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NAIC Health Care Affordability and Mitigation (B) Working Group
National Association of Insurance Commissioners
1101 K Street, N.W., Suite 650 Washington, DC 20005

Submitted via Email: Joe Touschner (jtouschner@naic.org)

RE: BCBSA Comments on Drafting Group 6: Direct-to-Consumer Drug Platforms

Dear: Ms. Harris and Mr. Beagan

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to provide feedback on the Direct-to-Consumer Drug Platforms Brief developed by the Health Care Affordability and Mitigation (B) Working Group Drafting Group #6.

BCBSA is a national federation of 31 independent, community-based and locally operated Blue Cross and Blue Shield companies (Plans) that collectively cover, serve, and support 1 in 3 Americans in every ZIP code across all 50 states and Puerto Rico. BCBS Plans contract with 95% of hospitals and 91% of doctors across the country and serve individuals covered through Medicare, Medicaid, employer-sponsored coverage, and the individual market.

BCBSA believes that everyone deserves peace of mind when it comes to their health care. As health care costs continue to rise, families, employers, and public programs are facing increasing financial pressure. Consumers are experiencing higher premiums, increased cost sharing, and rising out-of-pocket expenses, underscoring the need for solutions that address the underlying drivers of health care costs. BCBS companies are focused on addressing the root causes of rising costs and advancing a [roadmap](#) that could reduce health care costs by nearly \$1 trillion over 10 years through targeted reforms designed to improve affordability and promote a more sustainable health care system.

Given this commitment to improving health care affordability, BCBSA appreciates the Working Group's efforts to develop issue briefs that serve as educational resources for regulators and policymakers. These

resources provide a valuable overview of policy approaches being considered and implemented across states and can help inform ongoing discussions regarding strategies to improve affordability and access to coverage. BCBSA believes the briefs will be a useful resource for regulators seeking to better understand the range of state policy options, as well as the opportunities and tradeoffs associated with different approaches. BCBSA looks forward to working with the Working Group as it continues its examination of policies that can support affordable, high-quality health coverage and care.

As the Working Group continues to refine these resources, BCBSA encourages the adoption and maintenance of a standardized format across the issue briefs. A consistent structure, including the presentation of state examples, discussion of policy considerations, evaluation of available evidence, and identification of legal, operational, and implementation considerations, would strengthen the briefs and make it easier for regulators and other stakeholders to compare approaches across topics. In addition, BCBSA agrees with recommendations offered by our consumer representative colleagues that each brief clearly articulate the affordability challenge it is intended to address and explain how the featured state approaches are designed to respond to that challenge. Providing this context would enhance the educational value of the briefs and help readers better understand the relationship between specific policy interventions and affordability objectives.

BCBSA also encourages the Working Group to maintain the briefs as neutral educational resources consistent with their stated purpose. The briefs are most effective when they provide an objective assessment of state approaches, including implementation experiences, operational considerations, potential benefits and drawbacks, and any available evidence regarding outcomes. Because states face differing market dynamics, regulatory frameworks, and affordability challenges, the briefs can serve as a particularly valuable resource when they present information in a balanced and non-prescriptive manner, enabling regulators and policymakers to evaluate policy options within the context of their own markets.

Finally, we recommend that the briefs consistently identify when a highlighted policy, law, or regulatory approach is subject to ongoing litigation, legal challenge, enforcement stays, or other significant legal uncertainty. Providing this context is particularly important where legal proceedings may affect implementation, enforceability, or the ultimate viability of a policy approach. Including such information would help ensure regulators receive a complete and balanced understanding of the policy landscape and avoid inadvertently presenting unsettled approaches as established best practices.

In addition to the overarching comments outlined above, BCBSA has provided attached redlines and document-specific comments for the Working Group's consideration. These recommendations are intended to improve consistency across the briefs, enhance contextual information, support the briefs' educational purpose, and ensure that relevant implementation and legal considerations are presented in a balanced manner.

