



QUESTIONS ON PHARMACY BENEFIT MANAGERS AND FORMULARIES

By: Janet Kaminski Leduc, Senior Legislative Attorney

ISSUE

This report addresses questions relating to pharmacy benefit managers and formularies. The specific questions and answers follow.

What are pharmacy benefit managers (PBMs)?

PBMs administer the prescription drug, prescription device, or pharmacist services portion of a health benefit plan on behalf of plan sponsors (e.g., self-insured employers, insurance companies, labor unions, or HMOs) ([CGS § 38a-479aaa](#)).

Does the state regulate PBMs?

State law requires PBMs, with some exceptions, to obtain a certificate of registration from the insurance commissioner before operating in Connecticut ([CGS § 38a-479bbb](#)). PBMs must renew the registration annually. The law exempts from the registration requirement a PBM that is a line of business or affiliate of a Connecticut-licensed health insurer, HMO, hospital or medical service corporation, or fraternal benefit society.

To apply for registration, a PBM must give the Connecticut Insurance Department (CID) a completed application with information on the people running the PBM, a nonrefundable \$50 fee, and evidence of a surety bond between \$25,000 and \$1 million ([CGS § 38a-479bbb](#)). The PBM may request a hearing if the department denies registration ([CGS § 38a-479ddd](#)).

The law permits the commissioner, after notice and hearing, to suspend, revoke, or deny registration for specified causes, including unfair or deceptive business practices ([CGS § 38a-479ccc](#)). Anyone aggrieved by the commissioner's decisions may appeal to Superior Court.



In addition to registering with the department, PBMs must, upon written request from a pharmacy, pay claims to the pharmacy by electronic funds transfer ([CGS § 38a-479eee](#)). Such payments must be made in a timely fashion (e.g., within 60 days from receipt for claims filed in a paper format and within 20 days from receipt for claims filed electronically) (CGS §§ [38a-479eee](#) and [38a-816\(15\)\(B\)](#)).

Lastly, PBMs are subject to investigation by the insurance commissioner ([CGS § 38a-479hhh](#)).

What does "formulary limiting" mean?

A formulary is the list of prescription drugs that a health plan will cover. Formulary limiting broadly refers to the practice of limiting, changing, or reclassifying drugs on the formulary.

As new drugs become available to consumers or the price of existing drugs increase or decrease, insurers may update their formulary by adding or removing drugs, or moving drugs between different cost "tiers." Drugs placed in a higher tier may require an insured to (1) pay a higher out-of-pocket cost or (2) try a different, lower-tiered drug first, before insurance covers the higher-tiered drug (a process known as "step therapy").

According to CID, no Connecticut statute or regulation governs how often plans may change formularies. (For related information, see [OLR Report 2014-R-0291](#).) The department notes that health carriers (e.g., insurers and HMOs) generally describe formulary changes as either negative (non-advantageous) or positive (advantageous) for the consumer. For example, a negative formulary change may include shrinking the formulary, while a positive change may include adding new drugs on a lower cost tier. In practice, most insurers in Connecticut change formularies (1) negatively once or twice a year and (2) positively as needed. Some companies, however, update their formularies continuously, whether negatively or positively.

Can a health carrier or PBM switch an insured's medication during a contract year or increase a drug's co-payment at any time?

According to CID, if they use step therapy protocols, health carriers or PBMs may require an insured to switch medication, but they would do this only at the time the drug is filled. However, only a physician, physician assistant, advanced practice registered nurse, or other prescribing authority may write a new prescription for a patient.

Contractually, a health carrier cannot change the copayments charged for each tier during a plan year. However, a carrier can change the tier a drug is on at any time, which could increase or decrease the drug's copayment.

What recommendations did consumer advocates make in August 2016 about mid-year formulary changes?

In August 2016, consumer representatives issued a report recommending ways to improve access to prescription drugs. The report made a series of recommendations on ways to promote access, affordability, nondiscrimination, transparency, and oversight of prescription drug coverage. (See *Promoting Access to Affordable Prescription Drugs: Policy Analysis and Consumer Recommendations for State Policymakers, Consumer Advocates, and Health Care Stakeholders* at http://consumersunion.org/wp-content/uploads/2016/08/Promoting-Access-to-Affordable-Prescription-Drugs_Aug-2016.pdf.)

The report authors note that many health plans change their formularies during the course of a plan year. Mid-year formulary changes may be to (1) add or remove a drug from the formulary; (2) move a drug to a higher tier with a higher cost-sharing requirement; (3) otherwise increase the cost-sharing for a drug; or (4) impose more restrictive utilization management (UM) (e.g., prior authorization) requirements.

