The Insurance Federation of Pennsylvania, Inc.

www.ifpenn.org

February 18, 2020

To: The Honorable Members of the House Committee on Consumer Affairs

From: Samuel R. Marshall

Re: House Bill 853 – mid-term changes in health policies

We testified on this almost two years ago, and our views and questions remain, as does our commitment to work with all interested parties to assure quality care to our policyholders.

The bill is a broad prohibition of any changes in coverage during the course of a health policy. We're not aware of any insurer raising premiums, copayments, coinsurance or deductibles in the middle of a policy. There may be other types of changes, though, that would happen during the course of a particular policy and could therefore be seen as altering the policy itself:

- For instance, a provider may join (or leave) an insurer's network; or an insurer may drop a requisite of prior authorization and switch to an aggregate limit on visits to a provider; or a new procedure or device may come into being during a policy year. Those are the types of changes that logically could and should be folded into an insured's coverage as a policy year progresses, not wait for the policy's renewal.

The bill's focus seems to be changes in drug formularies, imposing what is commonly known as a "frozen formulary" requisite: An insurer couldn't change coverage of a particular drug that an insured has been getting during the course of that policy – those changes can happen, but only at policy renewal, not during the policy itself.

We don't think that helps individual patients or the broader consumer interest of getting the best prescriptions at the best prices. Changes in the efficacy or cost of a particular drug don't fit neatly into a policy term; they may evolve and change during the policy term, and so might other alternative drugs. Insurance coverage

should reflect that, not wait for the next policy period to stay current with developments in the pharmaceutical world, or to gain savings for our policyholders.

Some examples of the shortcomings of a frozen formulary requisite:

- If a new generic, new brand or new OTC medication is released during the policy year, why not incorporate it sooner than later?

- If there are changes to utilization management, why wait to implement them? Consider opioids as an example where more management has been recognized as necessary – why delay it?

We realize the patient's well-being is paramount, and nobody is suggesting mid-policy changes of medications that might jeopardize that. All health plans provide notice of any change in a drug formulary and allow a doctor to explain why a patient should remain on a particular drug even if less costly alternatives come along.

That might be a better focus: Why not let coverage of a particular drug evolve in real-time along with the science, availability and cost of it and any alternatives – but ensure that the insured not be faced with a switch that may undercut the quality of care being covered, as with assuring notice and appeal rights?

One note: The bill applies to insurance companies, but not to self-insured plans, and not to government programs, as with Medicaid. Why not ask DHS what it does and why?

One drafting concern: The bill amends the Unfair Insurance Practices Act, which is enforced by the Insurance Department. It also makes a violation subject to the Attorney General's enforcement. We're not sure why dual regulation is merited here. That's not only inefficient but potentially inconsistent.

Thank you for the opportunity to be part of this, and we welcome the chance to work with all parties to address concerns.

