The Medicaid Drug Rebate Program and Considerations for Generic Markets

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Executive Summary

Generic drugs play a key role in the US healthcare system. In Medicaid, coverage of outpatient prescription drugs is governed by the Medicaid Drug Rebate Program (MDRP), which requires manufacturers to pay rebates in return for guaranteed coverage. These rebates include a base rebate and an inflation rebate that applies when a drug's average manufacturer price (AMP) increases faster than the rate of inflation.

Intended to restrain drug price increases, the inflation penalty affects both brand and generic products, but poses unique challenges for generic manufacturers, due in large part to the differing dynamics of the multi-source (generic) versus single-source (brand) markets. Purchasing pattern fluctuations, including changes in customer base and seasonal changes in product usage, can raise a generic product's AMP even when the manufacturer did not increase the price. In addition, pricing for generic drugs is highly affected by the commoditized nature of the multi-source generic market. Price competition in many generic markets has driven prices down to just above production costs, with minimal margins to absorb any fluctuations (e.g., increases in manufacturing or ingredient costs). This downward pressure may result in price increases for generic manufacturers when input costs increase or when there is a shortage. This is particularly likely when the AMP benchmark is low, which occurs when a manufacturer enters the market after others or if it is an older generic drug (where there has been sustained price competition).

This paper details five scenarios of how AMP increases may occur and lead to a generic manufacturer being subject to inflation rebates in situations where the generic manufacturer is not taking a price increase beyond the inflation rate:

- Scenarios in which a generic manufacturer may be faced with a Medicaid inflation rebate without increasing the price of the drug:
  - Scenario A: Change in customer base (e.g., loss of high-rebate, high-volume contract)
  - Scenario B: Seasonal fluctuations in product usage and product costs
- Scenarios in which a generic manufacturer is faced with a Medicaid inflation rebate due to price increases driven by market pressures:
  - Scenario C: Increases in product input cost not reflected in the Consumer Price Index for All Urban Consumers (CPI-U)
  - Scenario D: Drugs in shortage
  - Scenario E: Mature generics and late entrants to the generics market

The application of inflation rebates in these instances can cause generic products to become unprofitable in Medicaid. This can lead to product withdrawals and, over time, less competitive and sustainable markets.

Overview of MDRP Requirements for Generics

Generic drugs play a key role in the US healthcare system. In 2023, generics and biosimilars represented approximately 90% of total prescriptions filled in the US and 13.1% of prescription drug spending.[1] Within the Medicaid program, generics play a similarly important role. In fiscal year 2021, generic drugs accounted for 84.7% of prescriptions in Medicaid and comprised 15.9% of Medicaid drug spending.[2]

Given their low prices and high utilization, generic drugs are critical for Medicaid beneficiaries who rely on prescription medications for acute problems and to manage chronic conditions.

Coverage of prescription drugs in Medicaid is governed by the MDRP. Under the MDRP, manufacturers are required to provide mandatory rebates. In exchange, states must cover rebated drugs. The MDRP rebate formula is set in statute and varies based on whether the drug is a brand or generic. For most brand name drugs, the rebate is the greater of 23.1% of AMP or the difference between AMP and "Best Price" (i.e., the greatest discount provided to certain purchasers).[3] For generic drugs, the rebate amount is 13% of AMP.[4]

For most drugs, AMP is defined as the average price paid to a drug's manufacturer by wholesalers and retail pharmacies, inclusive of associated discounts and rebates to those entities. The AMP calculation excludes bona fide service fees, manufacturer-sponsored direct patient assistance, and sales to entities other than wholesalers and retail pharmacies.