The authors recommend that plans have the flexibility to make some mid-year formulary changes, such as adding newly approved drugs, removing drugs that the U.S. Food and Drug Administration (FDA) deems unsafe, or eliminating UM requirements. However, they further recommend that plans be prohibited from making formulary changes that negatively affect plan enrollees. These include:

1. removing a covered drug from the formulary except when the FDA deems it unsafe or the manufacturer removes the drug from the market,
2. moving a drug to a higher tier or otherwise imposing higher cost-sharing, or
3. imposing more restrictive UM requirements.

For states that continue to allow plans to make mid-year formulary changes that reduce drug coverage for consumers, the authors recommend the following:

1. when removing a drug from a formulary, the plan should be required to either continue covering the drug for all affected enrollees at the same cost-sharing level for the remainder of the plan year or allow a special enrollment period to allow affected enrollees to change plans;

2. state insurance regulators should review and approve a mid-year formulary change that negatively affects enrollees before the change is implemented to ensure it does not discriminate against enrollees with significant health conditions; and
3. plans should provide at least 60 days advance notice to enrollees, prescribing providers, and in-network pharmacies when making a mid-year formulary change, and such notice should describe the plan's drug exceptions process (e.g., how an enrollee can request an exception from the change).

Summarize the Texas law that prohibits mid-year formulary changes.

Texas law generally prohibits mid-year formulary changes ([Tex. Ins. Code Ann. § 1369.0541](#)). Under the Texas law, individual and group health plans can make formulary changes only if:

1. the change is made at the plan's renewal date;
2. the change is effective uniformly for all individuals and groups covered by identical or substantially identical plans; and
3. the plan issuer provides at least 60 days advance written notice to state insurance regulators, plan sponsors, and enrollees.

Formulary changes subject to the restrictions include:

1. removing a drug from a formulary;
2. adding a requirement that an enrollee receive prior authorization for a drug;
3. imposing or altering a quantity limit for a drug;
4. imposing a step-therapy (e.g., fail first) restriction for a drug; and
5. moving a drug to a higher cost-sharing tier unless a generic alternative is available.

Have other states limited when insurers may make formulary changes?

Yes. Louisiana, Nevada, and New Mexico limit when insurers may change their formularies, according to the National Conference of State Legislatures (NCSL). Louisiana and Nevada do so through regulations, while New Mexico's restrictions are in statute. For details of these restrictions, see [OLR Report 2016-R-0090](#).

How does Connecticut law protect people from formulary changes?

In Connecticut, insurers may make formulary changes during a policy's term. But the law prohibits them from denying coverage for any drug removed from a formulary if the (1) insured enrollee was using the drug to treat a chronic illness and it had been covered before the removal and (2) enrollee's attending physician states in writing (a) that the drug is medically necessary and (b) why it is more beneficial than other drugs on the formulary (CGS §§ [38a-492f](#) and [38a-518f](#)).

State law also requires insurers using step-therapy protocols to have a process in place by which an insured's treating health care provider may request and receive an override of the step-therapy restrictions. The law also prohibits an insurer's use of step therapy for any prescribed drug for more than 60 days (CGS §§ [38a-510](#) and [38a-544](#)).

Additionally, federal regulations require all insurance contracts that have formularies to include procedures that allow an insured to request and gain access to clinically appropriate drugs not covered by the plan. This requirement, known as the "exceptions process," applies to drugs not included on the plan's formulary ([45 CFR 156.122\(c\)](#)).

Has legislation been proposed in Connecticut to limit when insurers may make formulary changes?

Yes. In 2016 the legislature considered [SB 373](#), which limited when insurers could make formulary changes. Under the bill, insurers could not remove a covered drug from a formulary or reclassify a drug into a higher cost-sharing tier during an insurance policy's term. However, the bill allowed insurers to remove a drug from a formulary at any time if it is deemed no longer safe and effective by the FDA or peer-reviewed medical literature generally recognized by the relevant medical community. Additionally, the bill allowed insurers to add drugs to the formulary during a policy term, as long as doing so would not affect the coverage or cost-sharing requirements for drugs already on the formulary. (The Senate referred the bill to the Appropriations Committee, where it died.)

Does Connecticut have a "sunshine law" that requires insurers or PBMs to disclose financial incentives to pharmacists or prescribers? Do any other states require such disclosure?

Broadly, sunshine laws require disclosure of conflicts of interest. Under a federal law commonly referred to as the Sunshine Act (§ 6002 of the Affordable Care Act), pharmacy manufacturers must report to the Centers for Medicare and Medicaid

Services (CMS) any payments, gifts, and other transfers of value to physicians and hospitals. CMS must publish the information on a public website.

We found no state or federal law requiring health insurers or PBMs to disclose financial incentives to pharmacists or prescribing health care providers. NCSL informed us that Massachusetts proposed a bill in 2015 that would have required insurers and PBMs to disclose to patients any financial inducement or reward offered to a practitioner for switching to a therapeutically equivalent drug in place of a drug the practitioner prescribed ([HB 2054](#)). The bill was not enacted.

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