MILLIMAN REPORT

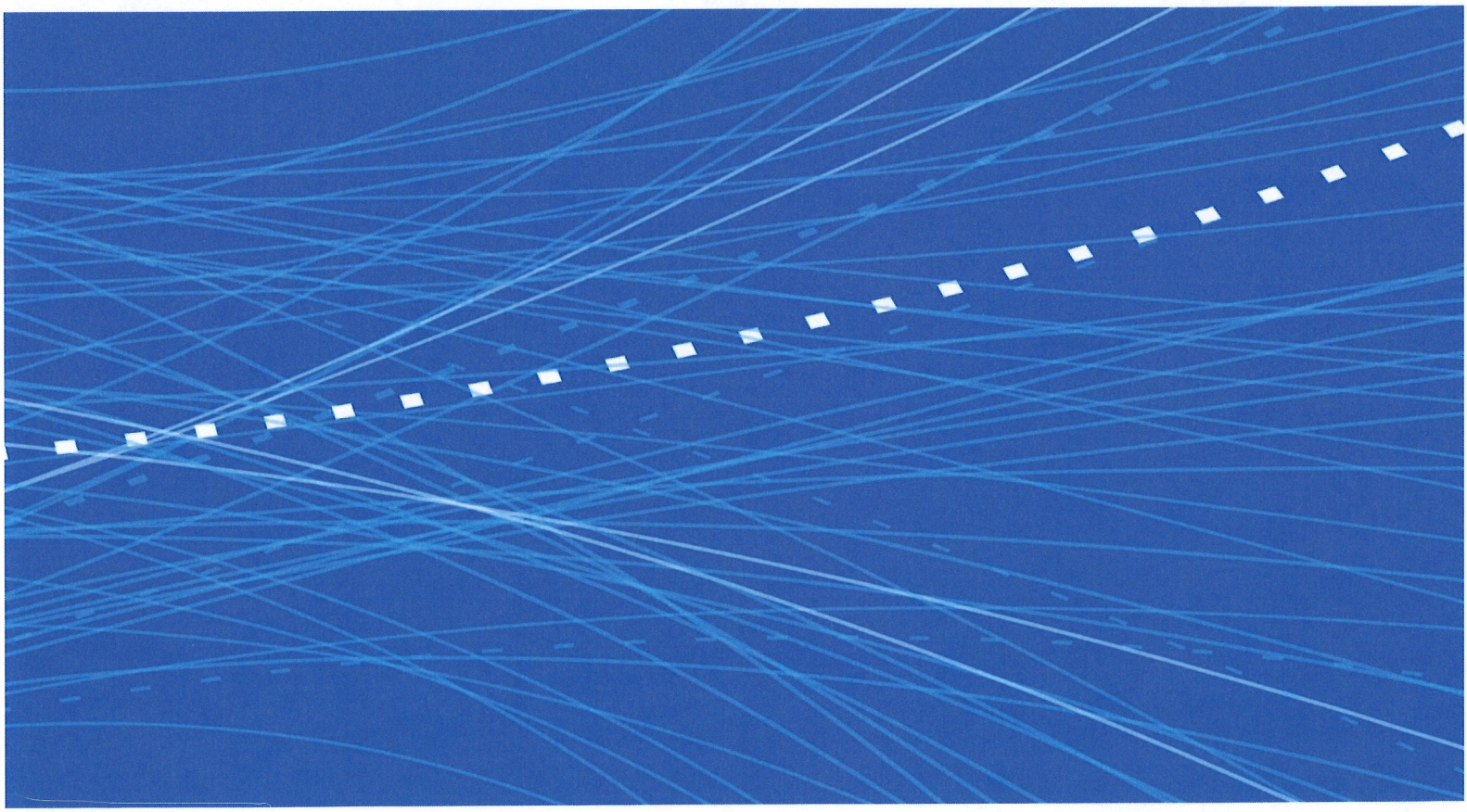
Estimated Cost of Potential "Frozen Formulary" Legislation

Fully-Insured Commercial Payer Impact, 2017-2021

Commissioned by Pharmaceutical Care Management Association

September 2017

David M. Liner, FSA, CERA, MAAA
Tracy A. Margiott, FSA, MAAA



Milliman


Milliman

Table of Contents

Executive Summary

The Pharmaceutical Care Management Association (PCMA) requested that Milliman assess the financial impact of potential "frozen formulary" legislation on fully-insured commercial health insurance market payer costs. "Frozen formulary" legislation refers to restrictions proposed by state legislators that would prohibit a pharmacy benefit manager (PBM) or health plan from making negative changes to a prescription formulary mid-year. Negative changes are any changes that would limit patient access or increase out-of-pocket costs for a specific medication. We will refer to health plans and PBMs as "payers" throughout the remainder of this document. The "frozen formulary" legislation does not restrict any "positive" formulary changes that would increase medication access or decrease out-of-pocket costs for health plan members.