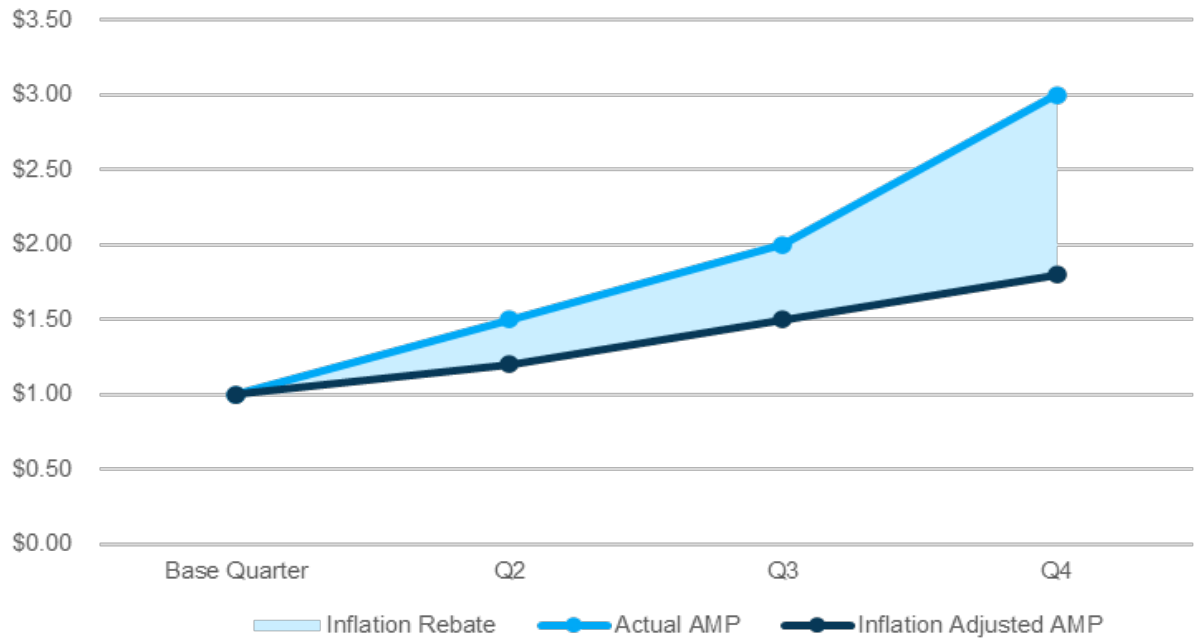
In addition, both brand and generic drugs are subject to MDRP inflation rebates. Inflation rebates for brand name products were established by the Omnibus Reconciliation Act of 1990 to address pricing trends among brand drugs, which often increase list prices each year.[5,6,7] The 1990 law did not establish an inflation rebate for generic drugs, likely because the generic market does not tend to experience the same price increase patterns as branded markets.[8]

More recently, the Bipartisan Budget Act (BBA) of 2015 applied the brand drug inflation rebate to generic drugs, effective January 1, 2017.[9,10] Under the BBA, generic manufacturers are required to pay an additional rebate when the AMP for a drug increases at a rate greater than inflation, as measured by the CPI-U.[11] This approach differs from that taken for Medicare under the Inflation Reduction Act of 2022 (IRA), which excludes most multi-source drugs from inflation penalties.

1 Association for Accessible Medicines. "The U.S. Generic & Biosimilar Medicines Savings Report." September 2024. Here
2 Medicaid and CHIP Payment Access Commission. Park, Chris. "Trends in Medicaid Drug Spending and Rebates." October 2022. Here
3 Certain blood clotting factors and drugs approved by the FDA exclusively for pediatric patients have a 17.1% base rebate.
4 Social Security Act Section 1927(c)(3)
5 H.R.5835 - Omnibus Budget Reconciliation Act of 1990, Here.
6 Wineinger N, Zhang Y, Topoi E, "Trends in Prices of Popular Brand-Name Prescription Drugs in the United States." JAMA Network Open. 2019;2(5):e194791. doi:10.1001/jamanetworkopen.2019.4791
7 Hawley, Julia. "How Pharmaceutical Companies Price Their Drugs." Investopedia. May 2024. Here.
8 Wineinger N, Zhang Y, Topoi E, "Trends in Prices of Popular Brand-Name Prescription Drugs in the United States." JAMA Network Open. 2019;2(5):e194791. doi:10.1001/jamanetworkopen.2019.4791
9 Public Law 114-74, Section 602, November 2, 2015.
10 Medicaid and CHIP Payment and Access Commission . "Medicaid Payment for Outpatient Prescription Drugs." May 2018. Here.
11 Centers for Medicare and Medicaid Services (CMS). "Medicaid Drug Rebate Program Notice for Participating Drug Manufacturers Release No. 97." April 15, 2016. Here

To calculate the inflation rebate, changes in a drug's AMP are tracked against a base AMP value and changes in inflation are tracked against a base CPI-U. In a particular quarter, if a drug's AMP is higher than the base AMP adjusted by the CPI-U, an inflation rebate equal to the difference is assessed (Figure 1).

