the individual market from removing a drug from a formulary during the plan year except in limited circumstances.²²² Insurers are similarly prohibited from moving a drug to a tier with higher cost-sharing unless the insurer adds a generic alternative at the same tier or a lower tier during the plan year. The regulations allow insurers to add a drug to a formulary at any time.

FIGURE 23:

Texas Limits Mid-Year Formulary Changes

Individual and group health benefit plans in Texas have been prohibited from making mid-year formulary changes since January 1, 2012. Prohibited changes include:

- Removing a drug from a formulary;
- Adding a requirement that an enrollee receive prior authorization for a drug;
- Imposing or altering a quantity limit for a drug;
- Imposing a step-therapy restriction for a drug; and
- Moving a drug to a higher cost-sharing tier unless a generic alternative is available.

Under Texas law, these changes can only be made at renewal and must be adopted uniformly for all individuals or groups covered by identical or substantially identical plans. Insurers must also provide at least 60 days advance notice to state regulators and each affected enrollee before the change goes into effect.

Source(s): Tex. Ins. Code §§ 1369.0541, 1501.108

In promulgating these regulations, the Nevada Division of Insurance cited its authority to review and approve policy forms and develop standards on fair marketing and health plan availability. Since many states have comparable protections, other states could consider a similar regulatory approach to limiting mid-year formulary changes.

Other states have limited but not prohibited mid-year formulary changes. In New Mexico, plans cannot make most mid-year formulary changes within 120 days of any previous changes.²²³ Such changes include removing a drug from a formulary, reclassifying a drug to a higher tier, imposing higher cost-sharing, or adopting or modifying certain UM restrictions. Insurers that make such changes have to notify affected enrollees at least 60 days in advance of the change.

Arkansas, Oklahoma, and Virginia have adopted similar notice requirements. In Arkansas, insurers and their designees must provide affected enrollees with at least 60 days advance written notice of a mid-year formulary change that increases an enrollee's financial responsibility.²²⁴ Oklahoma imposes similar requirements but only when a drug is being removed from a formulary.²²⁵ And Virginia requires insurers to provide at least 30 days advance written notice when moving a drug to a tier with higher cost-sharing requirements.²²⁶ Virginia also requires insurers to establish a process for enrollees to obtain continued access to drugs that they have been receiving for at least six months prior to a formulary change at a cost-sharing level that is no higher than the level imposed on formulary drugs.²²⁷ For more information on continuity of drug coverage, please see the section of this report on "Improving Access to Comprehensive Prescription Drug Coverage."

Federal Standards.

HHS has indicated that it is concerned about mid-year formulary changes, especially those that negatively affect enrollees.²²⁸ Although HHS has not prohibited mid-year formulary changes for QHPs, federal regulators have noted that insurers "generally may not make plan design changes, including changes to drug formularies, other than at the time of plan renewal" under guaranteed renewability requirements.²²⁹

In addition, HHS has required plans to provide a standard drug exceptions process, which allows an enrollee to request and potentially gain access to a medically necessary drug that is no longer covered under the formulary.²³⁰ This presents an opportunity for some enrollees to receive continued access to their medication; however, not all enrollees are aware of this option and not all exception requests are granted. For more information on exceptions and appeals processes, please see the section of this report on “Improving Access to Comprehensive Prescription Drug Coverage.”

Some mid-year formulary changes may implicate the Affordable Care Act’s nondiscrimination protections. This is particularly true if changes are imposed in a way that disproportionately burdens individuals with chronic conditions. For more information on discriminatory benefit design, please see the section of this report on “Nondiscrimination in Formulary Design.”



CONSUMER
RECOMMENDATIONS

Consumer Recommendations on Mid-Year Formulary Changes

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Allow insurers and designees to add new products—including drugs, biologics, and biosimilars—at any time during the plan year.
- Prohibit insurers and their designees from making mid-year formulary changes—changes made between the date on which open enrollment begins and the end of the plan year—that negatively affect enrollee access to drugs, including:
 - Removing a covered drug from a formulary except when the FDA deems a drug unsafe or a manufacturer removes a drug from the market;
 - Moving a drug to a higher formulary tier or otherwise imposing higher cost-sharing; or
 - Imposing new or more restrictive UM requirements.

CONSUMER SUPPORT TOOLS

Consumer-facing support tools—such as formulary search tools or other “smart tools” with interactive features—can increase consumer knowledge, satisfaction with the decision process, and selection of a plan that aligns with the consumer’s needs and preferences.²³¹ These tools can help fill significant gaps in consumer knowledge and highlight the need to consider certain plan elements, such as prescription drug coverage, to a consumer who might be unaware that benefits can vary dramatically by plan (Figure 24). Such tools may also be critical to attracting and retaining young people who expect to use consumer support tools to simplify their options and make a coverage decision.