We estimate the "frozen formulary" legislation would increase payer prescription drug costs in the fully-insured commercial health insurance market by approximately $4.84 billion over five years from 2017 through 2021 on a nationwide basis. "Cost" in this report refers to net plan liability, which is the portion of claims for which the payer is responsible (net of rebates and member cost sharing).

INTRODUCTION, SCOPE, AND PURPOSE

In the current fully-insured commercial health insurance market, payers are able to change their list of covered prescription medications and associated requirements (i.e., formulary) at any point throughout the plan year. Formulary changes may be scheduled to occur quarterly or at any time, given advanced notice. Several state legislatures are considering "frozen formulary" legislation, which would restrict the ability of payers to make negative formulary changes during the plan year. For example, payers may not be allowed to remove medications, move medications to a higher cost-sharing tier, or add utilization management (UM) restrictions to existing medications. UM programs are formulary restrictions intended to deliver necessary prescription medications in a cost-effective manner. Potential commercial market "frozen formulary" provisions vary by state.

The intent of "frozen formulary" legislation is to minimize member disruption by maintaining medication coverage throughout the plan year. However, the legislation may also limit the ability of payers to manage costs. Medication price inflation, the high-cost of newly approved medications, and increased utilization are all contributors to rising prescription costs. Payers utilize Pharmacy and Therapeutics (P&T) committees to review and respond to market events and implement formulary changes throughout the year. By limiting formulary control, payers will need to delay negative formulary changes until the end of the year, which may result in them paying higher prescription costs. For example, payers may not be able to optimally manage pharmacy costs through lower cost medications or negotiate for higher rebates with pharmaceutical manufacturers.

This report outlines our analysis of the estimated financial impact of this potential legislation for the fully-insured commercial health insurance market. We considered four key provisions that could trigger a negative formulary change to estimate the financial impact. These provisions are defined below:

1. **New generic medication launch**. This provision represents the inability to remove or up-tier the associated brand product from the formulary if a new generic product is released during the plan year.
2. **New brand medication launch**. This provision represents the inability to up-tier or increase member cost-sharing for existing medications if a new brand product is released during the plan year.
3. **New over-the-counter (OTC) medication**. This provision represents the inability to remove the associated prescription medication from the formulary when a product becomes available OTC during the plan year.
4. **New UM program**. This provision represents the inability to add prior authorizations (PA), quantity limits (QL), or step therapy (ST) during the year.

We model each provision assuming independence. We acknowledge that, in practice, some dependence may occur if "frozen formulary" legislation were implemented. For example, if a new, higher cost brand product launches, payers may implement a new utilization management program, such as step therapy, to manage utilization for the high-cost products in the class. Each of the above provisions may result in a wide range of potential financial and operational disruption.

SUMMARY OF FINDINGS

If the four key provisions above were implemented, we estimate the "frozen formulary" legislation would increase payer prescription drug costs in the fully-insured commercial health insurance market by approximately $690 million for an estimated 85 million members in 2017, increasing to $1.31 billion by 2021 on a nationwide basis. These estimates represent a 0.9% increase in prescription drug net plan liability for fully-insured commercial payers for 2017 through 2021 relative to the current environment. Assuming prescription drug expenditures represent 17% of total medical and pharmacy spending[1], this represents a 0.2% increase in total medical and prescription drug net plan liability. Figure 1 illustrates a range of financial outcomes due to the potential "frozen formulary" legislation.

FIGURE 1: ESTIMATED COST OF "FROZEN FORMULARY" LEGISLATION ($ MILLIONS)

	2017	2018	2019	2020	2021	2017-2021
Mid	$690	$790	$940	$1,110	$1,310	$4,840
High	$980	$1,130	$1,330	$1,570	$1,850	$6,860
Low	$390	$450	$540	$640	$750	$2,770

These estimates reflect the change in prescription drug cost solely attributable to payers in the fully-insured commercial market. Estimates for 2018 through 2021 reflect anticipated fully-insured commercial health insurance market enrollment and constant prescription drug expenditure trend. Figure 2 illustrates a range of 2017 financial outcomes for each of the four key provisions.

