MILLIMAN REPORT

Estimated Cost of Potential "Frozen Formulary" Legislation

Fully-Insured Commercial Payer Impact, 2017-2021

Commissioned by Pharmaceutical Care Management Association

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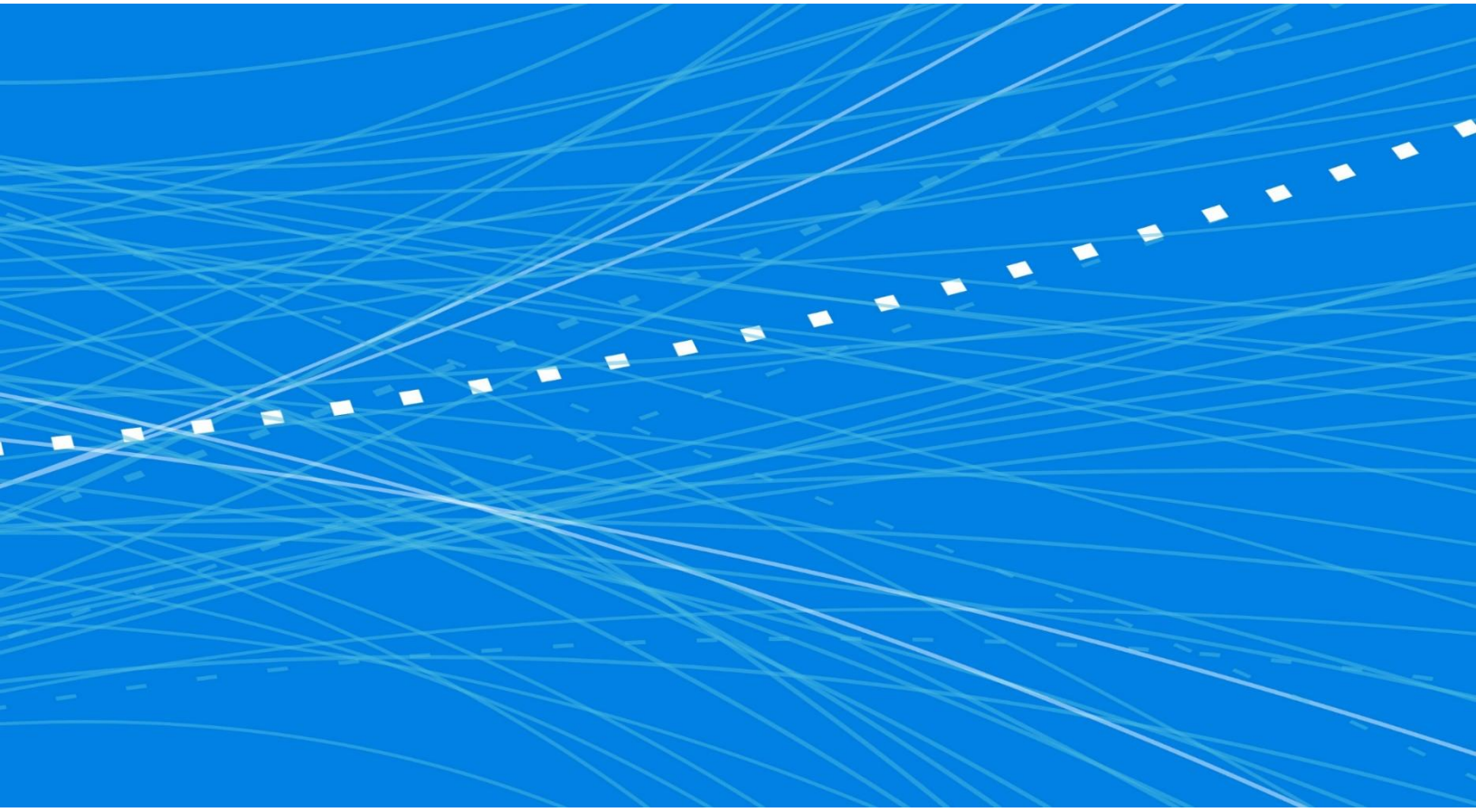

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Executive Summary

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.

