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Penalizing Generic Drugs with the CPI Rebate will Reduce Competition and Increase the Likelihood of Drug Shortages



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May 2, 2017

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This policy brief was supported by the Association for Accessible Medicines. The findings, analysis and opinions expressed represent only those of its authors, and do not represent the views or opinions of Bates White, LLC or of other Bates White employees or affiliates.

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I. EXECUTIVE SUMMARY

With the enactment of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), the US government imposed certain regulations on the prices of sole-source¹ (patent-protected) medicines so that drugs provided through Medicaid programs were subject to manufacturer rebates that assured that the Medicaid program paid no higher price than the lowest price offered to a commercial customer. In addition to these “best price” rebates, companies selling sole-source medicines have been subject to paying additional rebates to Medicaid based on the rate of price change over time relative to the overall rate of inflation as measured by the Consumer Price Index for urban consumers (CPI-U).² Essentially, if a product’s price has risen faster than the CPI-U, the company selling that product is required to rebate an additional amount to Medicaid that is equal to the amount by which the price of product has exceeded the rate of inflation.

As part of the Bipartisan Budget Agreement of 2015 (BBA), the US Congress extended the Consumer Price Index (CPI) rebate provisions to multisource generic drugs. This was done with little public debate and evidently little notice. The legislation established a base period against which future prices are measured and mandates that rebates begin to be calculated with the first quarter of 2017. Going forward, newly launched generics will have base prices established at the time they are first marketed in the United States.

As it has evolved in the United States, the generic drug industry is typically characterized by a high degree of economic competition. Under the provisions of the Hatch-Waxman Act, once all legal and regulatory exclusivity provisions applying to a medication have expired, any manufacturer is free to apply to the US Food and Drug Administration (FDA) for approval to market a product. Because the actual manufacturing cost of most drugs is relatively low, generic entry and competition have tended to result in low market prices driven by competitive entry.³

Basic economic theory suggests that price controls established in competitive markets will tend to result in disruptions. In equilibrium, suppliers in competitive markets earn only competitive rates of profit; price controls push those profits below competitive levels and lead companies to look for more attractive investment opportunities, including leaving the market altogether. Any company considering entering a competitive market must consider the risks and returns associated with entry and compare those to alternative investments. Price controls that lead to the prospect of less-than-competitive profits are likely to lead to fewer companies entering the market and hence, less competitive markets.

Using the CPI-U as a benchmark exacerbates the riskiness of this investment. Since the CPI-U measures price changes in the economy overall, it will not fully reflect changes in input costs that affect any economic subsector. So if at any point in time, the prices of inputs to the manufacturing process—such as a chemical input, manufacturing equipment, or even employee salaries—rise more rapidly than prices in the economy generally, the CPI-U will not rise as rapidly as these costs. Under the new BBA rules, generic drug manufacturers selling to Medicaid may not be able to raise their prices to Medicaid enough to cover their increased costs.

The new “CPI penalties” established for the generics drug sector are being imposed at a time when there has been significant concern about the prices of drugs generally, and in particular, about the prices of generic drugs. There have also been serious concerns about shortages and the availability of low-cost generics. Both of these concerns are likely to be exacerbated by the imposition of the CPI price cap on generics.

As a way of assessing the potential future impact of the CPI penalty for generic drugs, we examine publicly available data on historical drug prices and perform calculations of the potential impact of CPI-based rebates had they been in place

1 For the purposes of this report, sole-source medicines are those approved by the FDA under a New Drug Application or Biologics License Application.

2 The CPI-U is produced by the US Bureau of Labor Statistics and measures the changes in the prices of a basket of goods and services purchased by urban consumers.

3 David Rieffen and Michael Ward, “Generic Drug Industry Dynamics,” *Review of Economics and Statistics* 87, no. 1 (2005): 37–49.

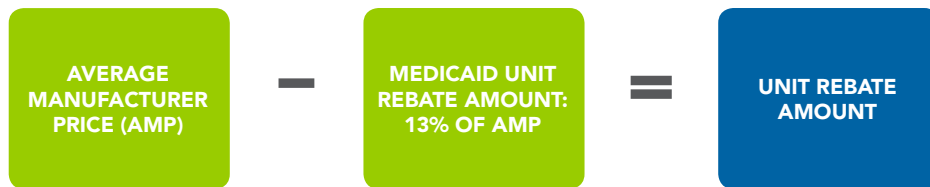
in the past. We find evidence to suggest that in certain cases, these price regulations may have precisely the opposite of their intended effect. The imposition of CPI penalties is likely to reduce competition in generic drug markets, lead to fewer companies competing in the market, and increase the likelihood of shortages.