FIGURE 2: ESTIMATED COST OF "FROZEN FORMULARY" LEGISLATION IN 2017 ($ MILLIONS)

	Low	High
New Generic Medication Launch	$130	$200
New Brand Medication Launch	$50	$170
New OTC Medication	$170	$500
New UM Program	$40	$110

New generic medication launch. We estimate this change will increase payer prescription drug costs by $130 million to $200 million in 2017. We estimate this provision will increase in value to $360 million in 2021.

New brand medication launch. We estimate this change will increase payer prescription drug costs by $50 million to $170 million in 2017. We estimate this provision will increase in value to $220 million in 2021.

New OTC medication. We estimate this change will increase payer prescription drug costs by $170 million to $500 million in 2017. We estimate this provision will increase in value to $620 million in 2021.

New UM program. We estimate this change will increase payer prescription drug costs by $40 million to $110 million in 2017. We estimate this provision will increase in value to $110 million in 2021.

Appendix I illustrates the projected financial impact from Figure 1 above by state. Appendix II shows the estimates from Figure 1 above on a per member per year (PMPY) basis. We estimate the four key provisions noted above would increase payer prescription drug costs in the fully-insured commercial health insurance market by approximately $8.40 PMPY in 2017, increasing to $15.80 PMPY by 2021. These estimates represent a 0.5% to 1.3%

[1] Milliman. 2017 Milliman Medical Index. Retrieved September 13, 2017 from http://us.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf

increase in prescription drug net plan liability for fully-insured commercial payers for 2017, primarily driven by the new OTC medication launch provision.

Cost estimates for future years are primarily driven by unit cost and utilization trend and reflect the impact of new brand and generic pipeline medications. Expected savings due to new generic medications is based on historical experience. The future drug pipeline will emerge differently than anticipated. The illustrated range of financial outcomes reflects this future uncertainty.

Findings

We estimate the "frozen formulary" legislation would increase payer prescription drug costs in the fully-insured commercial health insurance market by approximately $690 million in 2017, increasing to $1.31 billion by 2021 on a nationwide basis. The following sections provide detail on each modeled provision.

NEW GENERIC MEDICATION LAUNCH

Generic medications are inexpensive therapeutic alternatives to bioequivalent brand medications and can be substituted by a pharmacist without physician approval. For example, esomeprazole magnesium is the generic version of the brand medication Nexium®. Although the active ingredient is identical, the brand name medication (Nexium®) typically has a higher ingredient cost compared to its generic equivalent. Brand manufacturers facing patent expiration may provide significant rebates to payers, but generic price reductions typically outweigh these rebates over time. Brand manufacturers may also stop providing rebates once the generic loses exclusivity. In addition to having a lower net cost, generic products generally have lower member cost sharing than the respective brand product.

When a generic medication is approved and launched into the market, payers typically make formulary changes that require members to switch to the less expensive generic medication. For example, payers may implement new UM programs on the brand medication, up-tier the respective brand medication, or remove the brand medication from the prescription formulary. The formulary changes are typically effective immediately without advanced member notification. Members are informed at the point-of-sale and generic substitution occurs by the dispensing pharmacist.

The proposed "frozen formulary" legislation would prohibit mid-year negative formulary changes to the brand product that disadvantage it compared to the generic product. As a result, payers will be required to cover the brand product at the same member cost sharing level for the entire year regardless of whether a generic medication launches during the plan year. This situation would typically result in higher costs for payers and members, since we expect fewer members would switch from the brand medication to the generic medication compared to the current environment.

Figure 3 illustrates the estimated additional prescription drug cost due to this provision to fully-insured commercial health payers.