Thank you for the opportunity to provide feedback. We appreciate the Working Group's continued efforts to develop these resources and look forward to continued engagement as the briefs evolve. If you have any questions or would like additional information, please contact Randi Chapman at randi.chapman@bcbsa.com.

Sincerely,

A handwritten signature in dark ink, reading "Clay S. McClure". The signature is written in a cursive, flowing style.

Clay S. McClure, BCBSA
Senior Director, State Affairs

NAIC Health Care Affordability and Mitigation Working Group: Direct-to-Consumer Drug Platforms

The Health Care Affordability and Mitigation Working Group Briefs are intended to be short, informative briefings for regulators and policymakers on various affordability efforts states have undertaken in recent years to help make health insurance more affordable. They are intended to be high-level and not an exhaustive resource on each issue. They also do not represent policy positions of the NAIC, a given state, author, or workgroup member.

Submission Date

TBD

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Executive Summary

This document seeks to address three different types of direct-to-consumer drug purchasing pathways currently available, how those options do or do not interact with the pharmacy benefits typically available through health insurance, and the impact on overall health care affordability. State policy options will be presented along with their benefits and disadvantages. The creation, distribution, and purchasing of drugs is exceedingly complicated and involves many different players. Other NAIC groups are

investigating areas such as Pharmacy Benefit Managers and Prescription Drug Affordability Boards, so they will not be addressed here.

To fully investigate direct-to-consumer drug platforms, regulators should understand three different ecospheres of prescription drug distribution: discount cards, manufacturer assistance programs, and true direct-to-consumer platforms.

Discount Cards

Discount pharmacy plans and cards offer pre-negotiated cash prices for prescriptions. Discount card vendors often contract with PBMs to provide consumers (“members”) with access to discounted the lowest contracted prices available at their local participating pharmacies. Discount card transactions typically may include an administrative fee that is added to the lowest available contracted PBM rate and reflected in the amount paid by the “member” at the point of sale. Because the transaction occurs outside the health plan’s benefit structure, consumer payments generally are not applied toward plan deductibles, out-of-pocket maximums, or other cost-sharing accumulators.

Manufacturer Assistance Programs

Manufacturer assistance programs provide free or reduced-cost medications to under-insured and uninsured patients, often through manufacturer coupons used at a local or mail-order pharmacy or via direct shipment to the provider’s office or patient’s home. While the intention is for these programs to benefit the neediest consumers, often they are used by consumers who have insurance to avoid high out-of-pocket costs instituted by the plan. These programs typically lower a consumer’s immediate costs at the point of sale, but they may result in utilization of higher cost brand drugs when lower cost clinically appropriate alternatives are available. Although manufacturer assistance can reduce a consumer’s out-of-pocket spending, it is not cost-free to the healthcare system. By insulating consumers from the full cost of the drug, these programs encourage the continued utilization of higher cost products and support demand at the manufacturer’s list price rather than promoting competition from lower cost alternatives. While the value of this assistance generally is not applied toward the consumer’s deductible or out-of-pocket maximum, the consumer has incurred little or no direct cost because the manufacturer, rather than the consumer, is funding the assistance.

Manufacturer copay cards, or “coupon cards,” are used with commercial insurance claims to reduce a patient’s out-of-pocket cost at the pharmacy counter. The card applies a set amount toward the patient’s cost share and may be valid for one-time or multiple uses, subject to manufacturer limits. While the value of this assistance generally is not applied toward the consumer’s deductible or out-of-pocket maximum, the consumer has incurred little or no direct cost because the manufacturer, rather than the consumer, is funding the assistance.

Direct-to-Consumer Platforms

Direct-to-Consumer pharmacies provide consumers with access to medications at a cash price that is not adjudicated through their health insurance coverage. These pharmacies may offer lower prices for certain drugs; however, because the transaction occurs outside the health plan's benefit structure, consumer payments generally are not applied toward plan deductibles, out-of-pocket maximums, or other cost-sharing accumulators. Additionally, the health plan is generally not made aware of direct-to-consumer purchases, limiting its visibility into a member's full medication regimen, which may undermine efforts to support care coordination, medication adherence, and ability to identify potential drug interactions or duplicative treatment.

