

## Prescription Drug Formulary Changes

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### Issue

Provide a summary and comparison of 2019 legislation considered by the Connecticut and New York legislatures on prescription drug formulary changes. Also provide (1) a brief description of utilization management and formulary cost saving measures commonly used by health insurers and pharmacy benefit managers (PBMs) and (2) the number of New England states that restrict mid-year formulary changes and non-medical switching.

### Summary

A formulary is a list of prescription drugs covered by a health insurance plan, and often categorizes the drugs into different cost sharing levels called “tiers.” As the cost of prescription drugs [rises](#), many states have considered legislation to either reduce their cost or allow insureds to more effectively plan their health care spending by limiting formulary changes. In 2019, legislation considered in Connecticut (HB 6096) and New York (A-2969 and S-2849) generally would have prohibited health carriers from adversely changing a formulary during a plan-year (e.g., moving a prescription drug into a higher cost-sharing tier). The legislation also would have required carriers to notify patients and make exceptions for prescription drugs with generic equivalents or newly documented safety concerns. In general, the bills were supported in both states by patient advocates and opposed by health carriers citing concerns that limiting formulary flexibility would increase costs for all insureds.

In addition to formulary changes, health carriers (i.e., insurers and HMOs) and PBMs use utilization management (UM) tools to lower costs for insurers, insureds, or both. Examples of these tools include prior authorization, high-cost case management, and step therapy, which requires providers to prescribe drugs in a certain sequence. However, research is mixed on how UM tools affect the cost of prescription drugs.

Non-medical switching is when a patient or medical provider changes a stable patient's prescription mid-year for financial or non-medical reasons. This often occurs because of (1) a mid-year change in the patient's formulary or insurance plan or (2) the availability of a less expensive but therapeutically equivalent drug. We were unable to find any New England states that prohibit mid-year formulary switching, including non-medical switching, although Maine and Rhode Island impose certain notification requirements when a formulary is changed.

## **Prescription Drug Formulary Legislation in Connecticut and New York**

### ***Connecticut***

In 2019, the Connecticut legislature considered, but did not pass, [HB 6096](#). The bill, as amended by House Amendment "A," would have generally prohibited health carriers (e.g., insurers and HMOs) from removing a prescription drug from a formulary or reclassifying a prescription drug to a higher cost sharing tier during the plan year.

However, the bill would have allowed a carrier to remove or reclassify a drug under three circumstances. First, a carrier could do so only if it notified the patient and his or her treating physician at least 90 days before taking such action, and second, if the Food and Drug Administration (FDA):

1. questioned the drug's clinical safety (unless the treating physician stated in writing that the drug remained medically necessary for the patient) or
2. approved the drug for over-the-counter use.

The bill also would have permitted a carrier to (1) reclassify a drug to a higher cost-sharing tier if it was available for \$40 or less per month in any tier or (2) move a brand name drug to a higher cost-sharing tier if it added a lower-cost, FDA-approved, generic alternative to the formulary. The bill also explicitly authorized a carrier to add a prescription drug to a formulary at any time.

Existing law already prohibits health carriers from denying coverage for any drug removed from a formulary if (1) an insured person was using the drug to treat a chronic illness that had been covered before the removal and (2) his or her attending physician states in writing, after the removal, that the drug is medically necessary and why it is more beneficial than other formulary drugs ([CGS §§ 38a-492f](#) & [38a-518f](#)).

***Legislative History.*** The original bill ([HB 6096](#)) was supported by the Healthcare Advocate, Connecticut Orthopedic Society, and Connecticut Legal Rights Project, Inc., among others. It was

opposed by the Connecticut Conference of Municipalities, and Connecticare, among others. The Insurance and Real Estate Committee favorably reported it on March 19, 2019, by a vote of 16-4.

House Amendment “A” was introduced on June 1, 2019, by Representative Cook and adopted by a voice vote. The amendment replaced the underlying bill and added the provisions (1) allowing a carrier to move a drug to a higher cost-sharing tier if the drug was available for \$40 or less in any tier and (2) requiring carriers to provide patients and providers 90-days’ notice before removing or reclassifying a drug.

