

Tackling Drug Costs

A 100 Day Roadmap

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with Tim Horn

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on behalf of the

FAIR **P**RICING **C**OALITION

About the Fair Pricing Coalition

The Fair Pricing Coalition, founded by the late Martin Delaney of Project Inform, is a national coalition of activists and policy leaders who work on HIV and viral hepatitis drug pricing issues, and to help control drug costs for patients who are privately insured, underinsured and uninsured. The Fair Pricing Coalition also works to ensure access for individuals covered by state AIDS Drug Assistance Programs (ADAPs), Medicare, and Medicaid. For more information about the Fair Pricing Coalition and its history, visit: www.fairpricingcoalition.org.

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Executive Summary

Drug prices are too high. Record price increases stretch household and government budgets, and Americans are outraged. Net spending on drugs and biologics grew 8.5% in 2015 to \$310 billion.¹ Those increases hurt Americans' health – in 2015, 24% of Americans reported that affording their prescription medicine was difficult; nearly a quarter reported that they or a family member had not filled a prescription, skipped a dose, or cut dosing in half because of the cost.² Swift executive and legislative action is needed, and this report outlines a clear, achievable path to address drug prices in the Administration's first 100 days.

There is increasing bipartisan support for cost controls and a groundswell of consumer-based advocacy for novel, forward-thinking regulations. While radical ideas abound, prices can be dramatically lowered through tailored adjustments to existing regulatory programs. Cost control regulations and statutes already exist. Federal legislation, however, has not maintained pace with drug manufacturers' tactics to circumvent these measures. With this report, the Fair Pricing Coalition provides a roadmap to promptly modernize and strengthen existing regulations and statutes for controlling drug costs, drawing on existing authority and concrete legislative actions under four pathways: **Fix the Formulas, Enhance Existing Penalties, Pool Purchasing Power, and Pull Back the Curtain.**

The comprehensive but achievable reforms proposed here will:

- **Fix the Formulas:** Modernize and strengthen current ceiling price formulas to ensure that government payers are not paying more than commercial payers;
- **Enhance Existing Penalties:** Remove inflation penalty caps, increase penalties on drugs with the most egregious price hikes, and apply penalties to new drugs with launch prices far in excess of top sellers in the same class;
- **Pool Purchasing Power:** Increase inter- and intra-agency collaboration to consolidate Federal and State negotiating power; and
- **Pull Back the Curtain:** Buttress existing transparency tools while studying the effects of additional manufacturer price and payer cost disclosures.

The Administration and 115th Congress must prioritize swift and meaningful action against runaway drug pricing. This report is a roadmap of reforms that can feasibly be implemented through existing authority and new legislation in the first 100 days of the Administration, highlighting areas for immediate action and providing model legislation. Pharmaceutical manufacturers are steadfast in their determination to keep prices high, with plans to spend “hundreds of millions of dollars” to fight any new price control measures,³ but the American people demand action.

¹ IMS Health, “Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020,” April 2016, Page 6, available at: <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020>.

² DiJulio B, Firth J, Brodie M, “Kaiser Health Tracking poll: August 2015,” Henry J. Kaiser Family Foundation, Aug. 20, 2015, available at: <http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/>.

³ Karlin-Smith, Sarah, “Drug lobby plans counterattack on prices,” Politico, Aug. 4, 2016, available at: <http://www.politico.com/story/2016/08/drug-lobby-gears-up-for-massive-pr-campaign-226646>; Karlin-Smith, Sarah, Palmer, Anna, “Drug lobby adds \$100M to war chest ahead of pricing battle,” Politico, Oct. 25, 2016, available at: <http://www.politico.com/story/2016/10/pharma-lobby-pricing-battle-230277#ixzz4OrpD1ZJa>.

The First 100 Days

A Roadmap for Action

Fix the Formulas

Include all commercial discounts in Average Sales Price through existing administrative authority

Include all commercial discounts in Average Manufacturer Price and non-Federal Average Manufacturer Price through legislation

Ensure the government pays no more than the lowest commercial price while protecting additional discounts to safety net programs through legislation

Enhance Existing Penalties

Remove the cap on Medicaid inflation penalties through legislation

Double and triple the Medicaid inflation penalty for egregious price increases through legislation

Extend inflation penalties to new drugs with prices that drastically exceed average prices for widely-used drugs in their class through legislation

Pool Purchasing Power

Establish a coordinated national Medicaid negotiating pool while continuing to allow states to negotiate on their own through existing authority or legislation

Expand existing inter- and intra-agency negotiations through existing authority

Pull Back the Curtain

Strengthen existing transparency tools by modernizing price reporting formulas through existing authority and legislation

Require manufacturer disclosure of detailed drug development costs, marketing costs, and executive compensation for egregious price increases through legislation

Study whether additional transparency, such as public and private payer discount and rebate amounts, will reduce costs or lead to anti-competitive price fixing

Study the relationship between drug development costs and prices

Introduction

The American drug pricing system is in disrepair. Manufacturers continue to price prescription drugs and biologics beyond what the U.S. market and healthcare consumers can reasonably bear and evade long-standing requirements to offer discounted Federal prices. Moreover, political inertia and existing statutory penalties have failed to stop drug price increases. Short of ushering in significant changes to the ways in which drugs are priced and paid for in the U.S., the Administration and Congress can readily strengthen and modernize the existing framework to reduce Federal drug spending and discourage egregious price increases in the private market.

This report proposes four pathways to reform the existing system, providing concrete steps and model legislation that can be implemented within the first 100 days of the Administration.

These four pathways – **Fix the Formulas, Enhance Existing Penalties, Pool Purchasing Power, and Pull Back the Curtain** – work together to modernize existing drug pricing regulation while respecting the market-based system of American healthcare. These readily implementable proposals follow manufacturers' long-standing voluntary agreements to price regulation as a pre-condition for Federal reimbursement of their drugs under Medicare and Medicaid. By harnessing the power of the Federal purse to modernize existing drug pricing regulation, this plan offers a defined path to significant reductions in drug prices for both public and private payers.

Fix the Formulas

While runaway drug costs suggest that drug prices are completely unregulated, the U.S. actually has a well-established system of regulating drug prices for public payers. This system, however, has languished since its establishment in the early 1990s, while pharmaceutical markets have adapted to negate many of its regulations. Though the system has built-in penalties to discourage price gouging in the private market, manufacturers have changed the way they sell drugs to avoid triggering the penalties, raising costs for all Americans along the way. **By updating the formulas used to regulate prices for Medicare, Medicaid, and other Federal purchasers, the Administration can ensure that public payers are not overcharged for medications, simultaneously using the government’s purchasing power to encourage lower prices in the private market.**

Manufacturers choose to participate in Federal regulation of drug prices, signing voluntary agreements to be regulated in order to have their drugs covered by Federal healthcare programs. There are three main Federal prescription drug markets, and each has its own price calculation and regulatory structure. For coverage under Medicaid, manufacturers agree to report the Average Manufacturer Price (AMP) of their drugs and to offer rebates that reduce drug prices.⁴ For coverage under the Veterans Health Administration (VA), the Department of Defense (DoD), and all other Federal agencies, manufacturers agree to calculate the non-Federal Average Manufacturer Price (non-FAMP) and offer certain discounts under the Federal Supply Schedule (FSS) and the “Big-4” purchasing agreement.⁵ For coverage under Medicare Part B, manufacturers report the Average Sales Price (ASP) of their drugs as a condition of

⁴ Section 1927 of the Social Security Act (codified at 42 U.S.C. §1396r-8).

⁵ Section 603 of the Veterans Health Care Act of 1992 (codified at 38 U.S.C. §8126).

their Medicaid agreement.⁶ These agreements are tightly linked – in order for any of its drugs to be reimbursable under Medicare Part B, a manufacturer must offer discounts on all of its drugs to Medicaid and other Federal payers. In return, Medicare Part B reimburses drugs at their full market price, creating an incentive to provide discounted prices to other public payers.

Each of these formulas – AMP, non-FAMP, and ASP – are different, but they originate in the prices paid by wholesalers and pharmacies for drugs. When these formulas were established in the early 1990s, manufacturers negotiated discounted prices directly with wholesalers and pharmacies, and insurers encouraged pharmacies to negotiate deeper discounts and reimbursed them accordingly. Under this model, the various formulas accurately represented the average prices in the commercial market, ensuring that the government paid no more than general commercial prices.