II. HOW THE CPI PENALTY WORKS

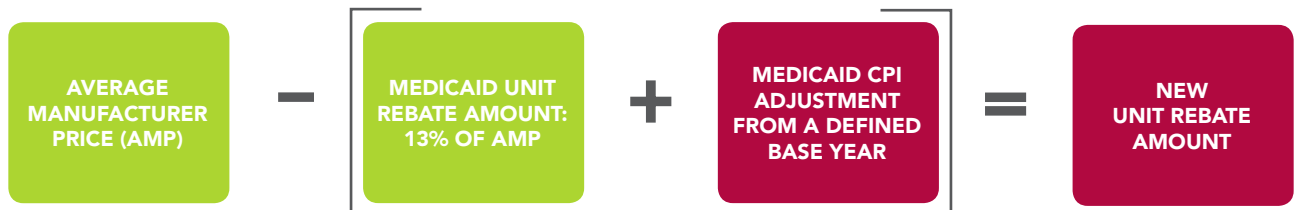
Prior to the BBA, the rebate for generic drugs (a discount paid by manufacturers to Medicaid) was set at 13% of the Average Manufacturer Price (AMP).⁴ Under the new BBA rules, generic manufacturers are now required to pay an additional rebate for each product for which the AMP rises more rapidly than the CPI-U. Figure 1 illustrates how the rebate amount has been affected by the passage of the BBA.

Figure 1. The Medicaid rebate applied to multisource generics

Prior to the 2015 Bipartisan Budget Act:



After the 2015 Bipartisan Budget Act:



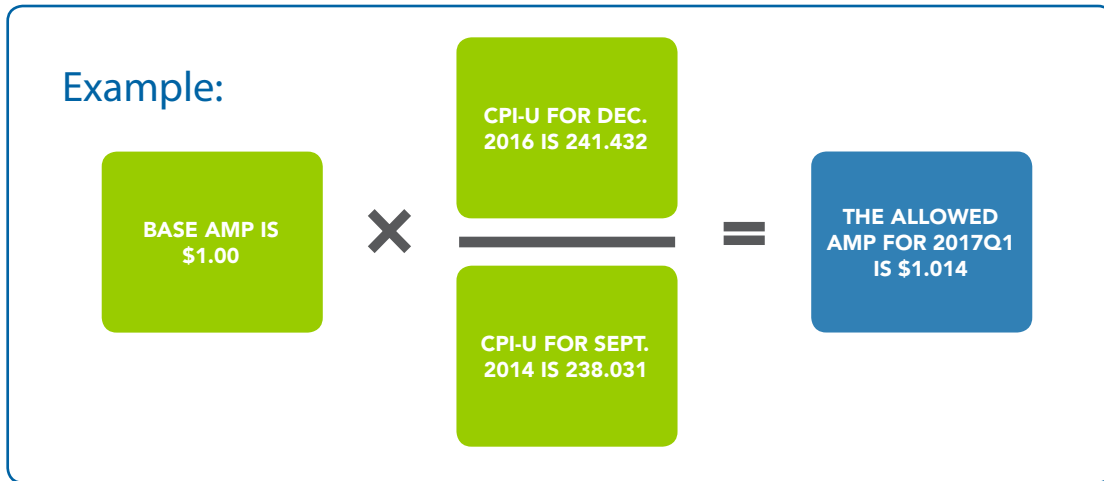
The additional CPI penalty that manufacturers of generics must pay to Medicaid is equal to the difference between the CPI-adjusted “allowed” AMP and the actual AMP for the rebate period. The rate by which the AMP is allowed to increase will depend on when the generic drug was originally marketed.