Figure 1: Calculation of Inflation Rebate (Illustrative Example)



A drug's base AMP and base CPI-U are determined by each drug's market date. For generic drugs marketed before April 1, 2013, the base AMP is equal to the AMP for the third quarter of 2014 and the base CPI-U is the CPI-U for September 2014. For generic drugs marketed after April 1, 2013, the base AMP is equal to the AMP for the fifth full calendar quarter after the drug is marketed and the Base CPI-U is equal to the CPI-U for the last month of the Base AMP quarter (Table 1). As a result, drugs launched after 2013 are anchored to their fifth quarter AMP, whereas drugs launched prior to 2013 may be anchored to an AMP years after their launch, after market forces such as multiple manufacturers entering the market may have increased or decreased AMP without the manufacturer changing price.

Table 1: Base AMP and CPI-U Based on Drug Marketing Date

	Base AMP	Base CPI-U
Drugs Marketed Before April 1, 2013	AMP for Q3 2014	CPI-U for September 2014
Drugs Marked After April 1, 2013	AMP for the fifth full calendar quarter after which the drug is marketed	CPI-U for the last month of the base AMP quarter

Generic Market Challenges

The application of a single-source inflation rebate model to a multi-source environment can create challenges for generic manufacturers. There are key differences in the market dynamics governing the amount purchasers pay for brand versus generic drugs. Unlike single-source (brand) products, generic drugs are produced by multiple manufacturers and are substitutable, competing based on price and volume. As more manufacturers enter the market for a given generic product, prices typically decline. These price decreases can be significant and often result in generics with very thin profit margins.[12]

