MILLIMAN REPORT

Estimated cost of potential state-level frozen formulary legislation

Fully insured commercial payer impact, 2024-2028

Commissioned by Pharmaceutical Care Management Association

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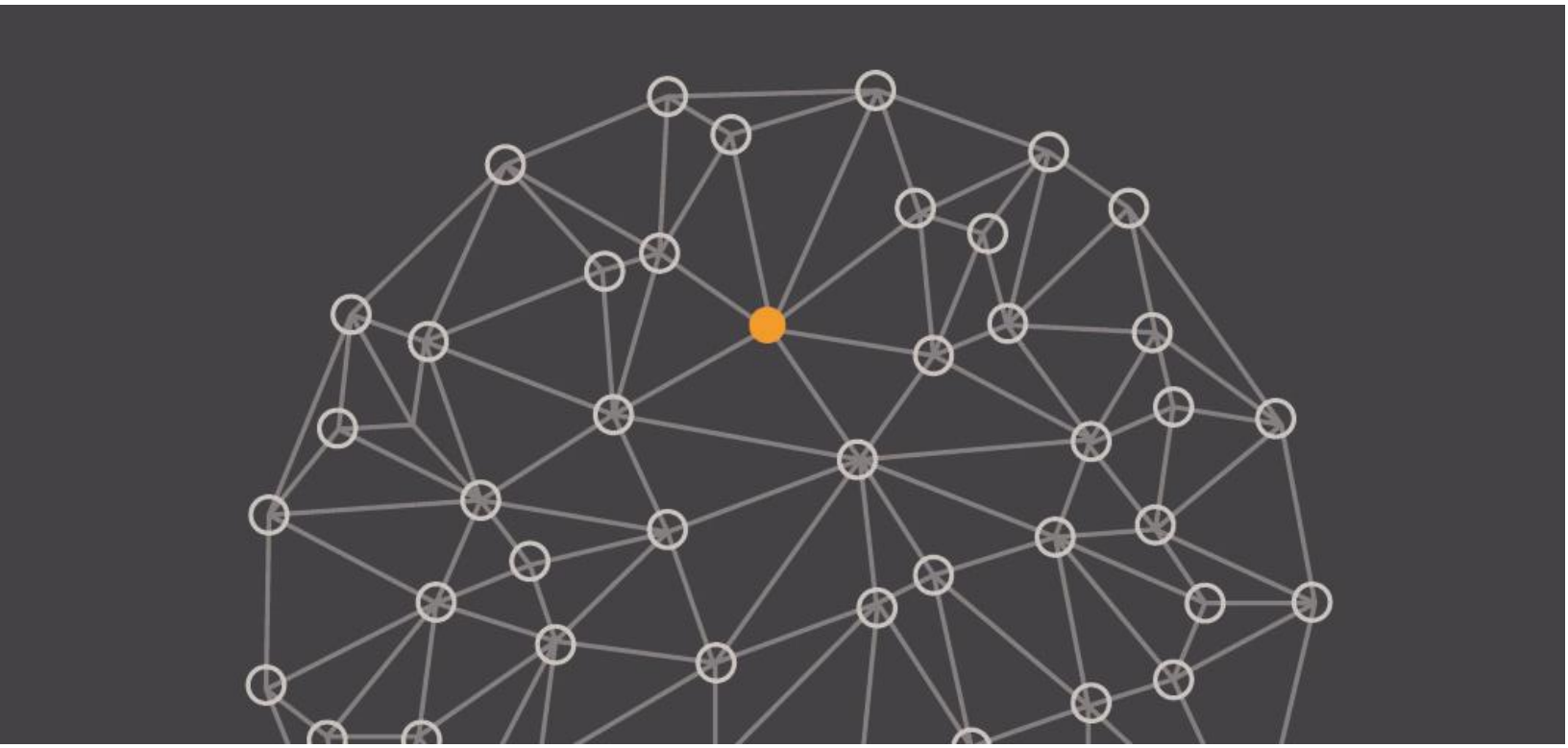

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Executive Summary

The Pharmaceutical Care Management Association (PCMA) engaged Milliman to assess the financial impact of proposed frozen formulary legislation on fully insured commercial health insurance market payer costs. A formulary is a catalogue of drugs – generics, brands, biosimilars – that are covered by a health insurance payer.[i] Frozen formulary legislation refers to a set of regulations proposed by state legislators that would limit the ability of pharmacy benefit managers (PBMs) and payers to implement negative formulary changes to prescription drugs. This legislation typically has two components: (1) restrictions on payers' ability to make negative mid-year formulary changes and (2) continuity of care requirements, which mandate that payers continue to support a patient's access to a drug for which the patient is currently prescribed even after changes to a payer's formulary.

The Centers for Medicare and Medicaid Services (CMS) defines a negative formulary change as a change that would negatively impact patients' access to prescribed drugs. This can include[ii]:

- Removing a drug from formulary
- Moving a drug to a tier with a higher patient cost sharing status
- Implementing more restrictive utilization management (UM) requirements (e.g., prior authorizations, quantity limits, and step therapy requirements)

Definitions of negative formulary changes in the fully insured commercial market vary by state; however, removing a drug from formulary, moving a drug to a tier with higher patient cost sharing, and adding more restrictive UM requirements are all considered negative formulary changes across the legislation considered in this report. Proposed frozen formulary legislation does not restrict positive formulary changes that would increase patients' access to drugs or decrease out-of-pocket costs for patients.

If implemented by states that have proposed frozen formulary legislation as of the date of this report, we project that frozen formulary legislation could increase payer prescription drug costs across the fully insured commercial market by approximately $1.1 billion to $2.5 billion over five years (2024-2028).[1] We estimate that, if implemented nationally, proposed frozen formulary legislation could increase the payer portion of prescription drug costs across the fully insured commercial health insurance market by approximately $2.8 billion to $6.1 billion over the same five years.

"Cost" in this report focuses on the portion of prescription drug claims covered by payers. Specifically, outpatient pharmacy claims net of rebates and patient cost sharing. "Rebates" are post-point of sale price concessions that PBMs negotiate with pharmaceutical manufacturers and pass to payers to decrease net drug costs. A "payer" is defined as the entity that ultimately pays for the prescription. We do not model the impact on self-insured payers, as they may not be subject to state-specific legislation because they are regulated by federal Employee Retirement Income Security Act (ERISA). Additionally, the financial impact to other key stakeholders including patients and manufacturers are not directly modeled in this report; however, they are outlined as considerations.

INTRODUCTION, SCOPE, AND PURPOSE

In the current fully insured commercial health insurance market, payers can generally update their formularies, along with the associated requirements for accessing a prescription drug, at any point throughout the plan year.[iii] Under current practice, these formulary updates – negative or positive – may be made at any time without advance notice. Pharmacy benefit management activities such as formulary changes and utilization management are payers' primary mechanism for controlling healthcare costs and ensuring that patients receive the appropriate, medically necessary medications given their clinical needs.[iv,v] With new pharmaceutical products and new indications for existing products continuously gaining approval, formulary changes, including mid-year formulary changes, enable payers to react to evolving market dynamics. In cases like this, formulary changes ensure patients have access to drugs and ensuring appropriate controls are in place so that patients access cost-effective, clinically appropriate drugs.

Payers frequently work with their PBMs to modify their formularies, with both positive and negative formulary changes, as they evaluate newly approved and existing medications for safety, efficacy, and cost information. With reduced

[1] Impact shown over five years to show the cumulative effect of proposed frozen formulary legislation.

latitude to execute negative mid-year formulary changes, payers may have reduced ability to shift utilization mid-year, or long-term in the case of continuity of care, which may result in higher prescription drug spending.