However, this model has changed with the advent of consolidated insurance markets and the rise of Pharmacy Benefit Managers (PBMs), coupled with manufacturers' desire to avoid offering discounts to public payers. The structure has been inverted – rather than offering discounts to wholesalers and pharmacies, manufacturers instead provide back-end rebates and incentive payments to insurers and PBMs in exchange for preferential formulary placement. Drugs are sold to wholesalers and pharmacies at small discounts, insurers fully reimburse pharmacies for their costs, and then the manufacturer pays a rebate to the insurer or PBM to lower the price of the drug. The existing formulas, however, don't capture these rebates, meaning that the "average" market prices used to calculate AMP, non-FAMP, and ASP are much higher than the net cost to insurers and PBMs, resulting in the government overpaying for drugs.

Manufacturers have expertly gamed these formulas. Consider AMP, which sets prices for Medicaid and the 340B program. As drafted in 1990, the formula only considered "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade;"⁷ under the Affordable Care Act (ACA), the formula was narrowed to consider only "the average price paid to the manufacturer for the drug in the United States by (i) wholesalers for drugs distributed to retail community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer."⁸ The only discounts or rebates that can be included in the average are "discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies."⁹ Yet even with this statutory requirement that AMP only include prices paid by pharmacies and discounts that accrue to pharmacies, manufacturers moved to specifically exclude "payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy."¹⁰ Manufacturers played the game well – they changed their business model to avoid extending commercial discounts to government

⁶ Section 1847A of the Social Security Act (codified at 42 U.S.C. §1395w-3a).

⁷ Section 4401 of the Omnibus Budget and Reconciliation Act of 1990.

⁸ Section 2503 of the Patient Protection and Affordable Care Act. The change from "retail pharmacy class of trade" to "retail community pharmacies" excluded many discounted sales to certain specialty and mail order pharmacies from inclusion in AMP, reducing manufacturers' rebate liability.

⁹ *Id.*

¹⁰ *Id.*

payers, and then they changed the law to ensure the government would never benefit from those discounts.

These discounts are substantial and would dramatically lower government prices if they were included in the averages. In 2014, manufacturers provided \$16 billion in “rebates and other price concessions” according to PhRMA, the trade association for brand name drug manufacturers.¹¹ In 2015, “discounts [and] rebates negotiated by payers rose sharply” to \$22 billion, according to PhRMA’s characterization of data from IMS Health.¹² Yet if these discounts and rebates are accruing to insurers and PBMs and not retail community pharmacies, they will be excluded from government price reporting calculations – leaving the government to pay above-market prices for drugs.

Manufacturers are clearly not including these discounts in government price reporting calculations. Pharmacy invoice prices are only 1 percent greater than the AMP for brand name drugs, consistent with the requirement that manufacturers only include pharmacy sales prices in the AMP calculation.¹³ Yet in 2015, “discounts, rebates, and other price concessions” on brand name drugs amounted to 27.1% of invoice drug costs.¹⁴ If these had been included in AMP, then AMP would be 27% lower than the pharmacy invoice price, not 1% lower. Shockingly, this implies that government could be paying more for drugs than the private market – while Medicaid and the FSS receive 23.1% and 24% discounts off the calculated market price, respectively, overall manufacturers offer discounts of 27.1%. Even if discounts to Medicaid and the FSS are included in the reported 27.1% net discount, Medicaid and all other Federal payers (excluding Medicare) only account for 13% of payments for outpatient prescription drugs,¹⁵ meaning Federal discounts cannot account for the full 27.1% net manufacturer discount. Instead, the commercial portion of that 27.1% discount should be included in calculated average prices, and Medicaid and the FSS should then receive additional 23.1% and 24% discounts from those averages.¹⁶

¹¹ PhRMA, “Prescription Medicines: Costs in Context,” Slide 10, available at:

<http://www.phrma.org/sites/default/files/pdf/prescription-medicines-costs-in-context.pdf>.

¹² PhRMA, “Prescription Medicines: Costs in Context (Updated August 2016),” Slide 15, available at:

<http://www.phrma.org/sites/default/files/pdf/prescription-medicines-costs-in-context-extended.pdf>; IMS Health, “Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020,” April 2016, Page 7, available at: <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020>.

¹³ HHS OIG, “Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices,” October 2011, Page 9, available at: <https://oig.hhs.gov/oas/reports/region6/61100002.pdf>.

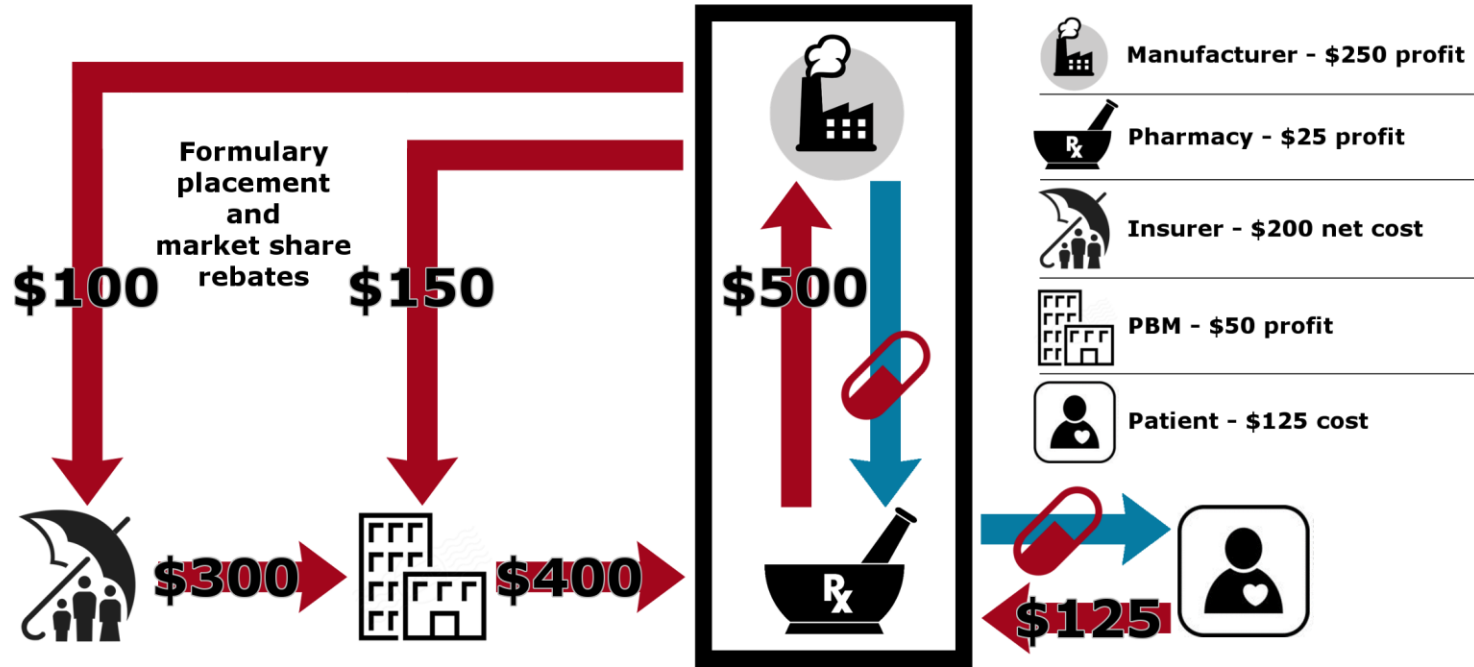
¹⁴ IMS Health, “Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020,” Page 6.

¹⁵ Centers for Medicare & Medicaid Services, “National Health Expenditure Accounts 2014,” available at:

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>.

¹⁶ Because Medicaid reimburses pharmacies based on their costs and then receives a rebate from the manufacturer to offset that reimbursement, reducing the AMP by including these discounts could decrease the rebates provided to Medicaid programs and result in short-term increased costs. However, changing the AMP and other formulas discourages manufacturers from passing discounts to insurers and PBMs instead of to pharmacies and patients, normalizing prices across all payers. Medicaid has other mechanisms to set reimbursement at the pharmacy level that can account for the distribution of the discounts, pressuring manufacturers to offer discounts at the pharmacy rather than insurer/PBM level.