We estimate this provision would not have a material impact on net plan liability for several reasons. First, brand manufacturers have recently received tremendous scrutiny due to large price increases. We therefore do not expect a significant number of medications will experience large price increases during the next several years. Second, most payers receive some form of inflation protection from their PBM, which limits the financial impact to the plan. Contracted pricing terms with brand manufacturers typically include price inflation protection, which limits the effective price increases that a plan pays to a manufacturer. This provision diminishes the majority of the impact caused by increased medication prices. The net payer cost remains stable, but members with coinsurance or high deductible health plans may experience increased cost sharing. Finally, the generic products with large increases may be on Maximum Allowable Cost (MAC) lists for health plans, which would limit the amount the plan pays for a specific medication until the pharmacies are able to renegotiate contracts and agreements for the MAC lists. For these reasons, we expect the financial impact of this provision to be small.

Stakeholder Behavior

We did not model any payer behavioral changes that may occur if "frozen formulary" legislation were enacted. If a payer is aware that negative formulary changes cannot occur mid-year, the payer may proactively negotiate formulary positions in anticipation of a future event. For example, a brand name product expecting to lose patent with generic entry in the upcoming year could be removed ahead of the next year.

"Frozen formulary" legislation may impact other stakeholders in the prescription drug supply chain. For example, this legislation may financially affect pharmaceutical manufacturers, wholesalers, and pharmacies.

Benefit Design

The estimated "frozen formulary" impact for a specific plan is dependent on the plan's tier-specific member cost sharing. The estimated costs above reflect a four-tier pharmacy plan with retail cost-sharing of $11 / $33 / 37% / 29% for generic / preferred brand / non-preferred brand / specialty tiers. For example, we assume that when a new generic medication launches, members pay an $11 copay for the medication, and the payer is responsible for the remaining drug cost. Actual payer costs will differ from the estimates in this report due to variations in member cost sharing and out-of-pocket limits by plan.

Medicare Part D Formulary Requirements

As a federal program, Medicare Part D is generally not subject to state legislation. However, the Medicare Part D program includes certain provisions that may be somewhat similar in nature but different operationally to the potential "frozen formulary" restrictions considered at the state level. Payers in the Medicare market are unable to enact negative formulary changes during a plan year without significant member outreach, physician outreach, and approval by CMS. Negative formulary changes include increasing member cost-sharing and imposing more restrictive UM programs, such as a PA, ST, or QL. However, Medicare Part D payers may remove existing brand medications from the formulary when an equivalent generic medication is released. In addition, brand and generic medications may also be removed from the formulary if the medication is recalled as a result of safety concerns or other reasons.

Our interpretation of commercial market "frozen formulary" proposed legislation is that existing brand medications may not be removed from the formulary mid-year regardless of whether a new brand or new generic medication launches. This is similar to the Medicare Part D restrictions for new brand launches, but differs from the Medicare Part D regulations for new generic launches. For example, when a new brand medication launches, Part D payers are restricted from up-tiering or removing existing brand medications from the formulary. The required commercial market "frozen formulary" provisions may vary by state. The amount of time required to implement requested mid-year formulary changes may also vary by state, and may differ from CMS' approval process timing for Medicare Part D formulary changes. We did not compare the estimated commercial market financial impact of potential state-level "frozen formulary" restrictions to the impact of current Medicare policies due to the key differences and confounding variables between the two markets.

Methodology

The following section outlines the approach and key assumptions for estimating the financial impact of potential "frozen formulary" legislation on the fully-insured commercial market.