Proposed frozen formulary legislation may reduce patient disruption by maintaining medication coverage and patient cost sharing throughout the plan year. For example, under current regulations, patients taking a brand drug could face an increase in cost sharing mid-year if a payer implements a negative formulary change to the drug. Under proposed frozen formulary legislation, however, patients would be guaranteed their original cost sharing on their existing prescription drugs.

Additionally, frozen formulary legislation may also provide advantages for healthcare providers. The stability and predictability of a frozen formulary may allow providers to plan more consistent treatment strategies. They can prescribe medications with the confidence that their patients will be able to receive them throughout the plan year. Furthermore, a frozen formulary may reduce the administrative burden on providers, as they may face fewer prior authorizations imposed by the payer and medication substitutions.

Several state legislatures (see Figure 1) are considering frozen formulary legislation that would restrict the ability of payers to make negative formulary changes during the plan year, and potentially long-term for patients who are stable on therapy. Proposed frozen formulary legislation varies across three key attributes:

Scope of Restriction: proposed frozen formulary legislation has varying breadths of reach. It can impact all patients, patients who are stable on any prescription drug, or patients who are stable on a certain type of prescription drug (e.g., drugs for mental illness).

Nature of Restriction: all proposed frozen formulary legislation restricts negative formulary changes, but the specifics of what constitutes a negative formulary change vary by state. For instance, some states prohibit any negative changes outright, while others permit changes to a brand drug if a more cost-effective generic or biosimilar enters the market.

Duration of Restriction: states have proposed frozen formulary legislation with varying periods of restriction. Some states' legislation prohibits mid-year changes, allowing for changes at the start of the new plan year. Meanwhile, other states' legislation restricts negative formulary changes for the duration of a patients' time on a given plan.

For more information on individual state's proposed legislation, please refer to the Figure 1. This table includes all states with proposed frozen formulary legislation at the time of the report.

FIGURE I: OVERVIEW OF PROPOSED FROZEN FORMULARY LEGISLATION BY STATE[vi,vii,viii,ix,xxi,xii,xiii,xiv,xv,xvi,xvii,xviii,xixxx,xxi,xxii]

States	Scope of Restriction	Nature of Restriction	Duration of Restriction
Arizona	■	●	▲
District of Columbia	■	●	▲
Florida*	■	● / ●	▲
Idaho	■	●	▲
Illinois	■	●	▲
Iowa	■	●	▲
Massachusetts	■	●	▲
Minnesota	■	●	▲
Mississippi	■	●	▲
Missouri	■	●	▲
Ohio	■	●	▲
Wisconsin	■	●	▲

Scope of Restriction	Nature of Restriction	Duration of Restriction
■ No mid-year change	● No substitution allowed	▲ Long-term
■ No change to members stable on therapy	● Biologic substitution allowed	▲ Plan-year
	● Generic substitution allowed	▲ 90 days
	● Generic and biologic substitution allowed	▲ 60 days

*Florida's frozen formulary state legislation requires no substitution for patients stable on therapy; however, it allows for generic and biologic substitution for the rest of patients.

We expect proposed frozen formulary legislation, in its varying forms, will impact how payers respond to three key market dynamics commonly seen in the industry: new generic/biosimilar drug launches, new brand drug launches, and established brand changes. These three key market dynamics typically prompt payers to execute negative formulary changes. Our analysis, outlined below, projects the financial implications of proposed frozen formulary legislation for payers in the fully insured commercial market. Specifically, we focus on the financial impact that may arise if payers were unable to execute negative formulary changes in response to these three market dynamics.

1. **New generic/biosimilar drug launch**
    - **Current state**: when a new generic or biosimilar drug becomes commercially available, payers can make a negative formulary change to the associated drug – either a multisource brand (MSB) in the case of a generic, or a reference listed drug (RLD) in the case of a biosimilar. This negative change could involve excluding the associated drug from the formulary, moving it to a higher patient cost sharing tier, or increasing its UM.
    - **Frozen formulary environment**: payers' ability to make negative changes to the MSB or RLD when a generic or biosimilar becomes available is restricted.
    - **Projected financial considerations**: a decrease in the conversion to lower-cost, therapeutically equivalent drugs, resulting from a negative formulary change to the MSB or RLD, is expected to increase both payer and patient costs.
    - **Additional considerations**: given that payers' ability to shift utilization to cost-effective generics or biosimilars is limited, pharmaceutical manufacturers may be less inclined to offer aggressive pricing

terms, typically in the form of rebates, to maintain their drugs' market share upon the approval of a generic or biosimilar. Specifically, proposed frozen formulary legislation could reduce manufacturer participation in 'brand for generic' deals, where manufacturers offer rebates to make their brands preferred over generic counterparts' thus preserving their market share while also reducing payers' costs.

In addition to potentially increasing payers' cost by reducing their negotiation leverage, proposed frozen formulary legislation may also lead to patients forgoing out-of-pocket cost savings. Patients may forgo out-of-pocket cost savings if they stay on the branded drug, MSB or RLD, rather than move to a more cost-effective generic or biosimilar.

2. **New brand drug launch**

   - **Current state:** when a new brand drug becomes commercially available, payers can use the new drug as leverage to negotiate improved pricing on competing, covered drugs. By leveraging their ability to shift utilization from the existing competing brand(s) to the new brand, payers push existing manufacturers to improve their pricing terms ultimately lowering the cost of the existing brand utilization.

     Assuming a drug has a lower cost than the existing competing brand(s), payers may choose to cover the new drug and restrict access to existing competing brand(s). This type of strategy would shift utilization to the new brand. Adjusting the drug mix between the higher and lower-cost drugs would enable the payer to decrease the overall cost of the drug class.
   - **Frozen formulary environment:** payers' ability to make negative formulary changes to existing products in the drug class is restricted. This limits their capacity to negotiate improved pricing terms for existing products and/or shift utilization to the newly launched, potentially lower-cost, brand.
   - **Projected financial considerations**: year-over-year rebate increases are expected to be largely forfeited as manufacturers of existing brands may no longer feel the pressure to compete against new brand launches.
   - **Additional considerations**: given the restricted ability of payers to make negative formulary changes to a drug, they may add fewer new drugs to formulary, or it may take them longer to add them. Limiting the number of new drugs added to the formulary can have implications for patients. New drugs often represent advancements in treatment, offering improved effectiveness, fewer side effects, or novel mechanisms of action that may be more suitable for certain patient populations. In a frozen formulary environment, patients may not have access to these new treatments, which could impact their health outcomes.

3. **Established brand changes**

   - **Current state**: payers can implement negative formulary changes to brands in favor of lower-cost drugs, or in favor of more clinically appropriate drug alternatives – which may have lower costs or be comparably priced to the original drug. This strategy typically involves shifting utilization to the lower-cost or comparably priced brand, either by excluding the higher-cost brand from the formulary, by placing it on a higher patient cost sharing tier, or by adding additional UM to it. Ultimately, this approach enables payers to leverage their formulary strategy to negotiate better pricing terms with manufacturers and to incentivize patients to use lower-cost drugs.
   - **Frozen formulary environment**: payers' ability to make negative formulary changes, including exclusions, is restricted. This limits their capacity to drive cost savings through formulary strategy and pricing term negotiations with manufacturers. While a payer may still have the option to exclude a brand drug, they are mandated to support existing utilizers' access to the brand, even if it is excluded.
   - **Projected financial considerations**: the net payer cost in a frozen formulary environment following a negative formulary change, specifically an exclusion, is expected to be higher than if the exclusion were to happen in the current environment. Furthermore, the net payer cost following a brand exclusion in a frozen formulary environment may be higher than if the exclusion were to have never happened. For instance, if a payer is required to allow previous utilizers to continue using a higher-

cost drug after it is excluded, then the impact is twofold. First, reduced utilization shifts to the lower-cost brand alternatives. This generates a significant opportunity cost compared to if this exclusion were to happen in the current state. Second, the utilization that remains with the higher-cost brand may be rebate ineligible following the exclusion when it was conceivably rebate eligible prior to the exclusion. The opportunity cost of rebates would also apply to up-tiering the product to a higher patient cost sharing tier or even to introducing new UM as these payer actions may result in reduced rebates. All three of these changes could result in the payer forfeiting rebate value that the payer was receiving prior to the exclusion.