Private Market

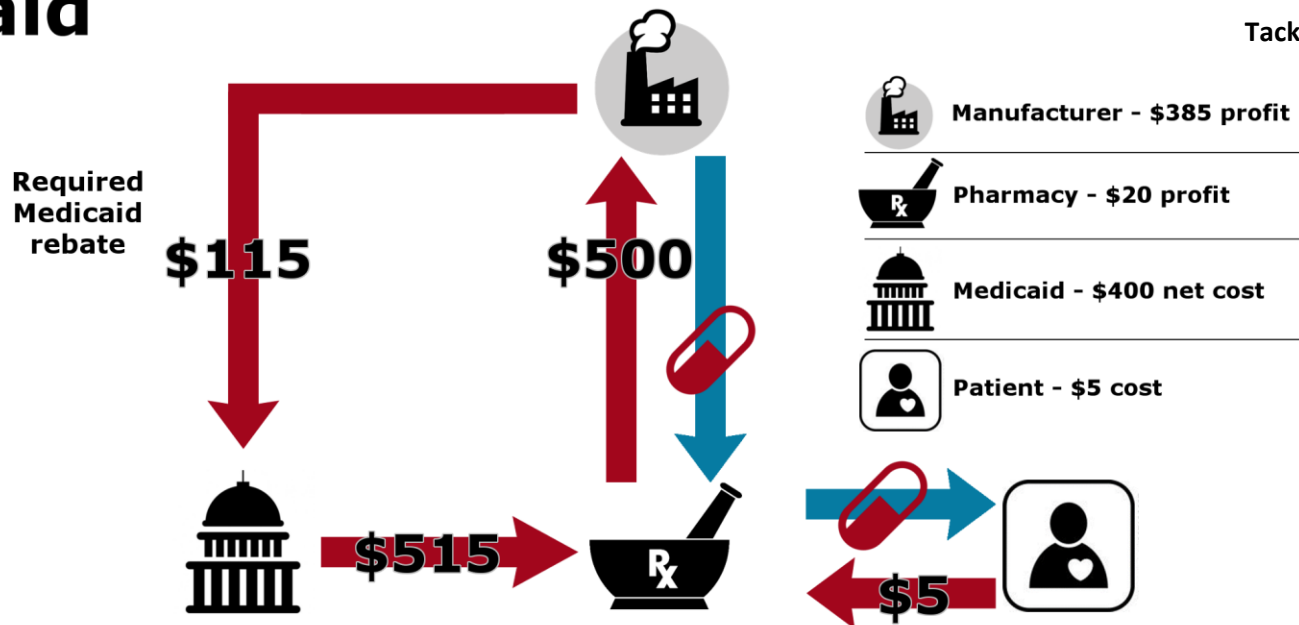


Average Manufacturer Price (AMP) is only calculated from sales and discounts that accrue to retail community pharmacies. Most discounts and rebates, however, accrue to insurers and Pharmacy Benefit Managers (PBMs), so they are not included in AMP.

Trace the Dollars

Fair Pricing Coalition
Tackling Drug Costs: A 100 Day Roadmap

Medicaid



The net Medicaid price depends on AMP. Medicaid reimburses pharmacies for their full costs of purchasing the drug, and the manufacturer pays Medicaid a 23.1% rebate to offset those costs. If AMP is artificially high, however, Medicaid can have higher net costs than private insurers.

Manufacturers will balk at including these discounts in average prices, arguing that they will reduce incentives to negotiate with private payers and that including them is too burdensome. Yet manufacturers already include these discounts in a limited set of calculations for drugs that are inhaled, infused, instilled, implanted, or injected (called the “5i AMP” drugs). Since these drugs are not commonly distributed through retail community pharmacies, manufacturers could claim that they did not have sales data to calculate AMPs for these drugs, thereby avoiding paying any Medicaid rebates for these drugs.¹⁷ Following the ACA, these drugs use an alternative AMP calculation that explicitly includes sales, discounts, rebates, and payments to PBMs, health maintenance organizations, insurers, hospitals, and other entities that are excluded from the standard AMP calculation.¹⁸ Changing the standard AMP calculation to include these sales, discounts, rebates, and payments would not be overly burdensome to manufacturers, and it would harmonize both the standard and 5i AMP calculations. Most importantly, though, including these transactions in the standard AMP calculation and all other government price reporting calculations would modernize the formulas and ensure that government payers are not charged more than private payers.

The Administration has the authority to incorporate these commercial discounts into ASP immediately,¹⁹ while their inclusion in AMP and non-FAMP will require legislation. The Government Accountability Office has called for modernization of the ASP calculation, noting that including additional discounts in ASP would have resulted in at least \$69 million in annual savings.²⁰ The Administration must swiftly implement these changes to ASP under its authority and simultaneously introduce legislation to modernize other calculations.

While fixing the formulas would ensure that government discounts are calculated from true market averages, individual private customers may still receive discounts that are greater than the government discount. Currently, both Medicaid and the FSS have requirements that manufacturers offer the lowest commercially available prices to the government. Yet those requirements, like the average price calculations, only consider discounts made directly to wholesalers or pharmacies. **These two requirements, Best Price²¹ and Most Favored Customer²² (Medicaid and FSS, respectively), must be modernized to ensure that they account for all sales, discounts, rebates, and payments to PBMs, insurers, and other entities.** Because these requirements extend the lowest commercial sale price to all government purchasers, they must be updated to exclude discounted sales to government and other safety net entities, including prisons, correctional facilities, and jails. Without that exclusion,

¹⁷ Manufacturers continue to attempt to avoid calculating AMP for certain drugs. *See, e.g.*, the Centers for Medicare & Medicaid Services’ (CMS’) discussion of not calculating an AMP for non-5i-drugs that are not distributed through retail community pharmacies, available at <https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/FAQ070616.pdf> (Question 22). *See also* 80 Fed. Reg. 5209 (discussing the need to calculate AMP for use in the 340B program and concern that some drugs may not have an AMP).

¹⁸ 42 U.S.C. §1396r-8(k)(1)(B)(i)(IV). *See* implementing regulations at 42 CFR §447.504(d).

¹⁹ 42 U.S.C. §1395w-3a(c)(3) (“For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.”).

²⁰ Government Accountability Office, “Medicare Part B: Data on Coupon Discounts Needed to Evaluate Methodology for Setting Drug Payment Rates,” July 2016, Page 13, available at <http://www.gao.gov/assets/680/678690.pdf>.

²¹ 42 U.S.C. §1396r-8(c)(1)(C).

²² General Services Administration Manual Subpart 538.2.

manufacturers may be unwilling to offer discounts to these entities, forcing them to pay ever-increasing high list prices for medications.

Including back-end discounts and rebates in government pricing calculations will benefit consumers in private insurance markets as well. Back-end price reductions keep pharmacy prices artificially high, increasing out-of-pocket costs to both uninsured consumers and insured consumers subject to high co-insurance rates.²³ Discouraging back-end rebates and discounts could lead to normalized prices across the entire drug delivery system, passing discounts onto consumers rather than to PBMs and private insurers.

Additional changes are necessary to ensure that government price reporting calculations accurately reflect market prices. **Sales of authorized generics should not be included in AMP, as they artificially lower AMP and reduce Medicaid and 340B rebates.**²⁴ Historically, these sales were not included in AMP, but manufacturer-led changes under the ACA added these sales in, substantially dropping AMP.²⁵ Removing these sales in conjunction with other small corrections would save \$5.6 billion over the next ten years.²⁶ ASP, which sets reimbursement for Medicare Part B, can currently be adjusted by the Secretary if it exceeds AMP, yet the Secretary is not required to adjust ASP. The Department of Health and Human Services Office of the Inspector General (HHS OIG) found that a moderate expansion of existing price substitution authority would save Medicare \$5.9 million annually.²⁷ **The Administration should act immediately to routinely review and adjust ASP if it exceeds AMP or widely available market prices under existing authority while pursuing legislation to require this review and adjustment.** Changing this authority to a requirement will ensure that even if the ASP calculation methodology does not change, ASP will not drastically exceed AMP. Non-FAMP must also be updated to ensure that it includes back-end discounts and rebates.