In bringing out the amendment, Rep. Cook argued that limiting formulary changes was good public policy and that the negative consequences of these changes could put people in a downward spiral. Rep. Pavalock-D’Amato agreed with the bill’s intent but expressed concern that the added costs would be passed onto consumers. Debate on the amendment was limited to the 90-day notification provision. The amended bill passed by a vote of 121-22 and referred to the Senate, which took no action.

### ***New York***

In 2019, the New York legislature passed two bills (A-2969 and S-2849), that generally prohibit federal Affordable Care Act compliant health insurance plans (i.e., non-grandfathered plans) from, during a plan year (1) removing a prescription drug from a formulary, (2) moving a prescription drug to a formulary tier with higher cost-sharing, or (3) adding utilization management restrictions to existing prescription drug coverage (e.g., prior authorization or step-therapy requirements). However, the bills allow insurers to (1) move prescription drugs to higher cost-sharing tiers if a generic version or interchangeable biologic of the drug was added and (2) remove prescription drugs from the formulary if the FDA determined they were unsafe. Under the bills, insurers are required to provide insureds at least 30 days’ notice on any formulary or tier changes occurring for a new, upcoming plan year and post the changes on its website.

***Legislative History.*** A-2969 was favorably reported by the House Insurance Committee on May 21, 2019, by a unanimous vote. It subsequently unanimously passed the Codes Committee on June 4, 2019, and the Rules Committee the following day. The House of Representatives passed the bill on June 17, 2019.

S-2849 was favorably reported by the Senate Insurance Committee on April 29, 2019, and was amended on the Senate floor. The amended legislation (A-2969) then passed the Senate on June 19, 2019. The governor vetoed it on December 23, 2019.

Neither bill received a public hearing but were both [supported](#) by the Medical Society of New York, [AARP New York](#), and at least [35 other medical groups](#). The bills were opposed by [The Business Council of New York](#), [New York Blue Cross and Blue Shield](#), and the [New York Health Plan Association](#), among others.

According to the Assembly debate transcript for [A-2969](#), opponents of the bill expressed concern over the collective bargaining provisions and of possible unintended consequences, such as insurers using multiple formularies for a plan year. The bill’s proponents argued that it was necessary to protect consumers’ rights. S-2849 was not debated in either chamber.

### ***Comparison of Connecticut and New York Legislation***

The Connecticut and New York bills described above are substantially similar, as shown in Table 1 below. Both generally prohibit adverse mid-year formulary changes but allow carriers to remove prescription drugs from formularies for safety concerns or shift them to higher cost-sharing tiers if a generic version is also added to a lower cost tier. Connecticut has a longer notification period of 90 days for formulary changes but limits the bill’s formulary tier provisions only to prescription drugs costing more than \$40 per month. Both New York bills include utilization management and collective bargaining provisions that are not present in Connecticut’s bill. Neither states’ bills address PBM or prescription drug manufacturer contracts.

**Table 1: Comparison of Connecticut and New York 2019 Formulary Bill Provisions**

<b><i>Bill Provisions</i></b>	<b><i>HB 6096 as Amended by House 'A'</i></b>	<b><i>NYS A-2969 &amp; S-2849</i></b>
Explicitly allows carriers to add new drugs to a formulary mid-year	Yes	No
Allows carriers to remove drugs from formularies at any time for safety concerns	Yes	Yes
Generally prohibits carriers from moving drugs to higher cost sharing formulary tiers	Yes, for prescription drugs that cost over \$40 per month	Yes
Allows carriers to move drugs to higher cost sharing tiers if generic versions are added to the formulary	Yes	Yes

**Table 1 (continued)**

<i>Bill Provisions</i>	<i>HB 6096 as Amended by House 'A'</i>	<i>NYS A-2969 &amp; S-2849</i>
Imposes notice requirements for formulary changes	90 days before a drug is removed from a formulary or moved to a new tier	30 days prior to the start of the new plan year
Includes PBM contracting provisions	No	No
Prohibits utilization management	No	Yes, generally prohibits adding utilization management restrictions to existing prescription drug coverage
Includes collective bargaining provisions	No	Yes, specifically provides that the bill does not supersede the rights to collectively bargain formulary changes

## Utilization Management

Insurers and PBMs use several different utilization management (UM) tools that may lower costs for insurers, insureds, or both. UM is a set of tools that manage health care costs by assessing the medical necessity, appropriateness, setting (e.g., hospital or outpatient clinic), and efficacy of health care procedures.