FIGURE 3: ESTIMATED COST OF "NEW GENERIC MEDICATION LAUNCH" PROVISION ($ MILLIONS)

	2017	2018	2019	2020	2021	2017-2021
Mid	$160	$200	$240	$290	$360	$1,250
High	$200	$240	$290	$350	$420	$1,500
Low	$130	$160	$190	$230	$290	$1,000

Figure 3 shows the estimated cost associated with not being able to remove a brand drug from the formulary during the plan year when a new generic medication enters the market. The estimates in Figure 3 reflect an increase in brand utilization as a result of potential frozen formulary legislation and do not reflect potential changes in associated rebate contracts. While expected generic launch savings underlies these estimates for each year, the values in Figure 3 are not estimates of generic launch savings. The range of cost estimates each year reflects uncertainty of future brand patent expirations.

NEW BRAND MEDICATION LAUNCH

When a new brand medication receives approval and is released in the market, the brand manufacturer may offer rebates in exchange for formulary placement. In therapeutic classes with competitive branded and/or generic medications available, payers may choose not to add a new brand medication until favorable pricing terms (i.e., rebates) are negotiated. In addition, payers can use the newly approved competitor as leverage to renegotiate the pricing for existing brands in the therapeutic class. Payers may up-tier an existing brand or remove it from the prescription formulary entirely. Flexibility to implement formulary changes mid-year enables payers to maintain or improve pricing terms with brand manufacturers, regardless of whether they ultimately make any formulary changes.

"Frozen formulary" legislation would restrict the ability of payers to remove or up-tier an existing brand medication, even if a competing brand were launched. Pricing terms for branded manufacturers may be based on limiting competition from existing brands as well as new brands. If the new brand is added, it may result in less favorable pricing terms for the existing formulary brand products. If the new brand is not added, pricing terms may be maintained, but access to the new medication may be delayed until the end of the year. Payers may also attempt to proactively negotiate pricing terms prior to the new brand launching. This proactive strategy may have limited effectiveness as the approved indication and price of the new brand is essential to the prescription formulary decision and is not known until the new brand is approved and launched. If a payer were not able to make any negative formulary changes when a new brand product launches, branded manufacturers would be able to maintain formulary status throughout the year and would have less incentive to renegotiate more favorable contract terms with the payer.

Figure 4 illustrates the estimated additional prescription drug cost to fully-insured commercial payers due to this provision. These values represent the opportunity cost of not being able to effectively renegotiate rebate contracts when a new brand medication launches. The increase in rebates due to a new brand launch varies widely by therapeutic class and amounts are typically confidential, so we illustrate a range of potential outcomes.

FIGURE 4: ESTIMATED COST OF "NEW BRAND MEDICATION LAUNCH" PROVISION ($ MILLIONS)

	2017	2018	2019	2020	2021	2017-2021
Mid	$120	$140	$170	$200	$220	$850
High	$170	$200	$240	$280	$330	$1,220
Low	$50	$60	$70	$90	$120	$390

Cost estimates for future years are primarily driven by unit cost and utilization trend. The overall assumed brand trends reflect the impact of new brand pipeline medications. Drug-specific cost and utilization impacts are not explicitly modeled in our analysis.

NEW OVER-THE-COUNTER MEDICATION

When a new OTC medication becomes available during the plan year, members may migrate from the covered prescription formulary medication to the typically lower-cost OTC medication. To encourage members to switch to the OTC medication, payers may opt to remove prescription formulary coverage for the equivalent medication(s) or implement UM programs. Typically, the removal of prescription medication coverage is a payer-driven decision to lower plan costs.

"Frozen formulary" legislation would limit the ability of payers to shift members toward effective OTC products. A reduced OTC utilization shift would result in higher costs for the payer, since more members will continue to use prescription formulary covered medications. Figure 5 illustrates the estimated additional prescription drug cost to fully-insured commercial payers due to this provision. The range of potential outcomes represents the range of expected utilization shifts to new OTC products.