Together, these proposals to Fix the Formulas will modernize how public payers finance prescription drugs, saving billions. By working within the existing drug pricing regulatory system, the Administration leverages existing institutions and practices to quickly implement necessary change.

²³ Langreth, Robert. "Secret Rebates: Why Patients Pay \$600 for Drugs That Cost \$300," Bloomberg, Oct. 5, 2016, available at: <http://www.bloomberg.com/news/articles/2016-10-05/patients-lose-out-on-big-pharma-s-secret-rebate-merry-go-round>.

²⁴ Authorized generics are a unique type of a generic product. Rather than a generic product manufactured by another company, authorized generics are manufactured by the brand name drug company and are typically from the same production line as the brand drug, just re-packaged and sold as generics. These drugs are sold at lower prices than the brand drug, promoting generic competition. However, including these lower prices in the AMP for the brand drug dramatically reduces AMP, allowing manufacturers to pay artificially low rebates to Medicaid based on generic pricing even when Medicaid paid full price for the brand name drug.

²⁵ HHS OIG, "Average Manufacturer Price Determinations by Selected Drug Manufacturers Generally Were Consistent with Federal Requirements," June 2014, Page 5, available at: <https://oig.hhs.gov/oas/reports/region6/61300014.pdf>.

²⁶ President's Budget for Fiscal Year 2017, HHS FY 2017 Budget in Brief, available at: <http://www.hhs.gov/about/budget/fy2017/budget-in-brief/cms/medicaid/index.html>.

²⁷ HHS OIG, "Comparing Average Sales Prices and Average Manufacturer Prices for Medicare Part B Drugs: An Overview of 2013," Feb. 2015, Page 6, available at <https://oig.hhs.gov/oei/reports/oei-03-14-00520.pdf>.

Enhance Existing Penalties

Penalties for aggressive drug price increases already exist, yet they have clearly failed to halt runaway prices. **Small adjustments to these penalties, such as increasing penalties relative to price increases and eliminating penalty caps, could increase their effectiveness, using the power of government purchasing to reduce price hikes in the private market.**

The FSS, Big-4,²⁸ and Medicaid have adjustments that protect them from price hikes; the FSS caps price increases at the rate of inflation,²⁹ while price increases incur an additional penalty discount under the Big-4 and Medicaid. Enhancing the Medicaid penalties would discourage manufacturers from raising prices in the private market. The Administration should move swiftly to implement the proposals below, sending a clear signal that drug prices should not increase faster than inflation.

The Medicaid penalty is called the “Additional Rebate.”³⁰ The Additional Rebate assesses whether the current quarter’s AMP is greater than the drug’s initial AMP adjusted for inflation to the present. For example, a drug was approved in 2005 and had an initial AMP of \$10. Adjusting that initial AMP for inflation, the current AMP should be \$15. However, the manufacturer reported a current quarter AMP of \$70. Based on this, the Additional Rebate would be \$55, the difference between the current AMP and the inflation-adjusted initial AMP. This rebate is then added to the base rebate of 23.1% (~\$16), for a

²⁸ The Big-4 include the Veterans Administration, the Department of Defense, the Indian Health Service, and the Coast Guard.

²⁹ 38 U.S.C. §8126(d).

³⁰ 42 U.S.C. §1396r-8(c)(2).

total rebate of \$71. Since the total rebate exceeds the quarterly AMP (\$70), the rebate is capped at \$70 – a practice that must be changed (see page 24 for a model-based example). A similar process adjusts Big-4 prices using non-FAMP.³¹

The cap on the total Medicaid rebate encourages manufacturers to take excessive price increases. Manufacturers are clearly willing to allow Medicaid sales at \$0 in exchange for massive price increases to other payers. Because of the Additional Rebate (also called the “inflation penalty”), Medicaid rebates on brand name drugs are, on average, three times higher than the privately-negotiated rebates paid to Medicare Part D plans.³² Medicaid drug expenditures before rebates, however, are only 9% of the market – and manufacturers are clearly willing to forgo profits on Medicaid to extort profits from the rest of the market.³³ Consider the 5,000% price for Daraprim, which established a net \$0 price for Medicaid. In Congressional testimony, Turing’s Chief Commercial Officer stated that two-thirds of Daraprim sales were sold at nominal cost due to the inflation penalty.³⁴ Yet, Turing still finds it profitable to give away two-thirds of its sales for free because of the revenue from the remaining third, highlighting the perverse incentives under the current penalty.

The Medicaid inflation penalty must be heightened, then, for Medicaid’s 9% market power to shape prices in the rest of the market. **This can be achieved by adding a multiplier to the Additional Rebate for large price increases and eliminating the rebate cap when the total rebate exceeds the quarterly AMP.** For price increases more than 5% greater than the rate of inflation, the Additional Rebate should be doubled; for increases more than 25% greater than the rate of inflation, tripled. Manufacturers should then be required to pay Medicaid the total rebate for the drug, even if it would result in a loss.

Conforming changes should also be made to the Big-4 inflation penalty. Enhancing the existing inflation penalty leverages long-standing policy and systems infrastructure and does not require government price-setting or controls on the private market; rather, manufacturers will have to rationally price drugs in the private market to ensure full reimbursement by government payers. Moreover, by fixing the formulas and including back-end rebates and discounts in the calculation of AMP, current AMPs should drop, lessening the immediate impact of the inflation penalty while still holding future price increases closer to the rate of inflation.

Reforming the existing penalties, however, will not address new drugs that come to market with high prices. While existing law holds line extensions of drugs (such as extended release formulations) to the rebate penalties in place for the existing formulations, there is no mechanism to limit new drug prices. **The Administration should cap the initial AMP of a new drug – the baseline for the inflation penalty – at a modest increase over the average inflation-adjusted initial AMPs of the top third of drugs prescribed in the same class or to treat the same condition.** For example, a new drug is approved with an initial AMP of \$100. There are ten other drugs in the class, and the average inflation-adjusted initial AMP of the top three drugs by prescription volume is \$50. Various thresholds could establish the

³¹ 38 U.S.C. §8126(c).

³² HHS OIG, “Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin,” April 2015, Page 7, available at: <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>.

³³ CMS, “National Health Expenditure Accounts 2014.” Medicare accounted for 29% of prescription drug spending, while patient out-of-pocket costs were 15% of prescription drug spending – more than all of Medicaid spending.

³⁴ House Committee on Oversight and Government Reform, “Hearing on Developments in the Prescription Drug Market: Oversight, Testimony of Nancy Retzlaff,” Jan. 26, 2016, Pages 5-6, available at: <https://oversight.house.gov/wp-content/uploads/2016/02/Retzlaff-Turing-Statement-1-26-Prescription-Drugs.pdf>.

allowable initial AMP for the new drug: if the average age of the top third of drugs prescribed in the class is over 10 years, the allowable initial AMP could be no more than 200% of the average inflation-adjusted initial AMP of the class; if the average age is 5-10 years, 150%; less than 5 years, 125%. This would allow reasonable comparisons of the new drug to the most frequently prescribed drugs in the class and would allow for greater initial AMPs for new innovation in a drug class filled with older drugs. Manufacturers should be able to petition the Secretary to allow for a different calculation based on the value of the drug if the drug is exceptionally novel, pursuant to regulations issued by the Secretary. Explicit definitions of, and calculations for, exceptionally novel drugs could be based on recommendations from a neutral body (e.g., the National Academy of Sciences) commissioned by the Administration to assess the impact and limitations of value-based tendering on access and public payer budgets. Manufacturers would continue to be free to price their drug as they see fit, but they will be subject to greater inflation penalties based on the modified initial AMP if prices are excessive.