APPROACH

We relied on cost and utilization experience from Milliman's 2017 Health Cost Guidelines to project average expected commercial, fully-insured payer prescription drug costs for 2017 to 2021. We first projected average market costs under the current environment ("baseline"). We then modified the projected unit cost, utilization, and other assumptions to reflect expected changes under potential "frozen formulary" legislation. The estimated dollar impact of potential "frozen formulary" legislation to payers is the difference between the baseline and "frozen formulary" projected costs. The estimated percentage impact of potential "frozen formulary" legislation to payers reflects the "frozen formulary" projected costs compared to the baseline costs. Key assumptions for the baseline and "frozen formulary" provisions are outlined below. For the "frozen formulary" provisions, we illustrate the potential impact for a range of assumptions based on our clinical experience.

We project pharmacy payer costs on a nationwide basis and allocate costs by state based on fully-insured commercial market enrollment and pharmacy spending by state.

We modeled four distinct "frozen formulary" provisions, listed below, and assumed independence among each provision. We acknowledge that in practice, some dependence may occur if any form of "frozen formulary" legislation were implemented. For example, if a new brand product launches, insurers may implement a new UM program as a result of the new product launch. The estimated cost of each "frozen formulary" provision reflects prescription drug costs only and does not reflect potential changes in medical costs which may result from formulary changes.

BASELINE ASSUMPTIONS

The following outlines key baseline (i.e., no "frozen formulary" change) assumptions. We assume these items do not change as a result of the "frozen formulary" legislation.

- **Plan Design.** Assumed a four-tier pharmacy plan with retail cost-sharing of $11 / $33 / 37% / 29% for generic / preferred brand / non-preferred brand /specialty tiers based on Kaiser Family Foundation's 2016 Employer Health Benefits Survey.[2] Mail order cost-sharing is assumed to be 2.5 times retail. We assume a $0 deductible and a $2,000 out-of-pocket maximum apply to the pharmacy benefit.
- **Discounts.** Assumed retail discounts from average wholesale price (AWP) of 80.0% / 18.0% / 18.0% and mail discounts of 82.5% / 25.0% / 25.0% for generic / brand / specialty medications. Discounts are based on industry knowledge and Milliman's Health Cost Guidelines.
- **Trends.** Assumed utilization trends of 1.0% / 1.0% / 12.5% and unit cost trends of 2.0% / 12.0% / 10.0% for generic / brand / specialty medications. Trends are based on industry knowledge and Milliman's Health Cost Guidelines. We apply these trends to project utilization and cost for 2018 through 2021.
- **Rebates.** Assumed rebates of 35% of wholesale acquisition cost (WAC) for brand products and 15% of WAC for specialty products. Rebates were reviewed for reasonability based on industry knowledge.
- **Dispensing Fees.** Assumed to be $1 per 30-day equivalent retail script and $0 per 90-day equivalent mail script based on industry knowledge and Milliman's Health Cost Guidelines.
- **Generic Launches**: We project savings due to generic launches by modeling shifts in brand to generic utilization and the expected generic cost post-launch. We develop individual utilization shift and cost assumptions for each generic medication where the corresponding brand has material market share. The utilization shift and cost assumptions are based on a combination of internal and external industry data. These assumptions reflect the expected timing of future brand patent expirations, as well as whether the generic will be offered exclusively by a single manufacturer or competitively across multiple manufacturers.

[2] Kaiser Family Foundation. 2016 Employer Health Benefits Survey. September 14, 2016. Retrieved July 19, 2017 from http://www.kff.org/health-costs/report/2016-employer-health-benefits-survey/

Appendix III includes a list of modeled 2017 and 2018 generic launches and the associated brand product. The impact of generic launches for 2019 to 2021 is based on the expected impact for 2016 to 2018 due to uncertainty of future brand patent expirations.

Future biosimilar launches were reviewed, but were excluded from the report findings. The adoption of the biosimilar medications is dependent on various formulary management strategies by health plans and PBMs to negotiate the lowest discount between the reference sponsor and biosimilar sponsor. Biosimilar medications do not follow similar cost and utilization patterns to new generics and were therefore excluded from the generic medication launches.