Although decision support tools can be very valuable to consumers, the quality of these tools depends on the availability of meaningful and relevant content.²³² One consistent barrier to developing effective consumer support tools is a lack of relevant and standardized content. This barrier is particularly relevant to the development of drug-specific support tools since there are few standardized machine-readable formats or reporting requirements for formularies.²³³

FIGURE 24:

Gaps in Consumer Knowledge

Consumers have significant gaps in knowledge about prescription drug coverage. In 2015, a report commissioned by the California HealthCare Foundation found that consumers were unfamiliar with common drug-specific coverage terms and highlighted the following examples:

- Most consumers did not know the term “formulary” and those who did were uncertain of its definition.
- Coinsurance was often mistaken for being secondary insurance.
- Drug tiers were often confused with metal level tiers.
- Consumers assumed that a preferred drug (compared to a nonpreferred drug) indicated a better drug rather than one with reduced cost-sharing.
- Consumers were unfamiliar with exception or appeals processes and could not find this information.

Source(s): HSM Group, Hidden from View: How Consumers Find Information About Prescription Coverage, California HealthCare Foundation (Aug. 2015).

Given the need for standardization, state and federal regulators can play a key role in requiring all plans to submit accurate, comparable formulary data. Marketwide data collection is particularly important because most consumers—57 percent of the individual market and 95 percent of the small employer market—are enrolled in plans sold outside the marketplaces.²³⁴ State regulators, in particular, can leverage their form review processes to require the submission of comparable formulary data and can ensure that State Electronic Rates and Forms Filing System data is accurate, reported consistently across plans and states, and submitted in a standardized machine-readable format.²³⁵

Marketplaces can use the data they have to develop prescription drug tools, as the federal marketplace and some state-based marketplaces have already done. The federal marketplace has, for instance, developed an integrated prescription drug directory that allows a consumer to enter the names of their medications and select the appropriate dosage amounts. The resulting plan options then identify whether each drug is covered by a given plan or not. The state-based marketplace in Colorado similarly developed a “medication look-up” tool where a consumer can enter the names of their medications. The marketplace then shows plans that cover those medications and links to a summary of each plan’s formulary and coverage of that medication, including cost-sharing requirements, the availability of mail-order prescription filling, and whether a generic drug is available. Such tools can allow consumers to easily and quickly see which plans cover their medications.

Marketplaces can also ensure that other tools—even where not drug-specific—incorporate information about covered medications, cost, and other information that consumers need to know to make an informed decision. These other tools may include cost calculators or the health condition consumer support tool used by the state-based marketplace in Connecticut. This tool allows a consumer to select options from a drop-down list about their health condition (e.g., asthma), any planned surgeries (e.g., total hip replacement), and the severity of their condition (e.g., low, moderate, or high). The tool then provides total cost ranges for plans on each metal level tier and projected premiums and out-of-pocket costs, including medical and pharmacy services.

FIGURE 25:

Importance of Consumer Testing

Consumer support tools are only as useful as their design and functionality. Tool design and presentation should account for consumer needs and preferences as well as consumer literacy, the intended use of the tool, and the complexity of the information.

Testing throughout the development process—including initial and post-launch focus groups, beta testing, and interviews with consumers—helps ensure that data displays, interactive features, and other design elements meet consumer needs. Given the importance of testing to ensuring that tools are well-understood and valued by consumers, we strongly encourage the use of consumer testing throughout any consumer support tool development process.

Consumer support tools are used in other federal health programs and the private sector. A prominent example is the Medicare Plan Finder, which allows Medicare-eligible consumers to enter the name of a drug as well as the dosage, quantity, frequency, and pharmacy type for each individual drug. This information is then used to sort various plan options and can be saved, edited, and compared across plans. In recent consumer testing, the Medicare Plan Finder was praised by consumers, even as compared to the Colorado marketplace tool and existing California marketplace displays, and could be a helpful example upon which to base future formulary tools.²³⁶ For more information on the importance of consumer testing, see Figure 25. Private sector examples of consumer support tools include the Consumers' Checkbook, Stride Health, and Clear Health Analytics, among others.²³⁷ Most of these tools allow for the consideration of drug-specific information.



CONSUMER
RECOMMENDATIONS

Consumer Recommendations on Consumer Support Tools

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Require insurers to use standardized formulary display requirements and submit formulary information in machine-readable formats so that designers of consumer tools and apps have full access to the data necessary to develop robust consumer support tools.
- Ensure that all plans in the individual and small group markets submit data on prescription drug benefits in the same machine-readable standardized formats at least 60 days prior to open enrollment each year and make this data available to the public.
- Develop electronically searchable, consumer-tested plan comparison tools that allow consumers to search for plans that cover their drugs and accurately calculate out-of-pocket costs.
- Promote the availability of consumer support tools among consumers, consumer and patient advocates, enrollment assisters, producers, and other stakeholders.