- **Additional considerations**: with reduced ability to shift utilization between products, payers may have limited ability to respond to key market dynamics, specifically wholesale acquisition cost (WAC) price changes. While we do not expect manufactures to take significant price increases, for reasons detailed below, it is reasonable to expect them to take year-over-year increases that are in-line with the medical consumer price index (medical CPI).[xxiii] Most inflation protection agreements protect payers against significant price increases leaving them vulnerable to small, annual price increases. Without inflation protection, the full impact of a WAC increase, no matter how small, will be incurred by the payer if the manufacturer does not concurrently increase the rebate or other manufacturer payment rate.

  Alternatively, when manufacturers decrease drug WACs, as several manufacturers have done in response to the removal of the average manufacturer price (AMP) cap discussed further in the Finding section of this report, [xxiv] payers may find themselves unable to fully capitalize upon these reduced costs due to the restrictions of a frozen formulary. In a frozen formulary environment, a payer can add or maintain drugs that have reduced their WAC. However, they cannot fully capitalize on these reduced cost as their ability to shift utilization to the lower-cost drug is limited.

  Lastly, the sporadic adoption of frozen formulary legislation across the United States could seriously impact the national value that payers project due to negative formulary changes. As a result, payers may need to update their modeling practices to account for frozen formulary requirements.

SUMMARY OF FINDINGS

If all three provisions above were implemented in the states that have proposed frozen formulary legislation as of the date of this report (see Fig. 1), we estimate payer prescription drug costs in the fully insured commercial health insurance market could increase by approximately $125 million to $270 million for an estimated 24 million patients in 2024, increasing to between $350 million to $835 million in 2028. These estimates represent a $1.1 billion to $2.5 billion increase in five-year aggregate prescription drug costs for fully insured commercial payers for 2024 through 2028 relative to the current environment. Figure 2 illustrates a range of financial outcomes due to the proposed frozen formulary legislation.

FIGURE 2: ESTIMATED PAYER COST OF FROZEN FORMULARY LEGISLATION IN STATES WITH PROPOSED LEGISLATION ($ MILLIONS)

	2024	2025	2026	2027	2028	2024-2028
Low	$125	$155	$195	$255	$350	$1,080
Mid	$195	$245	$315	$420	$590	$1,765
High	$270	$340	$435	$585	$835	$2,465

Estimates for 2024 through 2028 reflect anticipated fully insured commercial health insurance market enrollment and a year-over-year increase in prescription drug expenditure accounting for increased utilization and inflation. The low to high estimates reflect a range of assumed brand patent expirations and new brand drugs. Figure 3 illustrates a range of 2024 financial outcomes for each provision:

1. **New generic/biosimilar drug launch**. We estimate proposed frozen formulary legislation could increase payer prescription drug costs by $70 million to $125 million in 2024 and by $145 million to $270 million in 2028.
2. **New brand drug launch**. We estimate proposed frozen formulary legislation could increase payer prescription drug costs by $35 million to $110 million in 2024 and by $165 million to $495 million in 2028.
3. **Established brand changes**. We estimate proposed frozen formulary legislation could increase payer prescription drug costs by $20 million to $35 million in 2024 and by $40 million to $70 million in 2028.

FIGURE 3: ESTIMATED PAYER COST OF FROZEN FORMULARY LEGISLATION ACROSS STATES WITH PROPOSED LEGISLATION IN 2024 ($ MILLIONS)

Provision	Low	Mid	High
New Generic/Biosimilar Drug Launch	$70	$100	$125
New Brand Drug Launch	$35	$75	$110
Established Brand Changes	$20	$25	$35
Total	$125	$200	$270

Appendix I illustrates the projected financial impact from Figure 2 above by state. Current and proposed legislation varies by state. In our analysis, we estimate the impact under the assumption that all states implement their legislation that has been proposed as of the date of this report.

Cost estimates for future years are primarily driven by unit cost and utilization trend and reflect the impact of new brand, generic, and biosimilar pipeline drugs. Expected savings due to new generic, biosimilar and brand drugs is based on historical experience. The future drug pipeline (2025-2028) may emerge differently from what is anticipated. The illustrated range of financial outcomes is intended to reflect this future uncertainty.

Findings

We estimate that the proposed frozen formulary legislation could increase payer prescription drug costs in the fully insured commercial health insurance market by approximately $125 million to $270 million in 2024, increasing to $350 million to $835 million in 2028, if all states with proposed frozen formulary legislation as of the date of this report implement legislation. The following sections provide detail on each modeled provision.

NEW GENERIC/BIOSIMILAR DRUG LAUNCH

Generic drugs are lower-cost, chemically equivalent alternatives to brand drugs and can be substituted by a pharmacist without physician approval. For example, insulin glargine is the generic version of the brand drug Lantus. Although the active ingredient is identical, the brand name drug (Lantus) typically has a higher ingredient cost compared to its generic equivalent. Similar to generics, biosimilars can be also less expensive than their biologic brand, RLD; however, unlike generics, biosimilars are not an exact copy of their RLD. Rather, biosimilars have a structure that is highly similar to their RLDs.

Brand manufacturers facing patent expiration, to a generic or biosimilar, may provide improved pricing terms to payers in an effort to maintain share. However, generic and biosimilar price reductions offered by competing generic and biosimilar manufacturers may outweigh the value of these rebates over time. Notably, in addition to generally having a lower net cost, generic products also typically have lower patient cost sharing than their respective brand products.

To jointly reduce overall payer costs, as well as patient cost sharing, payers typically make formulary changes that incentivize patients to switch to the less expensive generic or biosimilar drugs through negative formulary changes to the original brand name drug when a generic or biosimilar drug is launched into the market. For example, payers may up-tier the original brand drug, add UM (e.g., step therapy), or remove the brand drug from the formulary altogether. In the case of generics, formulary changes are typically effective immediately without advanced patient notification; patients are informed at the point of sale and generic substitution occurs by the dispensing pharmacist.

Proposed frozen formulary legislation may prohibit negative formulary changes to the brand product intended to incentivize generic and biosimilar drug utilization. However, several states' proposed legislation allow for an exception which allows pharmacists to substitute a patient's drug with a generic equivalent or biosimilar. In fact, some states have established laws that require pharmacists to substitute generics for brands. This proposed frozen formulary exception, coupled with existing law, is expected to promote utilization shifting from brands to generics in a new generic launch situation. However, payers could be required to continue covering the brand product, at the original patient cost sharing level, for the rest of the plan year or longer, regardless of when a generic or biosimilar drug launches. Without a change to the benefit design, we expect fewer patients will make the switch to cheaper generic and biosimilar drugs. This situation may result in an opportunity cost for payers, who could have shifted utilization to generics or biosimilars with lower net costs, and patients, who could have been at a lower patient cost sharing level.

The estimates in Figure 4 reflect an increase in brand utilization as a result of potential frozen formulary legislation and do not reflect potential changes in associated rebate terms. While expected generic launch savings underlie these estimates for each year, the values in Figure 4 are not estimates of actual generic launch savings.

FIGURE 4: ESTIMATED PAYER COST AMIDST NEW GENERIC AND BIOSIMILAR DRUG LAUNCH ACROSS STATES WITH PROPOSED FROZEN FORMULARY LEGISLATION ($ MILLIONS)

	2024	2025	2026	2027	2028	2024-2028
Low	$70	$85	$105	$125	$145	$530
Mid	$100	$125	$150	$180	$205	$760
High	$125	$160	$195	$230	$270	$980

We do not attempt to estimate the impact of the generic and biosimilar pipeline in each specific year. Rather, these estimates are based on estimated average generic and biosimilar launches for 2023 and 2024, adjusting for date of

FDA approval and prescription drug utilization and inflation trends. The range of cost estimates each year reflects uncertainty of future brand patent expirations.