For drugs that were originally marketed on or before April 1, 2013, to calculate the 2017Q1 “allowed” price, manufacturers must take the drug’s AMP for 2014Q3 (\$1.00 in the Figure 2 example) and multiply that base price by the increase in CPI since the base period. This increase in the CPI is calculated by dividing the level of the CPI-U for the month before the month in which the rebate period quarter begins (December 2016, 241.432 in our example) by the CPI-U for September

⁴ The rules under which AMPs are to be calculated are established by Centers for Medicare and Medicaid Services regulations. Essentially, AMP corresponds to the average price the manufacturer charged to wholesalers and other buyers of their drug for a specific period of time. See Center for Medicaid and CHIP Services, “For Participating Drug Manufacturers” (Medicaid Drug Rebate Program Notice Release No. 97, Washington, DC, Apr. 15, 2016), available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-097.pdf>.

2014 (238.031 in our example). The product of the drug's base price and the calculated CPI increase results in the "allowed" price for 2017Q1, calculated as \$1.014 in our example.

Figure 2. Example calculation of allowed price limit



For drugs brought to market after April 1, 2013, the "allowed" price is calculated based on the AMP for the fifth full calendar quarter after which the drug was marketed. The allowed AMP is the base AMP multiplied by the increase in CPI since the base period. This increase in CPI is calculated by dividing the CPI-U for the month before the month in which the rebate period quarter begins (in this case, December 2016) by the CPI-U for the last month of the fifth full calendar quarter after which the drug was marketed. The product of the drug's base price and the calculated CPI increase results in the "allowed" price for 2017Q1.

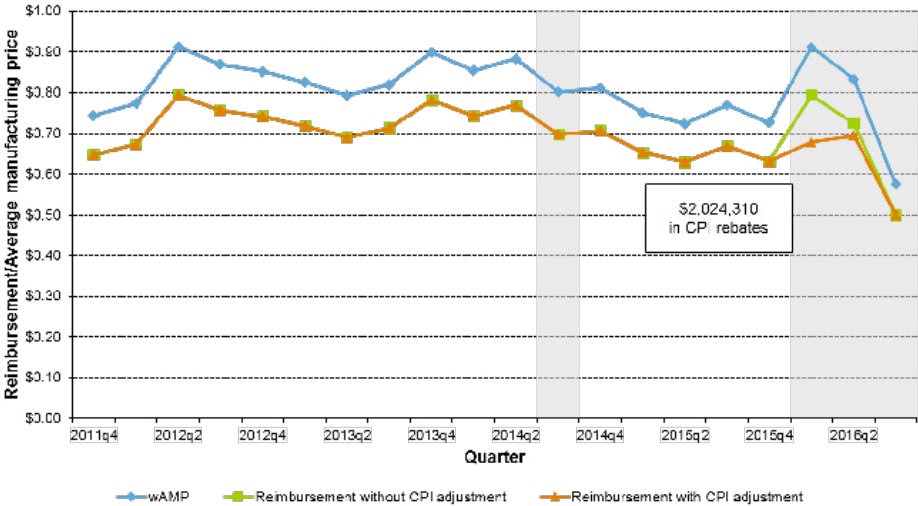
Regardless of the original date the drug was marketed, the additional CPI penalty is equal to the "allowed" 2017Q1 price minus the actual 2017Q1 AMP for the drug. In the example below, an AMP that exceeds \$1.01 in 2017Q1 will result in an additional CPI penalty rebated back to Medicaid. As discussed above, this CPI penalty is in addition to the base rebate of 13% of the 2017Q1 AMP. The total rebate due to Medicaid is thus equal to 13% of the 2017Q1 AMP plus the additional CPI penalty.

III. EXAMPLES OF HOW THE CURRENT PENALTY WOULD HAVE AFFECTED MEDICAID REBATES IF APPLIED IN THE PAST

This section offers examples of how the additional CPI rebate can affect the actual net prices received by generics manufacturers from Medicaid. For these examples, we rely on the weighted AMPs (wAMPs) made publicly available by the Centers for Medicare and Medicaid Services (CMS). These do not represent actual AMPs on a product-by-product basis, but are averages of all prices reported to CMS.⁵ As a result, the following examples are for illustrative purposes only and do not reflect actual rebate amounts. To ensure that only products subject to the Medicaid CPI rebate were included in this analysis, drugs with wAMPs were linked to Medicaid State Drug Utilization Data (SDUD) by their respective National Drug Code (NDC) number. NDCs that did not have a counterpart in the SDUD were dropped. The three examples below were selected in part because they were among Medicaid drugs most dramatically affected by the CPI rebate.

