PCMA

February 20th, 2024

The Honorable Donna Bailey
The Honorable Anne Perry
Members, Committee on Health Coverage, Insurance and Financial Services
Cross Building, Room 220
100 State House Station
Augusta, ME 04333

RE: LD 2114 An Act to Improve Patient Access to and Savings from Generic Drugs and Biosimilars; Opposed

Chair Bailey, Chair Perry, and Members of the Committee,

On behalf of the Pharmaceutical Care Management Association (PCMA), we wish to share comments related to LD 2114, which would require coverage of generics and biosimilars at the lowest cost out-of-pocket cost tier. PCMA is the national association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for millions of Americans with health coverage provided through large and small employers, health plans, labor unions, state, and federal employee benefit plans, and government programs.

In the prescription drug marketplace, carriers and PBMs use formularies and cost-sharing tiers to provide medications at various price points based on a patient's plan design. The ability of plans to negotiate the lowest net price possible for their patients is crucial, and this bill would obstruct that ability. This bill would undermine the negotiations made on behalf of patients to get to that lowest net cost price, no matter if the drug is a generic, brand, or biosimilar.

Generic exclusivity is also a concern with LD 2114. When a brand drug loses its patent, clinically equivalent generics can enter the market. There is about a 6-month exclusivity period where the generic can be priced almost as much as the brand until other generics enter the market. Typically, brand manufacturers offer rebates on the branded product, resulting in a lower net cost.

This bill would also give an advantage to biosimilars. Biosimilar manufacturers do not have to offer rebates because there is either no competition or patents protect them. Similarly, generics are rarely created in the specialty marketplace, so there is also a lack of competition in this space.

There have been attempts by drug manufacturers to take a brand name product off of the market and introduce an authorized generic to manipulate the system. These attempts are thwarted when PBMs refuse to include the authorized generic on their standard formularies because it would cost plans more. While the authorized generic list price is lower than the brand name's list price, it is a more costly product for health insurers and large employers, given the rebates on brand-name drugs that PBMs had negotiated.

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Plans and PBMs use Pharmacy & Therapeutic Committees comprised of independent experts, including physicians and pharmacists, to develop evidence-based guidelines used in drug management programs to ensure that all drugs on the formulary are clinically effective in treating various disease states. Then, drugs that offer the lowest net price are selected to drive costs down for both patients and plans. It is essential that any legislation considered does not erode methods that help patients and ensure a cost-effective pharmacy benefit. Therefore, PCMA opposes LD 2114 with the concern that this will raise costs unintentionally.

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How Drug Companies Use Authorized Generics To Keep Drug Prices High

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The particularly harsh winter across much of the country has made the last month particularly difficult for those who suffer from asthma. Exacerbating their distress is the fact that the price of inhalers has sharply increased of late, which caught Congress's attention. Senator Bernie Sanders and several of his colleagues recently sent letters to four drug manufacturers (here, here, here, and here) chastising them for their exorbitantly priced inhalers, and finger-pointing swiftly ensued, with at least one manufacturer blaming pharmacy benefit managers (PBMs), a common villain in the story drug makers like to tell about prices.

But the story is not that simple. Underlying this is the untold story of authorized generics. While authorized generics are not unique to Flovent, its use here is emblematic of the broader issue.

For example, Flovent HFA (fluticasone) is a widely used inhaler that was recently taken off the market by its maker, GlaxoSmithKline (GSK). Why would a manufacturer discontinue a drug with more than $400 million in annual revenue in the U.S.?

The answer lies in a change to Medicaid rebates enacted in the American Rescue Plan Act of 2021 (ARP).

Congress has long required drug manufacturers to pay both a fixed percentage rebate on all Medicaid sales and an additional rebate on any product whose price rises faster than inflation. This inflationary rebate was capped at 100 percent of a drug's average manufacturer price (AMP), but the ARP removed the cap, effective January 1, 2024.

The Congressional Budget Office projected that this change would generate more than $2 billion in annual savings to the federal government, but there is a notable wrinkle: this change imposes a *new* penalty on drug makers based on their *past* pricing decisions. Drug manufacturers had not previously been penalized for taking price hikes once they hit the cap, and the new policy effectively set aside the old rules. To mitigate their revenue loss, which will impact an estimated 15-20% of brand drugs, drug manufacturers have begun to look for strategic remedies.

Since Flovent's launch in 2005, GSK has raised its price more than sixfold, which means that the ARP inflationary rebate change would have led to a large penalty on GSK's Medicaid sales. Instead of dropping Flovent's price (which was the intent of the ARP provision), GSK decided to remove the product from the market altogether and shift patients to what is known as an *authorized generic*.

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By **Cassidy Horton** Contributor

An authorized generic is an unbranded version of a drug made by the brand manufacturer or a partner. With this maneuver, GSK could dodge the inflationary rebate since the authorized generic is—technically—a new product, even though it is actually the same medication.

However, GSK's attempt to manipulate the system was thwarted when the three largest PBMs refused to include the authorized generic on their standard formularies because it would cost them more. While the authorized generic list price is lower than Flovent's list price, it is actually a more costly product for health insurers and large employers given the deep discounts (manufacturer rebates) on Flovent that PBMs had negotiated. In fact, SSR Health data suggests that the list price of the authorized generic would be as much as three times higher than the average net price of Flovent.

GSK could have made the switch to the authorized generic, avoided the increased Medicaid rebates, and set the price of the authorized generic at the actual net price of the brand. Instead, they overreached and tried to avoid the increased rebates while also concomitantly increasing prices to commercial payers.

The result of this maneuvering—all of which should have been anticipated—is that instead of Flovent generating more revenue by avoiding Medicaid inflationary rebates (and making more on the authorized generic in the commercial market), the resultant sales decline means GSK will earn significantly less as commercial sales decline. On top of this, the fact that doctors are concerned about the unavailability of Flovent and lawmakers are upset about GSK's patent and pricing strategies for Flovent, are likely to be bothered by this tactic as well.

For this to be resolved, GSK will need to balance economic tradeoffs with other pressures. If GSK reduces the price of the authorized generic to recapture commercial market sales it will lose revenue in Medicaid, and if it does not cut its price it will miss out on sales in the commercial market. At the same time, the Medicaid policy change at the root of this problem is unlikely to be unwound. What we can expect is for lawmakers to point fingers everywhere except at themselves.

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