NEW BRAND DRUG LAUNCH

Pricing terms for brand manufacturers is frequently based on limiting competition from competing brands. This can come as improved formulary placement or UM vs. competing products. When a new brand drug receives approval and is launched into the market, the brand manufacturer may offer rebates in exchange for maintaining favorable formulary placement and/or deferring the addition of the new drug to formulary. In therapeutic classes with competitive brand and/or generic drugs available, payers may choose to not add a new brand drug until favorable pricing terms are negotiated. Similarly, payers may use the newly approved competitor as leverage to negotiate improved pricing terms for existing brands in the therapeutic class. Payers may up-tier, add UM, or exclude an existing brand from formulary if favorable terms are not reached. Flexibility to implement formulary changes mid-year allows payers to maintain or improve pricing terms with brand manufacturers, regardless of whether they ultimately make any formulary changes.

Proposed frozen formulary legislation would restrict payers' ability to make negative formulary changes to an existing brand drug even if a competing brand were launched mid-year thus providing leverage for renewed negotiations. With the payer unable to move against the existing brands, brands with favorable coverage (formulary placement and UM) may be less inclined to provide significant rebate increases to delay the addition of the new brand to formulary. The existing brand stands to lose some market share to the new brand if the new brand is added to a parity position; however, the existing brand does not risk the significant market share degradation associated with a negative formulary change.

In evaluating proposed frozen formulary legislation's impact on the dynamic of new brand launches, we considered two unique situations:

1. **New lower-cost brand**: In order to reduce their costs, we expect payers are more likely to make negative formulary changes to existing brands when a new brand launches at a lower price vs. existing competitive brands. This type of change could incentivize the use of the lower priced brand. For example, Mavyret launched in August 2017 to treat hepatitis C at a list price of $26,400 per course, approximately 65% lower than the list price of drugs Harvoni and Epclusa.[xxv] Commercial payers may have added Mavyret to their formularies in 2017 and removed or up-tiered coverage for Harvoni and Epclusa to incentivize the use of Mavyret. Rebates may also have been renegotiated due to the availability of additional hepatitis C treatments. Under the proposed frozen formulary legislation, payers could choose to cover Mavyret, but would not have been able to change coverage for Harvoni and Epclusa in 2017. This scenario is representative of our estimates in Figure 5.
2. **New more clinically effective brand with higher cost**: We expect payers are less likely to make negative formulary changes if a new brand has a higher price given that incentivizing the use of a higher priced drug may lead to an increase in payer costs. For example, Opzelura gained FDA approval in September 2021 as a topical drug to treat mild to moderate atopic dermatitis (AD).[xxvi] Opzelura launched with a significantly higher WAC than its existing competitor, Eucrisa. As of the date of this report, Opzelura's WAC is $2,045, while Eucrisa's WAC stands at $763.[xxvii] Commercial payers may have added Opzelura, due to efficacy results, to their formularies, but many payers may have maintained existing coverage of Eucrisa.[xxviiixxix] We expect favoring Opzelura could increase payer costs, as patients would be taking the more expensive drug. As a result, it is unlikely that payers would make a negative formulary change to Eucrisa ultimately rendering the impact of frozen formulary legislation in this type of situation to be negligible. As such, we do not explicitly model the impact of negative formulary changes to existing brands in favor of higher-cost new brands in Figure 5.

Figure 5 illustrates the estimated opportunity cost of improved rebate negotiations following new brand approvals due to proposed frozen formulary legislation. Specifically, these values represent the opportunity cost of not being able to effectively negotiate improved pricing terms when a new brand drug launches at a lower price than associated brand drugs in the class. The increase in rebates due to a new brand launch varies widely by therapeutic class and amounts are typically confidential. We also acknowledge that differences in gross cost and patient cost sharing may also affect

the estimated impact of this provision. For these reasons, we illustrate a range of potential outcomes to capture these dynamics.

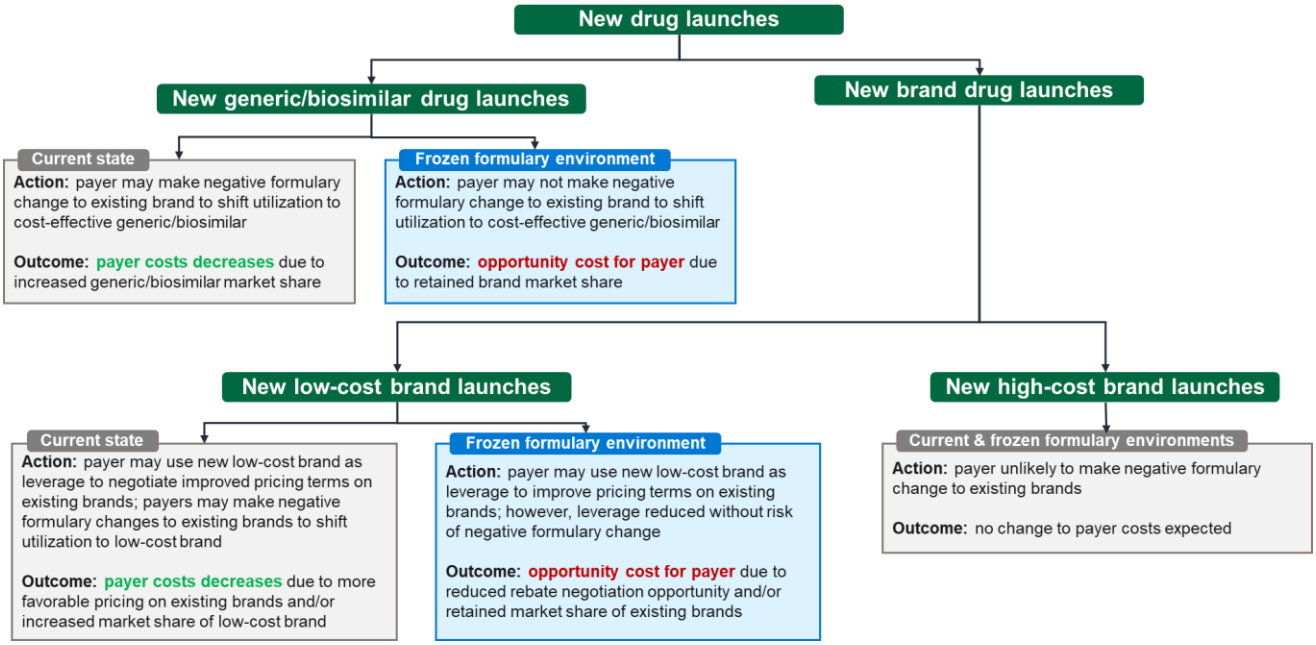
FIGURE 5: ESTIMATED PAYER COST OF NEW BRAND DRUG LAUNCH ACROSS STATES WITH PROPOSED FROZEN FORMULARY LEGISLATION ($ MILLIONS)

	2024	2025	2026	2027	2028	2024-2028
Low	$35	$45	$65	$95	$165	$405
Mid	$75	$90	$125	$195	$330	$815
High	$110	$135	$190	$290	$495	$1,220

Similar to new generic launches, we do not attempt to estimate the impact of the brand pipeline in each specific year. Rather, these estimates are based on estimated brand launches for 2024, adjusting for date of FDA approval and prescription drug utilization and inflation trends. The range of cost estimates each year reflects uncertainty of new brand approvals.

Figure 6 is an illustrative example of the new drug launch dynamics in both the current and frozen formulary environments.