The first product we consider is Piroxicam, a nonsteroidal anti-inflammatory drug that was first introduced in 1980 as Feldene and that has been available as a generic since 1992. As indicated in the chart, the wAMP is relatively stable at between \$0.70 and \$0.90 per dose with a general downward trend over most of the period. Figure 3 shows that, prior to the imposition of a CPI penalty, the net price Medicaid paid is 13% lower than the wAMP. Assuming that a base price had been established for this product in 2014Q3, the uptick in price observed in 2016Q1 would have triggered a CPI penalty rebate. Despite the fact that the price fell below \$0.60 within two quarters after this uptick, a manufacturer reporting these prices would have incurred an additional Medicaid rebate liability because the temporary uptick in price exceeded in the change in the CPI-U relative to the baseline for that quarter and remained slightly above the CPI-U ceiling for one quarter after. With the price decline that happened in 2016Q3, the CPI penalty would no longer apply, but if all manufacturers in the data set had the same prices and had incurred the penalty, additional rebates would have amounted to just over \$2 million.

Figure 3. Piroxicam



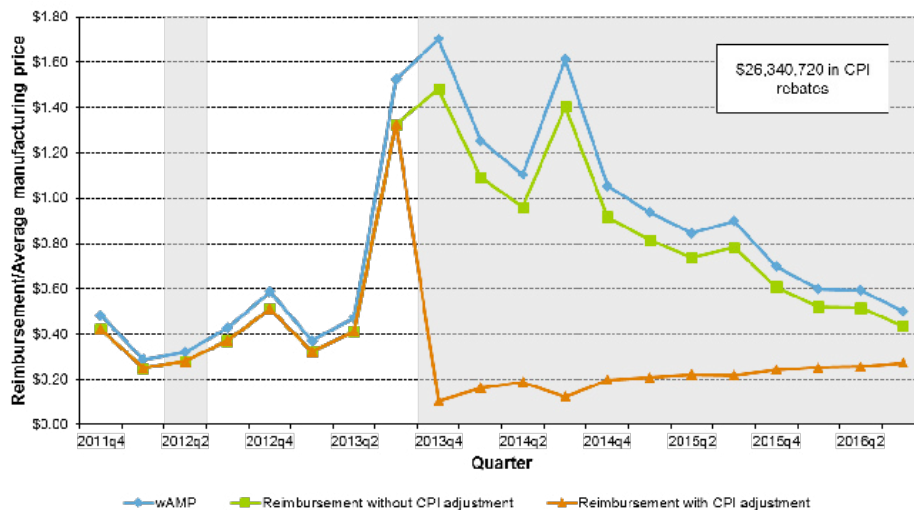
Source: CMS Federal Upper Limit wAMP data. First shaded area indicates the base period quarter. The second shaded area indicates the CPI adjustment period.

⁵ Note that CMS reports wAMP for products for which more than three manufacturers reported price data in any given quarter. Hence, these prices reflect average price changes rather than individual company price changes.

As illustrated in Figure 4, Divalproex experienced a substantial increase in price in mid-2013 that eroded over time. However, had the CPI penalty been in place as indicated in the figure, the net price to Medicaid would have remained below the prespike price for several quarters and would have generated additional Medicaid rebates in excess of \$26 million. To the extent that Medicaid made up a large share of the business for the sellers, there would have been reason to consider exiting this market, given the low net price received.

This effect could be exacerbated by the dynamics of the penalty as it would apply to any entering generic manufacturer. Suppose, for example, that a company not selling Divalproex prior to the increase in price begins selling the product (assuming it has an Abbreviated New Drug Application for the product or can obtain one in a timely way). If at the time of entry the going price is well above the former price, the new entrant has a baseline price (established at the time the product is first marketed) that is well above the baseline price of incumbent competitors. Therefore, it owes no additional rebate and has greater profits from the sale of the product than its incumbent competitors do. The differential profit levels across sellers introduce interesting strategic considerations. Do the low-profit companies stay in the market or do they leave? If they leave, the competitive effects that drive prices down over time are dampened and prices that remain are likely to remain higher for longer.