Direct-to-Consumer sales offered by pharmaceutical manufacturers involve providing medication to consumers at a discounted cash price. Consumers create an online account to obtain prescription medications at cheaper cash prices that are directly mailed to their homes via mail order pharmacy. Because the transaction occurs outside the health plan's benefit structure, consumer payments generally are not applied toward plan deductibles, out-of-pocket maximums, or other cost-sharing accumulators.

Direct-to-Consumer Telehealth platforms provide telehealth medical appointments and mail order drug purchases virtually to patients. Some platforms accept insurance; however, the model we are exploring in this paper does not accept insurance. Because the transaction occurs outside the health plan's benefit structure, consumer payments generally are not applied toward plan deductibles, out-of-pocket maximums, or other cost-sharing accumulators.

Premium Impact and Savings Analysis

The effects of direct-to-consumer drug platforms, discount pharmacy cards, and manufacturer assistance programs on health insurance affordability are complex. The effects depend on the drugs purchased, the prices available through each pathway, whether lower-cost alternatives are covered under one's insurance benefit, and value of the drugs acquired and how the programs impact the behavior of consumers, providers, plans, pharmacies, PBMs, and manufacturers ~~and other market participants~~. These programs could reduce ~~overall health~~ costs for individual consumers if when they provide affordable access to effective medications that ~~consumers they~~ would not otherwise find affordable. However, they may ~~raise-increase~~ overall health care costs if they lead to the use of more drugs or steer consumers toward more expensive drugs without commensurate health-clinical benefits. Because they operate outside of existing pharmacy benefits, they could shift spending reduce-outside the insurance benefit, including toward consumers, ~~costs~~ without reducing overall system costs, ~~instead shifting costs to consumers.~~

The impact of these drug programs also varies from person to person. For the uninsured, these programs may provide valuable discounts on drugs. For insured consumers, the savings are harder to quantify and depend on the drug, the consumer's insurance benefit design, the plan's formulary, and whether the consumer has already satisfied their deductible or out-of-pocket maximum for consumers with insurance. If a drug isn't covered by a consumer's plan, these drug programs *may* save the consumer money at the point of sale. However, it is important to remember there may be an alternative medication available (e.g., generic drug) that is covered by the plan or an exceptions process that could allow coverage for a drug excluded from a plan formulary. By using one of these programs instead of using a covered alternative, a consumer may incur out-of-pocket costs that are not applied to their deductible or out-of-pocket maximum.

It is important to distinguish between Direct-to-Consumer pharmacy programs, discount pharmacy cards, and manufacturer assistance programs. When a Direct-to-Consumer pharmacy or discount pharmacy card is used, the consumer pays the cost of the prescription out of pocket, often at a discounted cash price. These payments generally are not credited toward the consumer's deductible or out-of-pocket maximum because the claim is not processed through the health plan, thus the consumer incurs an actual financial expense.

Manufacturer assistance programs reduce or eliminate the consumer's out-of-pocket cost through financial support provided by the drug manufacturer. While the value of this assistance generally is not applied toward the consumer's deductible or out-of-pocket maximum, the consumer has incurred little or no direct cost because the manufacturer, rather than the consumer, is funding the assistance.

If a drug is covered by a consumer's plan, Direct-to-Consumer pharmacies and discount pharmacy cards may provide lower upfront costs, however, this could ultimately work against consumers because amounts paid for drugs purchased using Direct-to-Consumer pharmacies or discount pharmacy cards are typically not counted towards the consumer's deductible. As a result, a consumer may continue to incur cost-sharing obligations for other covered services, such as physician visits or medical procedures, for a longer period than if the prescription had been obtained through the health plan.