Examples of utilization management include:

1. step therapy, which requires providers to prescribe drugs in a certain sequence (e.g., requiring an insured to try the first drug in a sequence before an insurer covers the second drug);
2. prior authorization;
3. prospective, concurrent, or retrospective benefit reviews that assess a covered service's appropriateness, setting, and medical necessity; and
4. high-cost case management (e.g., additional requirements or incentives for specific high-cost services, such as chronic disease management).

Proponents of UM argue that it lowers costs for all insureds by ensuring that medical services are being provided appropriately for an individual's medical condition and reducing fraud. Additionally, proponents note that UM generally follows [accredited best practices](#) to ensure patients receives

proper care. Opponents argue that it removes medical decisions away from the patient and doctor and prioritizes profits over care.

## ***Cost-Savings***

In addition to the UM techniques described above, insurers and PBMs may use other cost-savings measures. For example, CVS Health uses the following strategies to lower prescription drug pricing:

1. intelligent purchasing, which includes negotiating for “aggressive rebates” and “competitive pricing;”
2. contracts that include price protection clauses that offer improved rebates and additional discounts if manufacturers increase prices over a specific baseline; and
3. formulary strategies that encourage patients to select lower-cost drugs or limit the impact of sudden prescription drug price increases (March 15, 2017, CVS Caremark “Insights Executive Briefing”).

Importantly, manufacturers set prices for prescription drugs, not PBMs. Research is mixed as to whether PBMs save consumers a significant amount of money. For example, a 2018 [Pharmaceutical Care Management Association \(PCMA\) presentation](#) identifies PBMs as saving consumers \$941 per year (see page 9). (PCMA is a PBM advocacy organization.) Conversely, the New York Committee Investigations and Government Operations reported in its “[2019 Final Investigative Report: Pharmacy Benefit Managers in New York](#)” that “the consolidation and vertical integration of PBMs has contributed to skyrocketing list prices and declining patient access” (see page 4).

***PBM Policy Considerations.*** The 2019 New York Committee Investigations and Government Operations Report above notes that PBMs generate cost-savings to themselves through spread pricing, which is the practice of charging the insurance plan more for a drug (usually a generic drug) than the price it paid to buy the drug from the manufacturer. The report recommends five additional policies:

1. increasing maximum allowable cost (MAC) list transparency (i.e., the maximum amount a plan will pay for certain drugs);
2. subjecting PBMs to state oversight by requiring licensure and registration;
3. prohibiting PBMs from requiring the use of specialty or mail-order pharmacies;
4. increasing pharmacy reimbursement transparency; and
5. requiring PBMs to pass through all discounts or rebates to consumers.

## **States Prohibiting Non-Medical and Mid-Year Formulary Changes**

Non-medical switching, which refers to a change in a stable patient's medication for financial or non-medical reasons, generally occurs when a patient asks his or her healthcare provider to change a prescription because of an increase in copayment or other out-of-pocket expense. As such, it is generally dependent on other factors, such as a formulary change. (It generally does not refer to instances when a pharmacist substitutes a generic version for a brand name prescription drug.)

We were unable to find laws in any other New England states that prohibit carriers from implementing mid-year formulary changes. Aimed Alliance, a nonprofit advocacy group, provides a [map](#) of nonmedical switching laws. (Although the map includes Maine and Rhode Island, the laws refer to notification and other formulary switching requirements, but do not outright prohibit formulary switching).

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