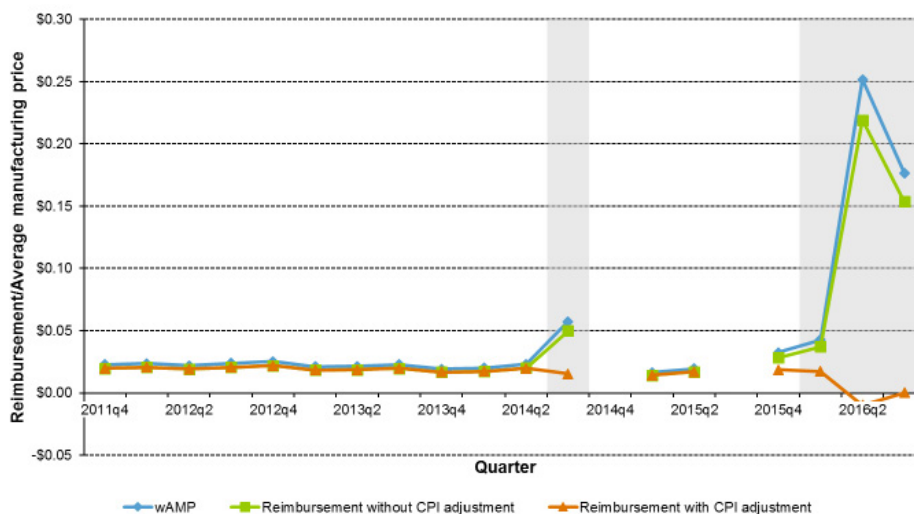
Figure 4. Divalproex



Source: CMS Federal Upper Limit wAMP data. First shaded area indicates the base period quarter. The second shaded area indicates the CPI adjustment period.

Figure 5 illustrates a scenario in which the manufacturer gets paid nothing for prescriptions dispensed under Medicaid. In this case, Fluconazole experienced an increase in wAMP in 2016 such that the CPI rebate plus the standard 13% rebate exceeds the wAMP for the product. As indicated by CMS's guidance on computing rebates, the manufacturer would owe a rebate equal to the wAMP and would receive a zero net price. This scenario underscores the risk that manufacturers would be assuming if they chose to enter markets that serve patients covered extensively by Medicaid.

Figure 5. Fluconazole



Source: CMS Federal Upper Limit wAMP data. First shaded area indicates the base period quarter. The second shaded area indicates the CPI adjustment period

IV. THE MEDICAID CPI PENALTY IS ARBITRARY

It may appear that a company could easily avoid the potential penalties illustrated in the previous section by simply not raising prices. That impression ignores some important realities of competitive markets.

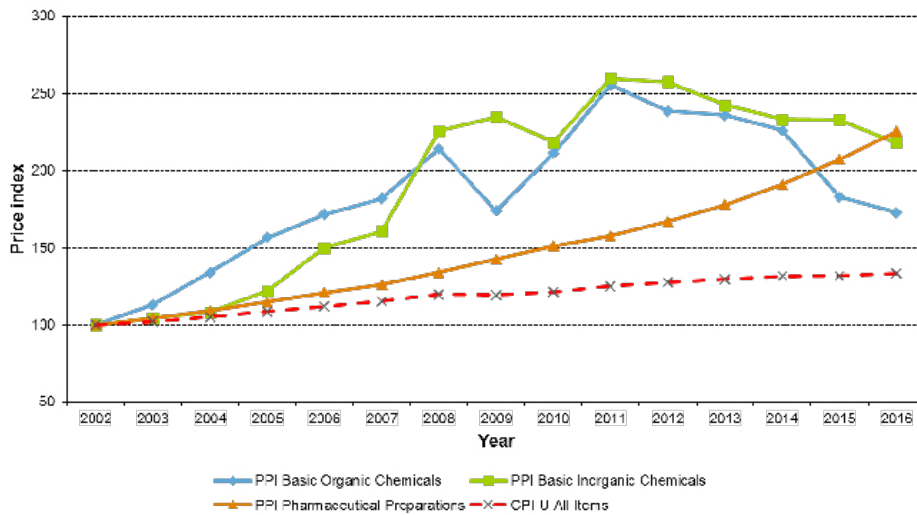
IV.A. PRODUCT PRICES CAN VARY CONSIDERABLY RELATIVE TO THE CPI-U

First, manufacturers in competitive markets are subject to prices determined in both output markets and input markets. In other words, they do not choose prices, but must react to prices that are set by market forces. Figure 6 shows the trends in producer price indexes for basic organic chemicals, basic inorganic chemicals, and pharmaceutical preparations compared with the CPI-U. Basic organic chemicals include products such as calcium citrate, isopropyl alcohol, and acetates.⁶ Basic inorganic chemicals include products such as caustic soda. While the Producer Price Index series are very broad categories, they illustrate that input and output prices associated with this industry have risen at a higher rate than the standard inflation rate since 2002. These series also illustrate the arbitrary nature of measuring price increases. Beginning in 2011, both the basic organic and inorganic Producer Price Indexes fell, relative to CPI-U.