- **Enrollment.** We estimate 85 million members in the United States receive prescription coverage through fully-insured commercial health plans for 2017. This estimate is based on 2015 US Census data[3], Kaiser's 2015 Health Care Coverage of the US Population data[4], and insured status data from the 2015 Medical Expenditure Panel Survey.[5] Enrollment trends from 2015 to 2021 are consistent with 2015 CMS National Health Expenditure projected enrollment trend rates for Private Health Insurance in years 2015 to 2021[6] and do not vary by state.
- **State Allocation.** We allocated national aggregate dollars across states using fully-insured commercial enrollment by state from the sources described above, along with prescription drug cost and utilization area factors from Milliman's 2017 Health Cost Guidelines. We assume the distribution of prescription drug medication expenditures by state remains constant from 2017 to 2021. Differences in state laws, mandated benefits, prescribing patterns, and other specific geographic variation is not reflected in this illustrative allocation.

"FROZEN FORMULARY" ASSUMPTIONS

The following section outlines our expectation of key changes under potential "frozen formulary" legislation. The assumptions presented below are based on our clinical experience. We illustrate ranges for each key assumption due to the uncertainty of future market changes. Future experience may vary from the modeled assumptions. For example, future emergence of new brand drugs is highly uncertain, and we illustrate a range of potential rebate changes based on historical experience. We verified important clinical assumptions with independent industry experts.

- **New generic medication launch.** When a new generic medication launches, we expect utilization to shift from the associated brand product to the generic. If plans were not allowed to remove the associated brand product from the formulary when a new generic launches, we assume a 50% reduction in the utilization that would be expected to shift to the generic (40% to 60% range) based on our clinical experience. This range reflects uncertainty in the mix of brand and generic utilization due to differences in state laws and prescribing patterns. This assumption affects both utilization and unit cost, since we assume increased utilization on the higher cost brand medication. The value of specific generic launches may change for future years depending on patent losses and litigations.
- **New brand medication launch.** When a new brand medication is released, we assume payers will renegotiate rebate contracts for products within the respective therapeutic class. When this occurs, we assume rebates for brand products within the class increase by 25% on average after the launch of the product (10% to 40% range). If payers were not allowed to renegotiate rebates during the year, we assume rebates for brand products within the therapeutic class would correspondingly decrease. We assume the

[3] United States Census Bureau. Annual Estimates of the Resident Population for the United States, Regions, States, and Puerto Rico: April 1, 2010 to July 1, 2016. January 18, 2017. Retrieved July 24, 2017 from https://www.census.gov/data/tables/2016/demo/popest/state-total.html

[4] Kaiser Family Foundation. 2015 Health Insurance Coverage of the Total Population. Retrieved July 24, 2017 from http://www.kff.org/other/state-indicator/total-population/

[5] United States Department of Health and Human Services. Medical Expenditure Panel Survey – 2015 Percent of private-sector enrollees that are enrolled in self-insured plans at establishments that offer health insurance by firm size and State. Retrieved July 24, 2017 from https://meps.ahrq.gov/data_stats/summ_tables/insr/state/series_2/2015/tiib2b1.pdf

[6] Centers for Medicare and Medicaid Services. 2015 National Health Expenditure Projections. Retrieved July 24, 2017 from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html

therapeutic classes with a brand patent approval account for approximately 6.4% of total brand utilization, based on 2015 and 2016 historical data. We incorporate a mid-year timing adjustment for this provision by assuming an average launch date of July 1st for all medications under this provision. We assume utilization for mid-year brand launches remains a constant percentage of total brand utilization throughout the projection period. The value of rebates may vary for future years depending on the competition of newly launched brand medications, rebates offered by brand manufacturers, and the negotiation leverage of payers in controlling the utilization of formulary medications.