The unique multi-source dynamics can create challenges for generics as they interact with the MDRP inflation rebate requirements originally designed for single-source brand products. Generic products may experience increases in AMP due to factors outside of the manufacturer's control, and these increases may trigger inflation rebates.

Scenarios Where a Generic Manufacturer May be Faced with a Medicaid Inflation Rebate Without Increasing the Purchase Price of the Drug

Generic manufacturers may face increases in AMP, and therefore inflation rebates, due to changes in purchasing patterns even when the prices that they charge to individual purchasers do not change.[13] There are two main scenarios where this can occur: (1) when there is a change in the customer base, and (2) when there are seasonal variations in buying patterns.

Scenario A: Change in Customer Base (e.g., Loss of High-Rebate, High-Volume Contract)

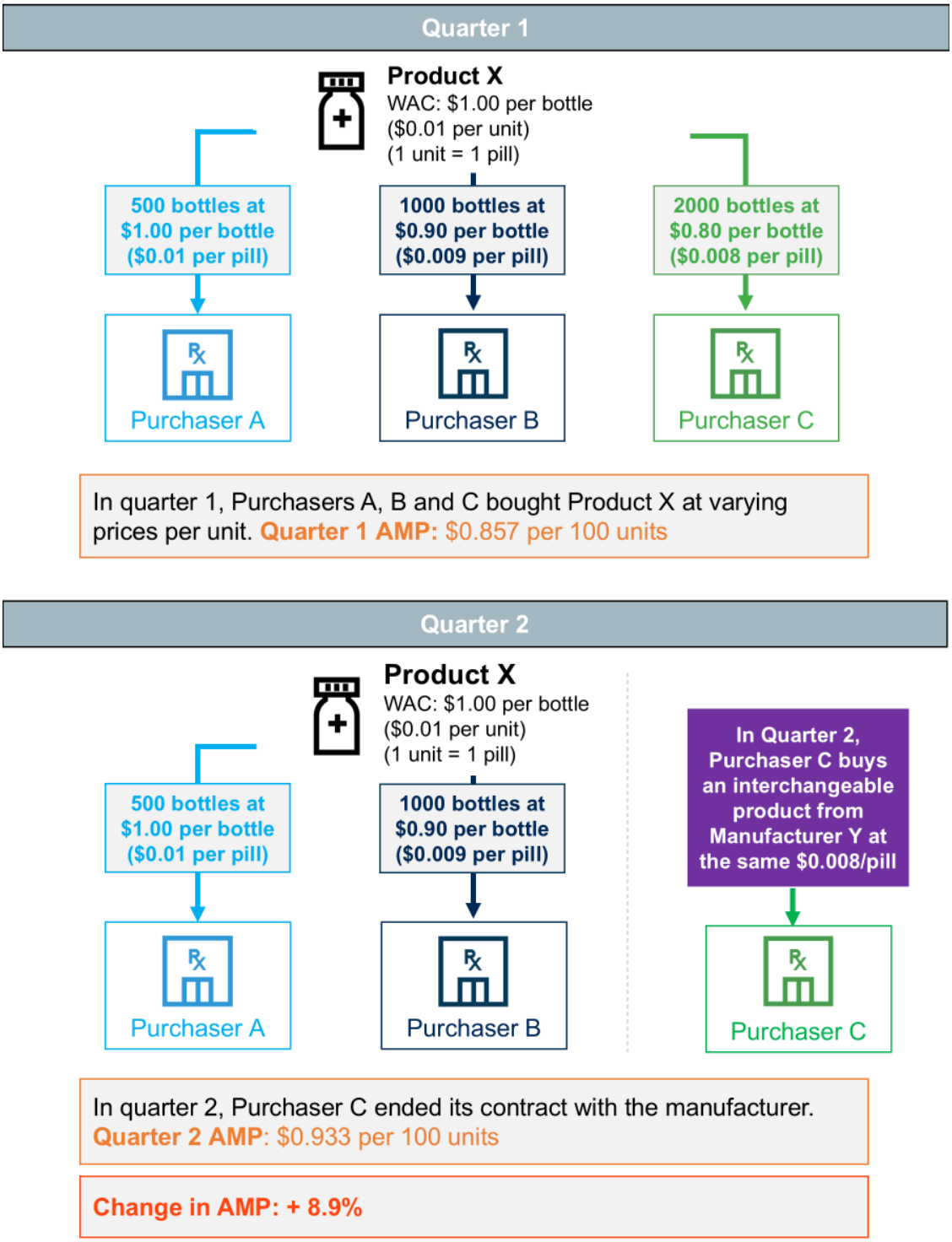
Generic manufacturers may face inflation rebates even when the prices they charge to purchasers do not change. Generic manufacturers often offer discounts on their products to purchasers, although the size of the discount typically differs among entities. For example, large orders may receive volume-based and prompt-pay discounts that are larger than small orders. When the volume of a product bought by a purchaser changes relative to other purchasers, it can influence a product's AMP, even if the manufacturer makes no modifications to pricing from quarter to quarter.