FIGURE 6: NEW DRUG LAUNCH DYNAMICS UNDER CURRENT AND PROPOSED FROZEN FORMULARY STATES



ESTABLISHED BRAND CHANGES

New product – brand, generic, or biosimilar – launches are not the only market disruptors payers are faced with. Payers' ability to execute negative formulary changes to brands enables payers to respond to additional market dynamics such as significant changes to brand-level pricing. These changes can be driven by improved rebates or wholesale acquisition cost (WAC) changes. [xxxxxxi]

Today, payers can make negative formulary changes to drugs in order to shift utilization to more cost-effective drugs in response to a pricing change. This flexibility contributes to price stability as it mitigates the cost impact if pharmaceutical manufacturers were to implement significant price changes. In a frozen formulary environment, on the other hand, payers may lose this capability during the plan year and potentially in perpetuity. Given our lack of visibility

into payers' rebate agreements, we exemplified payers' reactive strategy to price changes by focusing on WAC price changes. In today's market, WAC increases and decreases may trigger varying responses from payers.

WAC Increase: Today, payers may make a negative formulary change to a drug whose WAC increases. A change like this could enable payers to shift utilization to a therapeutically equivalent, more cost-effective drug(s). In a frozen formulary environment, on the other hand, payers may be unable to shift utilization via a negative formulary change, ultimately leaving the payers to absorb the cost of the increased WAC.

WAC Decrease: Today, WAC decreases present a mid-year opportunity for payers. If a drug undergoes a significant price decrease, payers may make a negative formulary change to one or more other competitive drugs in order to shift utilization to the lower-cost drug. In a frozen formulary environment, however, this type of change may be restricted for the plan year or potentially long-term.

We do not expect significant WAC increases to have a material impact on payer costs for several reasons. First, limited drugs are expected to experience large price increases over the coming years due to public scrutiny and legislative changes surrounding the removal of Medicaid's rebate cap. The removal of Medicaid's rebate cap, commonly referred to as the Average Manufacturer Price (AMP) cap, is a notable, recent legislative change enacted in the American Rescue Plan that eliminates the 100% of AMP cap that drug manufactures can pay to Medicaid effective January 1, 2024.[xxxii] The Medicaid rebate calculation includes a base rebate and an inflationary rebate. Drugs that have had significant price increases likely have incurred significant inflationary rebates. With the removal of the 100% cap, pharmaceutical manufacturers could be liable to Medicaid for a payment greater than the AMP of the product. Given this liability, it is unlikely that manufacturers will take significant price increases on their products in the coming years. Second, most payers receive some form of inflation protection from manufacturers, which mitigates the financial impact of significant price increases.

WAC decreases, on the other hand, may become increasingly more common. Several insulin manufacturers, including Eli Lilly, Novo Nordisk, and Sanofi, have implemented WAC reductions between 70% and 80% as of the date of this report.[xxxiii] Public scrutiny, legislative changes, and increased competition may result in this type of pricing strategy gaining more traction with additional pharmaceutical manufacturers. As with WAC increases, WAC decreases are expected to be heavily impacted by the removal of AMP cap. WAC decreases may be a response to liability associated with the removal of AMP cap. For instance, manufacturers that are liable for a rebate over 100% to Medicaid, may reduce the WAC of the product in order to reduce liability. In a frozen formulary environment, a payer may not be able to shift utilization from drugs that have maintained a higher WAC to drugs that have taken a WAC decrease. This could ultimately limit payers' ability to take full advantage of the cost-saving opportunities presented by these WAC reductions, leading to higher overall costs.

FIGURE 7: ESTIMATED PAYER COST OF ESTABLISHED BRAND CHANGES ACROSS STATES WITH PROPOSED FROZEN FORMULARY LEGISLATION ($ MILLIONS)

	2024	2025	2026	2027	2028	2024-2028
Low	$20	$25	$30	$35	$40	$150
Mid	$25	$35	$40	$50	$55	$205
High	$35	$45	$50	$60	$70	$260

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STATE-SPECIFIC ESTIMATES

Several state legislatures have considered various forms of frozen formulary legislation. PCMA requested that we illustrate the change in cost for fully insured commercial payers due to proposed frozen formulary legislation at both the national and state levels. We provided two versions of national projections. The first, "Nationwide – assuming 50 states adopt frozen formulary legislation", assumes that all states execute frozen formulary legislation that does not allow for mid-year changes, any product substitutions, and is long-term. The second, "Nationwide – assuming states with proposed legislation" reduces the projection to states with legislation proposed, accounting for state-level legislation nuances. Similar to the second nationwide projection, our state-level projection projects the financial impact by state according to proposed state-level legislation as of when this report was completed. Legislation may be modified or tabled. Appendix I details the above impacts.

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 drug expenditures by state remains consistent from 2024 to 2028. Nationwide enrollment trends from 2024 to 2028 are consistent with CMS National Health Expenditure enrollment trends and do not vary by state. The Methodology section below provides detail on the state-specific enrollment and prescription drug expenditure assumptions underlying the illustrative state allocation.

OTHER CONSIDERATIONS

Lower patient cost provision

Some proposed frozen formulary legislation allows for negative mid-year formulary changes if the change results in lower patient cost sharing. That is, negative mid-year changes would be permitted if they result in lower patient cost (same as in the current market) but would not be permitted if they result in higher patient cost.

Given that new generic drugs generally have lower cost sharing tiers, in addition to a lower price for the payer, we expect that new generics would be permissible under this condition of negative formulary changes.

This type of proposed frozen formulary legislation would have a mixed impact on new brand drugs. Lower cost new brand drugs may be placed at a lower cost share tier than existing products. This may result in limited disruption in payers' ability to exclude existing brand(s) in favor for a new lower cost brand. If a new brand drug launches at a higher price; however, it is reasonable to expect that payers may place the new drug in a higher cost share tier. According to this subset of legislation, payers would not be able to exclude the existing brands in favor of a new drug in a higher cost share tier. As a result, an exclusion could not happen in this case. While this may impact some specific situations, it is generally unlikely that payers would exclude existing products in favor for a higher cost product, so the disruption here is minimal.

Overall, the ability to make negative formulary changes in favor for a lower patient cost product provides payers additional flexibility and may increase the productivity of frozen formulary legislation.

Stakeholder behavior

The modeled provisions consider potential behavioral responses from payers, specifically in the realm of new brand, generic, and biosimilar launches. The following are additional behavioral changes that may occur in response to the proposed frozen formulary legislation that were not captured in our projections.

Less frequent positive formulary additions/changes: If a payer is unable to impact a patients' access to existing therapy, then formularies may be less likely to pursue broad, open coverage in the future. For example, if a payer knows there are risks to shifting utilization from a brand in the future, then the payer may be more selective with the brands that are added to formulary, especially at a low cost share tier.

Less brand for generic deals: Manufacturers may be less inclined to engage in 'brand for generic' deals with payers. In a 'brand for generic' deal, brand manufacturers provide rebate value in exchange for the brand to be preferred over its generic counterpart. This type of deal enables the manufacturer to maintain a significant portion of its existing market share. However, knowing that payers may have less flexibility to make a formulary change, then the manufacturer may decline to provide value for this type of deal.

Hyperinflation: Pharmaceutical manufacturers may be less aggressive in providing year-over-year rebate enhancements to maintain their formulary position as they know payers' ability to execute negative changes is reduced. While maintaining rebates, pharmaceutical manufacturers may concurrently increase their prices leading to an overall increase in net cost. While we do not expect manufactures to take significant price increases for the reasons outlined in the Findings section, it is reasonable to expect them to take year-over-year increases that are in-line with the medical consumer price index (medical CPI).[xxxiv] Most inflation protection agreements protect payers against significant price increases leaving them vulnerable to small, annual price increases. Without inflation protection, the full impact of a WAC increase, no matter how small, is expected to be incurred by the payer if the manufacturer does not concurrently increase the rebate or other manufacturer payment rate.

