Prescription Drug Formulary Legislation in Select States

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Issues
Describe and compare legislation in California, Connecticut, Louisiana, Nevada, New Mexico, and Texas prohibiting insurers from making mid plan-year prescription drug formulary changes (e.g., removing a drug from a formulary). List other states that considered legislation in 2017 prohibiting such formulary changes and, for New York, provide a summary and legislative history of its proposed legislation. Summarize a March 15, 2017 CVS Caremark “Insights Executive Briefing.”

Summary
Of the six states researched, Louisiana, Nevada, New Mexico, and Texas limit when health insurers may remove a drug from, or otherwise change, their prescription drug formularies, according to the National Conference of State Legislatures. Some of these states include exceptions, such as allowing removal of any drug found to be not clinically safe. California and Connecticut laws generally do not prohibit mid plan-year formulary changes. (This report is limited to private insurance plans and does not address rules governing a state’s Medicaid or other public benefit program.)

We identified at least 16 bills considered in 9 different states, including Connecticut, in the 2017 legislative session that prohibited or significantly limited mid-year formulary changes.

Formulary
A formulary is a list of prescription drugs that a health plan will cover.

As new drugs become available to consumers or the price of existing drugs change, health carriers may update their formularies by adding or removing drugs or moving drugs to different cost tiers.

Drugs placed in a higher tier may require an enrollee to (1) pay a higher out-of-pocket cost or (2) try a lower-tiered drug first before insurance covers the higher-tiered drug (i.e., step therapy).
Legislation considered in New York is similar to the laws enacted in the four states described above, and generally prohibits insurers from making mid-year formulary changes, including (1) removing drugs from a formulary; (2) moving a drug to a higher tier; or (3) adding prior authorization, step therapy, or certain other requirements.

The March 15, 2017 CVS Caremark “Insights Executive Briefing” describes, among other things, two primary methods CVS Health uses to reduce prescription drug costs for enrollees: contracts with price protection clauses and managed formularies. By employing certain formulary strategies, CVS Health (1) encourages patients to select lower cost drugs when available and (2) limits the impact if a drug manufacturer significantly increases a drug’s price. The report also describes factors contributing to higher prescription drug spending and explains how these factors are weighed against other trends that are reducing costs. The report concludes that, although drug spending grew year-over-year, cost reduction strategies reduced the rate of growth.

**Laws Limiting Formulary Changes in Select States**

Of the six states we researched, four generally prohibit formulary changes during a plan year: Louisiana, Nevada, New Mexico, and Texas. New Mexico limits formulary changes by prohibiting any changes within 120 days of a previous change. In addition, at least three states (Louisiana, New Mexico, and Texas) require insurers to notify covered individuals at least 60 days before a formulary change.

California and Connecticut do not limit formulary changes, although Connecticut requires insurers to continue to cover a removed drug in certain circumstances.

**California**

According to the California Insurance Department, California state law does not prohibit insurers from changing formulary designs mid plan-year. However, the department noted that insurers are prohibited from changing cost sharing requirements, including for prescription drugs, during the plan-year (Cal Ins. Code §§ 10199.48-.49).

**Connecticut**

In Connecticut, insurers may remove drugs from a formulary during a policy’s term. However, the law prohibits them from denying coverage for any drug removed from the formulary if the (1) insured was using the drug to treat a chronic illness and it had been covered before the removal and (2) his or her attending physician states in writing that the drug is medically necessary and indicates why it is more medically beneficial than other drugs on the formulary (CGS §§ 38a-492f and 38a-518f).
For more information about this law, see OLR Report 2017-R-0202 (forthcoming).

**Louisiana**

In Louisiana, a health insurer may modify a policy’s drug coverage only at a policy’s renewal and with approval by the insurance commissioner. Modifying drug coverage includes:

1. removing a drug from a formulary;
2. adding prior authorization requirements for a drug;
3. imposing or altering a quantity limit for a drug;
4. imposing a step-therapy restriction for a drug; or
5. moving a drug to a higher cost-sharing tier, unless a generic alternative is available ([La. Admin. Code tit. 37, pt. XIII, §§ 14111, 14115, & 14117](#)).

These requirements generally apply to both individual and group health insurance plans.

**Nevada**

Nevada generally prohibits a health insurer that offers an individual health benefit plan from removing a prescription drug from a formulary or moving a drug to a higher cost-sharing tier during the plan year ([Nev. Admin. Code ch. 689A.xxx(1) (R074-14)](#)). The regulation allows certain exceptions, including allowing a drug to be placed in a higher formulary tier if a generic is also added to the original tier.

We found no equivalent prohibition for group plans.

**New Mexico**

New Mexico generally prohibits individual and group health insurance policies and HMO contracts from changing a drug’s coverage within 120 days of any previous change, unless a generic version of the drug is available ([N.M. Stat. Ann. §§ 59A-22-49.4 & 59A-46-50.4](#)). Changing drug coverage includes:

1. removing a drug from a formulary,
2. increasing a drug’s cost-sharing,
3. establishing prior authorization requirements for a drug,
4. imposing or modifying a quantity limit for a drug,
5. imposing a step-therapy requirement for a drug, or
6. reclassifying a drug to a higher tier.