12 Hernandez, Inmaculada. Testimony Before the US Senate Finance Committee. December 2023. Here.

13 Because of multi-source competition, generic drugs are rarely sold at manufacturer list prices (e.g., wholesale acquisition cost). Avalere uses prices charged or purchase price to describe the actual prices paid by purchasers of multi-source generic drugs.

For example, Manufacturer X of a generic drug may sell its product to Purchasers A, B, and C. Purchaser A may buy a small quantity of the drug at the manufacturer's published wholesale acquisition cost, while Purchaser B buys more at a 10% volume discount, and Purchaser C buys the most at a 20% volume discount. In a certain quarter, Purchaser C may instead purchase from a competitor, Manufacturer Y, also at a 20% volume discount, and cancel its contract with Manufacturer X. In this scenario, neither the price charged by Manufacturer X nor the overall spending by Purchaser C changed. However, the product's AMP could increase, as Manufacturer X's average price per pill across all purchasers would increase. The resulting AMP percentage increase could result in an inflation rebate if it is larger than the CPI-U. Thus, in addition to lower total sales and lost market share, the manufacturer could face an inflation rebate, which may make the product unprofitable.

Figure 2: AMP May Change Due to a Change in Manufacturer-Purchaser Contracting (Illustrative Example)

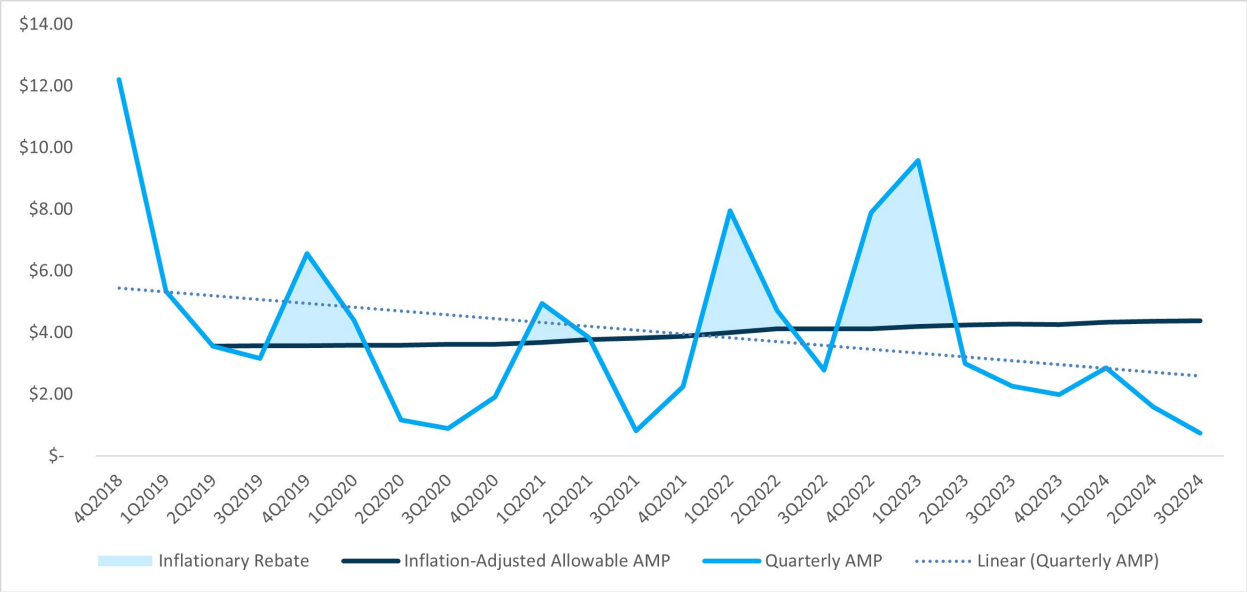


WAC: Wholesale Acquisition Cost

Scenario B: Seasonal Fluctuations in Product Usage and Product Costs

In addition to changes in purchaser behavior, fluctuations in the utilization of certain drugs can create variances in AMP. This dynamic can be illustrated with a drug that is used seasonally, such as oseltamivir, a generic for Tamiflu to treat influenza (Figure 3).[14] The first generic product was approved and marketed in December 2016.[15] By the end of 2021, generic products were marketed by 11 manufacturers. For an oseltamivir product launched in the first quarter of 2018, the base AMP would be set at the fifth quarter after launch (i.e., the second quarter of 2019). In that quarter, the AMP was $3.56 per capsule. A review of quarterly AMPs shows significant fluctuation, with higher AMPs in colder months when influenza is more prevalent, and lower AMPs in warmer months. Because of these seasonal variations, the drug has been subject to inflation rebates about one-third of the time since launch, even though the AMP has trended down since launch.

Figure 3: Example Inflation Rebate for Oseltamivir 75mg Capsules Launched Quarter 1, 2018



Scenarios Where a Generic Manufacturer is Faced with a Medicaid Inflation Rebate Due to Price Increases Driven by Market Pressures

Generic manufacturers may face inflation rebates when they increase a drug's price charged to purchasers due to market pressures such as production cost increases or shortages, or if a drug

14 Example adapted from IQVIA NSP invoice-based sales and units sold to pharmacies for a single national drug code (NDC). NSP is used as a proxy for AMP; examples are meant to be illustrative and do not reflect the actual AMP or inflation rebate for any specific product.

15 Oseltamivir, Capsule; Oral, 70mg. Food and Drug Administration. "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations." (accessed September 28, 2024). Here.

has a fluctuating AMP that is low (either due to being a mature generic or the later launch of a generic product).

In each of these scenarios the application of an inflation rebate may make the product unprofitable within the Medicaid program.

Scenario C: Increases in Product Input Cost Not Reflected in CPI-U

The cost of producing generic products depends on several factors, including ingredients and manufacturing costs. These costs can fluctuate based on market conditions and are often not captured by the CPI-U.[16] For example, in 2024 prices for the active pharmaceutical ingredient in naproxen increased significantly, due in part to increasing raw material costs, energy costs, and supply chain disruptions.[17,18] These input cost increases were far greater than the corresponding CPI-U, which was 2.9% in July 2024.[19] Since many generics are sold at a price close to the marginal cost of production,[20] manufacturers may not be able to absorb increases in ingredient costs without increasing the price charged to the customer. If ingredient cost increases, and resulting price increases, are greater than CPI-U, they can result in an inflation rebate.