Rebate volatility: If a frozen formulary is implemented, a manufacturer could decrease or eliminate rebates for a covered drug with limited risk of losing market share. Reducing or eliminating rebates results in increased costs.

Our analysis does not consider the impact of these, or other potential changes, but we acknowledge that behavior changes may occur and could have significant impacts on our estimates.

Benefit design

The estimated frozen formulary impact for a specific plan is dependent on the plan's tier-specific patient cost sharing. Actual payer costs will differ from the estimates in this report due to variations in patient cost sharing and out-of-pocket limits.

Other forms of formulary management

Additional forms of formulary management that were not modeled in this analysis include proposed frozen formulary legislation for over the counter (OTC) drugs and certain UM programs, such as prior authorization (PA), quantity limits (QL), or step therapy (ST). Proposed frozen formulary legislation for OTC drugs may restrict the ability of payers to enact formulary changes that incentivize patients to use newly available OTC products. Additionally, proposed frozen formulary legislation may impact payers' ability to leverage UM programs. Payers leverage UM programs in situations, like incentivizing patients to use newly available OTC products, to control costs while also delivering necessary prescription drugs. PA programs are intended to determine whether coverage is necessary and appropriate by ensuring that the drug is used in a clinically appropriate setting. ST programs require patients to try more clinically effective or equally clinically effective and/or less costly drugs (e.g., generics) before progressing to the selected drug. QL programs may prevent prolonged treatment that may be harmful, wasteful, or unnecessary. Proposed frozen formulary legislation could impact a payer's ability to implement changes to these programs.

Medicare Part D formulary requirements

Aspects of states' proposed frozen formulary legislations are analogous to the Medicare Part D program. Payers in the Medicare market are unable to enact negative formulary changes, such as increasing patient cost sharing and imposing more restrictive UM programs, during a plan year without significant patient outreach, physician outreach, and approval by CMS. Notably, Medicare Part D payers may remove existing brand drugs from the formulary when an equivalent generic drug is released. CMS is currently finalizing two changes to provide Part D payers with more flexibility to make substitution of biosimilars for their reference products: (1) all biosimilars may be substituted as "maintenance changes", which would not require prior CMS approval and (2) in certain cases, new interchangeable biological products may be immediately substituted for a reference product.[xxxv] In addition, brand and generic drugs may also be removed from the formulary if the drug is recalled as a result of safety concerns.

While Medicare Part D has set a precedent with legislation that prevents negative formulary changes from being applied to existing drugs in the context of new brand launches, several states are proposing novel legislation that would extend negative formulary restrictions to the context of new generic drug launches. Additionally, some states have proposed long-term frozen formulary restrictions which exceed Medicare Part D's plan year duration cap. 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.

Plan premiums

Due to frozen formulary legislation, payers' ability to shift utilization to lower-cost alternatives is reduced, leading to increased overall prescription drug costs. To manage these increased costs, payers may raise plan premiums, distributing the financial burden across the insured population. Increasing premiums would allow payers to offset their increased cost, so that they can continue to ensure the provision of necessary prescription drugs.

Methodology

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

APPROACH

We relied on cost and utilization experience from Milliman's 2023 Health Cost Guidelines and proprietary CHSD database to project average expected commercial, fully insured payer prescription drug costs for 2024 to 2028. 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 proposed frozen formulary legislation. The estimated dollar impact of proposed frozen formulary legislation to payers is the difference between the baseline and frozen formulary projected 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 experience and discussions with clinical experts (e.g., pharmacists).

We project prescription drug spending on a nationwide basis and allocate costs by state based on fully insured commercial market enrollment and prescription drug spending by state.

We modeled three distinct dynamics under frozen formulary environments – new generic/biosimilar drug launch, new brand launch, established brand changes –and assumed independence between each dynamic. The estimated cost of each reflects prescription drug costs and does not reflect potential changes in medical costs that may result from formulary changes.

BASELINE ASSUMPTIONS

The following outlines key baseline assumptions. We assume these items do not change because of proposed frozen formulary legislation.

- **Plan design.** Assumed a brand cost share of 9% and a generic cost share of 29% based on our Health Cost Guidelines.
- **Trends.** Assumed secular combined utilization and cost trends of 6.9% for brand drugs and 5.6% for all drugs in aggregate. Trends are based on industry knowledge and Milliman's Health Cost Guidelines. We apply secular trends to project utilization and cost for 2024 through 2028. We separately apply adjustments for generic launches (described below).
- **Rebates.** Leveraged SSR Health to assume average drug-level rebates. The SSR Health Data includes gross and net prices for the majority of active US brand name products. It utilizes product-level net revenues reported by publicly-traded pharmaceutical manufacturers.[xxxvi]
- **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 drug 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. Appendix III includes a list of 2023 and 2024 generic launches. Due to the uncertainty of future brand patent expirations, we projected the frozen formulary impact to these generic drugs launches and used this two-year average to estimate annual savings. This average estimate was then used to project the 2024 to 2028 generic launch impacts.
- **Enrollment.** We estimate that 89 million patients in the United States receive prescription coverage through fully insured commercial health plans for 2024. We estimate that in states with proposed frozen formulary legislation, 24 million patients receive coverage through fully insured commercial health plans in 2024.This estimate is based on 2023 U.S. Census data,[xxxvii] Kaiser's 2022 Health Care Coverage of the U.S. Population data,[xxxviii] and insured status data from the 2020 Medical Expenditure Panel Survey.[xxxix] Enrollment trends

from 2022 to 2028 are consistent with 2023 CMS National Health Expenditure projected enrollment trend rates for private health insurance in years 2023 to 2028[xl] 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 2023 Health Cost Guidelines (HCG). We assume that the distribution of prescription drug expenditures by state remains constant from 2024 to 2028. Differences in state laws, mandated benefits, prescribing patterns, and other specific geographic variation are not reflected in this illustrative allocation.

FROZEN FORMULARY ASSUMPTIONS

The following section outlines expected changes to new drug launch cost dynamics under proposed frozen formulary legislation. The assumptions presented below are based on our experience and discussions with clinical experts (e.g., pharmacists). We illustrate ranges for each key assumption based on historical data. Future experience may vary from the modeled assumptions. For example, the dynamic around future drug launches is uncertain so we illustrate a range of potential rebate impacts.

- **New generic/biosimilar drug launch.** When a new generic drug launches, we expect a portion of the associated brand's utilization to shift to the generic. However, based on our clinical experience, if payer is not able to remove the associated brand drug from the formulary, then we assume the utilization shift to be reduced by 50% (35% to 65% range). We also assume that, when an existing brand patent expires mid-year, then the proportion of the year is multiplied by the expected generic distribution rate. This assumption may vary according to the mix of brand and generic utilization, differences in state laws, and prescribing patterns.

  These assumptions affect both utilization and unit cost because 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. However, we expect these new generic drug launch frozen formulary assumptions to result in higher prescription drug spend than current state as we are assuming the higher-cost brand drug has larger utilization that in the current environment.

- **New brand drug launch.** When a new, lower-cost brand drug launches, we assume payers will renegotiate pricing terms for covered brand drugs within the respective therapeutic class. We assume that 50% of new brand launches will be competitive lower-cost brand drugs. When a lower-cost brand launches, we assume rebates for brand drugs within the class increase by 20% on average (10% to 30% range). In a frozen formulary environment where payers are not allowed to renegotiate rebates during the year, we assume rebates for brand drugs will be unchanged. Given the varying duration of negative formulary change restrictions across states, this opportunity cost is expected to be compounding year over year for states where proposed frozen formulary legislation has long-term components, while the opportunity cost was evaluated as a single year impact for states where proposed frozen formulary legislation is limited to the plan year.