FIGURE 5: ESTIMATED COST OF "NEW OTC MEDICATION" PROVISION ($ MILLIONS)

	2017	2018	2019	2020	2021	2017-2021
Mid	$330	$380	$440	$520	$620	$2,290
High	$500	$570	$670	$780	$920	$3,440
Low	$170	$190	$220	$260	$310	$1,150

NEW UTILIZATION MANAGEMENT PROGRAM

In the current fully-insured commercial health insurance market, payers have the ability to implement new UM programs throughout the year. The purpose of these programs is to deliver necessary prescription medications in a cost-effective manner. These programs may include PA, ST, and QL.

PA programs are intended to determine if coverage is necessary and appropriate by ensuring that the medication is used in a clinically supported setting. ST programs require members to try a more clinically effective or an equally clinically effective and/or less costly medication (i.e., generic) without success prior to the plan covering the selected medication. QL programs may prevent prolonged treatment that may be harmful or unnecessary. Collectively, UM programs may lower overall medication costs by improving quality or safety and preventing abuse or waste.

By limiting a plan's ability to implement new programs throughout the year, the plan may not be able to react to current market developments for delivering high quality outcomes to members in a cost-effective manner. For example, a quantity limit on selected opiates for members prescribed these medications could be implemented in response to the opioid epidemic. Restricting the implementation of these programs may lead to fraud, waste, and abuse of particular medications, which may result in undue costs on the health system.

Figure 6 illustrates the estimated additional prescription drug cost to fully-insured commercial payers due to this provision under the "frozen formulary" legislation. This estimated cost reflects the inability to implement new quantity limit programs during the plan year.

FIGURE 6: ESTIMATED COST OF "NEW UM PROGRAM" PROVISION ($ MILLIONS)

	2017	2018	2019	2020	2021	2017-2021
Mid	$80	$70	$90	$100	$110	$450
High	$110	$120	$130	$160	$180	$700
Low	$40	$40	$60	$60	$30	$230

The values in Figure 6 do not reflect PA or ST changes as these formulary changes typically are the result of other provisions (e.g., new generic or new brand). PA and ST programs are commonly applied to new brand products, which affects utilization for new medications rather than existing medications and are not considered negative formulary changes. We model each provision as distinct and mutually exclusive from all other provisions.

STATE SPECIFIC ESTIMATES

Several state legislatures are considering various forms of "frozen formulary" legislation. PCMA requested that we illustrate the estimated additional cost to fully-insured commercial payers due to potential "frozen formulary" legislation at both the nationwide and state level. While we illustrate the potential impact for all states, not all states are currently considering this type of legislation. Appendix I illustrates the projected financial impact by state.

The state-level estimates do not reflect current or potential future state-specific medication coverage requirements. Rather, we allocate the estimated nationwide cost impact based on state-specific prescription medication expenditures and fully-insured commercial health plan enrollment. We assume the distribution of prescription medication expenditures by state remains constant from 2017 to 2021. Nationwide enrollment trends from 2017 to 2021 are consistent with CMS National Health Expenditure enrollment trends and do not vary by state. The Methodology section in this report provides detail on the state-specific enrollment and prescription drug expenditure assumptions underlying the illustrative state allocation.

OTHER CONSIDERATIONS

Products Experiencing Mid-Year Price Increases

Currently, payers have the ability to remove medications from their formularies if prescriptions increase significantly in price to shift utilization to more cost-effective medications during the plan year. This ability to remove the product from a plan's prescription formulary mitigates the cost impact if pharmaceutical manufacturers were to potentially implement significant price increases.

Under the "frozen formulary" legislation, payers would not have the ability to properly manage medications experiencing significant price increases. In particular, if the medication is subject to a flat copay, members would be insulated from the increased ingredient cost, and the payer would lack any ability to shift the member's utilization to a more cost-effective and therapeutically equivalent medication. As a result, plan liability would typically increase compared to a situation in which the plan could remove, up-tier, or add UM to the medication during the year.