Scenario D: Products in Shortage

Generic products may also have AMP increases in the event of a shortage. Generic products may enter shortage for several reasons, including supply chain disruptions, production challenges, or manufacturer market exits. Manufacturer efforts to alleviate a shortage, such as by creating new production lines or re-sourcing raw materials, can often increase production costs.[21] As a result, drug costs may rise as manufacturers attempt to increase production. The increases in AMP observed during shortages may be larger than the CPI-U, which can result in the application of inflation rebates.[22]

Lawmakers have recognized the effects of drug shortages on manufacturing costs and have accounted for inflation rebates in the event of a drug shortage within other government

16 University of Minnesota Center for Infectious Disease Research & Policy. Van Beusekom, Mary. “Cost of China-made drug ingredients more than doubled during pandemic.” March 3, 2023. Here.
17 ChemAnalyst News. “Soaring Naproxen API Prices Raise Concerns for Drug Makers and Consumers Across the United States.” June 2024. Here.
18 ChemAnalyst News. Figuero, Gabriella. “North American Naproxen Surge: API Costs Set to Climb.” June 18, 2024. Here.
19 US Department of Labor, Bureau of Labor Statistics. “New Release: Consumer Price Index – July 2024.” August 2024. Here.
20 National Academies of Sciences, Engineering, and Medicine. “Making Medicines Affordable: A National Imperative.” November 2017. Here.
21 Ventola, C. “The Drug Shortage Crisis in the United States.” Pharmacy and Therapeutics. November 2011. Here.
22 Office of the Assistant Secretary for Planning and Evaluation (ASPE), “ASPE Report to Congress: Impact of Drug Shortages on Consumer Costs.” 2023. Here.

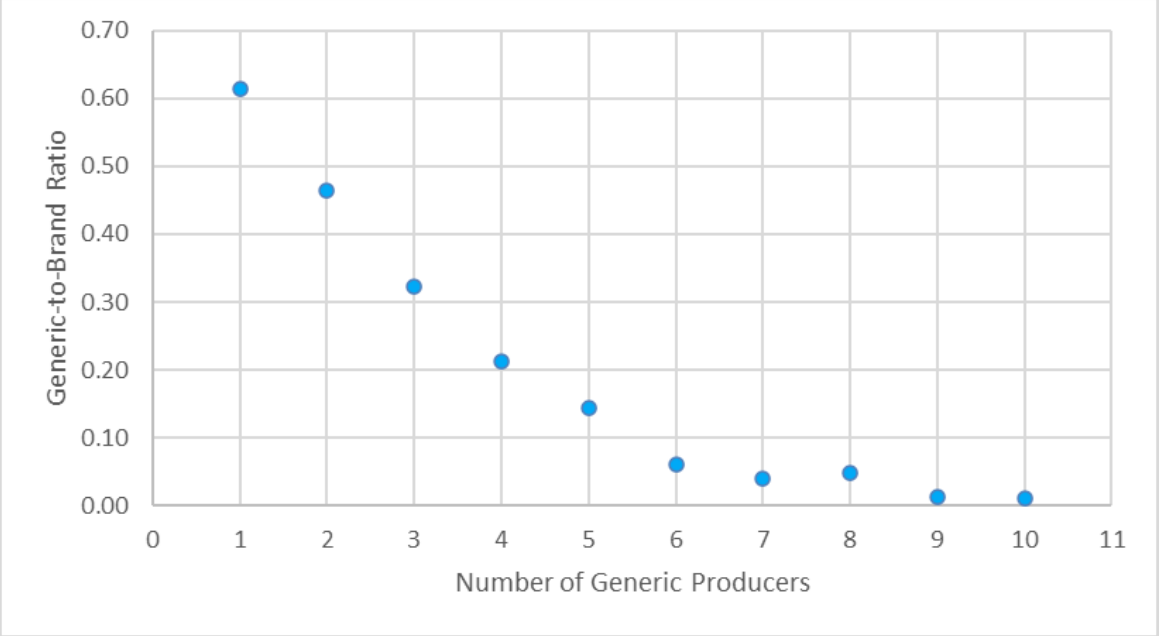
programs. For example, the IRA established inflation rebates within Medicare but included provisions to reduce inflation rebate liability for products in or at risk of shortage.[23]

Scenario E: Mature Generics and Later Entrants

If a generic product has a very low AMP (e.g., less than $0.05 a pill), then the product may be more likely to be subject to an inflation rebate if there are changes in market dynamics (e.g., increased costs of active pharmaceutical ingredients or key starting materials). For such products, even a small increase in AMP is likely to be proportionately large and trigger an inflation rebate. As an example, naproxen tablets are sold at about $0.03 each, so even a penny per unit purchase price increase could trigger an inflation rebate, depending on the base AMP and CPI-U. These inflation rebates would likely make the products unprofitable.

Mature generics and later market entrants tend to have lower AMPs, and therefore may be particularly likely to have AMPs near the production cost.[24] The FDA has noted that later entrants tend to have a lower AMP at launch (Figure 4).[25] As such, later entrants are priced closer to the overall production cost and small fluctuations in pricing may trigger an inflation rebate.