  This analysis was based off a 2024 brand pipeline established from discussions with clinical experts (e.g., pharmacists). We accounted for a mid-year timing adjustment for this provision by prorating the rebate opportunity cost according to expected FDA approvals. For instance, a new lower cost brand launching in January will generate a larger rebate opportunity cost than a new lower cost brand launching in December. Future year takes into account utilization and inflation growth; however, the frequency, impacted class spend, and overall class rebates for each year to mirror 2024.

  The value of rebates may vary for future years depending on the competition – pricing and clinical differentiation – of newly launched brand drugs, rebates offered by brand manufacturers, and the negotiation leverage of payers in controlling the utilization of formulary drugs. However, we expect these new brand drug launch frozen formulary assumptions to result in higher prescription drug spend than current state as payers may forgo mid-year incremental rebates associated with new brand drug launches as manufacturer will no longer have the risk of negative formulary changes mid-year. Additionally, payers are expected to have less control in shifting utilization from established, higher-cost brands to new, lower-cost brands.

- **Established brand changes.** When a brand exclusion occurs outside of the launch of a new brand or generic, we assume that the payer has made this change in order to shift utilization to either lower-cost drugs, net of

rebates, or competitively priced drugs that are more efficacious. In the case of specialty classes, our current state assumption is that 50% of the excluded drug's utilization will shift to competing brands in the class, weighted according to pre-exclusion market share. In the case of non-specialty classes, our current state assumption is that 90% of a drug's utilization will shift to competing brands in the class, again weighted according to pre-exclusion market share. The variance in specialty vs. non-specialty shifting assumptions is largely driven by the complexity of the conditions that these drugs are used to treat. Specialty drugs are often used for more complex, chronic conditions that require ongoing management. Whereas non-specialty drugs, due to higher predictability of treatment outcomes, their lower cost, and larger breadth of alternatives, are often assumed to have higher transferability between products. However, it is important to note that these are general assumptions and the actual utilization shift rates can vary based on a multitude of factors

In a frozen formulary environment, we would expect the efficiency of the exclusion to be reduced by 50% (35%-65% range). In the case of both specialty and non-specialty classes, we assume that less utilization will shift from the newly excluded branded product. Given that payers continuously update formularies, this impact is expected to be cumulative, carrying over into future years. New utilization; however, that is net new to the plan or from naïve utilizers, is expected to be allotted according to the standard exclusion methodology.

Despite the influx of new utilization that is not impacted by frozen formulary legislation, when utilization and drug trends are accounted for, the compounding future year impact (2025-2028) of frozen formulary legislation is expected to increase each year.

Caveats and Limitations

This Milliman report has been prepared for the specific purpose of estimating the financial impact of proposed frozen formulary legislation on payers. This report is focused on states with legislation proposed as of the date of this report. Legislation may be modified or tabled. 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.

The information presented in this report is provided for PCMA. PCMA may share this information with outside entities with Milliman's permission. Milliman does not intend to benefit, and assumes no duty or liability to, other parties who receive this work product. Any third-party recipient of this work product who desires professional guidance should not rely upon Milliman's work product but should engage qualified professionals for advice appropriate to its own specific needs. Any releases of this report to a third party should be in its entirety. This report must be read in its entirety and specialized knowledge of the industry is necessary to fully understand the report and its conclusions.

Milliman does not provide legal advice and recommends that PCMA consult with its legal advisors regarding legal matters.

MODEL AND DATA RELIANCE

Milliman has developed certain models to estimate the values included in this report. The intent of the models is to estimate the impact of proposed frozen formulary legislation on payer costs. We have reviewed the models, including their inputs, calculations, and outputs, for consistency, reasonableness, and appropriateness to the intended purpose and for compliance with generally accepted actuarial practice and relevant actuarial standards of practice (ASOP). We also relied on expertise from numerous clinical staff (e.g., pharmacists) in evaluating this proposal and developing our modeling assumptions.

The models rely on data and information as input to the models. We relied upon certain data and information outlined below. We accepted these data and information without audit but reviewed them for general reasonableness. To the extent that the data and information provided is not accurate, or is not complete, the values provided in this report may likewise be inaccurate or incomplete.

Data and information reliance includes:

- 2022 Kaiser Health Care Coverage of the U.S. Population data.
- U.S. Department of Health and Human Services: 2020 Medical Expenditure Panel Survey data.
- U.S. Census Bureau: 2023 Annual Estimates of the Resident Population for the United States, Regions, States, and Puerto Rico.

The models, including all input, calculations, and output, may not be appropriate for any other purpose.

SOURCES OF UNCERTAINTY

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 healthcare requirements that may arise in the future.

ACKNOWLEDGMENT OF QUALIFICATION

Tracy A. Margiott is an actuary for Milliman. She is a member of the American Academy of Actuaries and meets the Qualification Standards of the American Academy of Actuaries to render this opinion. To the best of her knowledge and belief, this information is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices.

Appendices

APPENDIX I: ESTIMATED PAYER COST OF PROPOSED FROZEN FORMULARY LEGISLATION BY STATE ($ MILLIONS)*

	2024	2025	2026	2027	2028	2024-2028
Nationwide – assuming 50 states adopt frozen formulary legislation	$785	$835	$890	$945	$1,000	$4,455
Nationwide – assuming states with proposed legislation	$195	$245	$315	$420	$590	$1,765
Arizona	$18.0	$18.7	$19.9	$21.2	$22.4	$99.7
District of Columbia	$1.2	$1.3	$1.4	$1.5	$1.5	$6.8
Florida	$58.9	$62.8	$66.9	$71.1	$75.1	$334.8
Idaho	$1.0	$1.0	$1.1	$1.2	$1.2	$5.6
Illinois	$31.7	$33.8	$36.0	$38.3	$40.4	$180.1
Iowa	$7.5	$15.6	$27.1	$45.4	$77.5	$173.1
Massachusetts	$15.4	$16.4	$17.4	$18.6	$19.6	$87.4
Minnesota	$11.2	$23.1	$40.2	$67.5	$115.1	$257.1
Mississippi	$6.3	$13.0	$22.6	$37.9	$64.6	$144.4
Missouri	$12.7	$26.3	$45.8	$76.8	$131.0	$292.6
Ohio	$20.8	$22.2	$23.6	$25.1	$26.5	$118.2
Wisconsin	$12.3	$13.1	$14.0	$14.9	$15.7	$70.0

**Please note that due to rounding, the sum of individual figures may not align precisely with the presented total.*

APPENDIX II: MODELED 2024 GENERIC AND BIOSIMILAR LAUNCHES

Note: These generic launches were modeled as of April 2024 and are uncertain for future years. This list is subject to change due to on-going patent litigations, FDA approval of the generic, and other factors.