The CPI-U is based on a market basket consisting of more than 200 categories of goods and services, ranging from men's and women's clothing to motor vehicle insurance. Changes in the CPI-U are driven by price increases for some products and price reductions for others. Prescription drug prices represent a small fraction of the CPI-U. As Figure 7 illustrates, for the purposes of implementing the CPI penalty, generic drug prices are compared to an index whose broadness does not reflect changes in prices for manufacturing inputs that directly impact production costs.

⁶ Producers used in this index are based on the definition of North American Industry Classification System code 325199 (all other basic organic chemical manufacturing).

Figure 6. CPI-U has risen more slowly than producer prices for basic chemicals



Source: Bureau of Labor Statistics; Note: Indices based on annual values with base year 2002.

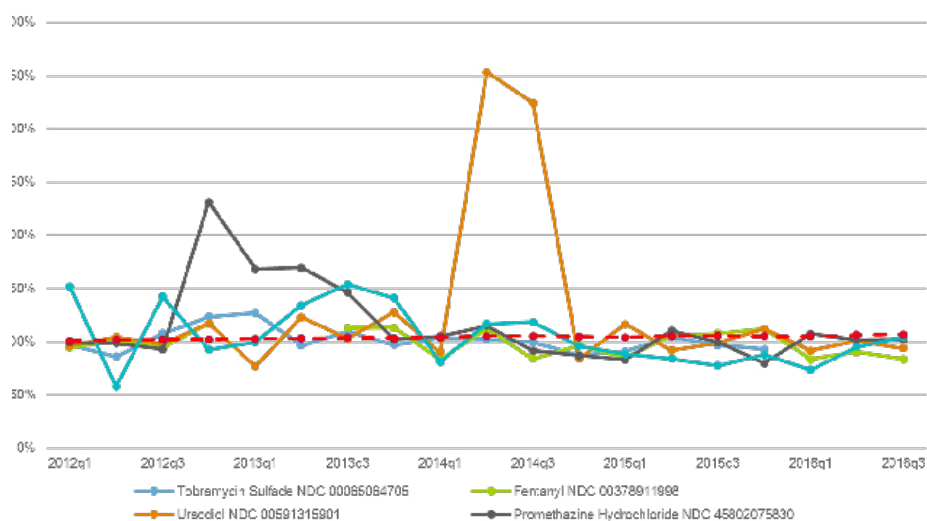
IV.B.AVERAGE MANUFACTURER PRICES ARE INHERENTLY VOLATILE

Patterns in the observed wAMP values are volatile. Over the period for which data are reported, wAMPs increase or decrease by several percentage points relative to their average values each quarter. This can happen for a variety of reasons, including such things as accounting for discounts and rebates paid to purchasers a quarter or more after the transaction occurred. Transitory increases in input costs can also lead to changes in average prices. Average prices can also be affected by prolonged active pharmaceutical ingredient (API) disruptions, resulting in a subsequent prolonged spike in the price of the final manufactured product.

Benchmarking volatile AMPs against the stable CPI-U benchmark will lead to a large percentage of generic Medicaid drugs being subject to the CPI rebate. For example, if the rebate were in place starting in 2016Q1, 3,607 of the 24,237 NDCs in our sample (15%) would have been a subject to a CPI rebate. At the drug ingredient level, more than a third of ingredients (199 of 577) in our sample would have been subject to a CPI penalty. Moreover, given that these numbers are limited to only three quarters of data, we would expect both the NDC and ingredient incidence of the CPI rebate to increase over time as volatile AMPs have more opportunities the cross over the CPI-U threshold.