Pool Purchasing Power

Federal purchasers have enormous power to negotiate prices, and the VA and some state Medicaid programs have achieved substantial discounts. However, these negotiations are uncoordinated across the multiple drug purchasing programs, which results in disparate access to care. **The Administration should assess what authority exists for coordinated negotiations and what legislation may be needed to allow Federal agencies to formally coordinate negotiations, strengthening existing Medicaid models and multi-agency negotiations.**

While state Medicaid programs have long been able to negotiate supplemental rebates, not all states access rebates at the same level. Four states – Hawaii, New Jersey, New Mexico, and South Dakota – do not have any supplemental rebate agreements; nineteen states only negotiate rebates on their own; fifteen states and the District of Columbia only negotiate in pools; and twelve states access both pool-negotiated rebates and negotiate their own additional rebates.³⁵ Further limiting the effectiveness of supplemental rebates, only eleven states have supplemental rebate agreements for drugs dispensed under Medicaid Managed Care Organizations. These uncoordinated negotiations lead to disparities in the costs of medications from state to state, ultimately resulting in disparate access to care as states limit who can access the most expensive drugs. **Federally coordinated negotiations would create baseline supplemental rebates for all states, while still allowing states to pursue additional**

³⁵ CMS, “Medicaid Pharmacy Supplemental Rebate Agreements,” June 2016, available at: <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf>.

negotiations on their own or in smaller groups. Federally-coordinated supplemental rebate negotiations for high-cost drugs would result in \$5.8 billion in savings over 10 years;³⁶ this proposal should be extended to allow for negotiations on all drugs.

The VA and DoD similarly pool their negotiating power for greater discounts on pharmaceuticals, and the Administration should assess what other Federal agencies can benefit from these arrangements. In 2003, the VA and DoD established a Memorandum of Agreement to jointly negotiate for pharmaceutical discounts, leveraging their joint purchase volumes to negotiate national committed volume contracts (National Contracts) and Blanket Purchase Agreements that establish sub-Big-4 prices.³⁷ **Other Federal agencies with predictable medication purchase needs, notably the other Big-4 agencies (Indian Health Service and Coast Guard), should join this negotiating pool.** While cross-Department agreements may be challenging to implement, the Administration should explore pooling Medicaid supplemental rebate negotiations with other Federal purchasers to achieve even greater discounts.

³⁶ President's Budget for Fiscal Year 2017, HHS FY 2017 Budget in Brief.

³⁷ Memorandum of Agreement Between The Department of Defense and The Department of Veterans Affairs, available at: <http://www.tricare.mil/dvpc0/downloads/MOA%20-%20Combine%20DoD%20and%20VA%20Buying%20Power%20to%20Achieve%20Lower%20Medical%20Materiel%20Costs%20SIGNED%207-23-03.pdf>.

Pull Back the Curtain

Federal drug pricing transparency programs exist, but they have failed to modernize with industry practices. Pharmaceutical manufacturers have adeptly hidden the true price of drugs, skirting the intent of Federal price reporting regulations by offering complex back-end discounts to insurers and PBMs. These practices are slowly being recognized by consumers, who are shocked to realize that they may pay \$600 for a drug while their insurer gets a \$300 rebate.³⁸ Because these back-end discounts are not included in Federal price reporting metrics, existing transparency tools fail to show true market prices. **Fixing the formulas is the first step to pull back the curtain on pharmaceutical prices by leveraging existing transparency tools, but additional transparency requirements must be implemented for egregious actors.**

Currently, the VA, in its role as administrator of the FSS, publishes various pharmaceutical prices available to government customers.³⁹ These prices include the FSS price (based on the market price given to the Most Favored Customer), the Big-4 price (a discounted price based on average market prices, calculated using non-FAMP), and additional discounts negotiated by the VA under National Contracts. In theory, these prices should inform consumers and healthcare organizations of the lowest prices available to a commercial customer (the FSS price, based on Most Favored Customer) and the average price to all commercial customers (reversing the Big-4 price calculation to reveal non-FAMP).

³⁸ Langreth, Robert. "Secret Rebates: Why Patients Pay \$600 for Drugs That Cost \$300," Bloomberg, Oct. 5, 2016.

³⁹ VA National Acquisition Center Contract Catalog Search Tool, available at: http://www.va.gov/nac/index.cfm?template=Search_Pharmaceutical_Catalog.

Since these price metrics were introduced, however, the pharmaceutical industry has changed how it sells and discounts drugs, and these price metrics no longer capture either the Most Favored Customer or average market prices. Similarly, ASP is publicly reported for purposes of Medicare Part B reimbursement.⁴⁰ As discussed previously, fixing the formulas requires Congressional action but will not place any additional burden on manufacturers – allowing the Administration to increase transparency through an existing mechanism without additional legislation.

Egregious price increases require even greater transparency. We propose that when the average manufacturer price of a drug increases more than the 25 percent greater than the rate of inflation since the drug’s introduction, as calculated by the Medicaid program, the manufacturer must provide a report to the Secretary outlining the following:

- research and development costs for the drug;
- production costs;
- marketing expenditures, including
 - provider detailing;
 - direct-to-consumer marketing; and
 - any activities or funding associated with supporting, communicating, or researching off-label uses of the drug;
- Federal and non-profit funding that supported the drug’s development (including prior to the manufacturer’s acquisition of the drug);
- detailed breakdowns of the patient population receiving the drug;
- detailed breakdowns of the number of prescriptions paid for by various private and public payers, the total amount expended for the drug by each payer, and any discounts or rebates provided to that payer; and
- detailed executive compensation.

The Secretary must release such reports to the public on a quarterly basis. This proposal will severely discourage price increases while providing essential information on practices that distort markets.

Any attempt to increase transparency will face ardent opposition. While the complexity of the pharmaceutical market means that additional transparency requirements may have unintended consequences, this necessitates careful implementation of new requirements, not outright abandonment. Existing transparency tools have shown that public and private payers can still negotiate substantial discounts even when average pricing data is made public, and any attempt to eliminate that transparency must be swiftly rebuffed. Further requirements, however, deserve additional study to ensure that they do not lead to anti-competitive price fixing or reduce public payers’ ability to negotiate discounts. Too little is known about the relationship between drug development and production costs and drug pricing, meriting additional study.

The Administration and Congress should commission two studies: 1) An assessment of the impact of additional transparency requirements, such as disclosure of all privately negotiated discounts or drug development costs, on the pharmaceutical market, addressing the potential for both lower prices and anti-competitive behavior; and 2) An examination of the average costs of drug production and

⁴⁰ CMS, Medicare Part B Drug Average Sales Price, available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>.

development, the relationship of those costs to drug prices, and the relationship between pharmaceutical manufacturer profits and the development of new drugs, including an assessment of the role of Federal, state, and non-profit funding and other incentives (such as tax abatements or other local corporate incentives).

Moving Forward

Absent a bipartisan commitment to explicit Federal regulation of private market drug prices, the Administration must swiftly introduce legislation reforming and modernizing existing drug pricing regulations. While a broader overhaul of the system is necessary – ensuring universal access to state-of-the-art drugs and biologics at appropriate prices while incentivizing scientific ingenuity and discovery – immediate reforms cannot be delayed. Implementing these reforms will give momentum to systematic reform, including heightened government regulation of the private market, nationalization and increased scrutiny of patents, importation of lower-cost innovator and generic drugs, greater authority to exercise march-in rights and eminent domain over drugs that are prohibitively expensive, and unified approaches to drug pricing and coverage. Americans are fed up with excessive healthcare costs, which continue undeterred by mounting public pressure.⁴¹ In response, the Administration must fix the formulas, enhance existing penalties, pool purchasing power, and pull back the curtain on drug prices.

Together, these proposals direct a clear path to reduce drug prices, leveraging existing tools to modernize a broken system. The Administration must move swiftly and decisively – the American people, including taxpayers and those facing an increasing number of barriers to life-saving prescription drugs, demand action.