Figure 4: Median Generic Prices Relative to Brand Price, By Number of Generic Producers

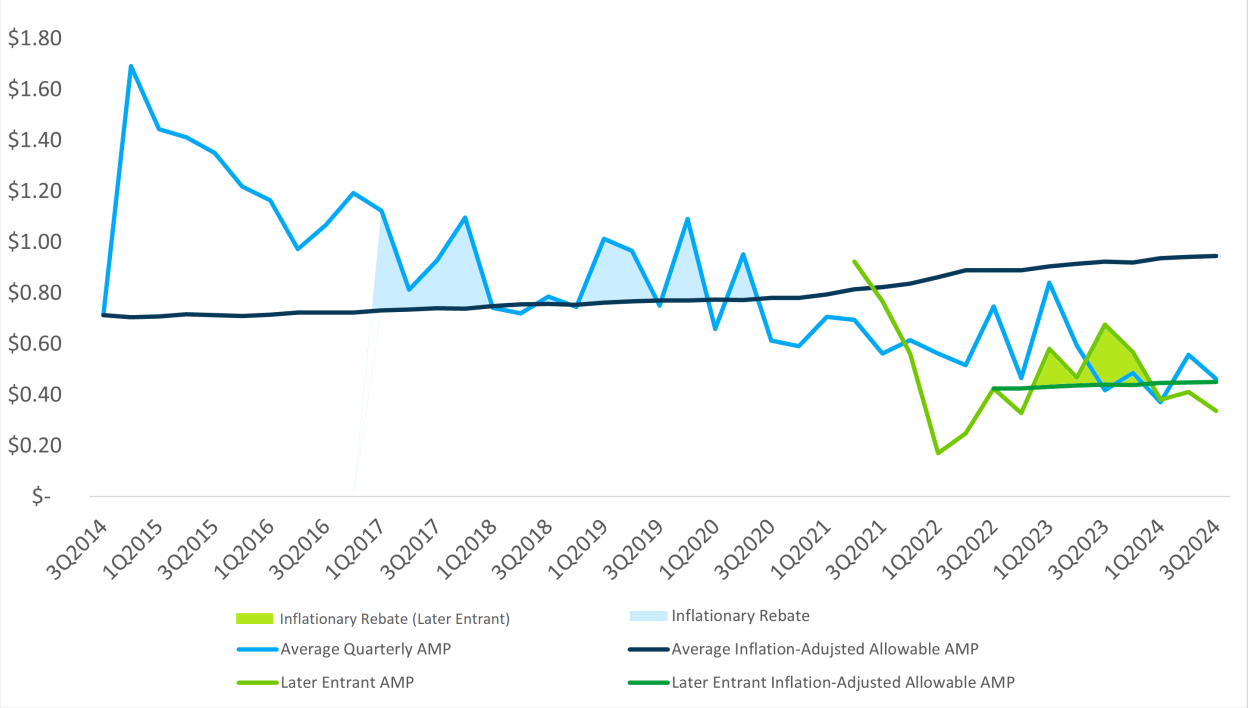


23 IRA of 2022 (HR 5375), 117th Congress. Here.
24 FDA. Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. December 2019. Here.
25 Ibid.

For example, the first generic equivalents for Keppra XR 500mg (levetiracetam extended-release tablet, 500mg) were marketed on September 12, 2011.[26] By the third quarter of 2014, the base date for generic MDRP inflation rebates, the weighted average AMP across 12 manufacturers was $0.714 per tablet. Over time, the weighted average AMP decreased, and by Q3 2020, the weighted average AMP was below the inflation-adjusted allowable AMP.

In the below example (Figure 5),[27] a later entrant levetiracetam product enters the market in Q2 2021. The product's AMP base date would be based on its Q3 2022 AMP, which is lower than both the weighted average AMP for equivalent generic products and the average inflation-adjusted allowable AMP. However, because of its low base AMP, if the product experienced even a small increase in AMP it could face inflation rebates. These rebates would apply despite the product being priced below other manufacturers.

Figure 5: Example Inflation Rebate for Levetiracetam Tablets Available Prior to the Third Quarter of 2014 Compared with Later Entrant



26 Levetiracetam Tablet, Extended Release; Oral, 500mg. FDA. "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations." https://www.accessdata.fda.gov/scripts/cder/ob/. (accessed September 28, 2024).