Brand Name	Generic/Biosimilar	Expected Launch Date
MIRVASO	Generic	1/2023
XYREM	Generic	1/2023
TROKENDI XR	Generic	1/2023
KEVEYIS	Generic	1/2023
HUMIRA	Biosimilar	1/2023
LATUDA	Generic	2/2023
AUBAGIO	Generic	3/2023
PYLERA	Generic	3/2023
LANTUS SOLOSTAR	Biosimilar	3/2023
UCERIS FOAM	Generic	4/2023
PREZISTA	Generic	6/2023
ONGLYZA	Generic	7/2023
FIRVANQ	Generic	7/2023
SYMBICORT	Generic	7/2023
KOMBIGLYZE XR	Generic	8/2023
SPIRIVA HANDIHALER	Generic	8/2023

VYVANSE	Generic	8/2023
ALPHAGAN P 0.1%	Generic	9/2023
ONEXTON	Generic	10/2023
MYDAYIS	Generic	10/2023
VOTRIENT	Generic	10/2023
FLOVENT DISKUS	Generic	10/2023
CAROSPIR	Generic	10/2023
LIVALO	Generic	11/2023
FORTEO	Generic	11/2023
CONDYLOX	Generic	12/2023
LEXETTE	Generic	12/2023
NASCOBAL	Generic	12/2023
RISPERDAL CONSTA	Generic	12/2023
FARXIGA	Generic	1/2024
XIGDUO XR	Generic	1/2024
PROLENSA	Generic	1/2024
KORLYM	Generic	1/2024
GRALISE	Generic	1/2024
NATESTO	Generic	2/2024
EMFLAZA	Generic	2/2024
ISENTRESS	Generic	4/2024
RAYOS	Generic	4/2024
EQUETRO	Generic	5/2024
VICTOZA	Generic	6/2024
ACTEMRA	Biosimilar	6/2024
TYSABRI	Biosimilar	6/2024
TASIGNA	Generic	7/2024
TEFLARO	Generic	7/2024
OXTELLAR XR	Generic	9/2024
SPRYCEL	Generic	9/2024
RYDAPT	Generic	10/2024
QSYMIA	Generic	12/2024

[i] GoodRx Health. (2022). Retrieved from https://www.goodrx.com/insurance/health-insurance/medication-formulary
[ii] CMS. (2016). Retrieved from https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf
[iii] Innovative Rx Strategies. (2024). Retrieved from https://innovativerxstrategies.com/understanding-pbm-formularies/
[iv] JMCP. (2024). Retrieved from https://www.jmcp.org/doi/full/10.18553/jmcp.2024.30.2.206
[v] PCMA. (2023). Retrieved from https://www.pcmanet.org/wp-content/uploads/2023/10/Utilization-Management-Talking-Points_FINAL.pdf
[vi] Bill Status Inquiry. (2024) Retrieved from https://apps.azleg.gov/BillStatus/BillOverview/80621
[vii] Legiscan. (2024). Retrieved from https://legiscan.com/DC/bill/B25-0124/2023
[viii] The Florida Senate. (2024). Retrieved from https://www.flsenate.gov/Session/Bill/2024/1543
[ix] The Florida Senate. (2024). Retrieved from https://www.flsenate.gov/Session/Bill/2024/924
[x] The Idaho Legislature. (2024). Retrieved from https://legislature.idaho.gov/sessioninfo/2024/legislation/S1389/
[xi] The Idaho Legislature. (2024). Retrieved from https://legislature.idaho.gov/sessioninfo/2024/legislation/H0596/
[xii] The Illinois General Assembly. (2024). Retrieved from https://ilga.gov/legislation/BillStatus.asp?GA=103&SessionID=112&DocTypeID=SB&DocNum=2789
[xiii] The Iowa Legislature. (2023). Retrieved from https://www.legis.iowa.gov/legislation/BillBook?ga=90&ba=SF86
[xiv] The 193rd General Court of the Commonwealth of Massachusetts. (2024). Retrieved from https://malegislature.gov/Bills/193/H982
[xv] The Minnesota Legislature. (2023). Retrieved from https://www.revisor.mn.gov/bills/text.php?number=HF294&version=0&session_year=2023&session_number=0
[xvi] LegiScan. (2023). Retrieved from https://legiscan.com/MN/bill/SF328/2023
[xvii] The Mississippi Legislature. (2024). Retrieved from https://billstatus.ls.state.ms.us/2024/pdf/history/HB/HB0339.xml
[xviii] The Mississippi Legislature. (2024). Retrieved from https://billstatus.ls.state.ms.us/2024/pdf/history/SB/SB2783.xml
[xix] The Missouri Legislature. (2024). Retrieved from https://house.mo.gov/BillsMobile.aspx?year=2024&code=R&bill=HB1682
[xx] The Ohio Legislature. (2024). Retrieved from https://www.legislature.ohio.gov/legislation/135/HB291
[xxi] The Wisconsin State Legislature. (2024). Retrieved from https://docs.legis.wisconsin.gov/2023/proposals/reg/asm/bill/AB773
[xxii] The Wisconsin State Legislature. (2024). Retrieved from https://docs.legis.wisconsin.gov/2023/proposals/reg/sen/bill/SB737
[xxiii] Peterson-KFF. (2023). Retrieved from https://www.healthsystemtracker.org/brief/how-does-medical-inflation-compare-to-inflation-in-the-rest-of-theeconomy/#Cumulative%20percent%20change%20in%20Consumer%20Price%20Index%20for%20All%20Urban%20Consumers%20(CPI-U)%20for%20medical%20care%20and%20for%20all%20goods%20and%20services,%20January%202000%20-June%202023
[xxiv] AlignRx. (2023). Retrieved from https://alignrxconsulting.com/medicaid-amp-cap-removal-market-changes-rx-strategies-amidst-new-provisions/#:~:text=To%20counterbalance%20the%20implications%20of%20the%20AMP%20cap,the%20WAC%20for%20select%20insulin%20products%20by%202024.
[xxv] Fierce Pharma. (2020). Retrieved from https://www.fiercepharma.com/special-report/mavyret-top-10-drug-launches-since-2017
[xxvi] Optum. (2021). Retrieved from https://professionals.optumrx.com/publications/library/drugapproval_opzelura_2021-0922.html
[xxvii] Medi-Span PriceRx Pro. (n.d.). Retrieved from https://pricerx.medispan.com/
[xxviii] Optum. (2024). Retrieved from https://www.optum.com/content/dam/o4-dam/resources/pdfs/forms/2024-select-standard-formulary.pdf
[xxix] SilverScripts. (2024). Retrieved from https://www.caremark.com/portal/asset/STRS_EGWP_HCAP_Comprehensive_Formulary.pdf
[xxx] Milliman. (2018). Retrieved from https://www.milliman.com/en/insight/a-primer-on-prescription-drug-rebates-insights-into-why-rebates-are-a-target-for-reducing
[xxxi] Drugs.com. (2024). Retrieved from https://www.drugs.com/article/average-wholesale-price-awp.html#:~:text=The%20wholesale%20acquisition%20cost%20%28WAC%29%20is%20the%20manufacturer%E2%80%99s,today%20by%20pharmacies%20to%20buy%20drugs%20from%20wholesalers.
[xxxii] KFF. (2021). Retrieved from https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-federal-policy-approaches-to-address-medicaid-prescription-drug-spending/
[xxxiii] GoodRx. (2023). Retrieved from https://www.goodrx.com/classes/insulins/inflation-reduction-act-lowers-insulin-prices
[xxxiv] Peterson-KFF. (2023). Retrieved from https://www.healthsystemtracker.org/brief/how-does-medical-inflation-compare-to-inflation-in-the-rest-of-the-economy/#Cumulative%20percent%20change%20in%20Consumer%20Price%20Index%20for%20All%20Urban%20Consumers%20(CPI-U)%20for%20medical%20care%20and%20for%20all%20goods%20and%20services,%20January%202000%20-June%202023
[xxxv] CMS Newsroom. (2024). Retrieved from https://www.cms.gov/newsroom/fact-sheets/contract-year-2025-medicare-advantage-and-part-d-final-rule-cms-4205-f
[xxxvi] AEI. (2022). Retrieved from https://www.aei.org/articles/best-practices-using-ssr-health-net-drug-pricing-data/
[xxxvii] U.S. Census Bureau. (2019). Retrieved from https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html#par_textimage
[xxxviii] Kaiser Family Foundation (2023). Retrieved from https://www.kff.org/other/state-indicator/total-population/
[xxxix] U.S. Department of Health and Human Services. (n.d.). Retrieved from https://meps.ahrq.gov/data_stats/summ_tables/insr/state/series_2/2018/tiib2b1.pdf
[xl] CMS. (n.d.). Retrieved from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html