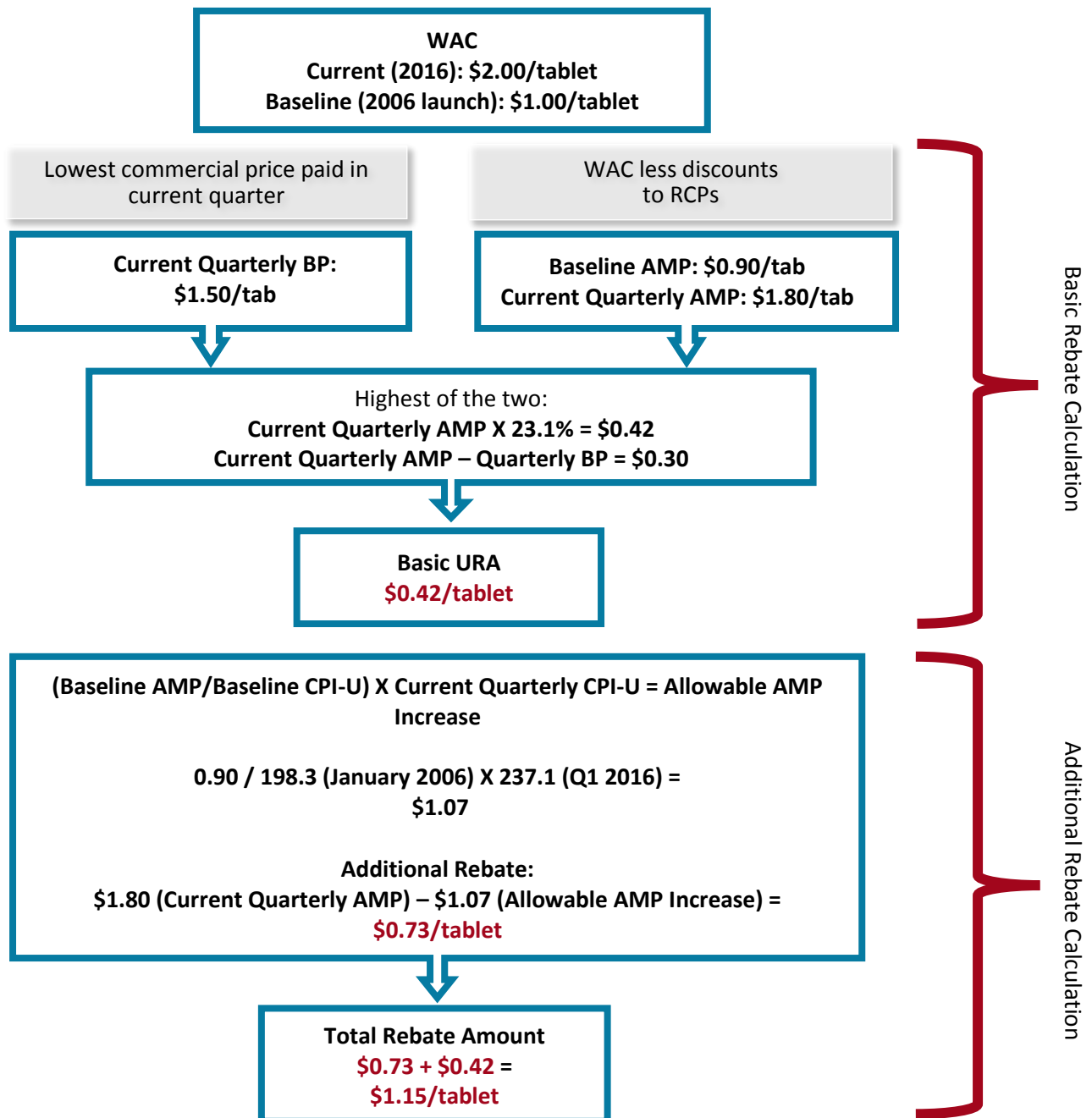
⁴¹ Sun, LH. “Despite being shamed for overcharging patients, hospitals raised their prices, again,” Washington Post, Oct. 20, 2016, available at: <https://www.washingtonpost.com/news/to-your-health/wp/2016/10/20/despite-being-shamed-for-overcharging-patients-hospitals-raised-their-prices-again/>.

| | Metric | Description | Calculations |
|-----------------|-------------------------------------|--|--|
| Commercial | Wholesale Acquisition Cost (WAC) | The price set by drug manufacturers and negotiated with wholesalers. Public price reported by manufacturers. | |
| | Average Wholesale Price (AWP) | The wholesaler’s catalog or list price and often the benchmark used for pricing of drugs for government and private payers. Public price ; reported in Thomson Micromedex’s <i>Red Book</i> and First DataBank’s <i>Blue Book</i> . | In the absence of AWP or suggested wholesale price provided by the manufacturer, a standard 20% markup over WAC is typically used to calculate the AWP https://micromedex.com/Portals/1/Assets/AWP%20Policy_Oct%202014.pdf . |
| Medicare Part B | Average Sales Price (ASP) | The price set for drugs covered by Medicare Part B. A public price calculated by CMS and applied to certain classes of drugs: vaccines, injected and infused medications, parenteral nutrition, and transplant drugs, for example. ASP comes out of the Medicare Modernization Act of 2003 (codified at 1847A of the Social Security Act), which aimed to curtail Medicare spending on these expensive drugs. ASPs available at: goo.gl/N6xNgh . | Before ASP, Medicare Part B drug cost reimbursements were frequently based on AWP. With hyperinflation of AWP and purchaser rebates, volume and prompt payment discounts, and cash payments by manufacturers, Medicare reimbursements based on ASP (plus 6%) controls spending by narrowing the spread between what is actually paid for the drug and what is actually billed to Medicare Part B. Not included in the ASP in the physician payment formula used to determine reimbursements for administering providers for administering these drugs. |
| Medicaid | Medicaid Drug Rebate Program (MDRP) | The MDRP establishes rebates for all prescription drugs covered under states’ Medicaid payment model (42 USC § 1396r-8). Federal unit rebate amount (URA) calculations are used to determine the confidential rebates that must be offered to state Medicaid programs for three categories of drugs: <i>N</i> (non-innovator multiple source drugs; “generics”), <i>S</i> (single-source innovator drugs; traditional “brand-name” name), and <i>I</i> (multiple-source innovator drugs). | URAs for <i>S</i> or <i>I</i> drugs are either a minimum of 23.1% of the AMP or the difference between the AMP and the BP (whichever is larger), plus additional rebates if the AMP increases since the drug’s launch price exceed the consumer price index-all urban consumers (CPI-U) marker of inflation (42 USC § 1396r-8) (see graphic on page 24). The current URA for <i>N</i> drugs is 13% of the AMP, without other mandatory adjustments; beginning with the first quarter of 2017, additional CPI-U “penalties” will also be required. In addition to URAs, many state Medicaid programs negotiate supplemental rebates with manufacturers. |

| | Metric | Description | Calculations |
|----------|--|---|---|
| Medicaid | Average Manufacturer Price (AMP) | The average price paid to manufacturers by wholesalers for most drugs sold to retail community pharmacies (RCPs)—specifically independent, chain, supermarket, and mass merchandiser pharmacies, as well as RCPs that purchase drugs purchased directly from the manufacturer (42 CFR §447.504). Confidential price reported to the U.S. Centers for Medicare & Medicaid Services (CMS) by manufacturers and is used to calculate the unit rebate amount (URA) for the Medicaid Drug Rebate Program (MDRP) and 340B Drug Discount Program. | Included in the AMP calculation are sales, nominal price sales, and various discounts, rebates, payments or other financial transactions (42 CFR §447.504). Not included in the AMP calculation are bona fide service fees; returned goods; Medicare coverage gap discounts; prices to other federal programs; sales or price concessions to physicians, insurers, pharmacy benefit managers (PBMs), hospitals, mail order pharmacies, or prisons; manufacturer-sponsored programs (e.g., copay assistance); free goods provided by the manufacturer; or customary prompt pay discounts (42 CFR §447.504). |
| | 5i Average Manufacturer Price (5i AMP) | The average price paid to manufacturers for 5i drugs (drugs that are inhaled, infused, instilled, implanted, or injected) that are generally not sold to RCPs (42 CFR §447.507). As with AMP, this is a confidential price reported to CMS and is used to calculate the URA for Medicaid and 340B programs. | The 5i AMP calculation excludes drugs for which 30% or more of sales were to RCPs or wholesalers for drugs distributed to RCPs (42 CFR §447.507). The calculation is applied to 5i drugs sold to physicians; PBMs; HMOs; insurers, hospitals, clinics, and outpatient facilities; long-term care and hospice providers; and mail-order pharmacies, all of which are excluded from standard AMP (42 CFR §447.504). Excluded are prompt-pay discounts; sales to government, charitable, or not-for-profit pharmacies; prices available under other federal programs; bona fide service fees, and either direct or indirect sales to patients (42 CFR §447.504). |
| | Best Price (BP) | The lowest drug price available to wholesalers, retailers, providers, HMOs, nonprofit entities, or government entities in the U.S. in any pricing structure (including capitated payments) (42 CFR § 447.505). Confidential price reported to CMS and used, along with AMP, to calculate the URA for the Medicaid and 340B programs. | Included in the BP are applicable discounts, rebates, or other transactions that adjust prices directly or indirectly to all entities in the BP category (42 CFR §447.505). Examples of best price calculation exclusions include: prices charged to certain federal purchases (e.g., those made through the federal supply schedule), patient assistance schemes (e.g., copay assistance programs), discounts or rebates to PBMs, direct-to-patient sales, state pharmacy assistance programs, bona fide service fees, and any prices charged to 340Bcovered entities (42 CFR §447.505). |