- **New OTC medication.** When a new OTC medication is released, we expect payers to implement utilization management programs or remove the associated covered medication from the formulary. When this occurs, we assume a 50% reduction in utilization on medications with new OTC equivalents (25% to 75% range). If payers were not allowed to make formulary changes during the year when an OTC product is released, we assume utilization of the covered formulary medication would correspondingly increase. We assume this provision applies to 1.7% of total market utilization. We incorporate a mid-year timing adjustment for this provision by assuming an average launch date of July 1st for all medications under this provision. Assumptions for OTC medications were based on historical data from 2015 and 2016.

  Uncertainty exists regarding new OTC launches, as these products depend on approvals by the Food and Drug Administration (FDA). In addition, the manufacturer must completely evaluate the safety and effectiveness of the medication prior to initiating an application to switch from prescription to OTC availability. In previous years, several medications classes have successfully transitioned from prescription to OTC availability, including proton pump inhibitors and nasal allergy products. However, some products have attempted, but have not been able to meet regulatory and clinical requirements. For example, lipid lowering therapies (i.e., statins) were investigated in clinical trials, but were not able to demonstrate that patients could manage their cholesterol levels.[7] Due to the potential risk for misdiagnosis and lack of monitoring cholesterol levels, the manufacturer terminated the program. Other classes (e.g. oral contraceptives) have been considered for many years.[8] The availability of future OTC availability will depend on whether medications demonstrate safe and effective use in self-treatment.

- **New UM program.** When a new UM program is introduced, we expect utilization to decrease as a result of the additional formulary restrictions.[9] If payers were not allowed to add UM criteria during the plan year, we assume utilization would increase. We illustrate a range of 10% to 30% reductions in utilization applied to 0.2% of total market utilization. We incorporate a mid-year timing adjustment for this provision by assuming an average launch date of July 1st for all medications under this provision. Payers have applied industry-wide quantity limits to classes such as attention-deficit/hyperactivity disorder and extended release opioid medications. Industry events and impact to specific therapeutic classes may differ in future years.

[7] Forbes. Pfizer Pulls the Plug on OTC Lipitor. July 29, 2015. Retrieved September 8, 2017 from https://www.forbes.com/sites/johnlamattina/2015/07/29/pfizer-pulls-the-plug-on-otc-lipitor-and-its-the-patients-fault/#5b90f5d8ee70
[8] Upadhya KK, Santelli JS, Raine-Bennett TR, Kottke MJ, Grossman D. Over-the-Counter Access to Oral Contraceptives for Adolescents. J Adolesc Health. 2017; doi: 10.1016/j.jadohealth.2016.12.024
[9] Express Scripts, Inc. A Comprehensive Solution to Reduce Opioid Abuse. June 7, 2017. Retrieved July 24, 2017 from http://lab.express-scripts.com/lab/insights/industry-updates/a-comprehensive-solution-to-reduce-opioid-abuse

Caveats and Limitations

David M. Liner and Tracy A. Margiott are actuaries for Milliman. We are members of the American Academy of Actuaries and meet the Qualification Standards of the American Academy of Actuaries to render this opinion. To the best of our knowledge and belief, this information is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices.

This Milliman report has been prepared for the specific purpose of estimating the financial impact of proposed "frozen formulary" legislation on payers. This information may not be appropriate, and should not be used, for any other purpose. Milliman does not endorse any public policy or advocacy position on matters discussed in this report.

This report may be distributed publicly at the discretion of Pharmaceutical Care Management Association. If shared externally, the report should be shared in its entirety unless otherwise approved by Milliman. We do not intend this information to benefit, or create a legal liability to, any third party, even if we permit the distribution of our work product to such third party. This report must be read in its entirety, and specialized knowledge of the industry is necessary to fully understand the report and its conclusions.

The results presented herein are estimates based on carefully constructed actuarial models. Differences between our estimates and actual amounts depend on the extent to which future experience conforms to the assumptions made for this analysis. It is certain that actual experience will not conform exactly to the assumptions used in this analysis. Actual amounts will differ from projected amounts to the extent that actual experience deviates from expected experience.