However, an insurer or HMO may remove a drug from a formulary at any time if the U.S. Food and Drug Administration deems it unsafe.
**Texas**

In Texas, a health insurer may modify a policy’s prescription drug coverage only at a policy’s renewal and the modification is generally uniform across all of the insurer’s group or individual plans, as applicable. Modifications include:

1. removing a drug from a formulary;
2. adding prior authorization requirements for a drug;
3. imposing or altering a quantity limit for a drug;
4. imposing a step-therapy restriction for a drug; and
5. moving a drug to a higher cost-sharing tier unless a generic drug alternative to the drug is available (Tex. Ins. Code Ann. §§ 1369.0541 & 1501.108).

These requirements generally apply to both individual and group health insurance plans.

**Considered Legislation**

Working with the National Conference of State Legislatures (NCSL), we identified at least 16 bills introduced in nine different states, including Connecticut, considered during the 2017 legislative session that prohibited or significantly limited mid-year formulary changes. The list of legislation considered is shown in Table 1. According to NCSL, none of these bills has become law.

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<th>State</th>
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Source: NCSL. In cases with more than one bill from a single state, additional bills may be companion legislation.\(^1\)Discussed in more depth below

You may also be interested in a [2016 report](#) by Consumers Union, a nonprofit advocacy group, which notes alternative measures some states have adopted, including more stringent notification and cost-sharing requirements (pp 69-71).
New York State Proposals

In the 2017-2018 legislative session, the New York State Assembly is considering at least two bills limiting mid-plan year formulary changes: S.5022-A and A.2317-A. The bills generally prohibit insurers, during a policy year, from (1) removing a drug from a formulary if the formulary includes multiple tiers, (2) moving a drug to a new tier with greater cost-sharing requirements, or (3) adding utilization management restrictions (e.g., prior authorization, step therapy, or quantity requirements). The bills allow the removal of drugs under certain conditions, including if a generic version of the drug is added to the formulary.

S.5022-A was amended and recommitted to the Insurance committee on 6/14/2017. A.2317-A passed the Assembly and was delivered to the Senate on 6/20/17.

We asked the NYS Legislative Library for a legislative history of the bills. According to the library, legislative histories are not compiled until a bill becomes law. However, the library provided what’s known as a “Sponsor’s Memo,” which provides certain background information on the proposal. According to the memo, the purpose of the bill is to maintain continuity of care for health plan enrollees. The memo indicates the sponsor expects it to have no fiscal impact on New York or its towns or political subdivisions.

Briefing Summary

You asked for a summary of the March 15, 2017 CVS Health “Insights Executive Briefing,” including how it pertains to price controls and formulary strategies.

According to the report, the rate of drug spending growth (i.e., “trend”) for CVS commercial pharmacy benefit management (PBM) clients declined from 5.0% in 2015 to 3.2% in 2016 and 38% of the clients had negative growth (i.e., spent less on prescription drugs in 2016 than in 2015).

Trend increased primarily due to (1) manufacturer-driven brand inflation; (2) increased cost and utilization of specialty drugs; and (3) overall utilization growth (i.e., the rate at which medicines are used), which the report attributes largely to an aging population.

Factors decreasing trend were (1) a higher generic dispensing rate, which generally refers to the ratio of generic use to overall prescription drug use, and (2) PBM management solutions, which include negotiated discounts, managed formularies, and other cost-management approaches. The availability and use of generics is the most important factor reducing trend.
**Price Controls**

To control prescription drug prices, CVS Health uses the following approaches:

1. intelligent purchasing, which is undefined in the report but includes negotiating for “aggressive rebates” and “competitive pricing;”
2. contracts that include price protection clauses, which offer improved rebates and additional discounts if manufacturers increase prices over a specific baseline; and
3. formulary strategies (see below).

**Formulary Strategies**

The report explains that one strategy to reduce prescription drug costs is to use multiple formulary designs. For example, CVS Health uses at least two different formulary designs to lower costs: a “value formulary” and a “standard formulary with drug removals.”

According to the [CVS/Caremark website](http://www.cvs.com), a value formulary is a formulary designed to cost the enrollee less money out-of-pocket, but may restrict the drugs available. There are generally three tiers of value formularies, each with varying benefit designs:

1. Value Formulary: generally covers all generic and listed brand name medicines, but does not cover unlisted brands or drugs.
2. Value Formulary Narrow: generally covers some generic and listed brand name medicines, but does not cover unlisted generic or other unlisted brands or drugs.
3. Value Formulary Tiered: generally covers all generics and listed brand names; it may cover unlisted brands, but in a higher cost tier.

The standard formulary with drug removals allows CVS Health to remove a drug from the formulary if it becomes too expensive and an alternative is available. The report notes that CVS Health conducts quarterly reviews to identify, evaluate, and potentially replace any drug with “significant price increases.” According to the report, individuals choosing a value formulary or standard formulary with drug removals incurred lower per member per month costs.

According to CVS Health, these formulary designs lower costs and increase generic usage. The report acknowledges that formulary changes, including removing drugs, can be disruptive for patients, and cites the need to communicate to patients why and when formulary changes take effect: “When members understand the change, why it is happening, and what they need to do to make the transition, they are more likely to make the best use of the benefit with minimal interruption of any ongoing therapy” (p. 8).