| | Metric | Description | Calculations |
|--------------------|---|--|--|
| 340B Program | 340B Ceiling Price | The 340B drug rebate program extends URAs to eligible health care organizations and covered entities, such as federally qualified health centers, Ryan White HIV/AIDS Program grantees, AIDS Drug Assistance Programs, and TB clinics in order to set a confidential maximum, or “ceiling,” price for outpatient drugs (42 USC § 256b). | The Health Resources and Services Administration (HRSA) obtains AMP and URA data from CMS. HRSA multiplies the total per-pill/unit URA calculation by the package size and case package size to produce the 340B Ceiling Price used by covered entities. Participating entities may negotiate discounts below the ceiling price; they are also allowed to bill public and private payers for reimbursements based on the public list prices with the savings reinvested in patient care and services. |
| Federal Purchasing | Federal Supply Schedule (FSS) | The FSS is a mechanism for government purchasers to access discounted prices. Manufacturers may choose to offer one discounted price to all federal purchasers, in which case the Federal Ceiling Price (FCP) is used, or be a “dual pricer” and offer the FCP to the “Big Four” purchasers—the Department of Veterans Affairs (VA), as well as the Department of Defense, Public Health Service/Indian Health Service, and the Coast Guard—and a higher price to all other government agencies. FSS prices are public (http://www.va.gov/nac/Pharma/List). | All manufacturers wishing to do business with federal purchases or Medicaid must list their drugs on the FSS (38 USC § 8126). Under dual pricing, the VA negotiates a discounted FSS price for other government agency customers based on sales data from the manufacturer showing its Most Favored Customer (MFC) (General Services Administration Manual Subpart 538.2). Big Four customers receive the FCP. The OGA FSS price is capped by annual inflation, while the Big Four FCP price can be subject to additional discounts if non-FAMP rises faster than inflation (38 USC § 8126). |
| | Non-Federal Average Manufacturer Price (non-FAMP) | The average price of a drug paid by wholesalers, or other entities that purchase the drug directly from manufacturers, used to calculate the Federal Ceiling Price (FCP), which applies to “Big Four” sales (38 USC § 8126). This confidential price is calculated quarterly and annually by the manufacturer and submitted to the (VA). | Non-FAMP calculation includes any discounts or similar price reductions to wholesalers or direct purchasers of drugs, but excludes any prices paid by the federal government (38 USC § 8126). Also excludes any rebates or discounts to end customers that are not paid to/through wholesalers. |
| | Federal Ceiling Price (FCP) | The FCP is the maximum price that manufacturers can charge the Big Four. The Big Four prices are publicly available and may be 40% to 50% of the AWP (http://www.va.gov/nac/Pharma/List). | The FCP for a drug is capped at no more than 76% of the previous year’s non-FAMP for the drug; an additional discount may be necessary if the non-FAMP increases higher than the CPI-U. Additionally, the FCP price cannot exceed the previous year’s FSS price (38 USC § 8126). All Big Four agencies can negotiate lower prices; historically, the VA average price is often lower than the price available to the Big Four because the VA negotiates further price reductions using its preferred formulary. |

Medicaid Rebate Calculation



Medicaid Math. Quarterly, the Centers for Medicare & Medicaid Services calculates mandatory drug rebate amounts for state Medicaid programs; this calculation also establishes the ceiling price covered entities under the 340B program. This graphic illustrates the calculations for the mandatory basic rebate and the additional rebate “penalty” for drugs with price increases exceeding the consumer price index-urban (CPI-U) marker of inflation.

Abbreviations: **AMP**, average manufacturer price; **Baseline AMP**, the AMP for the first quarter after the drug’s market/launch date; **Baseline CPI-U**, the CPI-U for the month prior to the first quarter after the drug’s launch date; **BP**, best price; **Quarterly AMP**, the AMP for the most recent quarter of sales; **Quarterly CPI-U**, the CPI-U value of the month prior to the quarter being calculated; **RCPs**, retail community pharmacies; **URA**, unit rebate amount; **WAC**, wholesale acquisition cost.

Model Legislation

The Prescription Reduction In Cost and Expenditures (PRICE) Act of 2017

Statutory text as amended

Revisions to Average Manufacturer Price - 42 U.S.C. §1396r-8

42 U.S.C. §1396r-8(k)

(k) Definitions.—In the section—

(1) Average manufacturer price.—

(A) In general.—Subject to subparagraph (B), the term “average manufacturer price” means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by—

- (i) wholesalers for drugs distributed to retail community pharmacies; and
- (ii) retail community pharmacies that purchase drugs directly from the manufacturer.

(B) Exclusion of customary prompt pay discounts and other payments.—

(i) In general.—The average manufacturer price for a covered outpatient drug shall exclude—

- (I) customary prompt pay discounts extended to wholesalers;
- (II) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);
- (III) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;
- (IV) payments, rebates, and discounts related to the sale or transfer of an authorized generic drug as that term is defined under section 505(t) of the Food, Drug, and Cosmetic Act;
- ~~(IV) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy; and~~
- (V) discounts provided by manufacturers under section 1860D–14A; and
- (VI) discounts provided to prisons, jails, or correctional facilities.

(ii) Inclusion of other discounts and payments.—~~Notwithstanding~~ Except as specified in clause (i), the following shall be included in the average manufacturer price for a covered outpatient drug—

(I) any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies;

(II) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order

pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy shall be included in the average manufacturer price for a covered outpatient drug.

...

(10) Retail community pharmacy

The term "retail community pharmacy" means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term includes pharmacies that dispense prescription medications to patients primarily through the mail and pharmacy benefit managers. Such term does not include ~~a pharmacy that dispenses prescription medications to patients primarily through the mail,~~ nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, or government pharmacies, or pharmacy benefit managers.

42 U.S.C. §1396r-8(c)(1)

(C) "Best price" defined

For purposes of this section—

(i) In general The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355 (c)]), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, pharmacy benefit manager, managed care organization, insurer, hospital, clinic, mail order pharmacy, long term care provider, manufacturer, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section (including inpatient prices charged to hospitals described in section 256b (a)(4)(L) of this title);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1395w-141 of this title; ~~and~~

(VI) any prices charged which are negotiated by a prescription drug plan under part D of subchapter XVIII of this chapter, by an MA-PD plan under part C of such subchapter with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1395w-132 (a)(2) of this title) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such subchapter, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1395w-114a of this title; and

(VII) any prices charged to a prison, jail, or correctional facility.

(ii) Special rules The term "best price" —

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount; and

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355 (c)], shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, pharmacy benefit manager, managed care organization, insurer, hospital, clinic, mail order pharmacy, long term care provider, manufacturer, or governmental entity within the United States, excluding those prices described in subclauses (I) through ~~(VII)~~ of clause (i).

(iii) Application of auditing and recordkeeping requirements-- With respect to a covered entity described in section 256b (a)(4)(L) of this title, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 256b (a)(5)(C) of this title.

42 U.S.C. §1396r-8(c)

(2) Additional rebate for single source and innovator multiple source drugs.—

...

(D) No maximum rebate amount.—Manufacturers are required to rebate the full sum ~~In no case shall the sum~~ of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period beginning after ~~December 31, 2009~~ January 1, 2018, even if such sum shall exceed 100 percent of the average manufacturer price of the drug.