Some insurers use copay adjustment programs to address the use of manufacturer-funded assistance programs. The two most common types are Copay Accumulators and Copay Maximizers. In both of these situations, consumers may use drug coupons, but the value of the manufacturer assistance is not applied to the plan's deductible or out-of-pocket maximum. consequently As a result consumers may have a greater difficulty reaching those limits and may face high out-of-pocket costs if manufacturer assistance is exhausted before the end of the plan year. If this happens, some maximizer programs are designed use a third-party

to spread the value of the manufacturer's assistance over the course of the benefit year, reducing the likelihood the assistance will be depleted prematurely.

Manufacturer coupons are issued for brand name drugs to keep them competitive with generics by offering consumers short-term savings at the pharmacy counter. Consumers pay less out of pocket, which encourages them to use the brand-name version of a drug, even when a cheaper, generic or biosimilar version might be available through their plan. Some insurers say this encourages the unnecessary use of more expensive drugs which results in higher overall costs for insurers leading to higher premiums overall.

Direct-to-Consumer Drug Platform State Policy Options Brief

State policy options for addressing Direct-to-Consumer drug platforms depend on policymakers' goals and the regulatory tools available for each of the Direct-to-Consumer pathways. States have established extensive regulation of health insurance issuers and pharmacy benefit managers but have less authority and regulatory experience regarding drug manufacturers and drug discount programs. States may wish to ensure out-of-pocket spending limits incorporate more of a consumer's actual out-of-pocket drug ~~spending, spending and distinguish between cost sharing amounts actually paid by the consumer and amounts funded by a manufacturer or other third party. States should also consider but they should also be aware of the premium impacts that can result when manufacturer assistance supports effects of~~ high drug list prices or steers consumer utilization toward higher cost products, which can be supported by manufacturer coupons.

States have taken several actions to direct how health insurance issuers apply spending to cost-sharing obligations and to make drugs available to consumers.

Rules on Out-of-Pocket Calculations

Twenty-five states, the District of Columbia, and Puerto Rico have laws to require any payment or discount made by or on behalf of a consumer to be applied to the consumer's annual out-of-pocket cost-sharing requirement. Some examples include:

Colorado

Beginning on January 1, 2028, a health insurance carrier shall account for and credit an out-of-pocket expense that the covered person incurs by purchasing a prescription drug directly from a pharmacy or direct-to-consumer platform when calculating a covered person's contribution to an out-of-pocket maximum or cost-sharing requirement. To receive a credit, an enrollee must

provide proof of payment for a direct purchase of a prescription drug, such as an itemized receipt or pharmacy record, within 90 days after making the purchase. The carrier may request additional information or documentation if the proof of payment is insufficient or incomplete. The carrier shall not apply a contribution credit if the amount of a covered person's out-of-pocket expense is greater than the amount the covered person would have incurred if they had obtained the same prescription drug in the same plan year from an in-network pharmacy and pursuant to the terms of their plan or if the enrollee does not comply with the carrier's utilization management processes, including prior authorization and step therapy protocols required under the plan.

Connecticut

Beginning July 1, 2026, Connecticut health carriers must credit to an enrollee's cost-sharing requirement any in-network out-of-pocket prescription drug payments made directly to a pharmacy or health care provider, as long as no claim for the drug was submitted to the carrier, the drug is a covered benefit, and the drug's price is below the plan's or policy's average in network discounted rate. Carriers must also create a proof-of-payment form for out-of-pocket prescription drug purchases, post the form online, and provide annual instructions to enrollees on how to access and submit it.

Maryland

Beginning on January 1, 2026, when calculating an enrollee's contribution to out-of-pocket costs, insurers shall include any discount, financial assistance payment, product voucher, or other out-of-pocket expense made by or on behalf of the enrollee for a prescription drug. The drug must be either covered under the plan and not have an AB-rated generic equivalent drug or an interchangeable biological product preferred under the health benefit plan's formulary or have an AB-rated generic equivalent drug or an interchangeable biological product preferred under the health benefit plan's formulary and the insured or enrollee originally obtained coverage for that product through prior authorization, a step therapy protocol, or the exception or appeal process of the issuer.