This volatility in wAMPs can represent a nontrivial cost to manufacturers that supply to Medicaid. In essence, the BBA requires that generic manufacturers absorb the costs of intermittent price increases, but provides no counter-incentive for reductions in AMP. This is despite the fact that the AMPs for many drugs are generally well behaved. Figure 7 shows wAMP trends for selected drugs compared to the CPI-U. As the figure illustrates, most drug wAMPs gravitate toward a long-term trend, but there are occasional short- and more medium-term spikes followed by reductions in average prices.

Figure 7. Price (wAMP) trends exhibit volatility relative to CPI-U



Source: CMS Federal Upper Limit wAMP data

This figure also illustrates the pitfalls associated with establishing an arbitrary base period to affix penalties for price increases. For example, whether or not the sellers of Ursodiol incurred a CPI penalty would depend on the timing of the drug’s baseline price. If its base period had been set at 2014Q1, the manufacturers would have incurred a substantial CPI rebate liability because of the temporary increase in price. However, if the base period had been 2015Q1, the product would have incurred no CPI rebate. Moreover, the Ursodiol example illustrates that the same market forces that resulted in the price spike also resulted in a reversion back to its trend—all without the need for a CPI penalty.

In sum, not only does the CPI-U fail to account for the general price trends specific to the pharmaceutical market, but its breadth penalizes movements in prices that most likely result from factors outside of the manufacturers’ control. As we discuss in the next section, this onerous price control policy will not only have little effect on generic prices, but it will also have the unanticipated and unintended consequence of increasing the likelihood of shortages for generic medicines.

V. ECONOMIC AND POLICY IMPACT

Several empirical studies have shown that a sharp and rapid reduction in prices is closely associated with supply interruptions or shortages of drugs. One study examined how a reduction in Medicare reimbursements for physician-administered drugs, which are primarily injectable products, affects the likelihood of shortage.⁷ The authors posit that lower reimbursement rates (and, by extension, lower prices) reduce incentives to increase the reliability and quality of these drugs and in turn increase the vulnerability of these products to supply interruptions. They find that shortages are associated with drugs that experienced a negative shock in prices. Separate studies performed by researchers from the FDA and the US Department of Health and Human Services had similar findings.⁸ The ASPE report recommended that:

7 Ali Yurukoglu, David Ridley, and Eli Liebman, “The Role of Government Reimbursement in Drug Shortages” (NBER working paper 17987, Cambridge, MA, 2012), available at <http://www.nber.org/papers/w17987>.

8 Janet Woodcock and Marta Wosinska, “Economic and Technological Drivers of Generic Sterile Injectable Drug Shortages” *Clinical Pharmacology and Therapeutics* 93, no. 2 (2013): 170–78. Office of the Assistant Secretary for Planning and Evaluation, “Economic Analysis of the Causes of Drug Shortages” (ASPE Issue Brief, Washington, DC, 2011).

Private organizations that purchase drugs and vaccines (including GPOs and insurers), can help alleviate future shortage by strengthening the failure-to-supply requirements in their contracts in exchange for increases in price [emphasis added]. Such contract changes are likely to lead manufacturers to invest in extra capacity of both production lines and API.⁹

Although much attention has focused on shortages of injectable drugs, the effects are not limited to this class. A study examining the association between additional costs from FDA oversight and shortages demonstrated that oral drugs are also subject to supply disruptions.¹⁰ It follows that decreasing the incentives for investment in and production of all types of generic drugs likely to be used by Medicaid beneficiaries will pose a risk for shortages.

As the previous sections demonstrate, the Medicaid CPI rebate operates as a *de facto* price cap in this market, essentially reducing or, in some cases, eliminating manufacturer payment for drugs reimbursed under Medicaid. Under this regime, the inability of manufacturers to recoup increases in input costs, address shortages in intermediate products, or respond to increased demand will lower available revenues for investment in increasing capacity. It also fundamentally changes the calculus manufacturers engage in when deciding whether to enter into a product market. By decreasing the expected returns from supplying the Medicaid market, the associated risks and opportunity costs may be high enough to deter manufacturers from entering the market.¹¹ This policy exacerbates the risk of shortages and offers little benefit in terms of reducing public spending.¹²

The CPI rebate will do little to control actual increases in prices. As noted above, the new rebate will discourage entry into the affected markets. Prices tend to be higher when fewer competitors exist. Reducing the incentive to compete will predictably lead to fewer suppliers and tend to result in increases in prices over time in at least two ways. First, new competitors will be discouraged from entering the market, suggesting that prices may not be reduced to the levels that have been reached in the past. Second, what have historically been transitory price spikes will predictably persist for longer because of diminished incentives for competitors to enter the market and perhaps encourage incumbents to exit.