(E) Additional rebate multiplier – The amount of the additional rebate specified in subparagraph (A) shall be –

(i) Doubled, if the average manufacturer price for the dosage form and strength of the drug for the period exceeds 1.05 multiplied by the amount calculated under clause (ii)(II) of subparagraph (A); and

(ii) Tripled, if the average manufacturer price for the dosage form and strength of the drug for the period exceeds 1.25 multiplied by the amount calculated under clause (ii)(II) of subparagraph (A).

(F) Consideration of baseline average manufacturer price

In the case of a covered outpatient drug approved by the Food and Drug Administration after January 1, 2018, if the baseline average manufacturer price is less than the average manufacturer price for the first full calendar quarter after the day on which the drug was first marketed, clause (ii)(II) of subparagraph (A) shall be applied by substituting “baseline average manufacturer price” for “average manufacturer price.”

(3) Rebate for other drugs

...

(C) Additional rebate

(i) In general

The amount of the rebate specified in this paragraph for a rebate period, with respect to each dosage form and strength of a covered outpatient drug other than a single source drug or an innovator multiple source drug of a manufacturer, shall be increased in the manner that the rebate for a dosage form and strength of a single source drug or an innovator multiple source drug is increased under subparagraphs (A), (D), (E), and (F) ~~and (D)~~ of paragraph (2), except as provided in clause (ii).

(ii) Special rules for application of provision

In applying subparagraphs (A) and (D) of paragraph (2) under clause (i)-

(I) the reference in subparagraph (A)(i) of such paragraph to "1990" shall be deemed a reference to "2014";

(II) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to "the calendar quarter beginning July 1, 1990" shall be deemed a reference to "the calendar quarter beginning July 1, 2014"; and

(III) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to "September 1990" shall be deemed a reference to "September 2014";

(IV) the references in subparagraph (D) of such paragraph to "paragraph (1)(A)(ii)", and "this paragraph", ~~and "December 31, 2009"~~ shall be deemed references to "subparagraph (A)", and "this subparagraph", ~~and "December 31, 2014"~~, respectively; and

(V) any reference in such paragraph to a "single source drug or an innovator multiple source drug" shall be deemed to be a reference to a drug to which clause (i) applies.

...

(4) Baseline average manufacturer price

(A) For a single source drug or innovator multiple source drug approved by the Food and Drug Administration after January 1, 2018, the Secretary shall calculate a "baseline average manufacturer price" for each drug. The baseline average manufacturer price shall equal—

(i) the average of--

(I) the average manufacturer prices for the first full quarter after the day on which each of the drugs were first marketed, each increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the newly approved drug was approved exceeds such index for the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed, for

(II) each of the single source drugs or innovator multiple source drugs in the top third of single source drugs or innovator multiple source drugs by sales volume in the quarter prior to approval in the same drug category or to treat the same condition as the newly approved drug.

(ii) multiplied by—

(I) 200 percent, if the average number of years since approval by the Food and Drug Administration of the drugs considered in clause (i)(II) of subparagraph (A) exceeds ten years;

(II) 150 percent, if the average number of years since approval by the Food and Drug Administration of the drugs considered in clause (i)(II) of subparagraph (A) exceeds five years but does not exceed ten years; or

(III) 125 percent, if the average number of years since approval by the Food and Drug Administration of the drugs considered in clause (i)(II) of subparagraph (A) does not exceed five years.

(B) Notwithstanding subparagraph (A), if a drug is determined by the Secretary to be so exceptionally novel that it cannot be compared to existing drugs in the same drug category or to treat the same condition, the Secretary shall calculate a baseline average manufacturer price that considers the improvement in treatment value over the drugs considered in clause (i)(II) of subparagraph (A). The Secretary shall issue regulations to determine “exceptionally novel” drugs and their baseline average manufacturer price.

(C) For a noninnovator multiple source drug approved by the Food and Drug Administration after January 1, 2018 which is therapeutically equivalent to a single source or innovator multiple source drug approved after January 1, 2018, as determined by the Food and Drug Administration, the baseline average manufacturer price shall be the baseline average manufacturer price of the innovator multiple source drug to which the noninnovator multiple source drug is therapeutically equivalent, reduced by 25 percent.

(D) For a noninnovator multiple source drug approved by the Food and Drug Administration after January 1, 2018 which is therapeutically equivalent to a single source or innovator multiple source drug approved before January 1, 2018, as determined by the Food and Drug Administration, the baseline average manufacturer price shall be the baseline average manufacturer price as calculated under subparagraph (A), reduced by 25 percent.

(E) The Secretary shall issue regulations implementing this provision within 180 days.

42 U.S.C. §1396r-8

(I) Disclosures for excessive price increases

(A) If a covered outpatient drug is subject to the additional rebate calculated under the methodology in 42 U.S.C. §1396r-8(c)(2)(E)(ii), including such an additional rebate under 42 U.S.C. §1396r-8(c)(3), the manufacturer of the covered outpatient drug shall submit a report to the Secretary within 90 days detailing research and development costs for the drug, production costs, marketing expenditures (including provider detailing, direct-to-consumer marketing, and any activities or funding associated with supporting, communicating, or researching off-label uses of the drug), Federal and non-profit funding that supported the drug’s development (including prior to the manufacturer’s acquisition of the drug), detailed breakdowns of the patient population receiving the drug, detailed breakdowns of the number of prescriptions paid for by various private and public payers and the total amount expended for the drug by each payer and any discounts or rebates provided to that payer, detailed executive compensation, and other such information as the Secretary shall determine. The Secretary shall release such reports to the public on a quarterly basis.

(B) The Secretary shall have authority to levy civil monetary penalties for failure to submit a complete and accurate report under this section, as determined by the Secretary through regulation.

Revisions to Average Sales Price - 42 U.S.C. §1395w-3a

42 U.S.C. §1395w-3a(d)

(3) Limitation on average sales price

(A) In general

The Secretary ~~may~~ shall disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).

(B) Applicable threshold percentage defined

In this paragraph, the term “applicable threshold percentage” means—

(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; ~~and~~

(ii) in 2006 ~~through 2017 and subsequent years~~, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both; ~~and~~

(iii) in 2018 and subsequent years, 5 percent.

(C) Authority to adjust average sales price

The Inspector General shall, on a quarterly basis, review all reported average sales prices to determine if the reported average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage. Should the reported average sales price for a drug or biological exceed the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—

(i) the widely available market price for the drug or biological (if any); or

(ii) 103 percent of the average manufacturer price (as determined under section 1396r-8 (k)(1) of this title) for the drug or biological.

Revisions to Non-Federal Average Manufacturer Price - 38 U.S.C. §8126

38 U.S.C. §8126

(c) With respect to any covered drug the price of which is determined in accordance with a pharmaceutical pricing agreement entered into pursuant to subsection (a)(2), beginning on or after January 1, 1993, the manufacturer shall provide a discount in an amount equal to—

(A) the amount by which the change in non-Federal price exceeds the amount equal to—

(1) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the last day of the month preceding the month during which the contract for the covered drug goes into effect (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period as the Secretary considers appropriate); multiplied by

(2) the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) between the last month of the period described in paragraph (1) and the last month preceding the month during which the contract goes into effect for which Consumer Price Index data is available.

(B) multiplied by—

(1) Two, if the amount by which the change in non-Federal price exceeds 1.05 multiplied by the amount calculated under clauses (1) and (2) of subparagraph (A);

(2) Three, if the amount by which the change in non-Federal price exceeds 1.25 multiplied by the amount calculated under clauses (1) and (2) of subparagraph (A); or

(3) One, if the amount by which the change in non-Federal price does not exceed 1.05 multiplied by the amount calculated under clauses (1) and (2) of subparagraph (A).

38 U.S.C. §8126(h)

(5) The term “non-Federal average manufacturer price” means, with respect to a covered drug and a period of time (as determined by the Secretary), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers, retail community pharmacies, and other direct purchasers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, including rebates or discounts provided to pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy but not taking into account—

(A) any prices paid by the Federal Government; ~~or~~

(B) any prices paid by or rebates or discounts to entities to whom sales are exempt from inclusion in the determination of “best price” under section 42 U.S.C. 1396r–8 (c)(1)(C)(i); or

(C) any prices found by the Secretary to be merely nominal in amount.