These projections assume no material changes in the enrollment or dynamics of the commercial, fully-insured health insurance market. The projections make no provision for any possible changes to the ACA or other healthcare requirements that may arise in the future.

In performing this analysis, we relied on publicly available data sources and other information from Kaiser Family Foundation, Centers of Medicare and Medicaid Services, the United States Census Bureau, and the Agency for Healthcare Research and Quality. Specifically, we relied on the 2015 Kaiser Employer Health Benefits Survey, 2015 Kaiser Health Care Coverage of the U.S. Population data, 2015 National Health Expenditure data, 2015 U.S. Census data, and 2015 Medical Expenditure Panel Survey data. We have not audited or verified this data and other information but reviewed it for general reasonableness. If the underlying data or information is inaccurate or incomplete, the results of our analysis may likewise be inaccurate or incomplete.

Milliman does not provide legal advice, and recommends that Pharmaceutical Care Management Association consult with its legal advisors regarding legal matters. The terms of Milliman’s Consulting Services Agreement with Pharmaceutical Care Management Association dated August 2, 2013 and the Indemnification agreement in the engagement letter dated June 29, 2017 apply to this report and its use.

Appendix

APPENDIX I: ESTIMATED COST OF "FROZEN FORMULARY" LEGISLATION BY STATE ($ MILLIONS)

	2017	2018	2019	2020	2021	2017-2021
Nationwide	**$690**	**$790**	**$940**	**$1,110**	**$1,310**	**$4,840**
Alabama	$11	$13	$15	$18	$20	$77
Alaska	$1	$1	$1	$2	$2	$7
Arizona	$8	$10	$11	$13	$17	$59
Arkansas	$6	$7	$8	$10	$11	$42
California	$82	$91	$119	$129	$147	$568
Colorado	$9	$10	$12	$15	$17	$63
Connecticut	$10	$11	$13	$16	$19	$69
Delaware	$2	$2	$2	$3	$3	$12
District of Columbia	$2	$2	$3	$3	$4	$14
Florida	$40	$46	$54	$64	$76	$280
Georgia	$17	$20	$23	$27	$32	$119
Hawaii	$3	$4	$4	$5	$6	$22
Idaho	$3	$3	$4	$5	$6	$21
Illinois	$23	$26	$31	$37	$44	$161
Indiana	$11	$12	$14	$17	$20	$74
Iowa	$7	$8	$9	$11	$11	$46
Kansas	$6	$7	$8	$10	$12	$43
Kentucky	$10	$11	$13	$16	$19	$69
Louisiana	$11	$12	$14	$17	$21	$75
Maine	$3	$3	$4	$5	$5	$20
Maryland	$16	$18	$22	$26	$30	$112
Massachusetts	$17	$20	$23	$28	$32	$120
Michigan	$27	$31	$37	$44	$53	$192
Minnesota	$12	$14	$16	$19	$24	$85
Mississippi	$5	$6	$7	$8	$11	$37
Missouri	$13	$15	$18	$22	$26	$94
Montana	$2	$2	$3	$3	$3	$13
Nebraska	$4	$5	$5	$6	$8	$28
Nevada	$5	$6	$7	$8	$10	$36
New Hampshire	$4	$4	$5	$6	$6	$25
New Jersey	$24	$27	$32	$38	$46	$167
New Mexico	$2	$3	$3	$4	$4	$16
New York	$56	$65	$77	$91	$107	$396
North Carolina	$21	$24	$28	$34	$40	$147
North Dakota	$2	$2	$2	$3	$3	$12
Ohio	$24	$28	$33	$40	$48	$173
Oklahoma	$8	$9	$11	$13	$14	$55
Oregon	$8	$9	$11	$13	$16	$57
Pennsylvania	$31	$36	$42	$50	$60	$219
Rhode Island	$4	$4	$5	$6	$6	$25
South Carolina	$10	$12	$14	$16	$18	$70
South Dakota	$2	$2	$3	$3	$4	$14
Tennessee	$14	$17	$20	$23	$28	$102
Texas	$57	$66	$78	$92	$110	$403