27 Later entrant (green line) example adapted from IQVIA NSP invoice-based sales and units sold to pharmacies for a single NDC. NSP is used as a proxy for AMP; examples are meant to be illustrative and do not reflect the actual AMP or inflation rebate for any specific product. The average quarterly AMP (blue line) is the weighted average AMP for all MDRP-participating equivalent levetiracetam generics as reported in CMS Federal Upper Limit files 2014-2024.

Considerations for Generic Market Stability

The multi-source market creates unique pricing dynamics for generic drugs. Generic drugs are substitutable, and therefore compete based on price and volume.[28,29] These factors can limit certain price increases—if a manufacturer were to increase the price charged relative to competitors, it would lose market share to other lower-cost, substitutable alternatives. However, generics often face inflation rebates due to factors such as increases in ingredient costs, changes in purchasing patterns, or seasonal variations in purchasing. When inflation rebates are applied in these instances, products may become unprofitable in the Medicaid market, as manufacturers may be unable to recoup production costs. When products become unprofitable, manufacturers may limit production or pull the product from the market entirely.[30] Decreases in the number of manufacturers can reduce supply chain resiliency and make the market more vulnerable to future shocks, which may ultimately lead to shortages.[31]

In 2023, the FDA reported 153 drugs and biologics in shortage, including 55 new shortages and 98 shortages ongoing from previous years.[32] In part due to the unique cost pressures generics face, generic drugs are disproportionately impacted by drug shortages. Between 2013 and 2017, 67% of drugs in shortage were drugs with generic versions on the market.[33]

Policymakers have considered ways to promote generic market stability and limit the occurrence of shortages. Over the past year, Congressional committees, including the Senate Finance Committee and the House Energy and Commerce Committee, have held hearings on drug shortages.[34,35] In addition, in April 2024, the US Department of Health and Human Services released a white paper detailing policy considerations to prevent drug shortages.[36] Throughout these hearings and publications, policymakers have discussed strategies to reform payment systems for generic drugs, in order to better align reimbursement to quality and promote supply chain resilience.

One solution proposed by lawmakers is modifying certain MDRP inflation rebates for generic drugs. In its white paper on drug shortages, the Senate Finance Committee expressed interest in "exploring the extent to which reforms of certain aspects of the MDRP can relieve generic drug shortages."[37] Most recently, the Senate Finance Committee included a policy to waive certain MDRP inflation rebates within its draft shortage legislation. The Committee's proposal would waive the MDRP inflation rebate for multi-source generics, single-source generics with an average annual cost of less than $100, and single-source generics that are in or at risk of

28 Hernandez, Inmaculada. Testimony Before the US Senate Finance Committee. December 2023. Here.
29 FDA. Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. December 2019. Here.
30 KPMG. "Generics 2030: Three Strategies to Curb the Downward Spiral." 2020. Here.
31 Wosinksa, Marta. "Congressional Hearing on Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective." Testimony to the US Senate Committee on Finance. December 5, 2023. Here.
32 FDA. "Report to Congress: Drug Shortages CY 2023." Here.
33 Drug Shortages Task Force. FDA. "Drug Shortages: Root Causes and Potential Solutions 2019." February 1, 2020. Here.
34 United States Senate Committee on Finance. "Hearing: Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective." December 5, 2023. Here.
35 United States House of Representatives Energy and Commerce Committee, "Health Subcommittee Hearing: Legislative Proposals to Prevent and Respond to Generic Drug Shortages." September 14, 2023. Here.
36 US Department of Health and Human Services. "Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States." April 2, 2024. Here.
37 US Senate Committee on Finance. "Preventing and Mitigating Generic Drug Shortages: Policy Options Under Federal Health Programs." January 25, 2024. Here.

shortage.[38] These provisions mirror exceptions to Medicare inflation rebates included in the IRA.[39] The Committee's proposed policy aims to provide greater pricing flexibility for generics, with the goal of preventing market exits and, ultimately, reducing shortages.

The unique pricing dynamics within the generic market are an essential consideration when evaluating the potential success and unintended consequences of changes to public policy. An understanding of how policies, such as the MDRP, influence generic market stability can help stakeholders craft solutions to mitigate and prevent drug shortages.

38 US Senate Committee on Finance. "Wyden and Crapo Release Draft Legislation to Combat Prescription Drug Shortages." May 3, 2024. Here.
39 Inflation Reduction Act of 2022 (HR 5375), 117th Congress. Here.

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