State Bulk Purchasing

California

CalRx: The California Affordable Drug Manufacturing Act of 2020, also known as CalRx, authorizes the state Health and Human Services agency to enter into contracts and partnerships for the purpose of making pharmaceuticals more affordable. The statute authorizes the creation of a California-branded label for generic drugs, with the goals of ensuring access to generic prescription drugs and lowering health care costs through savings to public health care programs and private health insurance coverage. To

date, the state has implemented two drug delivery models, promoting access to a biosimilar insulin injection product and a naloxone nasal spray.

- **Insulin:** Californians with diabetes often struggle to afford needed insulin. CalRx, in partnership with Civica, provides Glargine biosimilar insulin pens through participating pharmacies. CalRx Insulin is eligible for health insurance coverage and is available to patients with an existing prescription for similar insulin products. The product is currently priced at \$55 for a 10-pack of 3 milliliter pens. The product is not currently available in other formats, such as vials.
- **Naloxone:** While Naloxone is currently available without a prescription throughout the U.S., it is unaffordable for many consumers. California's CalRx program provides a twin pack of naloxone nasal spray to state residents through participating pharmacies and direct online sales. The product is provided free of charge to first responders, health care providers, schools and community organizations and at a reduced cost, currently \$19, to individuals.

The CalRx naloxone program is managed by the state Department of Healthcare Services (DHCS), through a partnership with a manufacturer, Amneal. The program receives financial support from an opioid settlement fund.

Sources

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Civica Rx. California Selects Civica Rx as Its Insulin Manufacturing Partner. https://civicarx.org/wp-content/uploads/2023/07/Civica-and-California-Partnership-PR-FINAL_3.20-.pdf

Colorado General Assembly. SB26-167: Prescription Drug Out-of-Pocket Expense Credit (2026). <https://leg.colorado.gov/bills/SB26-167>

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National Conference of State Legislatures. State co-pay accumulator laws. (11 December 2025).
<https://www.ncsl.org/health/copayment-adjustment-programs>

State of Connecticut Insurance Department. Notice to All Health Carriers Concerning Credit for Certain Out-of-Pocket Prescription Drug Purchases. (17 February 2026). https://portal.ct.gov/cid/-/media/cid/1_notices/prescription-drug-credit-notice.pdf

Further Reading

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Compares neurologic medication costs at Cost Plus Drugs with commercial insurance plan costs.

[Harris E. Discount Cards Could Save Patients Millions on Drug Costs. JAMA. 2023;330\(13\):1218.](#)
Compares actual out-of-pocket payments for common generic drugs with Amazon Prime and GoodRx Gold discount card prices.

[Hussain S. Lalani, Aaron S. Kesselheim, Benjamin N. Rome. Potential Medicare Part D Savings on Generic Drugs From the Mark Cuban Cost Plus Drug Company. Ann Intern Med.2022;175:1053-1055. \[Epub 21 June 2022\].](#)
Estimates potential Medicare Part D savings if Medicare had purchased selected generic drugs at Mark Cuban Cost Plus Drug Company prices

[Lalani HS, Kesselheim AS, Rome BN. Benefits and Limitations of Direct-to-Consumer Pharmacies in the US. JAMA Netw Open. 2025;8\(8\):e2527484. doi:10.1001/jamanetworkopen.2025.27484](#)
Overview.

[Lalani HS, Tessema FA, Kesselheim AS, Rome BN. Availability and Cost of Expensive and Common Generic Prescription Drugs: A Cross-sectional Analysis of Direct-to-Consumer Pharmacies. J Gen Intern Med. 2024 Sep;39\(12\):2187-2195.](#)
Compares availability and prices for expensive and common generic drugs across DTC pharmacies.