Utah	$7	$8	$9	$11	$13	$48
Vermont	$1	$2	$2	$2	$3	$10
Virginia	$20	$23	$27	$32	$38	$140
Washington	$14	$16	$19	$22	$27	$98
West Virginia	$3	$4	$4	$5	$7	$23
Wisconsin	$11	$12	$14	$17	$21	$75
Wyoming	$1	$1	$1	$2	$2	$7

APPENDIX II: ESTIMATED COST OF "FROZEN FORMULARY" LEGISLATION ($ PMPY)

	2017	2018	2019	2020	2021	2017-2021
Mid	$8.40	$9.70	$11.40	$13.40	$15.80	$11.80
High	$12.00	$13.80	$16.10	$19.00	$22.30	$16.70
Low	$4.80	$5.50	$6.50	$7.70	$9.10	$6.70

APPENDIX III: MODELED 2017 AND 2018 GENERIC LAUNCHES

Brand Product	Generic Product	Expected Launch Year
AZILECT	RASAGILINE MESYLATE	2017
LOTEMAX	LOTEPREDNOL ETABONATE	2017
VYTORIN	SIMVASTATIN/EZETIMIBE	2017
STRATTERA	ATOMOXETINE HYDROCHLORIDE	2017
QSYMIA	PHENTERMINE/TOPIRAMATE	2017
BUTRANS	BUPRENORPHINE	2017
BYETTA	EXENATIDE	2017
ADCIRCA	TADALAFIL (ADCIRCA)	2017
CIALIS	TADALAFIL	2017
VIAGRA	SILDENAFIL CITRATE (VIAGRA)	2017
VIREAD	TENOFOVIR DISOPROXIL FUMARATE	2017
QVAR	BECLOMETHASONE DIPROPIONATE	2017
VELPHORO	SUCROFERRIC OXYHYDROXIDE	2017
REYATAZ	ATAZANAVIR SULFATE	2017
SUSTIVA	EFAVIRENZ	2017
FLOVENT DISKUS	FLUTICASONE PROPIONATE (FLOVENT DISKUS)	2018
EFFIENT	PRASUGREL	2018
SOLODYN	MINOCYCLINE HCL (SOLODYN)	2018
TREXIMET	SUMATRIPTAN/NAPROXEN SODIUM	2018
SENSIPAR	CINACALCET	2018
ASMANEX TWISTHALER 60 METERED DOSES	MOMETASONE FUROATE INHALATION POWDER 60	2018
ASMANEX TWISTHALER 30 METERED DOSES	MOMETASONE FUROATE INHALATION POWDER 30	2018

ASMANEX TWISTHALER 120 METERED DOSES	MOMETASONE FUROATE INHALATION POWDER 120	2018
ADVAIR DISKUS	FLUTICASONE PROPIONATE/ SALMETEROL XINAFOATE	2018
REMODULIN	TREPROSTINIL	2018
XOLAIR	OMALIZUMAB	2018
ERBITUX	CETUXIMAB	2018
LEXIVA	FOSAMPRENAVIR	2018
ACANYA	BENZOYL PEROXIDE / CLINDAMYCIN	2018
LATUDA	LURASIDONE HCL	2018
LETAIRIS	AMBRISENTAN	2018
MOVIPREP	POLYETHYLENE GLYCOL ELECTROLYTE SOLUTION	2018
DAYTRANA	METHYLPHENIDATE HYDROCHLORIDE (DAYTRANA)	2018
ALOXI	PALONOSETRON	2018
LEVITRA	VARDENAFIL HCL	2018
VESICARE	SOLIFENACIN SUCCINATE	2018
RAPAFLO	SILODOSIN	2018
LYRICA	PREGABALIN	2018