This reduction in entry will have the opposite of the intended regulatory effect. Several studies have shown that the average price of a generic drug falls as the number of manufacturers increases, which is consistent with what happens to prices in general when a market is subject to increasing competition. Moreover, price reductions have been shown to be steepest after the second and third generic manufacturers enter the market.¹³ This relationship is illustrated in Figure 8, which shows data on prices and number of participants in generics markets as published by the FDA.

9 Office of the Assistant Secretary for Planning and Evaluation, "Economic Analysis of the Causes of Drug Shortages" (ASPE Issue Brief, Washington, DC, 2011), 15.

10 Chris Stomberg, "Drug Shortages, Pricing, and Regulatory Activity" (NBER working paper 22912, Cambridge, MA, 2016), available at <http://www.nber.org/papers/w22912>.

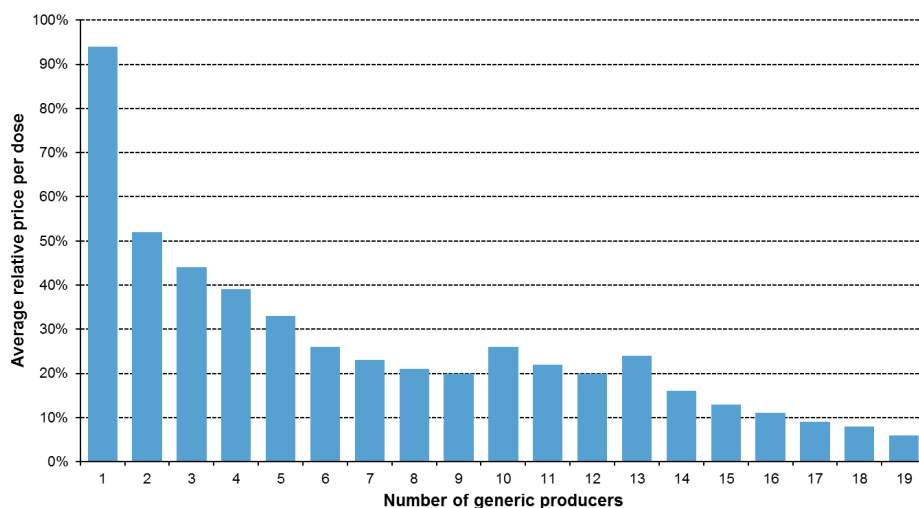
11 See Robert Pindyck and Daniel Rubinfeld, "Uncertainty and Consumer Behavior," in *Microeconomics*, 5th ed., 176–83 (Upper Saddle River, NJ: Prentice Hall Business Publishing, 2005).

12 ASPE has noted that "while [generic price increases] lead to increased costs in certain therapeutic areas, they have little influence on overall spending increases." Office of the Assistant Secretary for Planning and Evaluation, "Understanding Recent Trends in Generic Drug Prices" (ASPE Issue Brief, Washington, DC, 2016).

13 "The ratio of generic price to pre-expiry branded price falls from 0.880 with one generic competitor to 0.812 with two generic competitors, and continues to decline toward 0.631 as the number of competitors rises."

David Rieffen and Michael Ward, "Generic Drug Industry Dynamics" *Review of Economics and Statistics* 87, no. 1 (2005): 37–49.

Figure 8. Generic prices tend to be higher when there are fewer suppliers



VI. CONCLUSION

The recently passed legislation aimed at controlling drug prices in the Medicaid program uses a broad measure of inflation as its benchmark. In general, benchmarking supplier prices to an index is fraught with unintended consequences; in this case the consequences are quite clear. The extremely conservative benchmark being applied in this case will subject many drugs to an apparently unanticipated and arbitrary new rebate.

As described in depth above, the end result of this benchmark will increase uncertainty, reduce revenues, encourage manufacturers to exit the market, and discourage the entry of new manufacturers. The predictable effect of discouraging entry into competitive markets is that product availability will be hampered: shortages will be more likely, and the market forces that lead prices to fall will be dampened. In an environment rife with concern about prices, access, and product safety, none of these outcomes seems desirable.

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